REGEN MED

ARTICLE

CIRCLES OVERVIEW

October 2023

ABSTRACT: Real-world evidence is at the heart of value-based care and informed clinical decision-making. It supports better, lower-cost healthcare for all population groups. It is increasingly required for regulatory approvals.

RWE derives from real-world data. RWD derives from everyday patient-clinician interactions, tied to long term outcomes capture.

Circles capture RWD and develop RWE in a minimally burdensome and cost-efficient manner. Equally important, they generate clinical, scientific, and financial value for all Circle Members.

TABLE OF CONTENTS

THE MARKET NEED

The efficient collection and aggregation of real-world data -- and the generation therefrom of clinically-significant real-world evidence – can make a material difference in helping solve many of modern healthcare's most pressing challenges.

Clinical Trials and Other Studies

Regulators, legislative bodies and payers recognize the potential of real-world evidence to improve healthcare outcomes and reduce costs. [1] This has led to a proliferation of registries [2] and study designs -- pragmatic, quality improvement, observational, and other. [3]

A corollary is the requirement for more inclusiveness and diversity in clinical trial design. [4]

Value-Based Care

The trend towards value-based care is inexorable. [5] For many years, government and private insurers have adopted explicit or implicit reimbursement schema moving away from fee-for-service.

As their share of healthcare costs continues to rise, patients are selecting providers and treatments on the basis of perceived value.

Self-funded employer groups [6] and other forms of narrow networks are increasing, driven by the concept of value-based care.

Inequality In Healthcare Delivery

The U.S. spends far more per capita on healthcare than other countries, with worse outcomes in most categories. [7] Within the U.S., and many other countries, the accessibility and quality of healthcare services vary substantially by region and economic class. [8]

Cost and Complexity

To a large extent, the challenges identified above derive from high (and often opaque) costs and unnecessary complexity at all levels of the healthcare delivery system.

Physician and Patient Engagement

Even post-pandemic, healthcare professionals are demoralized, and leaving the industry altogether. [9]

There has been a steady decline of trust in healthcare leaders and the medical system. This erosion of trust is shared by many healthcare professionals. [10]

Faster Product and Protocol Development

The national legislation and regulatory developments illustrated in footnote 1 are the result of broad demand for faster, less expensive pathways to market for medical products, as well as more evidence-based

standards of care. [11]

Data Control and Ownership

As "big data" and other forms of anonymized healthcare datasets become prevalent, ownership by data sources and use by others of such datasets often remains poorly undefined.

Too Much Data

"Big data" and faster algorithms have disappointed many by failing to provide usable clinical evidence. [12] This is generally due weak data verifiability, lack of clinical context, and limited long-term outcomes data demonstrably linked to specific clinical interventions.

CIRCLES

Circles integrate clinical grade healthcare data platforms with processes focused on clinician- and patient-engagement. Each Circle addresses a specific real-world evidence objective, and is designed to generate a demonstrable return on investment in the form of clinical, scientific and/or financial value.

Technical Platform

Circles utilize the patented clinician-facing inCytes™ and patient-facing Benchmarc™ platforms [13]. This technology is competitive with much more expensive, and less user-friendly, EHR, CRO, PROM and similar data software. [14]

Processes

RegenMed can handle patient enrollment, long-term outcomes capture, report generation, publication, ongoing collaboration support, publication, industry funding, IRB support and similar administrative elements.

User Experience

Minimizing administrative burden for clinicians and their staff is an essential feature of all Circles.

Circles emphasize patient engagement, comprehension of medical conditions and proposed treatment paths, and long-term compliance.

Inherent Collaboration Support

Circle Members collaborate within and across institutional and national borders. Circle Hours [15], Circle Academies, and other RegenMed processes sustain that collaboration.

KOL and Investigator Recruitment

Join-A-Circle and associated RegenMed processes support the identification, onboarding and active involvement of clinical/scientific experts, as well as additional Circle Members.

Partnership and Return On Investment

RegenMed works with each client to determine its Circle objectives – clinical, scientific and/or commercial. These are translated into key performance metrics, which in turn are the basis for demonstrable ROI

SELECT USE CASES

Circles are used by large provider groups, sole practitioners, medical societies, product manufacturers, veterinarians, researchers and other healthcare constituencies around the world. Illustrative client approaches to the efficient generation of clinical, scientific and financial value are summarized below.

Clinical Decision Making

- Capture long-term outcomes.
- Develop, improve, confirm standards of care.
- Coordinate care pathway across multiple healthcare professionals. [16]
- Remote patient therapies and monitoring.
- Monitoring and treatment of chronic conditions.
- Incorporate evidence-based medical science into treatment protocols, including through integration of lab results.

