MOTIV™

MUSCULOSKELETAL OUTCOMES AND
TRACKING INTELLIGENCE VAULT

PEER-REVIEWED REAL-WORLD EVIDENCE
EXPANDED CMS TKA PRO-PM PROTOCOL

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The Power of Peer-Reviewed RWE

Real-World Evidence (RWE) is increasingly recognized by regulators, payers, researchers and providers as important to clinical decision-making, value-based care, product innovation, and health equity.

However, as the FDA points out, such RWE must be "fit for purpose." It should also be verifiable to primary clinical sources, current, and well correlated to long-term outcomes. MOTIV™ achieves these objectives by marrying OREF's rigorous peer-review process with the patented infrastructure of RegenMed's Circle Datasets.

Datasets Relevant To Modern MSK Treatments and Environments

The $1 billion musculoskeletal market includes not only traditional orthopedics, but many other diagnoses and treatment protocols. Practice environments are quickly expanding beyond large hospital systems. For example, TKAs and THAs for Medicare beneficiaries surged from 16% in 2018 to 72% by 2023.

Many MSK interventions are supported only by low levels of evidence. Whatever their practice environment, clinicians and their patients will benefit from the high quality and clinically-specific RWE datasets which the MOTIV™ initiative will generate.

Building Upon The CMS TKA PRO-PM

The initial MOTIV™ peer-reviewed Observational Protocol builds upon the CMS TKA Final Rule. In addition to meeting the Final Rule requirements, it enables clinically-efficient real-world data collection on:

- Implant models, surgical technique, Forgotten Joint Score, Pain Catastrophizing Score, and non-opioid post operative pain management techniques developed by Drs. Andrew Wickline and John Mercuri, and peer-reviewed by OREF.

- Different or additional TKA-related topics which particular physician cohorts may wish to analyze. (For example, kinematic or mechanical alignment, adjunct biologic therapy, specific post-operative rehab protocols)

Minimum Clinical Burden. Maximum Physician Value

RegenMed's patented Circles platform and processes – *Method and System For Processing Large Amounts Of Real-World Evidence* – ensure minimal interruption to normal clinical flow, and unambiguous dataset ownership rights for participating physicians.

Thus, the MOTIV™ initiative not only delivers high quality peer-reviewed RWE datasets in high demand by providers, payers, product manufacturers and researchers, it also generates growing value for MOTIV™ Circle Members.