



WHITE PAPER
CIRCLE DATASETS EXPEDITE THE CONVERSION OF
REAL-WORLD EVIDENCE TO PRACTICE OF MEDICINE

March 28, 2026

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INTRODUCTION

The structural failure of modern healthcare is best evidenced by the persistent temporal lag between the generation of clinical evidence and its routine integration into patient care. This disconnect, historically quantified at 17 years, represents a systemic inefficiency that compromises patient safety, inflates healthcare spending, and devalues the massive investments made in biomedical research.

While traditional health information technology has focused on the retrospective extraction of messy, fragmented data, the emergence of the RegenMed Circle Datasets provides a prospective, hypothesis-driven alternative designed to achieve real-time evidence-based translation.

By shifting the industry from a "data brokerage" model to a "sovereign ownership" model, the patented Circles Platform addresses the root causes of the 17-year gap—namely, the high noise-to-signal ratio of electronic health record (EHR) data and the misalignment of financial incentives.

PERSISTENT FRICTION IN THE EVIDENCE PIPELINE

The "17-year gap" was first popularized by Balas and Boren in 2000, who analyzed the lifecycle of clinical interventions—such as beta-blockers after myocardial infarction and diabetic eye exams—finding that it took nearly two decades for these evidence-based practices (EBPs) to reach a 50% utilization rate in clinical settings. More recent assessments suggest this gap has compressed slightly to 15 years for certain cancer control practices, such as mammography and HPV vaccination, yet the pace of reduction remains unacceptably slow; at the current rate of improvement, it would take another 150 years to reduce the research-to-practice gap to zero.

The delay is not merely an administrative oversight but a reflection of a fractured research and data dissemination lifecycle. The translation of research into practice is typically divided into two major phases: the transition from publication to inclusion in systematic reviews and textbooks (averaging 6.3 years), followed by the phase of routine clinical implementation (averaging 9.3 years). The cumulative effect of these delays means that by the time a practice is widely adopted, the underlying evidence may already be outdated.

Translational Phase	Duration (Average)	Key Barriers
Research to Publication	2–5 Years	Peer review bottlenecks, publication bias
Publication to Review/Textbook	6.3 Years	Systematic review resource intensity
Review to Clinical Implementation	9.3 Years	Lack of leadership, inadequate clinician knowledge
Total Cumulative Lag	~17 Years	Linear, non-collaborative workflows

The economic implications of this gap are profound. Millions and even billions of dollars are wasted on outdated, inefficient practices that persist simply because the system lacks the structural mechanisms to "de-adopt" non-beneficial treatments. For instance, despite research showing that bone cement for osteoporosis-related spine fractures or cervical cancer screening in women under 30 provides no benefit, these practices continue to consume significant resources.

Shortening this timeline requires a departure from traditional "implementation science," which often treats knowledge translation as a linear knowledge-transfer problem, toward an integrated architecture where evidence generation and practice occur simultaneously.

REGENMED CIRCLE DATASETS: A STRUCTURAL PARADIGM SHIFT

Circle Datasets address the 17-year gap through a fundamental architectural shift. Rather than hiding fruitful research results for years, or relying on the retrospective "scraping" of EHR and billing data which often contains a high noise-to-signal ratio and significant missingness, they utilize a “sequential hierarchy” centered on active medical practice.

The Sequential Hierarchy of Value

The Circle Platform's clinical architecture is built upon a prospective data capture framework that ensures every datapoint is clinically relevant and statistically significant from the moment of inception. This hierarchy consists of six critical components:

The Clinical Hypothesis: The process begins with a specific scientific or health equity objective originating from actual medical practice, rather than a theoretical laboratory setting. This ensures the research is grounded in real-world clinical needs.

The Observational Protocol (OP): This is a standardized, prospective framework that translates the clinical hypothesis into a structured data capture system. The OP serves as the blueprint for what data must be collected, how it must be formatted, and at what intervals.

Attributes: Each OP includes a broad variety of prospectively and retrospectively assigned characteristics such as anatomical area, diagnosis, treatment protocol, correlated long-term outcomes measures, potentially applicable medical codes and data-interoperability mapping (CPT, ICD, SNOMED, LOINC, USCDI, FHIR, etc.). Critically, all of these Attributes are inherited by all Cases generated on the basis of such OP.

