

# CIRCLES

## FOR OTC PRODUCT MANUFACTURERS

### ADDRESSING STRATEGIC IMPERATIVES

FEBRUARY 2024

## Introduction

OTC product demand is driven by perceived safety and efficacy among healthcare professionals and consumers. Moreover, legal/regulatory compliance is an increasingly important issue for manufacturers. <sup>1</sup>

Well-structured datasets comprising real-world evidence (RWE) are foundational to meeting both categories of requirements.

Through its HCP and consumer customers, an OTC product manufacturer can generate

a large amount of RWE comprising substantial clinical, scientific, and commercial value. OTC category leaders recognize this value, and have established programs to achieve it. <sup>2</sup>

Through Circles, RegenMed supports product manufacturers globally in developing RWE programs delivering demonstrable and sustained return on investment.

## Circles: Not A Cost Center, But A Strategic Imperative

RWE is a strategic imperative for OTC product manufacturers. <sup>3</sup> As an important signal of emerging trends, the FDA states that RWE “may provide an efficient means of generating the necessary clinical evidence to support regulatory decisions”.

Thus, RWE can be an important element of value-based care, new product development, reimbursement, HCP and patient engagement, health equity and evidence-based support for marketing claims.

However, the FDA also emphasizes that RWE must be “fit for purpose”. In other words, it must start with well-defined endpoints, be causally correlated to longitudinal outcomes, represent validated data, and otherwise conform to traditional parameters of properly designed and executed studies.

Circles-based RWE programs meet these criteria. They are efficient, cost-effective, flexible and scalable. As such, they can advance one or more strategic objectives for

any OTC product manufacturer, regardless of size and market position:

**Financial:** New product development. Improvement of existing products. IP capture. Support for new indications. Reimbursement.

**Competitive Differentiation:** Publication. Conference Presentations. Research. Deeper HCP and patient engagement.

**Brand Extension:** Recruitment and collaboration among HCP influencers and their peers. Evidence-based content for patient groups.

**Legal/Regulatory Compliance:** Regulatory submissions. Marketing claims. Adverse event reporting. Safety/efficacy reports for specific formulations.

Critically, an OTC product manufacturer owns the Circles-based RWE which it and its customers generate. It therefore maintains control over the resultant product development, publication, and other value creation opportunities. See [here](#) and [here](#) for more information.

## Learn More

[What Is A Circle](#)

[Join/Start A Circle](#)

[Ownership, Publication, Monetization](#)

[Value Propositions](#)

[Processes For Physicians](#)

[Contact Us](#)

## Endnotes

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<sup>1</sup> See for example [here](#), [here](#), and [here](#).

<sup>2</sup> See for example the [sunscreen study](#) materials disseminated by Johnson & Johnson.

<sup>3</sup> *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. *Use of Real-World Evidence to Support Regulatory Decision-Making For Medical Devices*, FDA, December 2023, <https://www.fda.gov/media/174819/download>.