CIRCLES

STRATEGIC VALUE FOR MEDICAL PRODUCT MANUFACTURERS

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TABLE OF CONTENTS

Abstract

A Real-World Evidence Program based on Circles can represent a strategic pillar of the business plan for any medical product company. It can generate sustained return on investment in the context of provider engagement, research initiatives, product development, company branding, and regulatory submissions/compliance.

RWE is fast becoming an essential component of value-based care, health equity, and controlling costs. RWE, in turn, is derived from the large amounts of real-world data (RWD) generated daily in busy clinical practices. Circles integrate the technology and processes required to capture RWD, generate RWE, and convert it into value. Importantly, Circles do so with minimal administrative burden, excellent

clinical and patient user experience, and at a low cost.

RegenMed works as a long-term partner with product manufacturers to help them achieve multiple strategic objectives through a Circles-based Real-World Evidence Program.

The Importance Of Real-World Evidence

Product manufacturers must rely heavily on research and trials for INDs, IDEs, PMAs, 510Ks, post-market surveillance and other regulatory approvals. However, the cost, delay, and exclusionary criteria of traditional clinical trials have become serious obstacles to genuine clinical translation for most indications and patient populations. [1]

As a result, pragmatic, "n of 1", properly curated registries [2], and other modern study designs based on RWE are seen as providing critical support for, and often alternatives to, traditional RCTs. Recent FDA draft guidance, for example, states that RWE "may provide an efficient means of generating the necessary clinical evidence to support regulatory decisions". [3]

RWE is fast becoming an essential element of most of the major trends in healthcare – value-based care, health equity/SDOH, controlling costs, regenerative medicine, and precision care and "bending the cost curve". [4]

Elements Of A Real-World Evidence Program

A Circles-based Real-World Evidence Program (RWP) can be modest or comprehensive. It is modular, flexible, and scalable. A typical RWP comprises the following sequence and elements:

- Development of two to three Circles targeting clinical/scientific endpoints with particular relevance to the manufacturer's targeted provider segment. Principal investigators are identified from current product users, or other thought leaders recruited by RegenMed.
- Recruitment of five or more current users as Circle co-investigators.
- Link to a Join-A-Circle page to enhance recruitment of additional existing and

prospective users as co-investigators. This is actively promoted by RegenMed.

- Establishment of dedicated research pages on the principal investigators' websites, which are also actively promoted by the investigators. This page describes Circles protocols, endpoints, principal, and co-investigators, and developing real-world data.
- Communications through posts from principal investigators, RegenMed newsletters and other suitable communication channels of preliminary aggregated data and related observations.
- Use of Circle Academies to host periodic "Circle Hours" among investigators and other Circle members. If desired, these discussions can be open to prospective Circle members/product users as well. These private discussions are moderated by principal investigators, and cover learnings from ongoing Circle activities to date.
- Circle Academies also support secure 24/7 interaction among Circle members and, if desired, other current and prospective product users. Industry space.
- Establish corollary initiatives with relevant medical societies and/or their research arms. Society sponsored investigator-initiated trials, training and education sessions, society meeting break-out sessions, newsletter posts, dedicated research page.
- Scaling of the program to include additional provider groups, international regions, research topics.

Strategic Benefits Of A Circle Program

Provider Engagement

A Circles-based Real-World Evidence Program allows manufacturers and their representatives to provide ethical, demonstrable, and sustained clinical and educational value to clinicians. It enables meaningful communications with product users regarding product expectations and leading to product improvements. Medical society conference presentations, break-out sessions, and dedicated research pages greatly amplify that value.

More Efficient Trials and Studies

An RWP establishes and executes comprehensive research protocols which are "fit-for-purpose" [5], and can accommodate

any level of complexity. An RWP nurtures a growing and committed base of influential principal investigators and co-investigators. It encompasses investigator training, and administration.

An RWP also handles study-specific patient consents, enrollment, long-term outcomes capture and compliance. It includes data validity confirmation, 24/7 real-time data access, sophisticated report generation and raw data export consistent with pre-established roles and permissions.

Product Improvement/Development

Busy clinicians, especially when collaborating with medical scientists, are the most valuable source of product development and improvement. RWPs deliver value and excellent user experience to those clinicians and scientists, enabling them to discover and refine their inventions, as well as establish corresponding safety/efficacy databases.

Consumer/Patient Branding

Compelling communication of the evidence-based safety and efficacy of a product is of course an essential part of the brand of any successful manufacturer. Incorporating into that brand the ***real-world*** evidence which is directly relevant to patients in the context of their specific indications, outcomes objectives and providers' treatment protocols is far more impactful. An RWP provides that RWE, developed by therapeutic influencers, on a sustained basis.

Cost Reduction

Cost control and improving operational efficiencies are basic strategic goals for any successful product manufacturers. A Circles-based Real-World Evidence Program is highly cost-effective and flexible. [6] RegenMed works as a long-term partner to ensure that each RWP delivers substantial and transparent return on investment to a product manufacturer in the context of its specific research, commercial and valuation objectives.

Learn More

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History and Principles
How Circles Work
Circles Value Propositions

Processes For Physicians
Processes For Industry
Circle Academies
Latest

LinkedIn
Pricing and Terms
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Endnotes

[1] These challenges have long been recognized. See for example Examination of Clinical Trial Costs and Barriers For Drug Development, US Department of Health and Human Services, 2014; Lack of Diversity in Clinical Trials Costs Billions of Dollars, Goldman et al, 2023; Why 90% of Clinical Drug Development Fails And How To Improve It, Sun et al, 2022.

[2] See AHRQ Registries Users Guide, cited above in footnote 1.

[3] Use of Real-World Evidence to Support Regulatory Decision-Making For Medical Devices, FDA, December 2023.

[4] The broad significance of real-world evidence is recognized the U.S. FDA, the European Medicines Agency, industry, and payers. See for example: Use of Real-World Evidence in Regulatory Decision-Making, (EMA). Creating Value From Next-Generation Real-World Evidence, (McKinsey). Real World Evidence, FDA, February 2023. Registries for Evaluating Patient Outcomes: A User's Guide, HHS/AHRQ, September 2020.

[5] As required by the FDA in its recently released draft guidance on the use of real-world evidence for regulatory decision-making. See footnote 3.

[6] Further information on pricing can be found here.