The Case: The Case is the fundamental unit of value within the Circles ecosystem. It tracks a single patient's journey from baseline diagnosis through long-term, standardized outcomes. Unlike fragmented EHR records, a Case is longitudinal and follows a unified protocol.

The Circle: A Circle is a collaborative engine consisting of physicians who collect Cases based on a shared OP. This collaborative model allows large academic medical systems as well as independent practices to aggregate their data to reach statistical significance far faster than they could individually.

The Circle Dataset (CD): The final output is a verifiable, regulatory-ready dataset composed of integrated Cases. These fully verifiable, unambiguously-owned, and continually accumulating Circle Datasets are available for licensing throughout the healthcare ecosystem in a wide variety of regulatory, scientific, commercial, value based-case and other licensing use cases.

By defining the data specifications *before* collection begins, the Circles Platform eliminates the need for the costly and time-consuming retrospective data cleaning and mapping that often takes years in traditional RWE studies. This prospective approach ensures that the data is "regulatory-ready" at the time of completion, effectively bypassing the multi-year delay associated with evidence reaching textbooks and reviews.

Deterministic Evidence vs. Inferred Data: The Precision Requirement

A core differentiator of the Circles Platform is its reliance on deterministic evidence rather than the inferred data common in legacy healthcare IT. In the context of identity resolution and clinical mapping, the choice between these two approaches determines the reliability, auditability, and ultimate value of the evidence generated.

Pre-Set OP Attributes: Defining the Deterministic Advantage

Deterministic models rely on exact, verified identifiers—such as Unique Device Identifiers (UDI) for implants or exact patient login credentials—to provide precise and certain outcomes. These models return clear-cut "yes/no" decisions based on hard-coded rules, which is essential for regulated environments where transparency and traceability are mandatory.

In contrast, probabilistic or "inferred" data uses statistical algorithms to estimate user journeys or clinical events. While probabilistic models can handle incomplete data by calculating a "confidence score" (e.g., an 85% likelihood that two records match), they introduce a level of uncertainty that can lead to "hallucinations" in AI models and rejection by regulatory agencies.

Metric	Deterministic Evidence	Inferred (Probabilistic) Data
Accuracy	95%–99%	60%–90%
Auditability	Direct, clear audit trails	Requires documentation of confidence thresholds

Implementation	Rule-based, manual updates	Statistical, learns from data
Clinical Value	Ideal for compliance and regulatory submission	Useful for broader identity resolution and marketing
Computation	Fast (< 1 second per rule)	Slower (0.1 to 5 seconds per rule)

In a simulation-based validation of EHR linkage, deterministic approaches achieved an average F1 score of 97%, demonstrating high precision across variables such as date of birth (DOB), sex, and medication history. This precision is vital for the 2026 registry standards, where the ability to track 90-day surgical site infections (SSI), readmissions, and returns to the operating room (OR) requires absolute certainty in patient-device linkage.

Eliminating AI Hallucinations

The Circles Platform leverages high-quality, longitudinal, deterministic data to train AI models. Traditional "big data" scrapes from varied EHR systems are prone to noise and gaps, which frequently cause AI models to hallucinate or generate biased results. By providing verifiable, protocol-driven data, Circle Datasets ensure that the AI orchestration layer—increasingly used by payers for pricing and claims processing—operates on a foundation of truth rather than statistical inference.

SOVEREIGN DATA OWNERSHIP AND THE SPLIT-IP MODEL

The traditional healthcare data economy is built on an extraction model where third-party brokers monetize provider and patient data through "silent" de-identification clauses. This model erodes trust, compromises patient privacy, and provides no financial return to the data sources. RegenMed replaces this with a Sovereign Ownership model, fundamentally realigning the economics of healthcare information.

The Split-IP Mechanism

At the heart of this new economy is the "split-IP model," a contractual framework that bifurcates ownership to favor those who generate and contribute the data:

The Practice: Maintains unambiguous ownership of the source data. This allows physicians to receive a majority share of any net license fees generated by the sale or use of their data in Circle Datasets.

The Platform: Owns the technical architecture, the protocols, and the aggregation logic used to build the Circle Datasets.

