RegenMed

MOTIV™ TKA OBSERVATIONAL PROTOCOL
CLINICAL AND ECONOMIC VALUE PROPOSITIONS

December 11, 2025

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EXECUTIVE SUMMARY

The Shift to Deterministic Data

For the last decade, healthcare data has been trapped in a "probabilistic" model—large "data swamps" where vendors scrape billing codes and messy EMR logs to infer what happened in the OR. This "Schema-on-Read" approach results in low-fidelity data that often misrepresents clinical reality.

MOTIV™ Observational Protocols represents a paradigm shift to **"Schema-on-Capture."** By recording the validated clinical fact at the moment of creation, we move from mining "data exhaust" to minting **"Ground Truth"**.

Clinical Value: The Synthetic Control Arm

MOTIV™ Circle Members do not merely log Cases, they are building high quality, verifiable control arms. The resulting "ground truth" data is precise enough to replace placebo groups in regulatory trials. Participating Members are thus effectively:

➢ **Supporting high-level research** without the administrative burden of traditional randomized clinical trials (RCTs).

➢ **Benchmarking outcomes** using validated instruments and comparing results against a deterministic and statistically significant average rather than probabilistic claims data.

Financial Value: Partnership, Not "Data Serfdom"

Historically, physicians generate the data, but third-party aggregators monetize it. MOTIV™ flips this model.

➢ **Revenue Share:** Participating physicians are treated as partners, retaining **50% of the net license fees** generated by their data.

➢ **Circle Datasets Value:** A statistically significant Circle Dataset is a high value asset, precisely because it is a verifiably high quality clinical/scientific asset. Circle Datasets increase in value over time – more Cases (n-value), and greater longitudinality.

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MOTIV™ TOTAL KNEE ARTHROPLASTY OBSERVATION PROTOCOL

This section details the specific data points captured in the current MOTIV™ TKA Protocol as designed by Doctors Wickline and Mercuri. [1]

Patient Pre-Operative Survey

➢ **Baseline Pain & Symptoms:** Captures current pain levels using the Visual Analogue Scale (VAS) for both the operative and contralateral knee, alongside a general assessment of pain in other major joints (hips, ankles).

➢ **Functional Status:** Evaluates morning stiffness severity and specific functional limitations in daily living (e.g., twisting/pivoting, straightening the knee fully, rising from sitting).

➢ **Psychosocial Risk Stratification:** Includes the **Patient Catastrophizing Score - Short Form (PCS-4)** to assess pain rumination and helplessness, offering predictive insight into potential chronic pain outcomes.

➢ **Quality of Life:** Administers the **VR-12 (Veterans RAND 12 Item Health Survey)** to establish a baseline for general physical and emotional health.

Clinician Pre-Operative Evaluation

➢ **Risk Factors & Comorbidities:** BMI, tobacco use, and a comprehensive comorbidity checklist (e.g., Diabetes, Cardiac History, Renal Disease).

➢ **Opioid History:** Screens for opioid use in the 90 days prior to surgery, including specific molecule identification (e.g., Oxycodone, Tramadol) and dosage to establish "opioid naïve" vs. "chronic user" status.

➢ **Clinical Baseline:** Records primary diagnosis (OA, Rheumatoid Arthritis, Post-Traumatic, etc.) and pre-operative Range of Motion (Flexion/Extension).

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[1] As covered below, the TKA Observational Protocol is flexible. RegenMed can replace/add surveys and questions fitting the specific practice realities and hypotheses of specific orthopedic groups. However, we strongly recommend maintaining the required CMS PRO-PM surveys, and including a carefully considered set of other questions likely to increase the clinical and therefore financial value of the resulting Circle Datasets.

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Clinician Operative Survey

- **Surgical Profile:** Logs the specific procedure code, ASA Physical Status Classification, and date of surgery.

- **Anesthesia & Pain Management:** Tracks anesthesia type (General, Spinal, Epidural), specific nerve blocks (Adductor canal, IPACK, etc.), and intra-operative pharmaceuticals (e.g., Tranexamic acid, Dexamethasone, COX-2 inhibitors).

- **Implant Specification:** Captures the specific manufacturer (Zimmer Biomet, Stryker, DePuy Synthes, etc.) and product system (e.g., Persona, Attune, Triathlon).

- **Surgical Technique:**
  - **Approach:** Medial/Lateral Parapatellar, Subvastus, Midvastus.
  - **Alignment Strategy:** Mechanical, Kinematic, Restricted Kinematic, or Functional alignment.
  - **Soft Tissue & Bone:** Tracks tourniquet use (time/pressure), patella resurfacing, PCL management (retained/sacrificed), and specific ligament releases.

- **Intra-operative Complications:** Categorized logging of bony fractures (femoral/tibial) or soft tissue injuries (MCL/LCL/vascular).

Clinician Post-Operative Survey (Immediate)

- **Discharge Status:** Records Length of Stay (LOS) and discharge disposition.

