

MCRA Clinical Services

Core Clinical Services

Clinical Study & Regulatory Submission Preparation

- Study Protocol & Budget Development
- Retrospective Clinical Data Compilation
- Literature Searches & Analysis
- Investigator Selection
- Compile IRB Packets, Coordinate IRB Approvals, Compile Investigator Brochures, & Creation Consistent Case Report Forms

Clinical Study Management

- Manage Data Entry & Analysis Through Subcontract to a CRO
- Manage Site Trainings & Monitor Site Status Reports
- Negotiate IRB Approvals
- Perform Study Statistics Analysis
- Write Final Clinical Study Report for Submission

Post Clinical Studies

- "Ghostwriting" for Peer-Reviewed Medical Journals, Whitepapers, PowerPoint Presentations & Abstracts for US & International Medical Conferences

Integration with MCRA's Other Divisions

Regulatory

- IDE/PMA, IND/BLA, HDE and/or 510(k) Protocol Development
- Clinical Data & Literature Search Analysis

Reimbursement

- Integrating Healthcare Economic Data Within Clinical Study Protocols for Future Coding Purposes
- Sponsor Health Economic Outcome Studies

Intellectual Property

- Redesigns & Improvement of Implants & Instruments

MCRAs unique clinical services enable international and US-based companies of all sizes to successfully execute a clinical study. As clinical affairs should be integrated with regulatory and reimbursement initiatives, MCRA's integration is perfectly positioned to optimize quality, cost, and time.

MCRAs uses dedicated and experienced clinicians to actively manage CRO's, statisticians, investigators and IRB's, leading to faster enrollment and ultimate success. Furthermore, MCRA's clinical team is adept at writing whitepapers and other clinical publications.

MCRAs clinical expertise, coupled with our global surgeon relationships, makes MCRA a valuable clinical service addition to any company.