RegenMed

MOTIV™ TKA CIRCLE DATASET

VALUATION AND FUNDING ANALYSIS

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EXECUTIVE SUMMARY

The evolving paradigm of musculoskeletal care is increasingly defined by the transition from volume-based procedural metrics to value-based longitudinal outcomes. Within this framework, the generation and acquisition of high-fidelity real-world evidence have become critical for medical device manufacturers, pharmaceutical developers, and public health agencies.

This report provides an analysis of the valuation and diverse funding pathways available for a 2,000-patient Circle Dataset being generated by physicians from around the country on the basis of the MOTIV™ TKA Observational Protocol co-authored by Doctors Andrew Wickline and John Mercuri. [1] The analysis considers the clinical granularity of the data, the current regulatory requirements for post-market clinical follow-up, the strategic utility of competitive intelligence in the orthopedic market, and the mechanics of accessing federal grants and state-level opioid settlement funds.

For a verified cohort with 12-month outcomes and extensive physician diversity, the market value is typically estimated between $3 million and $12 million, depending on the level of exclusivity granted to the buyer.

CLINICAL AND PSYCHOMETRIC INTEGRITY OF THE OP

The value of a clinical dataset is fundamentally anchored in the relevance and reliability of its underlying variables. The OP is on track to capture the complete journey of at least 2,000 total knee arthroplasty patients across dozens of physicians in diverse practice environments, covering pre-operative, intra-operative, and 12-month post-operative milestones. This temporal depth allows for the observation of the critical transition from surgical recovery to long-term functional stability, a phase where most standard surgical

[1] This MOTIV™ Wickline/Mercuri TKA Observational Protocol is referred to here as the OP, and the resulting integrated, longitudinal, and proprietary dataset is referred to as the Circle Dataset. This analysis is and cannot be a guarantee of final value. The actual value of the Circle Dataset may be higher or lower than the various estimates provided. In all events, the Circle Dataset become more valuable to multiple potential licensees as follow-up data longer than one year is captured.

registries provide insufficient detail.

Validated Patient-Reported Outcome Measures

The protocol utilizes a suite of validated (PROM) instruments that serve as the clinical gold standard for regulatory submissions and health-economic modeling. These include those mandated by the CMS PRO PM Final Rule, as well as others.

For example, KOOS-JR is a validated and responsive 7-item survey measuring knee health by evaluating stiffness, pain, and function in activities of daily living. The use of Rasch analysis in its development ensures that the instrument remains efficient while capturing the necessary functional domains without excessive respondent burden.

VR-12 is an essential public-domain tool that measures health-related quality of life across eight domains, including general health perceptions, physical functioning, and mental health. Developed with support from the Veterans Health Administration, it provides physical and mental component summary scores that allow for robust comparisons across diverse chronic disease populations and treatment cohorts. Its widespread use in national surveys makes it an ideal instrument for population-level benchmarking and risk adjustment in value-based care models.

A pivotal differentiator in the OP is the inclusion of FJS-12, which assesses joint awareness during daily activities. While many legacy surveys suffer from a ceiling effect—where high-performing patients all achieve maximum scores—the FJS-12 remains highly discriminative for patients with good-to-excellent results. Research indicates that the ceiling effect for the FJS-12 is approximately 8.4 percent, compared to more than 40 percent for traditional metrics such as the Lysholm score. This sensitivity makes the FJS-12 the ultimate marker of successful arthroplasty, where the patient no longer perceives the artificial joint as an external entity.

Granular Surgical and Opioid Tracking Variables

Beyond PROMs, the protocol captures high-fidelity surgical variables that are notoriously difficult to extract from standard EHR) systems. These include specific alignment strategies, such as mechanical, kinematic, restricted kinematic, and functional alignment, as well as surgical exposure techniques like subvastus or medial parapatellar approaches. The ability to link these technical nuances directly to 12-month outcomes provides a unique

dataset for product development and marketing claims.

Furthermore, the OP implements a precise opioid consumption tracking mechanism. Rather than relying on lagging pharmacy refill data, it measures actual patient pill counts from the pre-operative baseline through various post-operative intervals. This granularity is essential for identifying which surgical techniques or adjunct therapies, such as nerve blocks or cryotherapy, effectively minimize the transition from acute to chronic opioid use.

