CIRCLES

HEALTHCARE DATA:
OWNERSHIP, PUBLICATION AND MONETIZATION

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Abstract

Real-World Evidence (RWE) is fast becoming the most important data category in healthcare. More than EMR, payer, RCT and other types of data, RWE is essential to achieving value-based care, health equity and overall cost reduction in healthcare delivery. RWE, properly structured, has been recognized by regulatory authorities for its potential clinical and statistical significance.

Although RWE can be assembled from a variety of sources, the only necessary source – and by far the most powerful – is the real-world data (RWD) emanating from everyday clinical observations,

interventions, and long-term outcomes measures.

Circles utilize clinical grade technology to capture – and establish ownership of – the specific RWD which are "fit-for-purpose" in the context of the desired RWE. Integrated processes enable the efficient development of RWE from those data, as well as the development of clinical, scientific, and financial value.

Circles are cloud-based, low-cost, and impose minimum burden. As such they are a strategic profit center, not a cost center,for large as well as smaller healthcare stakeholders.

The Importance Of Real-World Evidence

General

Three of the most important trends in healthcare are value-based care, health equity, and controlling costs. RWE is an essential element of each of these. [1] RWE is also the foundation of government programs such as Precision Nutrition, RECOVER ("long-COVID") [2], All Of Us, Social Determinants of Health, and Precision Medicine.

Regulators and policymakers recognize that the cost, delay, and exclusionary criteria of traditional clinical trials have become serious obstacles to genuine clinical translation for most indications and many patient populations. Recent FDA draft guidance states that RWE "may provide an efficient means of generating the necessary clinical evidence to support regulatory decisions". [3] RWE can also help document good clinical practice. [4]

RWE already plays a central role in post-market surveillance, and emerging medical fields such as biologics, immunotherapies, cell therapies and other types of regenerative medicine.

RWE is important for improving clinical decision-making, streamlining regulatory approvals (INDs, IDEs, 510(k)s, PMAs,), and supporting marketing claims across all medical specialties.

Demand For Real-World Evidence

Given its broad relevance and value, RWE is becoming a strategic necessity to all healthcare stakeholders. Examples include:

- Medical product manufacturers for regulatory submissions and continuing compliance, new product development, supporting new indications, HCP education and training, and consumer/patient communications.

- Employers and other payers seeking to define and monitor narrow networks. [5]
- Provider and other groups participating in accountable care organizations.
- Research centers.
- Academic medical institutions with health equity/SDOH mandates.
- Medical societies with research, education, registries, and other initiatives.
- Governmental and private payers seeking to drive long-term value-based care.
- Providers seeking to deepen and lengthen patient engagement.
- Compounding pharmacies and nutraceutical companies for compliance with state licensing authorities, documenting safety and efficacy claims, developing evidence-based physician and consumer communications.
- Patient advocacy groups and healthcare foundations for increasing policy impact, member value and donor engagement.

Generating Real-World Evidence

Real-World Data

The FDA "is committed to realizing the full potential of fit-for-purpose RWD to generate RWE that will advance the development of therapeutic products and strengthen regulatory oversight of medical products across their lifecycle." [6]

Although the FDA indicates multiple sources of RWD, the requirements that it be "fit-for-purpose" and capable of generating "study-specific datasets" in order to qualify as usable RWE are critical qualifications.

As the FDA says in its December 2023 Draft Guidance, "the data should be accurate, as complete as possible, and of adequate data quality to credibly address the question at hand."

However, it is highly difficult if not impossible to generate compliant RWE from EMR records, prior studies and trials, registries, and other sources. Such datasets typically suffer from one or more of (i) lack of specific and coherent study context, (ii) incompleteness, (iii) inability to verify data validity, (iv) lack of correlated longitudinal outcomes, and (v) weak statistical or clinical significance.

Fit For Purpose

To be usable – whether for regulatory or other purposes – RWE should be "fit-for-

purpose". Well-designed protocols, endpoints, patient consent forms, population sample definitions, adverse event reporting, controls for bias and similar traditional study parameters should be observed.

In other words, one should carefully define at the outset the purpose for which a particular RWE dataset is to be used. This will in turn dictate the most suitable types and amount of RWD to be captured.

Causal Correlations

The RWD in aggregate must also establish causal correlations -- typically between a specific product or clinical intervention and long-term outcomes. (Other important datapoints can include lab tests, bio-sensor outputs, etc.) RWE also implies a large "n" or population sample size to achieve causal correlations which are statistically significant.

Data Integrity

The FDA has emphasized that its "guidance, when finalized, should not be construed to alter or change in any way the existing evidentiary standards applicable to FDA's regulatory decision-making." In particular, data availability, integrity, longitudinality, relevance, "linkages", structure, timeliness, and other characteristics are important for qualification as usable RWE. [7]

The Benefits Of Circles For RWE Programs

Purpose Built

Circles are built from the ground up to meet a Client's specific clinical, scientific, and/or financial objectives. They are cloud-based, clinical grade, and reflect excellent user experience.

Circles offer compelling value propositions for all healthcare stakeholders. They are low cost, impose no contractual commitments and are highly flexible and scalable. This allows clients to commence an RWE initiative modestly, and expand as it meets its desired KPIs.

