

TKA CIRCLE DATASETS LICENSING

February 2026

Overview

MOTIV™ (Musculoskeletal Outcomes and Tracking Intelligence Vault) is a collaborative initiative established by the Orthopaedic Research and Education Foundation (OREF) and RegenMed. The program generates high-quality, fit-for-purpose longitudinal real-world evidence (RWE) within the \$900 billion musculoskeletal care market. These physician-led "Circle Datasets" are designed to support regulatory strategy, product development, reimbursement positioning, and value-based care initiatives

The Methodology: Circle Datasets vs. EMR Scrapes

The fundamental unit of a Circle Dataset is a longitudinal Case. Unlike retrospective EMR data scrapes or weak inference-based approaches, Circle Datasets are built from the ground up by collaborating physicians using standardized Observational Protocols (OPs).

- **Verifiable Data:** Each Case comprises verifiable and well-correlated real-world data for a single patient journey.
- **Longitudinal Scope:** Data tracks patients from diagnosis through treatment to standardized long-term outcomes specifically related to that diagnosis and treatment.
- **Clinical Relevance:** OPs are derived from clinical hypotheses arising directly from the practice of MSK medicine.

The Wickline/Mercuri TKA Observational Protocol

The inaugural MOTIV™ OP focuses on Total Knee Arthroplasty, built upon the CMS TKA PRO-PM Final Rule. Developed by Doctors Andrew Wickline and John Mercuri, this OP captures structured data on:

- **Surgical Technique:** Specific methods and robotics vs. alignment strategies.
- **Implant Selection:** Detailed tracking of implant types and manufacturers.
- **Pain Management:** Structured data on post-operative protocols.
- **Outcomes:** Patient-reported outcomes, and post-op clinical results.
- **IRB Exempt:** Certificate of Action received from WCG Clinical confirming NHSR status of Circle Datasets collected pursuant to Wickline/Mercuri OP. (45 CFR 46.104(d)(4)).

OREF provided expert review of this OP to ensure clinical relevance, feasibility for real-world collection, and structural appropriateness.

Why Circle Datasets Matter to Industry

Circle Datasets provide the rigorous evidence required by modern regulatory and reimbursement frameworks.

- **Regulatory-Grade Evidence:** Alignment with recent FDA RWE guidance and the TEMPO (FDA) program.
- **Reimbursement Alignment:** Data structured to meet requirements for the CMS ACCESS program and value-based care initiatives.
- **Multi-Site Collaboration:** Scalable datasets built through a network of orthopedic surgeons.
- **Verifiable Accuracy:** Eliminates the "noise" of traditional big data through prospective, protocol-driven collection.

Core Use Cases for Industry Partners

The MOTIV™ framework facilitates critical commercial and clinical objectives:

- **Regulatory Submissions:** Support for 510(k) or PMA pathways using high-fidelity RWE and Synthetic Control Arms.
- **Product Differentiation:** Comparative effectiveness data regarding surgical techniques and implant performance.
- **AI & Data Science:** High-quality, structured longitudinal data for training robust clinical AI models.
- **Value-Based Care:** Demonstrating the clinical and economic utility of specific interventions to payers and providers.

Current Traction & Access

Circle Members performing over 2,000 TKAs annually have already begun enrolling Cases under the Wickline/Mercuri OP. Participation is expanding as more sites join this important MOTIV™ initiative.