RegenMed

ARTICLE

THE GROUND TRUTH FOR MEDICINE: WHY REAL-WORLD EVIDENCE MUST EVOLVE

www.rgnmed.com | circles@rgnmed.com

THE CRISIS OF CLINICAL KNOWLEDGE

Medicine is entering an age of paradox. Data volume has exploded, yet decision confidence is eroding. Clinicians are overwhelmed by digital noise — billions of disconnected points in electronic health records, research databases, and claims repositories that rarely align. Every algorithm promises insight, but few can guarantee truth.

The result is what the *New England Journal of Medicine* (2024) termed a "**crisis of verifiable knowledge**": massive informational abundance, minimal evidential reliability. The underlying problem is not technology but **epistemology** — how we know what we think we know.

WHAT REAL-WORLD EVIDENCE WAS SUPPOSED TO SOLVE

The real-world evidence (RWE) movement emerged to complement randomized controlled trials (RCTs) with insights drawn from routine clinical practice. Regulators, payers, and clinicians hoped RWE would fill the gap between efficacy and effectiveness, providing broader, faster, and more inclusive understanding of how therapies perform in reality.

But first-generation RWE largely failed to deliver. Most datasets are opportunistic EHR extractions — incomplete, inconsistently coded, and unverified. They describe events but cannot establish causality; they record encounters but cannot trace outcomes. In short, they are **big data without deep truth**.

As *Nature Medicine* summarized in 2023: "Real-world evidence can accelerate discovery only if it becomes real-world science."

THE CORE PROBLEM: LOW SIGNAL, HIGH NOISE

Uncurated EHRs and billing records were never designed for inference. They reflect administrative workflows, not scientific ones. Measurements vary by device, terminology, and context; diagnoses are inferred from billing codes; outcomes are rarely standardized. AI trained on such inputs amplifies inconsistency at scale.

Signal-to-noise ratios in unstructured clinical data are so poor that even advanced models produce statistically impressive but clinically unreliable results. Without validated context, a million data points can mislead as easily as they inform.

THE NEXT STEP: PROTOCOL-DRIVEN EVIDENCE GENERATION

RegenMed's answer is the **Circle Dataset** — a new class of structured, longitudinal, high-quality RWE built through the **Circles Platform**, implemented via the inCytes™ (clinician-facing) and Benchmarc™ (patient-facing) systems. Unlike EHR dumps, Circle Datasets are:

- **Structured**: defined by observational protocols, not opportunistic charting.
- **Validated**: each data element carries provenance and audit trails.
- **Longitudinal**: following patients, conditions, and interventions over time.
- **Interoperable**: mapped to FHIR-compatible standards (ICD, CPT, LOINC, SNOMED).

Every data point exists within context, verified by the clinician who generated it and confirmed by the system's validation layer. This transforms documentation into research — **care into evidence**.

WHY STRUCTURE MATTERS

Structure is the difference between observation and understanding. When data follow a defined protocol, they become comparable across patients, time, and institutions. That comparability enables real statistics, reproducibility, and learning.

As the **FDA's Real-World Evidence Framework** (2023) emphasized: "Fitness for regulatory purpose depends on demonstrable provenance, completeness, and traceability." Circle Datasets institutionalize those qualities, ensuring that every metric is clinically meaningful and computationally verifiable.

VALIDATION AS A CONTINUOUS PROCESS

Traditional datasets treat validation as an event — a one-time audit or publication checkpoint.

In Circles, validation is **continuous**. Each new record triggers automated quality checks, coding reconciliation, and peer-level review. Anomalies are flagged in real time; provenance is immutable.

This "always-on" validation loop not only guarantees data quality but produces an evolving evidence stream — a living database that learns as care unfolds.

THE LONGITUDINAL ADVANTAGE

Healthcare is temporal. Disease evolves, treatment responses fluctuate, and patient behavior changes. Only longitudinal data can capture those trajectories. Circles follow patients across visits, interventions, and outcomes, enabling precise time-series analyses and real-world cohort tracking.Longitudinality turns snapshots into stories — and stories into **scientific signal**.

INTEROPERABILITY AND FHIR COMPATIBILITY

Circles will adhere to the **Fast Healthcare Interoperability Resources (FHIR)** standard, ensuring data compatibility across systems and geographies. Every data element maps to international vocabularies — ICD for diagnoses, CPT for procedures, LOINC for labs, SNOMED CT for concepts. This standardization makes Circle Datasets exportable, verifiable, and integrable into AI training pipelines without loss of meaning.

THE HIGH-SIGNAL ALTERNATIVE

By combining structure, validation, longitudinal tracking, and interoperability, Circles achieve an unprecedented **signal-to-noise ratio**.

This precision enables machine learning models to generalize safely, clinicians to compare outcomes reliably, and regulators to trust conclusions confidently. It is the difference between having data and **having evidence**.

CONCLUSION — THE NEW GROUND TRUTH

Real-world evidence was meant to democratize discovery. To fulfill that promise, it must mature from opportunistic collection to deliberate observation. Circle Datasets represent that maturation: a rigorous, transparent, and continuously validated foundation for medical intelligence.

They are, in effect, **the ground truth of modern medicine** — a living infrastructure of verified care, built to power both AI and human judgment.

SELECTED SOURCES

- New England Journal of Medicine. The Crisis of Verifiable Knowledge (2024).
- Nature Medicine. Real-World Evidence as Real-World Science (2023).
- U.S. Food and Drug Administration. Real-World Evidence Framework (2023).

CONTACT US

RegenMed | www.rgnmed.com
circles@rgnmed.com