The Art of the Possible Doable

How COVID-19 became a galvanizing event for the use of real-world data **BY PHILLIP PANTUSO**

• For years, biopharma and healthcare organizations have fantasized about making better use of real-world data. The appeal has long been clear: Even as researchers struggle with the challenge of interpreting the information correctly, such data can help them understand how patients behave outside a controlled environment.

With the rise of wearable tech and biosensors, as well as the increasing systematization of electronic health records and clinical data repositories, technologists have captured and standardized more real-world patient data than ever before. However, the missing piece has been a galvanizing event, one that would showcase in an intuitive and meaningful manner precisely how the use of real-world data can create better health outcomes.

Enter COVID-19.

It's no exaggeration to say that there has never been a larger active patient population for a single life-threatening condition. Between the number of people who have been infected and the 2.5 billion who have received a vaccine dose, there is an abundance of data — about everything from post-shot reactions to the extent to which vaccination has curbed community spread to the potential need for booster shots.

So has the role of real-world data in healthcare truly been redefined during the pandemic? The answer is complicated.

"To borrow an expression from Matt Damon in *The Martian*, we 'scienced the shit out of it' to come up with these wonderful new mRNA vaccines," notes Ronald Elwell, CEO and cofounder of Swoop and IPM.ai. "What we didn't do is science the shit out of

the marketing and communications, to use real-world data to get in front of what have become major issues with vaccine hesitancy."

Indeed, while the gathering of real-world data has improved, the application of insights derived from it has been inconsistent, according to ZS CEO Pratap Khedkar.

"We've built these giant enterprise data lakes in commercial or R&D, or payers doing the same thing," he explains. "The challenge was that the side that needed to use the data to change what they do was not adopting it very much. Business leaders and people making treatment and R&D decisions—they are very siloed in their thinking. They felt the data was incomplete or didn't want to change their processes."

As a result, it may seem as if real-world data has been no more effectively leveraged during the pandemic than it was previously. Two problems inherent to real-world data are ensuring its quality and fitness for purpose. This can involve arduous work during the best of times — cross-referencing different data sets, systematizing unstructured data, putting data into the right buckets and more.

Similarly, when real-world data and evidence have been utilized, their applications have tended to be narrow. "Prior to the pandemic, real-world data was largely seen as valuable to clinical operations and designing clinical trial protocols," notes Seth Duncan, chief data officer at Real Chemistry. "From a marketing perspective, we were just starting to dabble in commercial applications for it, such as setting up sales ops."

That's partly due to what Duncan describes as a "lack of literacy in terms of how to leverage this data for stuff beyond patient-

TPICAL WETCOM VIEW



finding and some basic targeting." That remains a hazard even at this late stage of the pandemic.

"If you look at how vaccine hesitancy has been addressed, it's a model of how a lot of drugs are launched, where there's an overreliance on self-report survey and polling, and an under-reliance on large sets of real-world data," Duncan continues.

But the scope of the messaging problem wrought by the pandemic also contains the seeds of opportunity. The increasing convergence of technology and data had made the use of real-world data and evidence much more possible before the pandemic, says Klick Health VP, data science Ali Vahit Esensoy. "Then the pandemic hits, and we see a rapid acceleration."

In effect, the pandemic posed a huge question for which real-world data might provide an answer. But because of how theoretically valuable that data is, a lot of it had been proprietary and guarded zealously, Esensoy says. Those silos started to break down due to what he calls "a shift in the health-data mindset," spurred by a sense of togetherness that prompted established industry players to be more open-source and collaborative.

"The pandemic really helped the real-world data landscape by creating this more open atmosphere," he notes. That was necessary, he adds, because "everyone from individuals to governments needed near-real-time understanding of this disease. Even with the evolution of real-world data repositories, none were ready to take on the challenge of COVID. It was a stark wakeup call."

An amalgamation of citizen volunteers, researchers, comms shops and public functionaries initially filled the void. They created

the COVID Tracking Project, COVID Exit Strategy and other dashboards that aggregated infection, hospitalization and other critical local data. In so doing, they provided resources that state and local leaders, individuals and even healthcare companies could tap in order to make better informed decisions.

COVID Exit Strategy was founded in April 2020 by Ryan Panchadsaram of Kleiner Perkins. During his tenure in the Obama administration, he had served as U.S. deputy chief technology officer, a role in which he helped make data more open and transparent via the redesign of the data.gov website.

Panchadsaram believes industry and governments can learn plenty from these prior efforts. "Politics can't hide from realworld data," he stresses. "That's why it's important to collect it, to make it transparent and to educate people on it With data, people can have their own agency to make decisions."

Khedkar, for his part, says the pandemic affected healthcare's use of real-world data in several ways. He notes that healthcare was delivered differently in a socially distanced world (telehealth, at-home monitoring), long-term risk monitoring was disrupted and the vaccination effort enrolled hundreds of millions of people into EHRs.

All of these factors had distorting effects on the collection and interpretation of real-world data. A recent National Pharmaceutical Council white paper called on researchers to account for them.

"Despite increased urgency and use of RWE during the pan-

demic, many still doubt future use due to data gaps that the pandemic has created," the authors wrote. "Lack of clarity on how to handle these disruptions creates the risk that decision-makers may disregard any real-world evidence studies that include data collected during the COVID-19 pandemic — creating a lasting impact on the acceptance and use of RWE in the years to come.'

But crisis begets opportunity, and these disruptions in business practice met with the urgency of the moment to finally shake biopharma out of some old habits. New capabilities were built, existing ones were better utilized and more data were shared.

"Those same people who were naysayers before are saying,

'OK, now we know we can work differently, because we were forced to," Khedkar explains.

That creates a virtuous cycle, which leads to another way the pandemic changed the use of real-world data, according to Khedkar: Those leaders and decision-makers who may have been skeptical of real-world data before now have confidence in it.

"People have seen the art of the doable, as opposed to just talking about the art of the possible," he says. "My belief is we're going to stay with it and build upon this."

Esensoy is similarly optimistic, especially in his belief that emerging methodologies, such as natural language processing and online search analysis, can unlock new repositories of real-world data. In March 2020, Klick scraped social media data to analyze symptoms that were indicative of COVID-19. He says the company picked up the loss of taste and smell as hallmark symptoms before they were reported in the medical literature.

Esensoy believes that's important because medical practice is often set in its ways. "There are certain questions we always ask, certain assessments we do," he explains. "If we only use medical data sources, we're biased by what clinicians deemed to be important. But social media is a conversation and people are much more forthcoming about their experiences on social media than in conversations with their physicians."

The pandemic may have changed the playing field for real-world data, but Duncan argues that the main driver for its increased adoption of real-world data will be the continued personalization of healthcare and medicine.

"If you look at what's in the pipeline for most pharma and biotech companies, as well as what's getting approved, it's basically creating smaller and smaller patient populations better and more effectively," he says. "The idea of using mass campaigns as an effective form of marketing is slowly dying, and when pharma companies see that physicians like engaging with them more because they're using these insights — that they're actually creating a better experience for the physicians — that's going to be the thing that pushes everybody to adopt this."

That eventual normal may have been dragged forward in time by necessity. When Real Chemistry pitches to clients now with insights and messaging drawn from real-world data, it's finding increased receptivity.

"It's almost like space aliens have landed and shown them the future," Duncan says, "which is a great position to be in."

"Politics can't hide from realworld data. That's why it's important to collect it, to make it transparent and to educate people on it."

PANCHADSARAM. **COVID EXIT** STRATEGY