Data Category	Specific Variables	Strategic Utility
Surgical Technique	Alignment Strategy (Kinematic vs Mechanical), Exposure, PCL Management	R&D optimization; surgeon-level technical marketing
Clinical Outcomes	FJS-12, KOOS-JR, VR-12, Range of Motion	Regulatory submissions (FDA/MDR); reimbursement dossiers
Health Economics	Opioid Pill Count, Length of Stay, Adjunct Therapy Use	Value-based care contracting; opioid abatement claims
Population Context	Comorbidities, BMI, Demographic Data	Risk adjustment; generalizability of real-world results

ECONOMIC VALUATION MODELS AND INDUSTRY BENCHMARKS

The valuation of the Circle Datasets being generated pursuant to the OP is structured across multiple economic models, including market comparisons, internal cost-avoidance models, and per-record multiples.

Commercial Market Comparison and Licensing Structures

Commercial RWE vendors typically charge between $2 million and $5 million per year for non-exclusive access to orthopedic datasets that are often half the size of the expected Wickline/Mercuri cohort. The pricing of such assets is driven by the regulatory grade of the

data and the depth of its longitudinal follow-up.

The licensing structure dictates the strategic premium. A non-exclusive license, which allows multiple manufacturers to benchmark their products, is valued at the lower end of the spectrum, between $3 million and $5 million. Semi-exclusive licenses, limited to one or two manufacturers in a specific segment, command $5 million to $9 million. A full exclusive sale, granting proprietary rights to the clinical insights, can exceed $12 million dollars, with an additional $2 million to $4 million dollar premium if the dataset includes derived predictive risk models.

Internal Cost-Avoidance Analysis

A significant driver for dataset acquisition is the avoidance of the multi-year capital burn required for a manufacturer to generate equivalent data internally. To recruit 100 clinical sites and manage 2,000 subjects through a 12-month follow-up, an internal project team would incur costs exceeding 11 million dollars. This estimate includes site startup fees, IRB monitoring, CRO) management, and data cleaning.

Expense Category	Internal Build Cost Item	Estimated Cost (USD)
Site Startup	Recruitment, contracting, and training for 100 physicians	$1,500,000
Patient Enrollment	Per-patient enrollment fees and recruitment marketing	$2,000,000
Clinical Monitoring	CRO fees for source data verification and adherence	$4,500,000
Data Management	EDC build, validation, and complex data cleaning	$1,200,000
Regulatory/Stats	Preparation of fit-for-purpose reports for FDA/MDR	$800,000
Physician Honoraria	Fair market value payments for data entry labor	$1,000,000
Total Project Budget	Fully Loaded Internal Build	$11,000,000

The Hidden Costs of Delay

While the capital avoidance is substantial, the strategic time-to-value premium often represents a higher figure for business development teams. Internal studies suffer from a three-year evidence gap, consisting of one year for recruitment, one year for follow-up, and one year for analysis and publication. Purchasing a verified dataset allows for immediate market claims, potentially capturing two to three years of additional market share while eliminating the risk of patient attrition, which can exceed 40 percent in long-term observational studies.

Per-Record Multiple and Market Scaling

Industry benchmarks for curated longitudinal health records suggest a valuation range of $1,300 to $6,500 per patient record. For a 2,000-patient cohort, these multiples support a core asset value that is significantly higher than that of simple administrative data.

The global market for RWE solutions was valued at approximately $3 billion dollars in 2025, and is projected to grow at an annual rate of up to 16% through 2035. This expansion is fueled by the maturation of AI analytics and the increasing acceptance of non-traditional data by regulatory bodies.

Regulatory Utility and Compliance Frameworks

The premium valuation of the Wickline/Mercuri Circles Dataset is predicated on its ability to withstand regulatory scrutiny. Manufacturers do not merely buy numbers; they purchase the legal right to use those data points in formal submissions to agencies such as the FDA and EU notified bodies.

