



Musculoskeletal Clinical
Regulatory Advisers, LLC

R **The Clinical Trial**
Reimbursement Solution

**Parallel Data Collection for
Reimbursement & Regulatory**

- **Optimizes** Value Creation
- **Insures** Capital Investment



Integrated Clinical Trial Support

Coverage During Trial

Collection of Payment & Claims Information

Real Time Reporting

Post Approval Commercialization Support

You are working under financial, time, competitive and regulatory constraints. Therefore, the rapid commercialization of your company's technology is imperative. At the same time, the medical reimbursement landscape is changing drastically, ever faster than either regulatory or intellectual property law. MCRA believes the real question is not whether your technology will be FDA approved, but whether the waiting United States commercial market will ultimately reimburse your technology.

It is clear that the clinical data needed for a successful regulatory approval does not necessarily encompass the clinical data required for successful reimbursement of a technology. The common bond for bridging this gap is the design and collection of clinical data, which accounts for both regulatory and reimbursement considerations. We believe that these disparate needs can be solved with an integrated regulatory and reimbursement strategy that is well-planned and executed.

MCRA's Clinical Trial Reimbursement Solution (CTRS) was designed to optimize parallel clinical trial data collection for reimbursement and regulatory. Whether your trial is in development or has mostly been enrolled, MCRA can offer either the full suite of services or only what you need to maximize the opportunity.



MCRA was founded in 2003 and provides "first-in-class" regulatory, clinical, reimbursement, intellectual property and quality assurance services to its clients through its superior knowledge base, global surgeon relationships and deeply experienced management team. MCRA places particular emphasis on working with companies at all stages of development, whether they are single-product companies or companies with several thousand technologies.

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CLINICAL TRIAL SUPPORT

By integrating reimbursement early in the trial design, MCRA's CTRS is able to advise company management, sites, and payors by offering both strategic and administrative support, ultimately taking the burden off of clinical sites, and speeding the clinical trial. Specifically, these services are as follows:

- Analyze & Facilitate Study Site Development
- Clinical Trial Agreements
 - Assess & Negotiate
- Counsel for Current Codes Applicable
- Produce Collateral Reimbursement Tools
 - For Sites & Sponsors
- Coding, Coverage & Payment Study Support
 - For Sites' & Investigators' Billing Staff
- Implement Publication Portfolio Strategy

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COVERAGE DURING THE TRIAL

MCRA seeks to obtain coverage to secure payment with carriers during the trial. Key value creation to your study includes:

- Speed Future Sales Cycle by Coverage During Trial
- Establish Precedent Setting Coverage NOW
- Early Payor Integration
- Offset Clinical Trial Costs
 - Having your Technology Potentially Paid For

Strategic & Administrative Support

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COLLECTION OF PAYMENT & CLAIMS INFORMATION

Whether your technology has a code or not it is imperative to optimize your clinical trial by collecting the appropriate claims and payment information. Specifically, these services include:

- Leverage Level I Clinical Data
 - Creation of an Optimal Coding Solution
 - Future RVU Assignments
- Manage Data with MCRA's Proprietary Reimbursement Database
- Market Intelligence
 - Who Is Paying?
 - How Much?

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REAL TIME REPORTING

Real time reporting offers control and transparency to gauge day-to-day activity and to report critical information to:

- Management
- Board of Directors
- Investors

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POST APPROVAL COMMERCIALIZATION SUPPORT

The data being collected during a clinical trial provides market intelligence and, more importantly, builds the case for future payer coverage decisions. Specifically, these services are as follows:

- Society Endorsements
 - Coverage Support & Position Statements
 - Supporting Permanent CPT-4 Coding
- Drive CMS to Action
 - Ensure Appropriate DRG & APC Mapping
- Execute Payor Adoption of Your Technology
 - Addressing the Disease & Treatment Options
- Integration of the Technology
 - Within Local Use Protocols