

# EXPERT-REVIEWED REAL-WORLD EVIDENCE OBSERVATIONAL PROTOCOLS

## PHYSICIAN DATA OWNERSHIP

February 2026

### Beyond "Data Swamps"

Traditional "big data lakes" have largely become "data swamps," characterized by opaque, algorithm-driven synthesis from heterogeneous EMR, claims, and pharmacy records. These methods result in higher costs and less reliable conclusions. MOTIV™ represents a shift toward high-quality data lakes that are:

- Captured at the primary point of care.
- Structured according to practice-of-medicine clinical hypotheses.
- Tied to correlated long-term outcomes.
- Fully verifiable to clinical sources.

### A Powerful Strategic Partnership

MOTIV™ marries the rigorous expert-review process of the Orthopaedic Research and Education Foundation (OREF) with the patented technical infrastructure of RegenMed's Circle Datasets. This ensures the generation of RWE that is "fit for purpose" as defined by FDA guidance.

### Wickline/Mercuri OP: Expanded CMS TKA PRO-PM Protocol

The initial MOTIV™ expert-reviewed Observational Protocol (OP) builds upon the CMS TKA Final Rule. In addition to mandatory requirements, it enables the collection of high-value clinical data on:

- Surgical Techniques and Implant Models: Tracking specific procedural nuances and device performance.
- Advanced Scoring: Integration of the Forgotten Joint Score and Pain Catastrophizing Score.
- Non-Opioid Pain Management: Utilizing protocols developed by Drs. Andrew Wickline and John Mercuri.
- Expert Review: OREF provides clinical review distinct from its typical grant process to ensure scientific relevance.
- IRB Exempt: Certificate of Action received from WCG Clinical confirming NHR status of Circle Datasets collected pursuant to Wickline/Mercuri OP. (45 CFR 46.104(d)(4)).

### Clinical Efficiency

The program utilizes RegenMed's patented Circles platform—including the inCytes™ (physician-facing) and Benchmarc™ (patient-facing) modules. This system is designed to ensure minimal interruption to normal clinical flow, and excellent physician and patient user experience.

## Unambiguous Data Ownership

In traditional models, providers who generate records see little to none of the multi-billion dollar value created by data synthesis. Circle Datasets invert this model:

- Participating physicians retain unambiguous ownership of their data.
- Circle Members hold a share of the resulting RWE Intellectual Property.
- Physicians retain publication rights and the ability to use data for evidence-based clinical decision-making.

## Monetization and Financial Return

RegenMed and OREF actively pursue monetization opportunities on behalf of Circle Members, targeting licensees such as product manufacturers, payers, life sciences companies, and AI model developers.

- Circle Dataset License Fee Distribution: 50% of net license fees are returned to the participating physicians.
- Growth Potential: Dataset value grows over time as longitudinal outcomes and Cases accrue.
- Example: A Circle of 10 collaborating physicians utilizing 4 MOTIV™ OPs to create 12 licensable datasets (at 5 licenses each for \$25,000) could generate estimated revenue of \$75,000 per physician in the first year.

## Professional Benefits and Mentorship

Membership provides access to sustained and meaningful collaboration among orthopedic surgeons.

- Peer Collaboration: Participation in regular "Circle Hours" for education and mentorship.
- Physician Promotion: Integration into the Physicians Promotion Program.
- Cohort Reporting: Compare clinical hypotheses and personal standards of care against clinically and statistically significant Circle Datasets generated by peers across the country.

## Simple Membership Structure

- Cost: \$5 per longitudinal Case (covers Benchmark™ long-term outcomes collection).  
Subscription: \$35 per month per Subscriber.
- Flexibility: Simple Circle Membership Agreement with no long-term commitments; cancel any time on 30 days' notice.
- Patient enrollment and other materials customized for each physician. Robust reporting features. Ongoing experienced support.