



ARTICLE

**FROM EMPIRICAL PAIN RELIEF
TO PREDICTIVE PRECISION:
HOW REGENMED CIRCLES ENABLE
CLINICALLY AND STATISTICALLY
SIGNIFICANT PNS PROTOCOLS**

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HOW REGENMED CIRCLES ENABLE CLINICALLY AND STATISTICALLY SIGNIFICANT PNS PROTOCOLS

Peripheral Nerve Stimulation (PNS) is transforming the landscape of pain management. Once seen as a last resort for intractable neuropathic pain, it now stands at the forefront of non-opioid, precision-based interventions. Yet, despite its promise, PNS has long been held back by one fundamental gap: the inability to reliably predict which patients will benefit, and under which stimulation parameters. Clinical success has often relied on trial-and-error rather than science. RegenMed Circles changes that paradigm.

CLOSING THE EVIDENCE GAP WITH CIRCLES

RegenMed Circles is a real-world evidence (RWE) platform designed to bring scientific rigor and statistical power to PNS therapy. By standardizing observational protocols, integrating validated Patient-Reported Outcome Measures (PROMs), and aligning with payer-recognized ICD-10 indications, Circles enables a new generation of PNS research – one that is clinically meaningful, reproducible, and regulatory-grade.

Circles moves beyond empirical feedback to structured, data-driven insights. It systematically collects pain intensity, functional outcomes, psychological metrics, and opioid utilization data across diverse populations, allowing clinicians and manufacturers to identify what truly drives long-term success.

IMPLEMENTING CLINICALLY AND STATISTICALLY SIGNIFICANT PNS PROTOCOLS

Our recently published [White paper](#) proposes three important Observational Protocols (OPs) for PNS therapy – each designed to address high-impact clinical challenges and generate evidence suitable for coverage expansion:

- **Post-Amputation Pain:** Validates early PNS intervention as a prophylactic, opioid-sparing therapy to prevent phantom limb pain.

- **Genicular Nerve Stimulation:** Measures pain relief and functional restoration in chronic knee pain, linking PROMs such as WOMAC and KOS-ADL to payer-relevant outcomes.
- **Postherpetic Neuralgia**:** Evaluates durable efficacy of permanent PNS implants in severe neuropathic pain, with a focus on quality of life and sleep interference metrics.

Each OP leverages Circles' architecture to achieve clinically and statistically significant results. By standardizing inputs and outputs across multi-center sites, Circles delivers the statistical power necessary to draw credible conclusions – transforming individual case studies into population-level insight.

FROM EMPIRICAL PRACTICE TO PREDICTIVE PRECISION

The future of PNS lies not just in better devices, but in better data. Circles integrates anatomical, psychological, and outcome data to inform predictive models for stimulation optimization. This shift from reactive to predictive programming aligns PNS therapy with modern precision medicine standards.

By embedding computational modeling, validated PROMs, and longitudinal tracking, Circles enables clinicians to personalize therapy while giving payers and regulators the reproducible evidence they demand. The result: safer, more effective, and financially sustainable PNS care.

A PLATFORM FOR CLINICAL, REGULATORY, AND MARKET SUCCESS

In a market projected to more than double by 2033, RegenMed Circles positions stakeholders to lead. It provides manufacturers with evidence for FDA and CMS alignment, clinicians with actionable insights, and payers with proof of value. By uniting clinical outcomes with compliance integrity, Circles builds a foundation for scalable, non-opioid pain care.

CONCLUSION

RegenMed Circles turns the promise of PNS into predictive precision. By designing and executing clinically valid, statistically robust observational protocols, it bridges the gap between innovation and validation – unlocking the full therapeutic and commercial potential of peripheral nerve stimulation.

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