

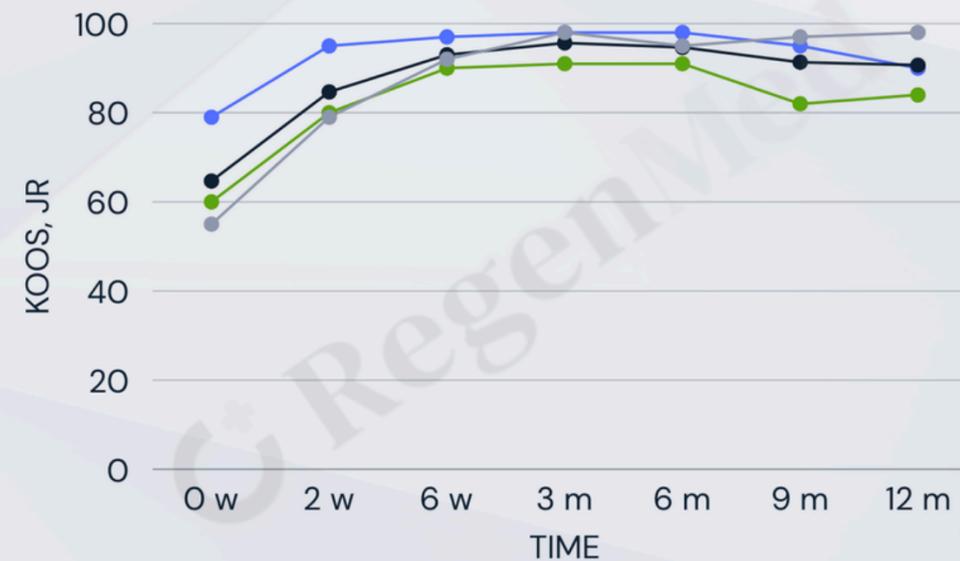
# CIRCLE HOUR

## MOTIV™ WICKLINE/MERCURI TKA OBSERVATIONAL PROTOCOL

DR. WICKLINE 

### Circle: Total Knee Arthroplasty

**Principal Investigator:**  
Andrew Wickline, MD



-  **All Circle Patients**  
n=1004
-  **Implant 1**  
n=278
-  **Implant 2**  
n=370
-  **Implant 3**  
n=356

\*Illustrative numbers only

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# WHY THIS MATTERS: TODAY'S ENVIRONMENT

Practice of medicine is defined by:

## Clinical Care

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Reimbursement. Purchasing.  
Time. Admin. Regulatory. AI.

## Financial

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Fee-for-service. Salary.  
RVUs. PE Firms. M&A. AI.

## Professional Knowledge

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Journals. Conferences. Sales  
Reps. Social Media. AI.

## Research

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Limited time, opportunity,  
funding, and incentive. AI.

# WHY THIS MATTERS: WHAT IS CHANGING

Tomorrow, *practice of medicine* will drive:

Standards of Care. Healthcare economics. Research/innovation. Education.

**Why? It is the foundation of high quality real-world evidence**

**And RWE is recognized as the solution to:**

Current systemic failures. Policy pressure. Value-based care. Regulatory shifts. Patient trust mandate. AI.

## IN SHORT . . .

***High quality* RWE will be the foundation of the healthcare system**

**Everyday clinical care is the foundation of high quality RWE**

**Physicians will regain primacy in the healthcare system**

### **Notes:**

*Doubtful? Look at other sectors of the economy.*

*AI is the common denominator throughout healthcare already. Just the beginning.*

## REAL-WORLD EVIDENCE: MACRO TRENDS

**Current Approach:** \$50B, 20% CAGR. Data Lakes: heterogeneous clinical records. Opaque algorithms. Registries. Weak clinical inferences. Poor data provenance.