Circle Members: The patented closed Circles Platform enables RegenMed to contractually assign up to 85% ownership and monetization rights to participating Circles Members in proportion to their Case contributions to each Circle Dataset.

The Patient: RegenMed's [Circle Health Coins](#) will soon be an integral part of all Circle Datasets. Through them, each patient will maintain blockchain-level security over their Case-level healthcare data, as well as the right to control and benefit from the use that data at any time.

Thus, the Split-IP model undergirding Circle Datasets treats data as infrastructure rather than a neutral commodity. It acknowledges that personal data are "rights-laden emanations of the person" and should be protected as a human right. By decentralizing data storage—keeping it at the primary point of care—the platform satisfies global privacy and residency requirements while enabling federated research. This is where the future is inevitably going regarding personal healthcare data – RegenMed is bringing that future forward to the present.

Non-Linear Appreciation of Longitudinal Data

The value of healthcare data grows non-linearly as it becomes longitudinal. In the legacy model, data is often a "snapshot" of a single encounter. However, in the Circles model, a 12-month Case is significantly more valuable than a 6-month Case because it allows for the tracking of treatment durability and long-term complications.

This is particularly relevant for high-cost therapies, such as gene treatments, where payers

require long-term evidence of clinical efficacy to justify substantial upfront costs. The appreciation of data value can be modeled:

$$Value = \frac{Quality \times Service}{Cost}$$

As Circle Datasets provide more deterministic evidence of quality and long-term outcomes over the service life of a Circle Dataset – which is inherently multi-year given real-world setting in which Cases are generated and the split-IP model providing ongoing compliant motivation to patients and physicians to continue contributing such Cases -- the information value increases, allowing providers to negotiate better terms in value-based contracts.

Quantifying the Economic Benefits for Stakeholders

The structural compression of the 17-year gap via Circle Datasets generates significant ROI for all healthcare stakeholders. To take but three examples:

Healthcare Providers: Revenue Cycle Transformation

For providers, the economic benefits of participating in the RegenMed ecosystem extend beyond mere clinical quality. The platform turns data collection—historically an administrative burden—into a profit center.

Direct License Revenue: By retaining ownership of their data, participating physicians receive a majority share of licensing fees from their Circle Datasets. This creates a diversified revenue stream that is independent of fee-for-service reimbursement.

Performance-Based ROI: Registry participation has been linked to a 63% reduction in customer (patient) attrition and a 50% increase in productivity. Furthermore, providers who use standardized data to satisfy CMS quality requirements (e.g., MIPS or Hospital Value-Based Purchasing) can avoid negative payment adjustments of up to 9% and earn positive bonuses. And Circle Datasets are far more value-added for providers than mere registries.

Operational Efficiency: Circles not only deliver powerful, compliant motivation to

patients and physicians for long-term participation, they do so with modern, attractive user experience, which does not interrupt normal clinical flow.

Payers: Genuine Value-Based Care, Medical Loss Ratio, Risk Management

Payers face increasing pressure from rising medical costs, which are projected to trend at 8%–9% through at least the end of 2026. The RegenMed platform provides payers with the deterministic evidence needed to manage their MLR—the percentage of premium income spent on medical claims.

Prevention of Avoidable Costs: RWE derived from Circle Datasets allows payers to identify therapies that work consistently in the real world versus those that only show efficacy in "idealized" clinical trial settings. This in turn allows them to bend the cost curve by eliminating ineffective spending on procedures that have no benefit.

Management of High-Cost Specialty Drugs: The rise of GLP-1 drugs for obesity and diabetes, for example, has significantly impacted payer budgets. Deterministic longitudinal data allows payers to track the real-world effectiveness of these drugs and negotiate outcome-based agreements with manufacturers, where rebates are issued if the drugs fail to meet specific clinical markers (e.g., HbA1C levels).

Risk Adjustment Accuracy: AI-driven analysis of unstructured medical records within the RegenMed ecosystem can reduce fraud, waste, and abuse by up to 50% while ensuring risk-adjustment codes are fully supported by clinical documentation.

For Patients: Data Dividends and Self-Sovereign Identity

Patients are increasingly proactive and informed, with 75%–80% of younger generations using health tech monthly. The RegenMed model offers them a "digital social contract" grounded in dignity and participation.

