

# FINANCIAL OFFSETS DURING IDE CLINICAL TRIALS

To reduce your study costs and save valuable time to enrollment, call MCRA today.

## MCRA Assists Clinical Trial Sponsors in Reducing Study Costs, Expediting Enrollment & Educating Payors

Clinical studies are expensive endeavors. Reimbursement integration has now become critical to commercialization and future product positioning.

Clinical services and technologies may be afforded coverage and provider payment during the clinical trial. Did you know that Medicare requires pre-determination of coverage from its Medicare Administrative Contractors (MACs) before clinical services are provided? Timing and effective communication with MAC administrators, study sites, and sponsor directly reduce study costs and administration.

### KEY VALUE DRIVERS OF MCRA'S IDE SERVICES

- Offsets Study Costs
- Expedites Enrollment
- Educates Payors Toward Technology Adoption
- Expedites Time-to-Market

### CASE STUDY

MCRA was engaged in 2009 by a multinational medical device corporation to assist its IDE study sites with Medicare pre-determinations (approx 200 sites; 2,500 enrollees). 100% of clinical costs were obtained for Medicare patients as a result of MCRA's processes. MCRA decreased time to pre-determination approvals, from 63 calendar days to 35 calendar days (44% improvement).

Average improvement in time-to-approvals through MCRA:  
44% - 70% faster approvals study-wide.

Average Medicare approval time savings through MCRA:  
30 - 40 days of Medicare enrollment saved per site.



CTA Negotiations • FMV Payments • Protocol Reimbursement Review • CRF Review  
Reimbursement Guides • Site Education • MAC Filings • Payor Education

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# MAC PRE-DETERMINATION PROCESS MANAGEMENT

## Integration into an IDE Clinical Study

### PHASE 1

#### Site Selection & MAC Requirements Analysis (Pre-Submission)

Pre-Submission MAC Analysis and Requirements Memorandum

MCRA consultants assist in determining appropriate potential study sites based on MAC requirements, known behavior (i.e. turn-around time of review/approval), and status of contracting with CMS.

MCRA issues a memorandum based on specific needs of the particular IDE study, in light of CMS approval issues.

MCRA assists CRO and/or Sponsor with a final Site Listing based on CMS approvals data compared against other applicable metrics.

### PHASE 2

#### Pre-Submission Site Support & Communications: MACs, Study Sites

Pre-Submission MAC and Site Communications

MCRA educates sites by creating a Reimbursement Guide, and by holding reimbursement teleconferences.

MCRA obtains or helps identify MAC(s), and CMS points of contact (POCs) at each study site, responsible for Part A/B pre-determination request submissions.

MCRA emails Site Listings and regulatory documents to MAC(s) (includes sites' PI's name, facility's name, POC's name, relevant contact information, FDA correspondence, study protocol, and relevant clinical articles).

Once regulatory documents are available (IRB and CTA where applicable), MCRA emails instructions and template materials for specific MAC(s) to site.

### PHASE 3

#### MAC-Internal Submissions & Pre-Determination Decisions

### PHASE 4

#### Post-Submission Site Support & Communications: MACs, Study Sites

Post-Submission Tracking Communications

One week after submission, MCRA requests that site POC confirms MAC receipt of submission.

At specific intervals determined by MCRA consultants, MCRA requests that sites follow-up with MAC regarding status of review.

MCRA records and maintains approvals data, metrics, and documentation within its proprietary database.

### MCRA REPORTING

At specific intervals (i.e. monthly, weekly), MCRA reports on CMS approvals, MAC turn-around times, and any other relevant issues.

Reporting supports Study Start-Up or Maintenance functions, and may be used in newsletters sent to study sites.

Reporting includes upcoming CMS approval renewal due dates or other downstream activities impacting the sponsor or study enrollment.

Upon request, MCRA provides ad hoc reports to address specific needs of the study.

PRE-SUBMISSION

PRE-SUBMISSION

SUBMISSION

POST-SUBMISSION

ONGOING OR UPON REQUEST