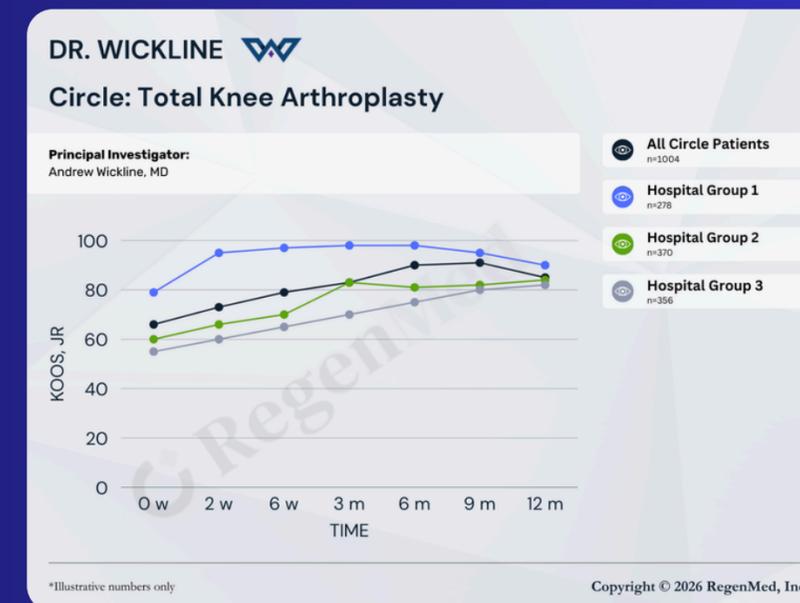
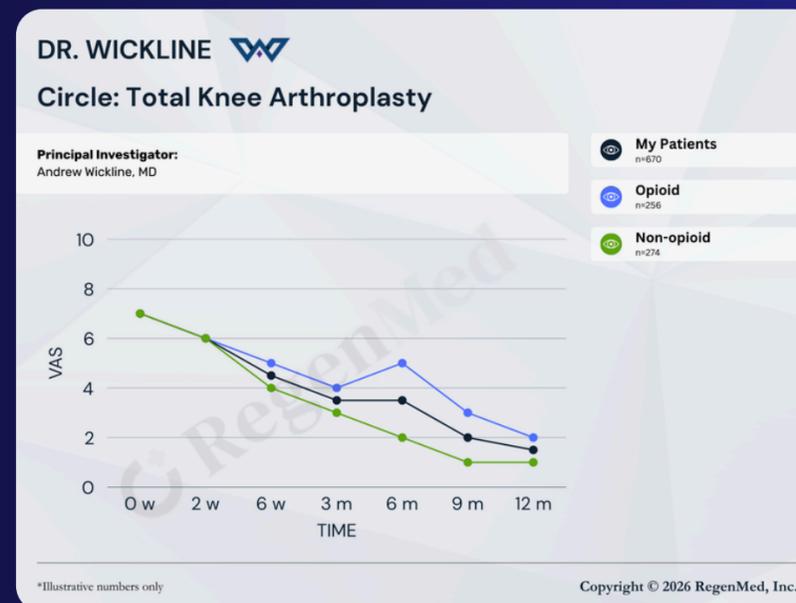
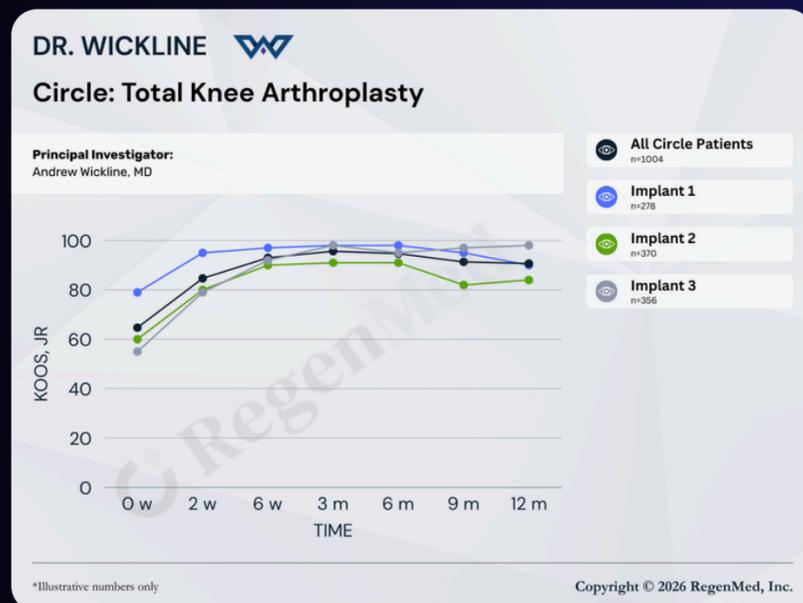
**FDA Shift:** Faster hypothesis-to-patient care through RWE. Fit-for-purpose, verifiable. TEMPO (Technology-Enabled Meaningful Patient Outcomes).

