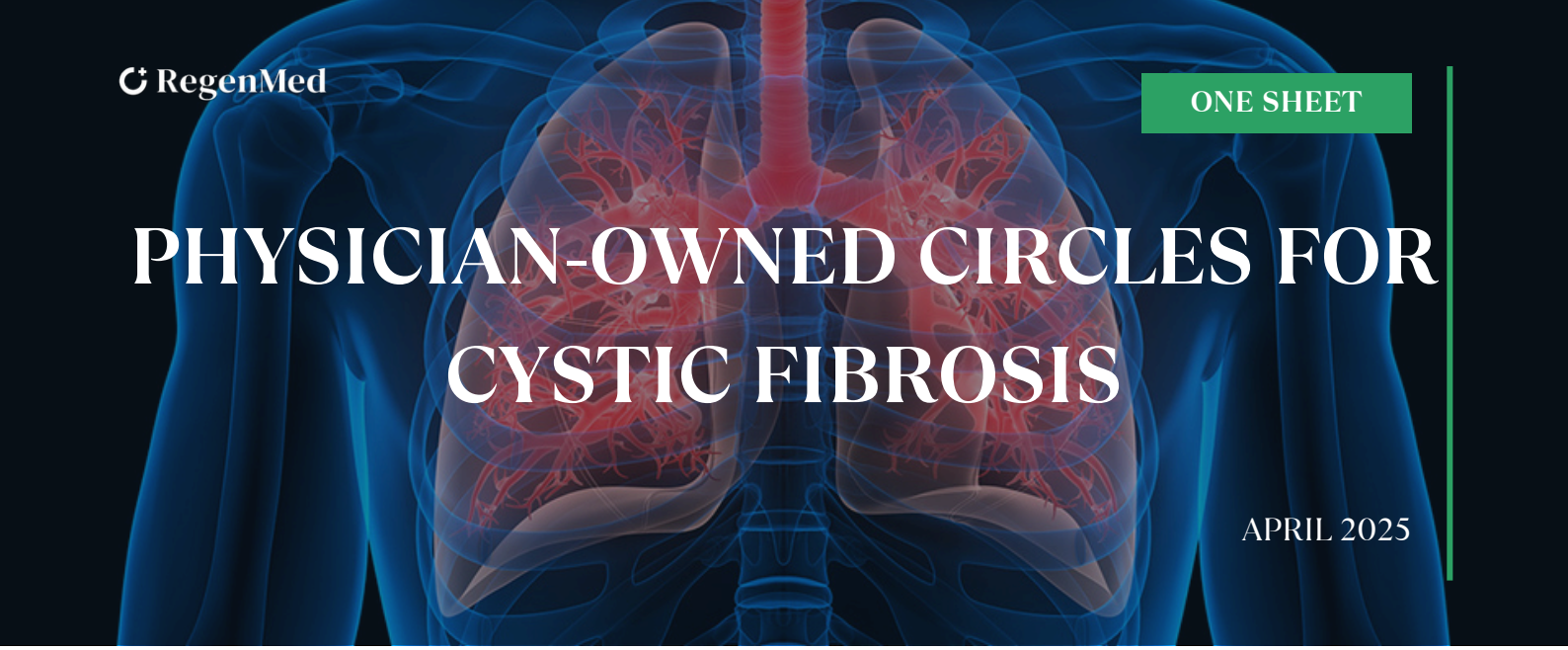
RegenMed

ONE SHEET



PHYSICIAN-OWNED CIRCLES FOR CYSTIC FIBROSIS

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BACKGROUND

Cystic Fibrosis (CF) is one of approximately 7,000 recognized rare ("orphan") diseases, which collectively impact around 25 million people in the United States and 350 million worldwide. Despite this, about 95% of rare diseases still lack an approved treatment.

In the U.S., nearly 15 million children are affected by rare diseases, with one-third tragically not surviving past the age of five.

The financial burden of living with a rare disease is significant — estimated to be 15 times higher per patient than for more common conditions.

To drive innovation, policies like the U.S. Orphan Drug Act have encouraged pharmaceutical investment in rare diseases, fueling a market projected to reach $262 billion by 2025, growing at a 12% annual rate.

However, major challenges persist: small patient populations, ethical concerns over placebo-controlled studies, frequent delays in diagnosis, difficulties in tracking long-term outcomes, and barriers to patient access.

POCS FOR CYSTIC FIBROSIS

Cystic Fibrosis Circles are sustained collaborations among physicians worldwide, focused on cystic fibrosis-specific treatments and outcomes.

Each Circle operates under an Observational Protocol (OP) that defines the scope: a single pathology (CF), standardized treatment approaches, and structured longitudinal outcome tracking.

Through these Circle studies, primary data are captured directly from physicians and patients, producing clinically and statistically meaningful datasets. All CF Circle data are fully compliant with HIPAA, GDPR, and 21 CFR Part 11 regulations.

An overview of POCs is **here**. A description of the physician and patient user experiences is **here**.

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Physician-Owned Circles

For practitioners treating or otherwise interested in a specific orphan disease, POCs offer the following advantages:

- Sustained collaboration with peers and experts in developing clinically-significant longitudinal datasets.
- Minimal cost and burden.
- Earlier, more accurate diagnoses.
- Evidence-based protocols.
- Deeper patient engagement, education.
- 85% of resulting license fees to POC Members.
- Professional advancement (articles, conference presentations, etc.)

Benefits For Industry

For product manufacturers, clinical researchers, and value-based organizations, POCs offer several benefits:

- Validatable, clinically-relevant datasets at a fraction of typical costs.
- Integrated and longitudinal support for regulatory submissions.
- No gaps, errors, undisclosed data manipulations, ownership claims, clinical irrelevance and other weaknesses inherent in “big data” solutions.
- Enable adaptive trial designs and single-arm studies, without compromising rigor.
- Long-term outcomes directly correlated to original clinical hypotheses.
- Ability of Sponsor to define Observational Protocol.
- Multi-center studies enlarging patient populations.
- Access to global experts and current clinical/scientific hypotheses.
- Continued post-market surveillance.

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