EU MDR and Annex XIV Requirements

Under the EU MDR, specifically Annex XIV, Part B, manufacturers of Class III and Class IIb implantable devices must conduct continuous clinical evaluations throughout the product lifetime. This post-market clinical follow-up process (PMCF) is intended to confirm long-term safety, identify emerging risks, and ensure the continued acceptability of the benefit-risk ratio. It is likely that U.S. regulators will adopt similar mandates.

A verified dataset of 2,000 patients providing 12-month outcomes satisfies the requirements for annual PMCF reports, which are part of the required technical documentation. This is particularly critical for legacy devices transitioning from the previous directive to the new regulation, as many of these products require updated clinical data to maintain their CE mark.

FDA GUIDANCE ON REAL-WORLD EVIDENCE

The FDA has issued updated guidance to clarify how real-world data is evaluated to determine whether it is of sufficient quality—specifically relevance and reliability—to generate RWE for regulatory decision-making. The 21st Century Cures Act has accelerated this trend, allowing for RWE to supplement or partially replace traditional clinical evidence in certain circumstances. Notably, the agency has removed barriers by accepting de-identified datasets without always requiring identifiable individual patient data, provided the database provenance is auditable.

Data Integrity and the ALCOA+ Standard

For data to be fit-for-purpose in a regulatory filing, it must adhere to the ALCOA+ principles, which define the cornerstone of data integrity in clinical research. This framework requires that data be Attributable, Legible, Contemporaneous, Original, and Accurate (ALCOA), with the addition of being complete, consistent, enduring, and available.

The protocol under review ensures compliance through a validated, closed and patented Circles EDC system featuring secure, time-stamped audit trails and unique electronic signatures. This system-level validation is essential for meeting 21 CFR Part 11 requirements, which govern the use of electronic records and signatures in clinical investigations.

STRATEGIC VALUE OF COMPETITIVE INTELLIGENCE

Competitive intelligence is a primary value driver for medical device manufacturers in the

high-stakes orthopedic market, where market share is often determined by individual surgeon preferences rather than broad consumer demand.

Surgeon-Level Targeting and Performance Benchmarking

The ability to monitor surgeon-level habits and competitor performance is foundational to a manufacturer's commercial strategy. This Circles Dataset will provide insights into the technical philosophies of dozens of physicians, including their preferred alignment strategies and implant choices. Knowing which surgeons are trialing a rival's product—and more importantly, why—allows a manufacturer to react immediately via research and development or targeted marketing to protect their share.

The intelligence provided by the protocol moves beyond simple volume tracking to linked clinical outcomes. If a rival's implant is associated with higher FJS-12 scores or a shorter hospital stays, the manufacturer must pivot its education programs or product lines before significant leakage occurs. Protecting a 5% market share from erosion in the multibillion-dollar orthopedic market is worth hundreds of millions of dollars in retained revenue

Pricing and Reimbursement Strategy

Pricing for orthopedic implants is notoriously opaque, and over 80 percent of surgeons admit to having poor knowledge of the actual costs of the devices they use. The dataset provides the metrics needed to justify premium pricing to a hospital's value analysis committee by demonstrating the total episode cost-effectiveness of a particular implant or technique. If an alignment strategy results in one fewer day of hospitalization or fewer post-operative physical therapy visits, the manufacturer can refine its average selling price without losing volume.

FUNDING SOURCES: FEDERAL GRANTS AND PUBLIC HEALTH UTILITIES

Securing federal funding from agencies such as the U.S. Department of Defense or the National Institutes of Health shifts the positioning of the dataset from a commercial asset to a public health utility. These agencies provide substantial non-dilutive capital, often exceeding $2 million to $3 million per award.

Department of Defense: Peer Reviewed Orthopaedic Research Program

The DoD views orthopedic injuries as a primary threat to military readiness, as musculoskeletal conditions account for more than 50 percent of non-deployable statuses among service members. PRORP received $20 million in fiscal year 2026 to fund research optimizing return-to-duty strategies and functional restoration.