**CMS Shift:** Value-Based Care. Long-term outcomes. SDOH. ACCESS (Advancing Chronic Care with Effective, Scalable Solutions).

## IMPLICATIONS FOR PHYSICIANS

- Clinical Hypotheses:** Profoundly important. Arise during regular practice of medicine. Proved/disproved in the same environment. Historical basis for most important medical innovations.
- Require:** Structure (ask the right questions). Statistical significance (physican collaboration). Minimal burden and cost. Fair, ethical exchange of value.
- The Power Of Ownership:** Control. Authorship. Intellectual Property. Royalties, license fees. Accumulating equity.

# THE ASSETS: CIRCLE DATASETS (CD)



**Clinical and statistical significance. Full data provenance. Clear ownership.**

**Dozens of CDs. Many licensees/CD. Accumulating value.**

**Value of single CD: >\$3 m. (2,000 TKAs, 1 year follow-up)**

## PROVIDER GROUP RWE INITIATIVES



Duke Health



Mayo Clinic

*Circle Datasets enable any type or size of provider group to generate, own and benefit from its RWE*

# OREF COMMENTS

## **MOTIV™**

**Aligns with OREF mission to advance musculoskeletal research and strengthen the clinical evidence ecosystem across orthopedics.**

## **RegenMed Partnership**

**Support development of clinically meaningful real-world data initiatives designed to reflect actual practice patterns and patient outcomes.**

## **Impact**

**High-quality RWE central to MSK research. Participants can help shape that evidence. Contributing data that is practice-informed, scalable, and impactful for patient care.**

# CLINICIAN UX

**Minimal Burden:** 2 minutes/Case. Copy-over function. Any device. Flexibility.

**Pain Points:** 2FA. Patient, physician Medicare numbers.

**Balance:** Data entry = clear ownership = value

**Support:** Human. Knowledgeable. Responsive. RegenMed is a partner, not a vendor.

**CLINICIAN OPERATIVE SURVEY** Page 16 of 39

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**Nerve blocks:**

Adductor canal  IPACK

Femoral nerve  Sciatic

Genicular

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**Who manufacturers the implant?**

Zimmer Biomet

Stryker

DePuy Synthes

Smith & Nephew

Exactech

DJO Global (Enovis)

Medacta

MicroPort Orthopedics

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**Which Zimmer Biomet product are you using?**

\*This question will become visible if the answer to question Who manufacturers the implant? is equal to "Zimmer Biomet"

Persona® The Personalized Knee® System

NexGen® Complete Knee Solution

Vanguard® Knee System

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**PERSONA® THE PERSONALIZED KNEE® SYSTEM**

\*This question will become visible if the answer to question Which Zimmer Biomet product are you using? is equal to "Persona® The Personalized Knee® System"

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**NEXGEN® COMPLETE KNEE SOLUTION**

\*This question will become visible if the answer to question Which Zimmer Biomet product are you using? is equal to "NexGen® Complete Knee Solution"

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**VANGUARD® KNEE SYSTEM**

\*This question will become visible if the answer to question Which Zimmer Biomet product are you using? is equal to "Vanguard® Knee System"

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**TRIATHLON® KNEE SYSTEM**

\*This question will become visible if the answer to question Who manufacturers the implant? is equal to "Stryker"