Ownership

Data ownership – especially for valuable data such as RWD – is an increasingly important topic. It has major implications for publication rights, as well as for monetization opportunities. In addition to traditional use cases, the power of social media channels and generative AI have increased the attention paid to data ownership and value extraction. [8]

Most healthcare data platforms provide little or no ownership rights to the principal sources of such data. Indeed, some

platforms do not allow export of data entered by such sources.

In contrast, Circles RWE programs not only develop data worth owning, but they also enable both ownership and the generation of value from that ownership.

Publication

Journal articles, conference presentations, treatment protocols, and registries are among the ways knowledge in healthcare is disseminated. To these traditional channels, one should add Internet search results, social media, and the fast-emerging capabilities of generative AI.

Evidence-based observations are at the heart of such knowledge. Circle-based RWE programs develop publishable content, and enable that publication and associated influence through multiple channels. Importantly, the ownership of RWD and RWE developed through Circles remains in the hands of those responsible for such data.

Monetization

Ownership is necessary to monetizing data, but not sufficient. As indicated above, multiple healthcare constituencies highly value RWE.

RegenMed develops ethical relationships between Circle founders and those constituencies. A common vehicle underpinning such relationships is the investigator-initiated study. There are also other important avenues to meaningful monetization of RWE.

An Illustrative RWE Program

Program Elements

A Circles-based RWE Program can begin modestly, allowing members to join one or more of the dozens of Circles already available. The corresponding cost is only $5 per Case, and $35 per month per subscriber.

This is a good way for any Client to appreciate the functionality, user experience and potential uses of an RWE Program.

Given the inherent flexibility of Circles, a Client can expand into a more-value added approach on its own schedule. A typical sequence follows. Each element is optional, and all elements are tailored to the goals and budget of the Client.

- Development of two to three Circles targeting clinical/scientific endpoints with particular relevance. Principal investigators are identified from among current relationships, or with the assistance of RegenMed.
- Recruitment of five or more society members as Circle co-investigators.
- Link to an actively promoted Join-A-Circle page to enhance recruitment of additional co-investigators.

- Establishment of a dedicated website research page, which is also actively promoted. This page describes Circles protocols, endpoints, principal and co-investigators, and developing real-world data.
- Communications through Client and RegenMed newsletters and other suitable communication channels of preliminary aggregated data and related observations.
- Use of Circle Academies to host periodic "Circle Hours" among Circle members. These private discussions among society members, moderated by principal investigators, cover learnings from ongoing Circle activities to date.
- Circle Academies also support secure 24/7 interaction among Circle members and, if desired, other society members.
- Engagement with industry and donor organizations to support investigator-initiated trials, training and education sessions, society meeting break-out sessions, and other value-added initiatives.
- Publication of select Circle activities and/or results by the principal investigators through conferences, articles, and social media.
- Scaling to capture inherent network effects of Circles as original key performance indicators are met.
- Ongoing development of monetization opportunities resulting from honoraria, investigator fees, product development, conference sponsorship, data licensing and other pathways.

Pricing and Partnership

Properly designed and executed, a Circle-based RWE program delivers substantial and ongoing data ownership, professional influence, and monetization opportunities. Pricing is low and flexible. The program can be terminated at any time. Full pricing and terms can be found through the link in Learn More, below.

RegenMed works as a long-term partner to ensure that each Circle and associated RWE program is tailored to a Client's specific objectives.

Learn More

Leadership	Processes For Physicians	Latest
History and Principles	Processes For Industry	LinkedIn
How Circles Work	Circle Academies	Contact Us
Circles Value Propositions	Pricing and Terms	

Endnotes

[1] *Real World Evidence*, FDA, February 2023. https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence. *Registries for Evaluating Patient Outcomes: A User's Guide*, HHS/AHRQ, September 2020, https://www.ncbi.nlm.nih.gov/books/NBK562575/. *Creating Value From Next-Generation Real-World Evidence*, McKinsey July 2020. See Deloitte Insights, 2018, https://www2.deloitte.com/content/dam/insights/us/articles/4354_Real-World-Evidence/DI_Real-World-Evidence.pdf. McKinsey, Real-World Evidence: From Activity To Impact In Healthcare Decision-Making, 2022, https://www.mckinsey.com/industries/life-sciences/our-insights/real-world-evidence-from-activity-to-impact-in-healthcare-decision-making#/

[2] See https://www.nih.gov/news-events/news-releases/nih-launches-long-covid-clinical-trials-through-recover-initiative-opening-enrollment. See also employer groups such Health Transformation Alliance, https://www.htahealth.com/.

[3] *Use of Real-World Evidence to Support Regulatory Decision-Making For Medical Devices*, FDA, December 2023, https://www.fda.gov/media/174819/download. ("FDA Draft Guidance".)

[4] "Many of the considerations and best practices for generating RWE are derived from the same principles that govern generation of clinical evidence from traditional clinical studies, which are generally referred to as good clinical practice". FDA Draft Guidance.

[5] The majority of U.S. companies are self-insured for healthcare liabilities. See https://www.statista.com/statistics/985324/self-funded-health-insurance-covered-workers/.

[6] https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence.

[7] See lines 377 – 630 of the Draft Guidance.

[8] See the multi-billion-dollar lawsuit by the New York Times against Microsoft and Open AI for alleged appropriation of copyrighted materials. https://apnews.com/article/nyt-new-york-times-openai-microsoft-6ea53a8ad3efa06ee4643b697df0ba57.