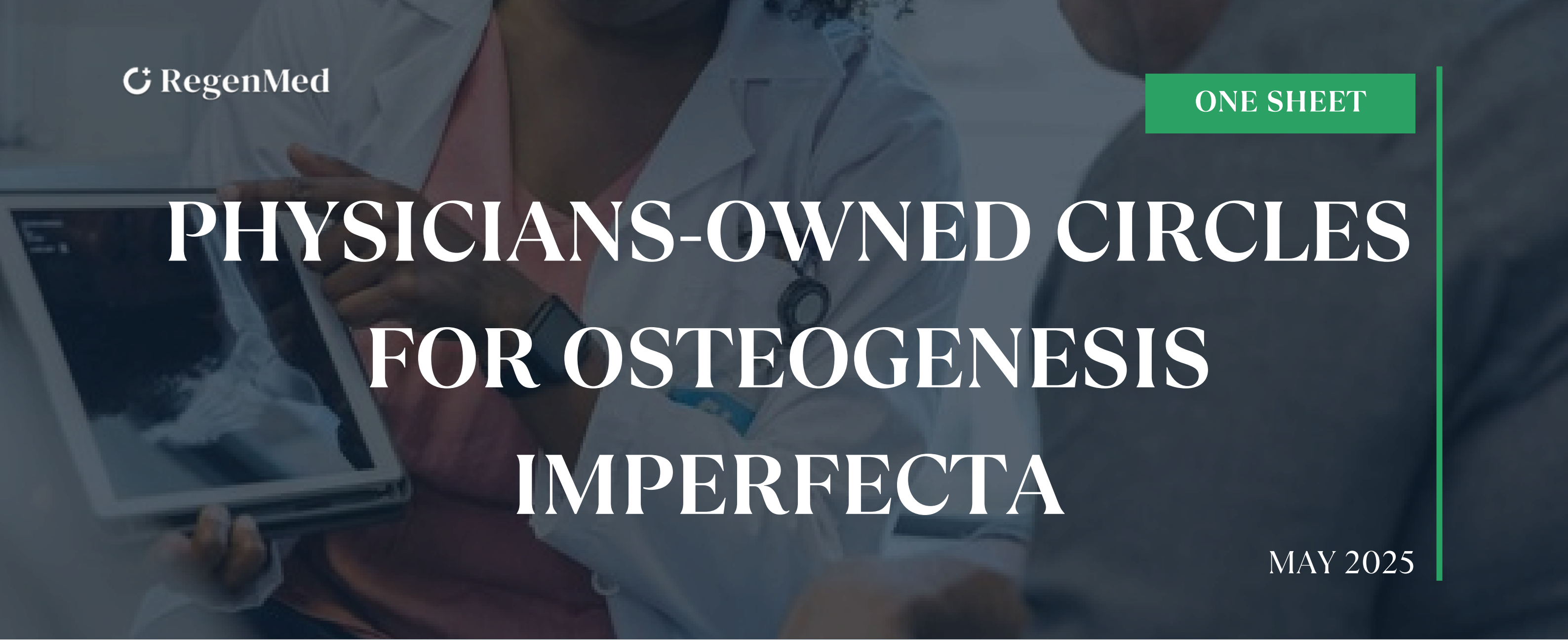

RegenMed

ONE SHEET

PHYSICIANS-OWNED CIRCLES FOR OSTEOGENESIS IMPERFECTA

MAY 2025

BACKGROUND

There are over 7,000 rare ("orphan") diseases affecting 25 million people in the U.S. and 350 million worldwide, with 95% having no approved treatment.

Osteogenesis imperfecta (OI), a rare genetic disorder primarily characterized by fragile bones, impacts 25,000 to 50,000 people in the U.S. alone.

OI's complexity — spanning multiple types, varying severity, and complications like bone density issues, pain, growth delays, hearing loss, and respiratory problems — makes it challenging to study in traditional clinical trials.

The financial burden for rare diseases like OI is substantial, with per-patient costs 15 times higher than those for more common diseases. Early diagnosis, access to coordinated care, and long-term monitoring remain major challenges.

Encouraged by the U.S. Orphan Drug Act and global rare disease incentives, industry investment in orphan drug development is accelerating, with the market projected to reach $262 billion by 2025, growing at 12% annually.

POCS FOR OSTEOGENESIS IMPERFECTA

Physician-Owned Circles (POCs) provide a new framework for advancing research and care in osteogenesis imperfecta (OI). By connecting physicians across different sites and specialties, OI POCs enable the collection of real-world, treatment-specific data..

Each Circle study is centered around an Observational Protocol (OP) that targets a specific treatment strategy — such as bisphosphonate therapy, surgical management, or physical rehabilitation — while monitoring long-term clinical outcomes.

A POC thus generates from primary sources (physicians and patients) clinically and statistically significant datasets. All POC datasets are HIPAA, GDPR and Part 11 compliant.

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

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Benefits For Clinicians

For practitioners treating or otherwise interested in OI, POCs offer the following advantages:

- **Expert Collaboration:** Work directly with peers and OI specialists to share insights and clinical experience.
- **Earlier Diagnosis:** Identify OI subtypes and complications faster through shared clinical evidence.
- **Evidence-Based Protocols:** Help develop standardized treatment approaches based on real-world results.
- **Low Clinical Burden:** Seamlessly integrate participation into routine patient care with minimal extra effort.
- **Financial Incentive**: Receive 85% of license fees generated from Circle data.
- **Professional Advancement**: Opportunities for authorship, research presentations, academic recognition, etc.

Benefits For Industry

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

- **Access to Targeted Real-World Data**: Gain validated, treatment-specific datasets in OI, generated directly from clinical practice.
- **Support for Regulatory Submissions:** Use integrated longitudinal data to strengthen applications for OI therapies and devices.
- **Cost-Effective Research:** Acquire clinically relevant, high-quality data at a fraction of the cost of traditional trials, without the gaps or biases common in large registries.
- **Protocol Flexibility:** Define observational protocols that align with product development goals, including specific OI subtypes, therapies, or interventions.
- **Broader Patient Access:** Multi-center participation enlarges patient populations and ensures data reflects the full range of OI severity and presentations.
- **Post-Market Surveillance:** Maintain ongoing real-world evidence collection to support product safety, efficacy, and market expansion in OI.