Data Dividends: Through the Circle Health Coin, patients will receive direct measurable compensation for contributing their data to the healthcare ecosystem, essentially becoming "creators" receiving IP-based royalties from their own digital assets.

Reduced Out-of-Pocket Costs: By steering patients toward clinical practices proven to be effective and away from unnecessary procedures, the platform reduces the out-of-

pocket burden, which is a major concern for 71% of consumers.

Sovereign Identity: SSI, incorporated into Circle Health Coins, allows patients to manage their identifiers and health credentials via private keys and zero-knowledge proofs. This ensures that only relevant facets of their data are shared with providers, minimizing the risk of identification and data breaches.

Stakeholder	Economic Mechanism	Quantified Impact/Target
Provider	CMS Quality Incentives	Up to +9% payment adjustment
Provider	Administrative Automation	\$2M–\$10M annual savings
Payer	Fraud/Waste Reduction	Up to 50% reduction
Payer	VBC Shared Savings	30% reduction in readmissions bonus
Patient	Data Dividends	Consensual participation rewards
Market	RWE Solutions Growth	16% CAGR (to \$12B by 2035)

AI: MOVING TO NEAR-REAL-TIME SYNTHESIS

The ultimate mechanism for shortening the 17-year gap is the integration of Circle Datasets into AI-assisted evidence synthesis. Traditional systematic reviews are the primary bottleneck in the knowledge translation process, often taking years to complete. However, by using the structured, standardized outputs of the Circle Datasets, AI can compress this

timeline from years to days.

To take one example, the "otto-SR" system, an LLM-based approach, has demonstrated the ability to update 12 Cochrane reviews—spanning 146,276 citations—in under 48 hours. This system not only matches human accuracy but exceeds it, achieving a 97% sensitivity in literature screening compared to 82% for human reviewers.

For healthcare executives, this means that Evidence-as-a-Service is now a technical reality. Modern platforms can act as core infrastructure that continuously synthesizes new patient data and delivers context-aware evidence updates directly into the EHR at the point of care.

Predictive Modeling and Patient Funnels

Circle Datasets also support the generation of "value stories" for pharmaceutical and medical device products. By identifying specific patient profiles or subpopulations most likely to benefit from a treatment, these datasets inform predictive market models and "patient funnels". This stratification enables more targeted interventions and supports evidence-based decisions to remove barriers to access, thereby advancing personalized medicine strategies and accelerating market access.

Market Projections and the Future of the RWE Ecosystem

The global market for RWE solutions is poised for exponential growth as regulatory agencies and payers shift their focus from static clinical trial results to continuous post-market surveillance streams.

Growth Trajectory: The market size was estimated at \$2.6 billion in 2025 and is projected to reach \$12 billion by 2035.

Regulatory Adoption: The proportion of FDA approvals containing RWE increased from roughly 5%–10% in 2020 to nearly 50% by 2024. Regulatory agencies are now rejecting single-arm trials that lack synthetic control arms derived from longitudinal health records, making verifiable and unambiguously-owned Circle Datasets essential for drug and device manufacturers.

Deployment Models: Cloud-based models captured 64% of the market in 2025, benefiting from elastic compute and pay-as-you-go pricing. This aligns with RegenMed's

[Federated Healthcare Data Capture](#) model, where data remains at the point of care but can be queried and analyzed via secure, cloud-based infrastructure.

STRATEGIC IMPERATIVES FOR HEALTHCARE EXECUTIVES

The clinical evidence-to-practice gap is no longer an insurmountable reality, but a structural problem with a technical solution. RegenMed's Circle Datasets provide the necessary architecture to bypass the linear, fragmented workflows of the legacy data economy. By adopting a prospective Sequential Hierarchy and a Sovereign Ownership model, health systems can transform their data from a liability into a capital asset that benefits providers, patients, and payers alike.

The transition to "deterministic evidence" is the critical first step in this journey. In the era of AI-mediated healthcare, the quality and sovereignty of data will determine the winners and losers. By shortening the evidence gap, RegenMed does not just improve the efficiency of the healthcare system; it fulfills the fundamental promise of biomedical research: that the discoveries of today should become the care of tomorrow, without a 17-year delay.

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