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ARTICLE

THE REGULATORY I NFLECTION POINT: REAL-WORLD EVIDENCE AND MARKET PROJECTIONS TO 2035

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The global landscape for clinical evidence is undergoing a fundamental shift as regulatory agencies and payers move away from static clinical trial results toward continuous post-market surveillance streams. This transition is driven by the increasing necessity for longitudinal data to support drug and device approvals, particularly in an environment where traditional single-arm trials face higher levels of scrutiny.

THE RISING MANDATE FOR REAL-WORLD EVIDENCE

Regulatory adoption of Real-World Evidence (RWE) has accelerated significantly over the last several years. The proportion of FDA approvals containing RWE increased from approximately 5% to 10% in 2020 to nearly 50% by 2024. This shift is not merely a change in preference but a structural requirement; regulatory agencies are now frequently rejecting single-arm trials that lack synthetic control arms derived from longitudinal health records. The economic implications of this shift are reflected in the projected growth of the RWE solutions market, which was estimated at $2.6 billion in 2025 and is expected to reach $12 billion by 2035. Furthermore, cloud-based deployment models now capture approximately 64% of the market, as they provide the elastic computing power and pricing models required for large-scale data analysis.

THE CIRCLE DATASET INTERVENTION: FEDERATED DATA CAPTURE AND REGULATORY READINESS

A primary challenge in meeting these new regulatory standards is the difficulty of accessing verifiable, high-quality longitudinal data that remains compliant with global privacy and residency requirements. **Circle Datasets** address this through the **Federated Healthcare Data Capture** model.

A key feature of this model is that clinical data remains at the primary point of care—ensuring compliance with data residency laws—while being accessible for analysis via secure, cloud-based infrastructure. This architecture ensures that the resulting datasets are verifiable, unambiguously owned, and "regulatory-ready". This provides drug and device manufacturers with the synthetic control arms now essential for securing FDA approval. By adopting this prospective architecture, health systems can transform their data from a liability into a capital asset that benefits providers, patients, and payers alike.

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

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