MCRA
Corporate Presentation

MCRA's integrated approach creates value and mitigates risk throughout the technology innovation lifecycle.

Company Overview

- **World Leading Global Medical Device and Biologics CRO & Consulting Firm**
  - 16-year history pioneering the medical device integrated professional services market
  - >150 team members in 3 offices – US (Washington D.C.; Hartford CT; NYC)
  - Experienced management team w/ employee-based model creating long term client value
  - High client retention (70% by total client, 90% by revenue)

- **Strategy, Implementation, & Due Diligence**
  - US & International Regulatory
  - Global Clinical Research Organization (CRO)
  - Reimbursement – market access, coding, coverage, patient access programs, & hot lines
  - Quality & Manufacturing
  - Digital Health Advisory & Cybersecurity Support
  - Healthcare Compliance – clinical trial, reimbursement, surgeon & corporate ethics

700+	300+	700+	~90%
Clients Since Inception	Clients Annually	Projects Annually	Employee Retention

Deep Therapy Specialization & Integration of Services

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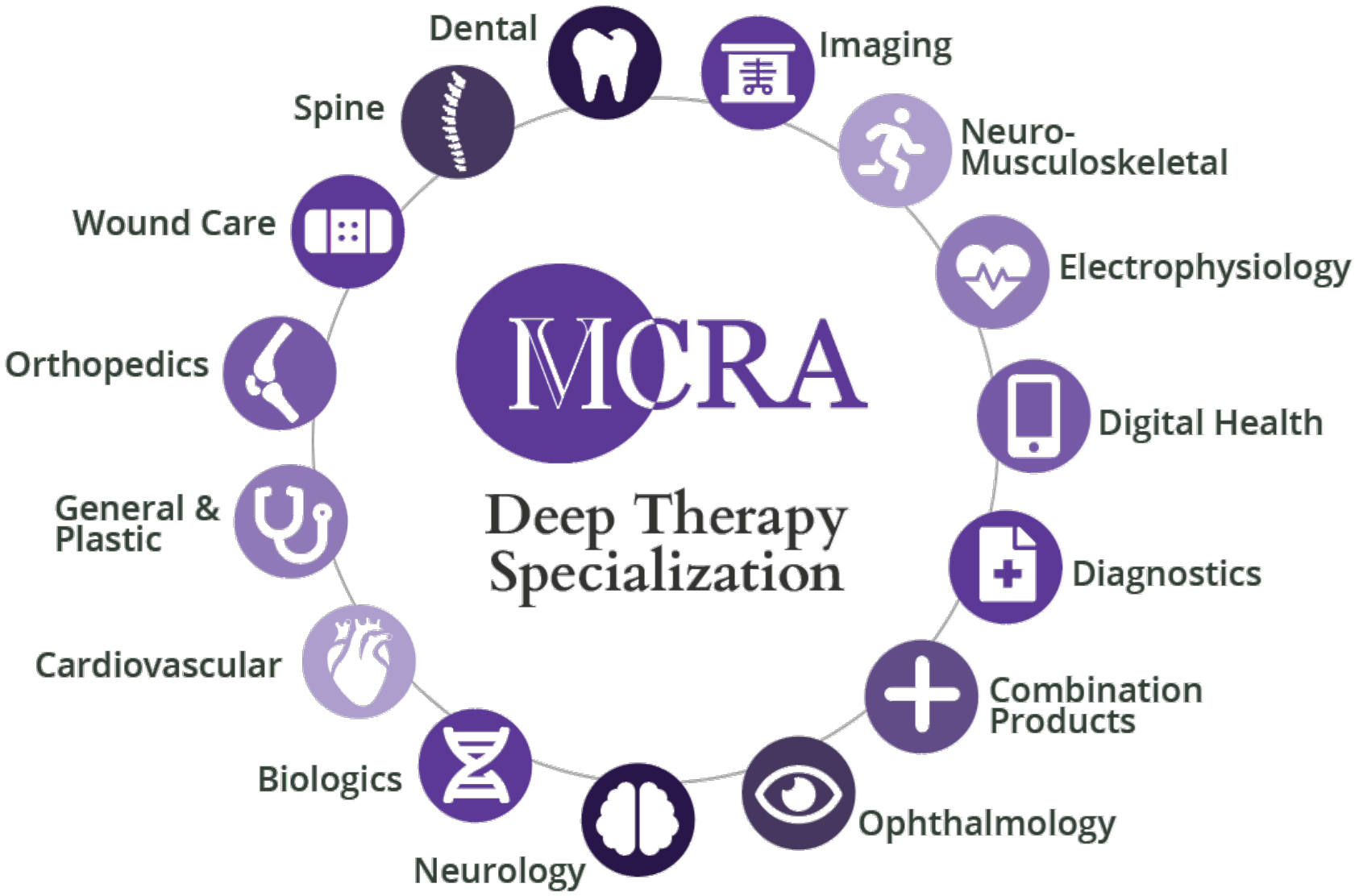
MCRA Master Therapy Specialization



