RegenMed

# ARTICLE

## ACCELERATING DEMAND FOR VALIDATED REAL-WORLD EVIDENCE

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### EXECUTIVE SUMMARY

Real-World Evidence (RWE) has emerged as a cornerstone of modern healthcare innovation, regulatory science, and payer strategy. Once considered supplementary, RWE now informs pivotal regulatory decisions, market access strategies, and post-market evaluations.

The U.S. Food and Drug Administration (FDA), through the 21st Century Cures Act and subsequent guidance, has formally embraced RWE — defined as clinical evidence derived from real-world data (RWD) such as electronic health records (EHRs), insurance claims, and patient-generated information.

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# THE NEW ROLE OF REAL-WORLD EVIDENCE (RWE)

RWE's legitimacy has been reinforced by landmark regulatory approvals, including Medtronic's CRT-D device and label expansions for drugs like Ibrance and Tecentriq, all supported by high-quality RWD. Industry and payers alike are accelerating investment in RWE strategies. A 2023 Deloitte survey revealed that 92% of life sciences firms have RWE strategies, with two-thirds planning increased investments. Likewise, payers such as UnitedHealthcare and Aetna are leveraging RWE to drive value-based care.

# THE IMPERATIVE FOR PRIMARY, VALIDATED RWD

Despite the growing utility of retrospective datasets, the RegenMed's recent White Paper argues for the superiority of purpose-collected, prospective RWD. These data sources—gathered directly from clinicians and patients—offer several compelling advantages over administrative or passively collected data:

**1. Fit-for-Purpose Design**

EMR and claims data, collected primarily for billing, often lack the precision and completeness required for rigorous research. Purpose-built datasets enable the use of validated instruments, structured formats, and contextually relevant clinical endpoints.

**2. Clinical Nuance**

Structured physician reporting captures nuanced clinical insights, including treatment rationale, staging, and intent — data points typically obscured in EMRs.

**3. Patient-Reported Outcomes**

Prospective data collection engages patients directly, capturing metrics like pain, functionality, and satisfaction — offering a fuller picture of treatment efficacy than retrospective proxies.

# THE IMPERATIVE FOR PRIMARY, VALIDATED RWD

**4. Agility and Timeliness**

Real-time data collection enables swift adaptation to emergent clinical trends, whereas retrospective data sources lag by months or years.

**5. Data Integrity**

Purpose-collected data allows immediate validation at the point of entry. Structured electronic case report forms (eCRFs) and integrated logic checks dramatically reduce error rates.

**6. Regulatory Credibility**

High internal validity and transparent provenance make prospectively collected RWD more persuasive in regulatory and payer contexts.

# CIRCLES: REGENMED'S RESPONSE TO THE RWE CHALLENGE

To meet the demand for validated RWD, RegenMed regularly publishes and executes "Circles"— an ecosystem of statistically robust, domain-specific datasets focused on discrete pathologies, anatomical regions, and standardized outcomes. These datasets are:

- Built from physician-generated, real-world clinical data.
- Structured to answer specific scientific or clinical questions.
- Fully de-identified and HIPAA/GDPR compliant.
- Designed for flexibility in observational protocol (OP) development.

Circles empower clinicians to contribute cases while sharing in dataset monetization, aligning incentives and driving long-term data growth. Importantly, Circles data typically do not require IRB review, as they are gathered during routine care for quality improvement purposes rather than interventional experimentation.

# REAL-WORLD APPLICATION: TKA AND THA DATASETS

The White Paper includes illustrative Circles reports on Total Knee Arthroplasty (TKA) and Total Hip Arthroplasty (THA), demonstrating Circles' potential for granular, verifiable insights. These reports exemplify how customized observational protocols, rich clinical detail, and long-term patient-reported outcomes converge to support practice-changing analytics and licensing opportunities.

# CONCLUSION

Validated real-world data, collected directly from clinicians and patients with rigor and intent, is no longer optional — it is essential. As regulatory bodies, payers, and innovators continue to demand more actionable, credible, and agile evidence, RegenMed's Circles platform positions itself as a next-generation solution. By aligning clinical insight, scientific design, and economic incentives, Circles transforms real-world data into real-world impact.

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