



## Closing evidence generation gaps improves health outcomes for healthcare organizations

**D**igital health solutions are increasingly common in healthcare, with over 300,000 health apps available and more than half of U.S. adults using digital health tools.

While adoption is widespread, the vast amount of data generated by wearables, sensors and digital therapeutics isn't being used to its full potential. There is a concerning lack of evidence to support the effectiveness of many digital health solutions, meaning insights that could be used to improve patient care and overall health outcomes are likely being missed.

Health systems, insurers and life sciences companies have an opportunity to better leverage data to understand the effectiveness, safety and value of digital health interventions or treatments. More efficient and accessible evidence generation and analysis will allow healthcare organizations to refine digital health utilization, expand care access and improve health outcomes.

### Why evidence generation gaps exist

A significant obstacle to demonstrating the efficacy of digital health solutions is the persistent lack of robust evidence. A study of U.S.-based digital health companies revealed 44% lacked regulatory filings or clinical trials, highlighting a wide evidence gap.

Several factors contribute to this problem. Many tech innovators, while savvy developers, lack familiarity with clinical research principles. This reality, combined with the need for rapid deployment of digital health solutions during the COVID-19 pandemic, limits the rigor of solution development and testing. Additionally, high costs deter investment in traditional research methods such as randomized controlled trials (RCTs).

"It is so expensive to set up a protocol, validate the protocol and go through the extensive efforts of site investigator selection and startup," said Shannon LaRusso, Senior Vice President - Product Management and Strategy for PurpleLab®. "The longer all of that takes, the longer it takes to get the therapy to patients."

Traditional clinical trials also often have strict inclusion and exclusion criteria, whereas Real-World Data (RWD) can monitor a drug or diagnostic tool's impact on diverse populations, according to Steven Emrick, Senior Vice President - Clinical Informatics Solutions for PurpleLab.

"The patients participating in a clinical trial may not always mirror the patient population experiencing the disease burden in the real world," he said.

Additionally, rapid innovation in digital health often outpaces the ability of RCTs to provide timely and comprehensive evaluations of these complex and evolving solutions.

Amid these constraints, closing the evidence gap in digital health will require innovative research methods and policy changes.

### **Bridging the evidence gap: Innovative approaches**

Real-World Evidence (RWE) derived from [RWD sources](#) like electronic health records (EHR), claims data and digital health technologies can provide valuable insights into how digital solutions perform in varied patient populations and real-world settings.

In this way, RWE complements traditional clinical trial data. Emrick points to the case of Ibrance® (palbociclib), which [received](#) a label expansion in 2019 to treat male breast

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cancer based on RWE from medical and pharmacy claims, as well as EHR data. This example underscores the power of RWE, particularly for smaller patient populations where clinical trials are less feasible.

With growing support from regulators and payers, RWE could become more accessible, Emrick explained. Government initiatives like state and regional health information exchanges and the ONC's Trusted Exchange Framework and Common Agreement (TEFCA) have fostered the development of [Qualified Health Information Networks \(QHINs\)](#), which health systems can connect with to access comprehensive patient data for six permitted Exchange Purposes (treatment, payment, healthcare operations, benefits determination, public health and individual access services).

But while QHINs have established essential data-sharing infrastructure, there are challenges with data standardization, as well as in industry professionals' technical ability to extract meaningful insights from vast datasets, according to LaRusso. Many healthcare leaders

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lack coding expertise and must wait for technical teams to process and interpret data.

Platforms such as [PurpleLab's Health Nexus](#), which automates complex queries and ensures data consistency across sources, can significantly reduce the time and resources required to generate actionable insights.

“One of the benefits to being in the [Datavant ecosystem](#) is we have the capability of connecting our dataset, or working with our customers to get (their data) tokenized to link it to our data set,” LaRusso said. “They have benefited from having that pulled together.”

### Closing the evidence gap for better health outcomes

Closing the evidence gap in digital health can benefit various industry stakeholders,

from life sciences companies working to identify target populations, to health systems focused on addressing care gaps and delivering personalized medicine.

With robust evidence, healthcare organizations can make more informed decisions about which digital solutions to adopt, leading to enhanced patient safety and improved treatment outcomes.

Furthermore, bridging the evidence gap strengthens the entire digital health ecosystem. Greater transparency and demonstrable efficacy will foster increased trust in digital health technologies, driving wider adoption. This, in turn, will accelerate the delivery of innovative solutions to patients, ensuring they have access to the most effective tools.

By paving the way for innovative approaches to evidence generation, including the strategic use of RWE, healthcare can unlock the full potential of digital health.

“The North Star is using Real-World Evidence to improve patient care, healthcare delivery, policy and outcomes,” said Emrick. “The more Real-World Evidence we can provide to our stakeholders across life sciences, health systems and providers, the more positive changes can be made to the health system.” ■

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