Trials and Studies

- Formal clinical trials. Including engagement with IRBs and medical ethics committees.
- Real-world study formats, including private, pragmatic, N of 1, observational, quality control, prospective, retrospective, research.
- INDs, IDEs, PMAs, post-market surveillance, other regulatory submissions.
- Single or multi-center. Any size or complexity.

Education and Training

- Residents, fellowship, and other department programs.
- Augment CME courses.
- Mortality and morbidity conferences.
- Medical practice website and patient literature.

Registries

For medical societies, foundations, narrow networks, payers, hospital departments, product manufacturers, ASCs.

Commercial/Financial

- Evidence-based branding.
- Product improvement and development.
- New service lines and indications.
- Reimbursement.
- Reduction of administrative, IT, research, regulatory submission, and marketing costs.
- Payer negotiations/ ratings.
- KOL recruitment, influence expansion.
- Honoraria, Investigator fees, product discounts, travel purses.
- Data licensing.
- Professional advancement.

Publication

- Journals.
- Conference presentations and posters.
- HCP and patient communications.
- Newsletters.
- Department abstracts.
- Grant proposals.

Legal/Regulatory Compliance

- Support novel, compassionate use, right-to-try, experimental and similar treatment protocols.
- Confirm adverse event tracking.
- Expert medical opinions and other forensic uses.

FOR FURTHER INFORMATION

RgnMed.com/Circles/General

Join/Start A Circle

KnowledgeBase

LinkedIn

Latest

Contact Us

FOOTNOTES

1 See for example FDA, Real World Evidence, FDA, Post-Market Surveillance Programs; The 21st Century Cures Act; NIH Grants Program For Real-World Studies; Expect To See More RWE-Based Regulatory Decisions, Robert Califf, FDA Commissioner; Use Of Real-World Evidence In Regulatory Decision Making, European Medicines Agency.

2 See Registries for Evaluating Patient Outcomes: A User's Guide: 4th Edition, Agency for Healthcare and Quality and Research, U.S. Department of Health and Human Services.

3 See Pragmatic Trials, NEJM, Ford and Norrie, Quality Improvement Projects and Clinical Research Studies, Faiman, and Quality Improvement In Practice, Backman.

4 See for example, Diversity and Inclusion In Clinical Trials, NIH; Why Diverse Clinical Trial Participation Matters, Schwartz et al, New England Journal Of Medicine.

5 See for example Value-Based Health Care at an Inflection Point: A Global Agenda for the Next Decade, Larsson et al, New England Journal Of Medicine; Value-Based Care: What It Is and Why It's Needed, The Commonwealth Fund; Value-Based Programs, U.S. Center For Medicare and Medicaid Services; Understanding The Value-Based Insurance Design, U.S. Department of Health and Human Services, National Center For Chronic Disease Prevention and Health Promotion.

6 The 2020 Kaiser Family Foundation Survey of Employer Health Benefits reports that 67 percent of employed, insured workers are covered under self-insured, or self-funded, arrangements. See also, example, Health Transformation Alliance and Self-Insurance Institute Of America.

7 See How Does The U.S. Healthcare System Compare To Other Countries?, Peter G Peterson Foundation.

8 See Healthcare Access In Rural Communities, Rural Health Information Hub; Serving Vulnerable and Underserved Populations, U.S. Department of Health and Human Services.

9 See Physician Suicide, Matheson, American College of Emergency Physicians; Strengthening The Healthcare Workforce, American Hospital Association.

10 See Trust In Medicine, The Health System and Public Health, MIT Press; Surveys Of Trust In The Health Care System, University of Chicago.

11 See Transforming Medicare Coverage: A New Medicare Coverage Pathway for Emerging Technologies and Revamped Evidence Development Framework, Fleischer et al., Center For Medicare and Medicaid Services; Center For Clinical and Translational Science/Product Development Pathways, Mayo Clinic. What Is The Evidence For Our Standards Of Care?, Turka et al, The Journal Of Clinical Investigation.

[12] See Medical Innovation and Digital Snake Oil, American Medical Association; Why Does Big Tech Often Fail In Healthcare?, Healthcare Information and Management Systems Society.

[13] U.S. patent number 11720567, *Method and System For Processing Large Amounts Of Real-World Evidence*.

[14] HIPAA, GDPR, Part 11, FHIR HL7 Compliant. Scalable. All data and edits fully auditable. Multilingual. Real-time 24/7 accessibility by patients and clinicians from any device in any location. Robust role, permission, clinician branding, and other customization settings.

[15] Regular livestream and recorded sessions among Circle Members reviewing observations, best practices, study variations and emerging correlations.

[16] For example, surgery and rehabilitation, referring and treating physicians in context of "medical tourism", radiation oncology and wound care/plastic surgery.