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The Future State

Covid-19 taught the industry not to rely so heavily on the time and manual effort of clinicians and research staff to keep the research enterprise functioning.

“Our focus in real-world data is through automated data networks — the first step in learning health systems — where research and practice are intertwined and interoperable systems enable both. That is where our industry needs to move with our clinical partners to get to a new future state,” says Richard Gliklich, M.D., CEO of OM1.

Dr. Gliklich says focusing on collecting, processing, delivering, and applying real-world clinical data to accelerate medical research will advance personalized healthcare. “Initially, our most significant opportunities came from our novel technological approaches to developing data networks and processing that data, which enabled more complete and rapid data collection at lower costs. These enabled our customers to move from traditional registries and post-marketing surveillance programs to large, automated, RWD collection with minimal provider burden.”

He notes as a result of 21st Century Cures Act, interest in comparator cohorts or external control arms has grown dramatically as companies seek to test results of early phase trials in real-world data (RWD) sets and regulators demonstrate willingness to use such data in certain approvals. “However, most companies are still only seeing the tip of the opportunity iceberg with clinical RWD,” Dr. Gliklich says. “For forward-thinking organizations, RWD is viewed as a strategic asset across the product lifecycle. These companies leverage our data and machine learning models for understanding the market for early discovery, identifying disease subtypes, designing and executing clinical trials, including identifying patients, lowering costs for meeting post-marketing requirements, demonstrating comparative effectiveness and value, and partnering with providers and payers.

“At the same time, the role of RWD in personalizing healthcare is still in its infancy, with most success still limited to oncology, but we see the opportunity here in the longer term as enormous,” Dr. Gliklich continues. “Being able to apply AI on top of condition-focused, high-quality RWD to deliver targeted treatments and care based on individual benefit:risk profiles and phenotypic biomarkers will be paradigm shifting for life-sciences companies, providers, payers, and most importantly, patients.”

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