A longitudinal dataset linking 12-month functional outcomes to surgical techniques fits the PRORP mission by identifying the optimal profile for restoring a service member to full operational capacity. Clinical research awards under this program typically cap at $2 million over four years, while clinical trial awards can provide up to $3.2 million. To secure these funds, proposals must explicitly state the military relevance, focusing on late-career service members, veterans, and the reduction of medical non-readiness due to chronic joint pain.

National Institutes of Health: HEAL and NIAMS

The NIH offers significantly higher funding ceilings for research that addresses the public health impact of the opioid crisis and chronic joint dysfunction. The Helping to End Addiction Long-term (HEAL) initiative has billions allocated for pain management effectiveness research, focusing on the prevention of the transition from acute to chronic pain. The Circle Dataset's ability to provide real-time, longitudinal opioid pill counts is a major differentiator for NIH reviewers.

Furthermore, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) prioritizes research that addresses the ceiling effect of current outcomes, making the FJS-12 a high-value metric in an R01 research project grant application. These awards typically provide $500,000 or more per year in direct costs over a three-to-five-year period.

ACCESSING OPIOID SETTLEMENT FUNDS FOR ABATEMENT RESEARCH

The pursuit of opioid settlement funds requires a shift from a commercial licensing model to a public-health abatement model. While the Purdue Pharma settlement is currently stalled by federal litigation, more than $50 billion from other manufacturers, distributors, and retailers is currently being distributed to states and local municipalities.

The Abatement Strategy Framework

To receive funding, a project must qualify as an opioid remediation under the Exhibit E framework of the national settlement. This framework includes research and data collection designed to identify high-risk populations and evaluate the effectiveness of abatement strategies. The Circle Dataset will help identify the specific surgical and pharmacological factors that lead to the lowest rates of chronic opioid use post-surgery, directly fulfilling these abatement criteria.

For a single state or large municipality, a 2,000-patient abatement research contract typically ranges from $0.5 million to $2.5 million per year

Mapping the Protocol to Approved Uses

Exhibit E Strategy	Protocol Application
Strategy 9: Data Collection & Research	Longitudinal tracking of 2,000 patients and 100 physicians to evaluate abatement effectiveness
Strategy 6: Provider Education & Outreach	Developing evidence-based toolkits for surgeons to minimize post-operative opioid transition
Strategy 6: Prevention Programs	Real-time monitoring of the transition from acute recovery to chronic opioid dependency
Core Strategy: Research on Innovative Abatement	Utilizing validated clinical metrics like FJS-12 to identify early indicators of patient risk

MODULAR LICENSING AND REVENUE MULTIPLIERS

The practice of modular licensing—breaking a master longitudinal dataset into targeted data products—is a highly effective revenue strategy. Slicing the data into specific cohorts creates dense niche products that solve commercial problems for different buyer types, often allowing for higher price-per-record valuations.

SKU-Based Productization

Targeting MedTech robotics teams, a robotic and navigation module can prove that the high capital expense of these platforms results in superior FJS-12 scores or more consistent alignment compared to manual instrumentation. A non-exclusive annual license for such a module is worth between $1.5 million and $3 million dollars.

Pharmaceutical companies and payers will pay a premium for a pharmacological pain module that provides clean opioid-consumption data linked to return-to-activity milestones. This information is essential for building reimbursement dossiers for novel non-opioid analgesics and can command annual licenses of $1 million to $2.5 million dollars.

Large hospital systems and other integrated delivery networks can utilize institutional benchmarking modules. These products allow a facility to see how its surgeons perform against the national MOTIV benchmark in terms of 90-day readmissions and length of stay. This is often licensed as a software-as-a-service performance dashboard with annual subscriptions ranging from $150,000 to $350,000 per facility.

CONCLUSION

The Wickline/Mercuri TKA Circle Dataset will, after one year, represent a high-value clinical and economic asset characterized by its longitudinal depth, technical specificity, and regulatory readiness. Its market valuation of $3 million to $12 million is supported by robust benchmarks in internal cost avoidance and commercial data licensing.

By implementing a dual-track strategy that targets both commercial manufacturers and public sector funding agencies, stakeholders can maximize the asset's impact on musculoskeletal care while addressing the pressing needs of regulatory compliance, competitive intelligence, and public health abatement.

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