Deep Therapeutic Experience Throughout Medical Devices

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Integration Optimizes Medical Device Continuous Life Cycle

- Regulatory Execution Creates Technology Value
- Clinical Evidence Required for All Stakeholders
- Reimbursement is Multifaceted in Constituents & Policies
- Quality System Requirements Becoming More Demanding
- Healthcare Compliance Considerations Help Mitigate Risk

Clinical Evidence Generation w/ World Class Regulatory & Reimbursement Integration Creates Long Term Value

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CRO Overview

Clinical Trial Experience

- Currently working on >20 Studies
- ~90% team retention rate v. 25% turnover rate in CRO industry

Full-Service CRO with Boutique Advantages

- Direct access to senior management
- Flexibility for full outsourcing or ad-hoc support
- Customer-centric CRO

Integrated Service Specialization

- Only firm with integrated clinical trial, regulatory, reimbursement, & compliance

World-Class Clinical Quality

- 40+ Quality Management System SOPs
- 10+ successful BIMO inspections in the past 12 month

Deep Therapy Experience

- Orthopedics & Spine
- Cardiovascular
- Neurology
- Digital Health
- General & Plastics Surgery
- Wound Care
- Biologics & Combination Devices
- Other Medical Devices

Investigator and Site Familiarity

- 350+ established relationships with investigators & sites
- ~200 sites over past 5 years

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MCRA Services Snapshot (See appendix for more information)

All Services Required Throughout Entire Product Cycle

Regulatory	CRO	Reimbursement	Quality & Compliance	Digital Health & Cybersecurity
• Regulatory Strategy • Pre-Submission Strategy & Execution, & Pre-IND • Regulatory Submissions (PMA, 510(k), IDE, IND, BLA, De Novo, Breakthrough) • FDA Panel Meeting Preparation & Execution • Labeling • Marketing Compliance • CE Marking & International Regulatory • Total Product Life Cycle Management • Breakthrough Designations • Non-Clinical Testing Strategy	• Global Clinical Trials • Clinical Study Design & Strategy • Investigator & Site Selection • Study Set-up & Initiation • Project Management • Site Monitoring & Management • Data Management & Biostatistics • Audit & FDA Inspection Preparedness Training • Risk Based Monitoring & Data Visualization • Clinical Events Committees, Physician Advisory Panels, & DSMB • CMC Review & Strategy	• Strategic Reimbursement Planning & Execution • Bottom Up, Case-by-Case Coverage Support w/ Tailored Patient Access Program • Top Down, Individualized Payer Outreach • Life Sciences Expert Advisory Panel- current and former payer medical directors, CPT advisors & health economists • Coding Applications & Healthcare Economics • Add-on & Transitional Pass-Through Payment Applications • Due Diligence & Investor Relations • Clinical Trial Coverage Support	• Quality System Creation, Remediation & Streamlining • FDA Inspection Preparation and Backroom Management • OUS Quality: ISO 13485, MDSAP, & EU MDR • Manufacturing & Design Quality: Top-Level DHFs & DMRs • Pre-Acquisition Quality Assessments: Companies & Devices • Core Healthcare Compliance • Compliance Program Management • Chief Compliance Officer (CCO) Outsourcing • Corporate Compliance Issue Investigation & Remediation • HIPAA Privacy	• Regulatory Strategy for DH technologies • Regulatory Submissions (PMA, 510(k), IDE, IND, BLA, De Novo, Breakthrough) for DH technologies • Medical Device: Cyber Security Regulatory Advisory, Pre-Market Cybersecurity Documentation Development & Review, Threat Modeling & Device Testing, Cybersecurity Risk Assessment • Organizational Cybersecurity Support: Full Service Cybersecurity Program Development & Implementation, Cybersecurity Policy Development.

>100 Individual Services Can be Integrated to Maximize Technology Value