- **Immediate Outcomes:** Documents post-operative Range of Motion prior to discharge.

- **Prescription Stewardship:**
  - **Opioids:** Exact auditing of discharge prescriptions (molecule, dose, pill count).
  - **VTE Prophylaxis:** Tracks specific regimen (Aspirin, Xarelto, Eliquis) and duration.

- **Adverse Events:** Flags any immediate events occurring on the day of surgery.

Clinician Longitudinal Follow-Up (2w, 6w, 6m, 12m)

- **Recovery Metrics:** Serial measurement of Range of Motion (Flexion/Extension) at every interval.

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➢ **Adjunct Therapies:** Tracks utilization of post-op therapies such as Blood Flow Restriction (BFR), Cryotherapy, Laser Therapy, or CPM.

➢ **Medication Consumption:** Audits actual patient consumption of opioids (pills taken vs. prescribed) to determine cessation timelines.

➢ **Complications:** Monitors for ER visits, chest pain, or infection.

Patient Longitudinal Follow-Up (2w, 3m, 9m)

➢ **PROMs:** Repeat administration of **VAS** (pain) and **KOOS, JR** (stiffness, pain, function) to track trajectory against baseline.

➢ **Health Status:** Repeat **VR-12** survey to monitor broader quality of life impacts.

Patient Longitudinal Follow-Up (6w, 6m, 12m)

➢ **Joint Awareness:** Introduces the **Forgotten Joint Score - 12 (FJS-12)** to measure the ultimate goal of arthroplasty: the patient's ability to forget the artificial joint during daily life.

➢ **Long-Term PROMs:** Continues tracking VAS, KOOS JR, and VR-12 for year-over-year comparison.

ZERO-BURDEN INFRASTRUCTURE

For busy physicians, "digitization" (EMRs and similar data platforms) has historically increased costs and decreased physician efficiency, creating the "Pseudo-Productivity Paradox". The RegenMed infrastructure is engineered to reverse this trend.

Every RegenMed inCytes™ clinician survey is responsive, device-agnostic, and designed to require no more than 30 seconds to complete. This ensures that data capture occurs within the natural flow of care, not as "pajama time" paperwork.

Through Benchmarc™, the longitudinal data capture burden is lifted from clinical staff. The system automatically handles the distribution of patient surveys (Pre-op, 2w, 6w, etc.) via electronic logic, ensuring high compliance for PROMs.

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STRATEGIC ADVANTAGES

Collaborative Intelligence: From Silos to "Circles"

By adopting the MOTIV™ Protocol, physicians join a network of peers speaking a unified clinical language, moving beyond the fragmented "data silos" that currently hinder multi-center research.

Because all participants capture "ground truth" using the same "Schema-on-Capture" methodology, they can instantly aggregate outcomes with colleagues to form clinically and financially valuable Circle Datasets, or even larger fully verifiable registries.

This capability transforms collaboration from anecdotal sharing into rigorous, data-driven inquiry, allowing participating physicians to pool longitudinal cases for statistical power and objectively compare surgical techniques across different practice environments with full confidence in the data's veracity.

Data Sovereignty: Clinical Agency and Asset Monetization

RegenMed's patented closed Circles platform ensures physician control, ownership rights, and value participation of the resulting Circle Datasets. This is in sharp contrast to traditional "data serfdom" where physicians generate data value but third parties monetize it.

This ownership model delivers a threefold advantage: clinically, it provides granular, longitudinal feedback on specific outcomes (e.g., Forgotten Joint Scores) to refine decision-making; academically, it provides the "deterministic evidence" required for high-impact publication without data cleaning delays; and financially, it converts chart work into a recurring revenue stream.

Beyond Compliance: A CMS-Aligned, High-Value Asset

This MOTIV™ TKA Observational Protocol is architected to satisfy and exceed the CMS Patient-Reported Outcome-Based Performance Measure (PRO-PM) for Total Knee Arthroplasty. It incorporates the mandated standard instruments—specifically the VR-12 for health-related quality of life and the KOOS, JR for knee-specific function -- ensuring seamless regulatory alignment.

However, this protocol expands the dataset to include high-demand commercial and clinical variables often missing from standard registries, such as granular implant identification and precise "molecule-to-milligram" opioid stewardship tracking.

Adaptive "Schema-on-Capture": Tailored to Specific Hypotheses

Unlike rigid legacy registries, RegenMed's "Schema-on-Capture" architecture is designed for agility. Because every datapoint is linked to a verified clinical hypothesis at the moment of creation, this MOTIV™ TKA Protocol serves as a flexible template rather than a fixed constraint.

RegenMed can rapidly modify survey questions to reflect the unique realities of your practice or to investigate emerging clinical theories -- such as comparing specific alignment strategies or testing the efficacy of novel adjunct therapies. This ensures that your Circles data collection remains relevant to your specific clinical questions, evolving in real-time as the standard of care advances.