



# ARTICLE

## THE CIRCLE METHOD: PROTOCOL-DRIVEN REAL-WORLD EVIDENCE

*Transforming clinical practice into  
continuous, verifiable research.*

[www.rgnmed.com](http://www.rgnmed.com) | [circles@rgnmed.com](mailto:circles@rgnmed.com)

## THE REAL-WORLD EVIDENCE IMPERATIVE

Real-world evidence (RWE) has become the cornerstone of modern medicine's credibility. Regulators demand it, payers require it, and innovators depend on it. Yet most healthcare data, while abundant, fails to qualify as usable evidence.

Electronic health records were designed for billing, not science. Registries are fragmented, incomplete, and non-standardized. Research databases, though precise, are expensive and episodic.

The result is a paradox: healthcare generates terabytes of information but produces little that regulators, payers, or AI systems can reliably trust.

## THE CIRCLE METHOD: FROM OBSERVATION TO PROTOCOL

The **Circle Method** resolves this paradox by treating real-world data capture as a *designed scientific process*, not an administrative one.

At its core are **Observational Protocols (OPs)** – structured frameworks that define:

- **Clinical objectives** – what outcome or relationship is being studied.
- **Variables** – standardized measurements aligned with controlled vocabularies (LOINC, SNOMED, ICD, CPT).
- **Timing** – when data should be captured for longitudinal completeness.
- **Consent and provenance** – ensuring traceability and compliance.

Each OP transforms routine clinical encounters into **research-grade data events**, seamlessly integrated into care.

## INTEGRATION WITHOUT BURDEN

The elegance of the Circle Method lies in its workflow compatibility. Clinicians don't become data clerks; the system captures structured evidence as a byproduct of normal documentation.

In the **inCytes™** clinician platform, OPs appear as guided workflows; in the **Benchmark™** patient interface, as standardized follow-up interactions.

Because both sides operate on the same underlying protocol, data remains synchronized, longitudinal, and verifiable. The result is continuous RWE generation – without disrupting care.

## FROM STATIC REGISTRIES TO LIVING DATASETS

Traditional registries collect data retrospectively, often with missing fields or inconsistent definitions.

Circle's protocol-driven approach replaces this with **living datasets** – evidence that grows and verifies itself over time.

Every new patient encounter, outcome update, or protocol revision automatically propagates across the network, maintaining internal consistency.

This continuous integrity makes Circle datasets uniquely suited for:

- Regulatory submissions (FDA, EMA).
- Post-market surveillance.
- AI model training and validation.
- Value-based care measurement.

In effect, Circle turns RWE from a project into an **operating system for evidence**.

## THE FEDERATION ADVANTAGE

Because each OP can be implemented across multiple institutions, data can be federated without centralization. Each site retains ownership and privacy control while contributing standardized observations to the global evidence network.

This model balances two priorities:

- **Scientific rigor** through consistent structure.
- **Institutional autonomy** through decentralized governance.

It's the first architecture that scales trust without sacrificing control.

## STRATEGIC OUTCOME

The Circle Method redefines how healthcare generates, validates, and applies real-world evidence. It transforms observation into design, and design into proof.

By embedding scientific rigor into routine clinical workflows, it creates an ecosystem where every patient encounter strengthens the collective evidence base. In a world where regulators and investors demand reproducibility, and clinicians demand practicality, **the Circle Method is how real-world evidence becomes real.**

## KEY TAKEAWAYS

Stakeholder	Practical Implication
<b>Clinicians &amp; Researchers</b>	Capture research-grade data during routine care using standardized observational protocols.

Stakeholder	Practical Implication
<b>Health Systems</b>	Integrate real-world evidence generation into normal operations without increasing workload.
<b>Investors</b>	View protocol-driven RWE as a new standard for compliance, validation, and data asset maturity.

## GET INVOLVED OR LEARN MORE – CONTACT US TODAY!

If you are interested in contributing to this important initiative or learning more about how you can be involved, please [contact us](#)\*:

 [RegenMed | www.rgnmed.com](http://www.rgnmed.com)

 [circles@rgnmed.com](mailto:circles@rgnmed.com)



\*If the links do not work for you, please download the PDF.