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ARTICLE

MARKET PROJECTIONS 2035: CAPTURING VALUE IN A $12 BILLION RWE SOLUTIONS ECOSYSTEM

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The global market for Real-World Evidence (RWE) solutions is entering a period of exponential growth, driven by a fundamental shift in how regulatory agencies and payers evaluate clinical interventions. As the industry moves away from a reliance on static clinical trial results toward continuous, post-market surveillance, the demand for high-fidelity longitudinal data is increasing. Market valuations reflect this transition; the RWE solutions market, estimated at $2.6 billion in 2025, is projected to reach $12 billion by 2035. This represents a compound annual growth rate (CAGR) of approximately 16%.

THE SHIFT TO CLOUD-BASED SURVEILLANCE

A significant portion of this market growth is tied to the adoption of cloud-based deployment models, which captured 64% of the market share in 2025. These models provide the elastic compute capacity and pay-as-you-go pricing necessary to manage the massive datasets required for modern post-market surveillance. However, for healthcare executives, the challenge lies not just in the volume of data, but in its provenance and regulatory utility. Legacy data brokerage models often struggle to provide the level of auditability and ownership transparency required by 2026 registry and FDA standards.

THE CIRCLE DATASET INTERVENTION: VERIFIABLE OWNERSHIP FOR MARKET ACCESS

A primary feature of **Circle Datasets** is the provision of **verifiable and unambiguously-owned evidence**, which is essential for navigating the $12 billion RWE ecosystem. As regulatory agencies increasingly reject single-arm trials that lack synthetic control arms derived from longitudinal health records, the value of a dataset is determined by its "regulatory-readiness".

Circle Datasets address the challenge of data provenance by utilizing a **Federated Healthcare Data Capture** model. This allows clinical data to remain at the point of care while being queried and analyzed through secure, cloud-based infrastructure. By ensuring that data is both owned by the contributing physicians and fully auditable by regulatory bodies, the platform provides the structural integrity required for drug and device manufacturers to secure market access in an increasingly rigorous post-market environment.

Download RegenMed white paper *"Bridging The 17 Years Evidence to Practice Gap"* to go deeper.

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