EVERSANA™

TURNING THEORY INTO ACTION: REAL-WORLD EVIDENCE DRIVES CLINICAL RESEARCH AND IMPROVES PATIENT OUTCOMES

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Time For an Upgrade

Historically, it has taken at least 10 years for a new drug to complete the journey from initial discovery to the marketplace, with clinical trials taking six to seven years alone. The overall probability of clinical success – the likelihood that a drug entering clinical testing will eventually be approved – is shockingly low. **Less than 5% of drugs make it to a phase 3 clinical trial,** leading to billions of dollars in wasted investments and limited treatment options for patients.

Drug development remains a massive undertaking. Researchers, manufacturers and patients face the consequences of costly, time-intensive clinical trials, as well as fragmented datasets that widen the evidence gap between clinical research and ultimate treatment success. Real-world evidence (RWE), however, is helping bridge that gap by leveraging real-world data (RWD) to generate insights faster and more efficiently, giving power to the patient voice and providing a more in-depth look at how therapeutics perform in real-world settings.

Amplifying the Patient Voice

Leveraging RWD in the clinical development process enables life sciences stakeholders to conduct regulatory-grade research studies, generate evidence and provide data-driven insights and proactive support to improve the patient experience. RWD offers an unobstructed view into the longitudinal patient journey, providing a deeper understanding of how a patient's comorbidities, socioeconomic status and other clinical and nonclinical factors connect to the quality of clinical outcomes.

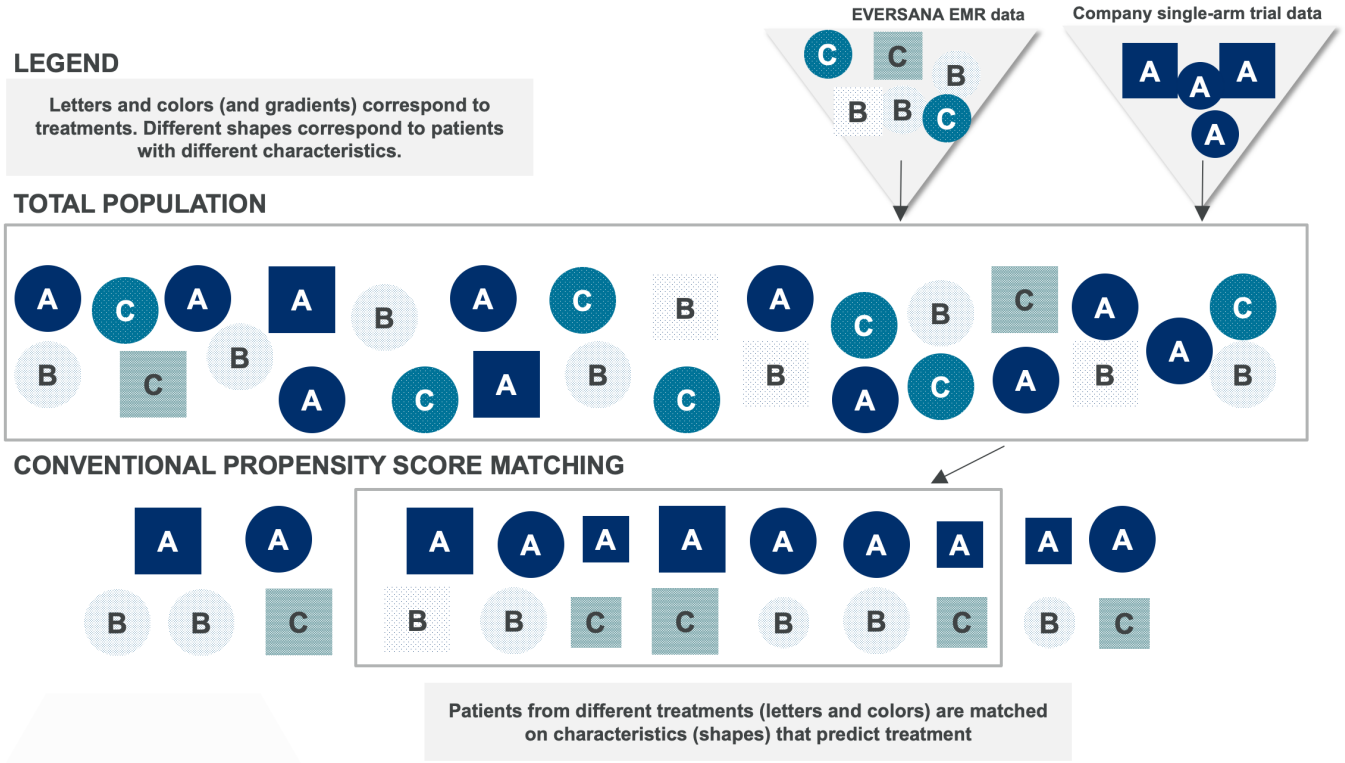
For instance, EVERSANA's Chronic Disease RWD Solution covers more than 80 million deidentified patients across a slew of therapeutic areas, including immunology, cardiovascular, neurology and rare disease conditions. Even further, the solution integrates digital and hub-collected patient experience insights from EVERSANA's hub and patient services. Having the data-driven context around what patients actually experience in real-world settings allows researchers and manufacturers to deliver on outcomes that positively impact underserved communities and those who may be overlooked in clinical trial settings. From pain and fatigue to socio/behavioral aspects of disease and treatment, chronic disease is marked by often difficult aspects of the patient experience, and leveraging RWD ultimately results in better, safer treatment options for patients.

Redefining Evidence Generation

Across the entire healthcare ecosystem, RWE is playing a larger role in regulatory decision-making, clinical outcome studies and accelerating research advances. The combination of scaled RWD with unstructured content and an expert curation team enables regulatory-grade, auditable determination of clinical endpoints and scoring used in clinical trials, thus generating synthetic control comparisons that can speed study times and offer important signals about how therapies perform in real-world settings.

EVERSANA recently partnered with an organization that required for its oncology product comparative data against other treatments, but only a single-arm trial was available. Using real-world evidence from EMR data and a registry, EVERSANA developed a synthetic control arm to generate comparative data for the product. By incorporating RWD, researchers were able to adjust for the covariates that otherwise may have led to a confounded conclusion that one patient group had a better prognosis than the other.

Synthetic control arms represent a safe, cost-effective way to generate RWE, specifically for rare diseases with small populations and limited resources or disease areas for which patients face a poor prognosis or difficult adverse events. Fear of being assigned to a placebo is one of the top reasons patients choose not to participate in clinical trials. Through synthetic control arms, researchers can ensure that all patients receive the active treatment in a clinical trial, thus enhancing the patient experience, as well as broader evidence generation strategies.



Delivering Critical Value Across the Life Sciences Pipeline

Life sciences companies have made significant investments in RWD, but most established providers can deliver only a fraction of what's needed to be impactful. Not only is the breadth and scalability of data critical to evidence generation, but stakeholders also need the HEOR and data science expertise to make RWD a core part of their clinical and medical strategies for product launch. Breaking down traditional healthcare silos for a more innovative approach to drug development can shorten the research and development timeline while substantially reducing wasted investments along the way.

From the beginnings of drug discovery through post-market safety monitoring, partnering with pioneers who can deliver best-in-class RWD and RWE becomes critical in getting better, safer therapies to patients faster.

Leveraging RWD/RWE allows life sciences stakeholders to:

- Reduce wasted investments
- Deliver value and outcomes
- Accelerate clinical trials and time to market
- Accelerate launch and marketing strategy