# PATIENT UX

**Minimal Burden:**

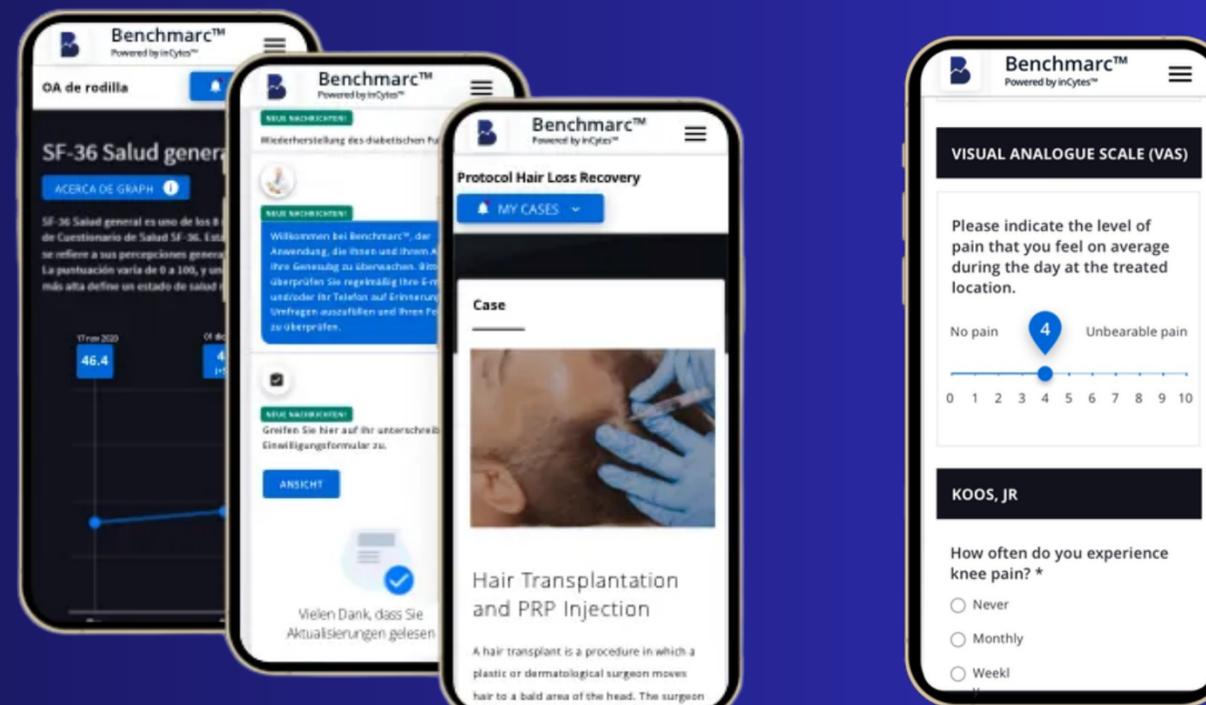
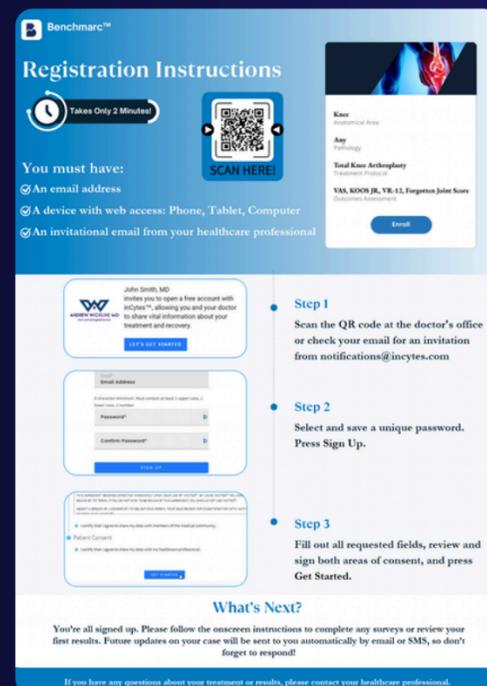
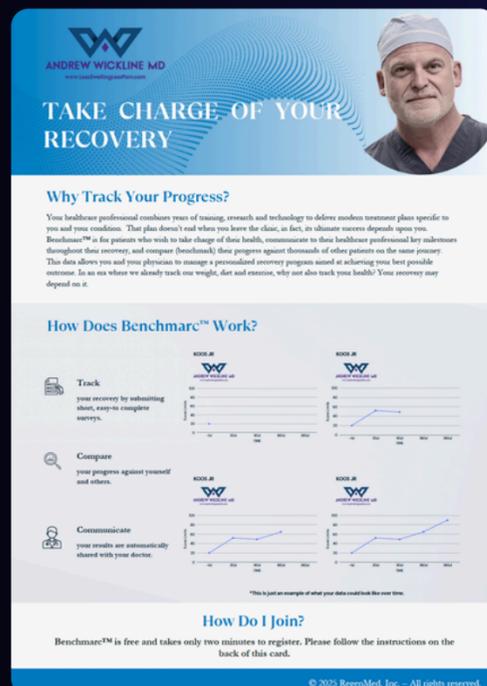
Easy, secure enrollment, baseline and outcomes capture.

**Motivation:**

Physician-customized communications. Updated outcomes chart provided immediately upon survey completion.

**Education:**

Human. Knowledgeable. Responsive. Partner, not vendor.



# NON-HUMAN SUBJECT RESEARCH (NHSR) EXEMPTION



**Certificate of Action**

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<b>Board Action Date:</b> 02/03/2026	<b>Work Order Number:</b> 1-1935312-1
<b>Sponsor:</b> RegenMed, Inc.	<b>Protocol Approval Expires:</b> 02/03/2046
<b>Sponsor Protocol Number:</b> None	<b>Continuing Review Frequency:</b> No CR Required
<b>Amended Sponsor Protocol Number:</b>	
<b>IRB Tracking Number:</b> 20260305	
<b>Protocol Title:</b> MOTIV™ Total Knee Arthroplasty (TKA) Observational Protocol	

**THE FOLLOWING ITEMS ARE APPROVED:**  
 Clinician Operative Survey #45446755.0 - As Submitted (source: Clinician Operative Survey)  
 Clinician Post-Operative Evaluation Survey #45446756.0 - As Submitted (source: Clinician Post-Operative Evaluation Survey)  
 Clinician Post-Operative Surveyrepeated #45446757.0 - As Submitted (source: Clinician Post-Operative Survey)  
 Clinician Pre-Operative Evaluation Survey #45446758.0 - As Submitted (source: Clinician Pre-Operative Evaluation Survey)  
 Incytes License Terms and Conditions #45420427.0 (source: incytes license terms and conditions)  
 Patient Post-Operative Followup Survey #45446759.0 - As Submitted (source: Patient Post-Operative Follow-Up Survey)  
 Patient Pre-Operative Survey #45446760.0 - As Submitted (source: Patient Pre-Operative Survey)  
 Protocol (01-26-2026) Version 1.0 (source: motiv total knee arthroplasty protocol pdf)

**Please note the following information about this review:**  
 EXMPT D1-6 - The research [is] exempt under [45 CFR 46.104(d)(4)]. Per submission form no information collected in the study will be submitted to or held for future submission to the FDA. This exemption determination can apply to multiple sites, but this does not apply to any institution that has an institutional policy of requiring an entity other than WCG IRB (such as an internal IRB) to make exemption determinations. WCG IRB's determination of an Exemption only applies to US regulations; it does not apply to regulations or determinations for research conducted outside of the US. Future changes to the project may affect its exempt status, and you may want to contact WCG IRB about the effect these changes may have on the exemption status before implementing them. WCG IRB does not impose an expiration date or closure requirements on its IRB exemption determinations. As indicated above, the protocol was determined to meet criteria not requiring ongoing IRB oversight. As a result, all collaborating investigators at your institution may participate regardless of only the submitted investigator being listed on the Certificate of Action and HIPAA Waiver documentation if provided.

**ALL WCG IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:**

- Ensure the consenting process included in the submission is being followed. Any changes to this process must be submitted to the IRB for review

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization submitting shall promptly communicate or provide, and where necessary cause each investigator to promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.
- Please note that any advertisements or subject material that contain both English and translated content must be submitted through the translations process in addition to standard review to have the translated content approved.

This is to certify that the information contained herein is true and correct as reflected in the records of WCG IRB. WE CERTIFY THAT this IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.




## NHSR Exemption Letter

# MOTIV™ PRIVATE CIRCLE PAGE

**FAQs**

**Resources**

**Tutorials**

**Contacts**

**Updates**



# ANDREW WICKLINE

**Better education**

**Anti-inflammatory diet**

**Cryoneurolysis**

**No tourniquet**

**Low step count**

**Non-aggressive PT**

**Essential amino acids**

**Cooling pre-op**

**Dexamethasone 20mg**

**Suzetrigine**

**Spinal vs. general**

**Kinematic Alignment**

**No MCL injury**

**Subvastus**

**Cryocompression**

**Anti-inflammatory wash**

**Intra-articular local anesthetics**

**Essential amino acids**

**Limit electrocautery**

**Keep knee flexed in PACU**

**Vitamin C infusion**

**Edema controlling stockings**

**Extended length TXA**

# JOHN MERCURI

## Discharge Medications:

- 1950 mg TXA daily (4 days)
- 4 mg Dexamethasone BID (4 days)
- 1000 mg Tylenol TID (10 days)
- 75 mg Lyrica BID (10 days)
- 50 mg Journavx BID (10 days)
- 15 mg Meloxicam daily (30 days)
- 81 mg ASA BID (30 days)

**THANK YOU**

**Q & A**

# **BENEFITS OF JOINING**

**Compare Yourself to Peers**

**Deeper Patient Engagement**

**Easy For Your Staff to Administer**

**Publication**

**Financial**