MCRA

Our Target is *Your* Success

GLOBAL CRO & ADVISORY FIRM

OPTIMIZE THE VALUE OF YOUR
HEALTHCARE INNOVATION

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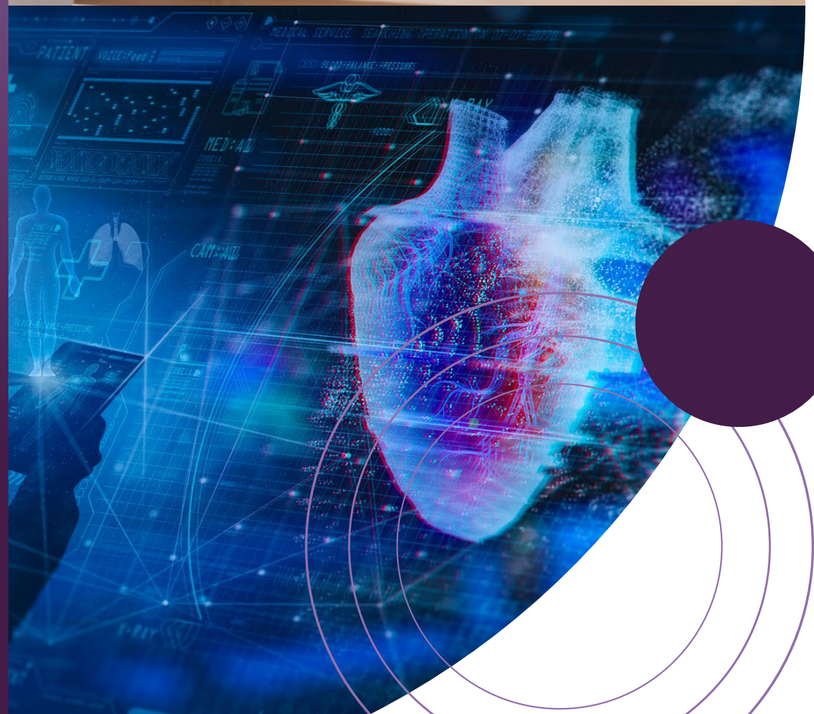
Our Values

Trusted Partners Since 2004

Our culture is the foundation of our success. We are an employee-based firm that has set a standard of employee prioritization, diversity and inclusion for nearly 20 years. We employ 200 team members globally, across the US, Europe and Japan. With an employee retention rate that exceeds 90%, we ensure continuity for our clients. MCRA is not a result of acquisitions — it is a firm that has grown in success due to referrals from satisfied clients. Our team members are the people that make our exemplary track record possible.

"MCRA was established to foster promising technologies and products for the benefit of physicians and patients in need. Because of our extensive FDA experience, we have a deep appreciation of the time, effort and money it takes to bring solutions to market. Success demands we apply the highest level of expertise, attention and passion to usher new products from concept through commercialization. We partner with our clients every step of the way, helping them advance healthcare innovations that will ultimately benefit physicians and patients."

Glenn Stiegman, M.S.
Senior Vice President, Clinical and Regulatory Affairs



A track record you can trust.

MCRA is a Global CRO & Advisory Firm

MCRA INTELLIGENCE + DEEP THERAPY SPECIALIZATIONS

Maximizing the value of your healthcare innovation is our priority. The MCRA Integrated Approach offers bespoke product pathways and strategies informed by the entirety of the commercialization process. From pre-clinical to post-approval stages, each MCRA service team applies their expertise to optimize the market value of your innovation.

MCRA TALENT: INNOVATIVE THOUGHT LEADERS

Our team includes 25+ former FDA officials, notified body decision makers, payer medical directors, industry veterans and partners from the world's most respected medical institutions. Our talented employees work at the speed of innovation, and their world-class expertise unlocks multiple barriers to success.

25+
Former FDA Officials
MCRA's Talent Unlocks Your Company's Potential
US REGULATORY

100%
PMA Approval Rate
MCRA Delivers the Best PMA Track Record in the Medical Device Industry
US REGULATORY

90%
Employee Retention Rate
MCRA Has More Than 200 Employees
CRO

100+
Coding & Payment Applications
REIMBURSEMENT

30+
Countries
Regulatory Success Including EU MDR & Japan
GLOBAL REGULATORY

1,000+
Clinical Site Relationships
Partnering With the World's Most Respected Institutions
CRO

What Our Clients Are Saying

“We are extremely pleased with the guidance and input provided by Peter Bowness of MCRA in assisting us in bringing CELOX PPH CE certification much more quickly than expected into the European market. The CE certification represents an exciting milestone for Medtrade Products Ltd, as well as for mothers and clinicians who will benefit significantly from this highly effective innovation to control and treat PPH.”
RUSS MABY, CEO, MEDTRADE

“Working with MCRA's team of experts has been a true pleasure. Our De Novo submission was supported by their wealth of expertise, allowing us to receive marketing authorization in a short period of time. We look forward to continuing to work with MCRA's wide range of experts as we expand in the medical device industry."
SHRI RAGHUNATHAN, CEO AT NOCTRIX HEALTH

"The Chocolate Touch is a novel platform to treat PAD while minimizing the need for stents. It represents a significant advancement in the therapeutic options for patients suffering with PAD. We are pleased to have partnered with such a skilled regulatory and quality consulting firm to bring this innovative cardiovascular product to patients in need."
SHIVA ARDAKANI, SR. VP OF RA/QA & COMPLIANCE AT TRIREME MEDICAL, LLC

"Through our collaboration with and guidance from the MCRA reimbursement team, we are pleased to report a successful panel meeting and the issuance of a permanent CPT code that will allow providers to report use of the prodisc L Total Disc Replacement technology at two levels.”
VINCENT LESNIEWSKI, SENIOR DIRECTOR, MARKET ACCESS, AT CENTINEL SPINE

MCRA Intelligence Delivers Value

MCRA's integrated approach to guiding healthcare innovation makes us unique among our competitors and ensures the optimal product pathway for success. By combining strategic intelligence with the expertise of more than 25 former global regulators, we help maximize your company's value to attract the attention of potential acquirers.

Assisted Exits Totaling More Than $200B

"MCRA was a dedicated and diligent partner in our evaluation of Envoy Medical, and we are grateful for their perspective on the pathways to FDA approval and Medicaid/Medicare reimbursement."

WHITNEY HARING-SMITH
FORMER CEO OF ANZU SPECIAL ACQUISITION CORP 1

MCRA works with the world's leading healthcare and technology organizations.

Our tailored solutions bring value to companies of every stage and size.

START-UP COMPANIES

- Holistic partner to support clients through the full product lifecycle
- Guide interactions with potential investors and partners
- Provide transparency to the future journey

MID-SIZED COMPANIES

- Support company scaling
- Supplement workforce to enhance bandwidth
- Company training
- Board meeting attendance and advisory

LARGE COMPANIES

- Senior advisory
- Specific expertise
- Process efficiency improvement
- Bandwidth support

Abbott · Johnson & Johnson · Medtronic · PHILIPS · Boston Scientific · CRG

INVESTORS

- Senior advisory
- Due diligence
- Networking

JAM CAPITAL PARTNERS · orbimed · Longitude CAPITAL · WB · BainCapital · CRG

MCRA

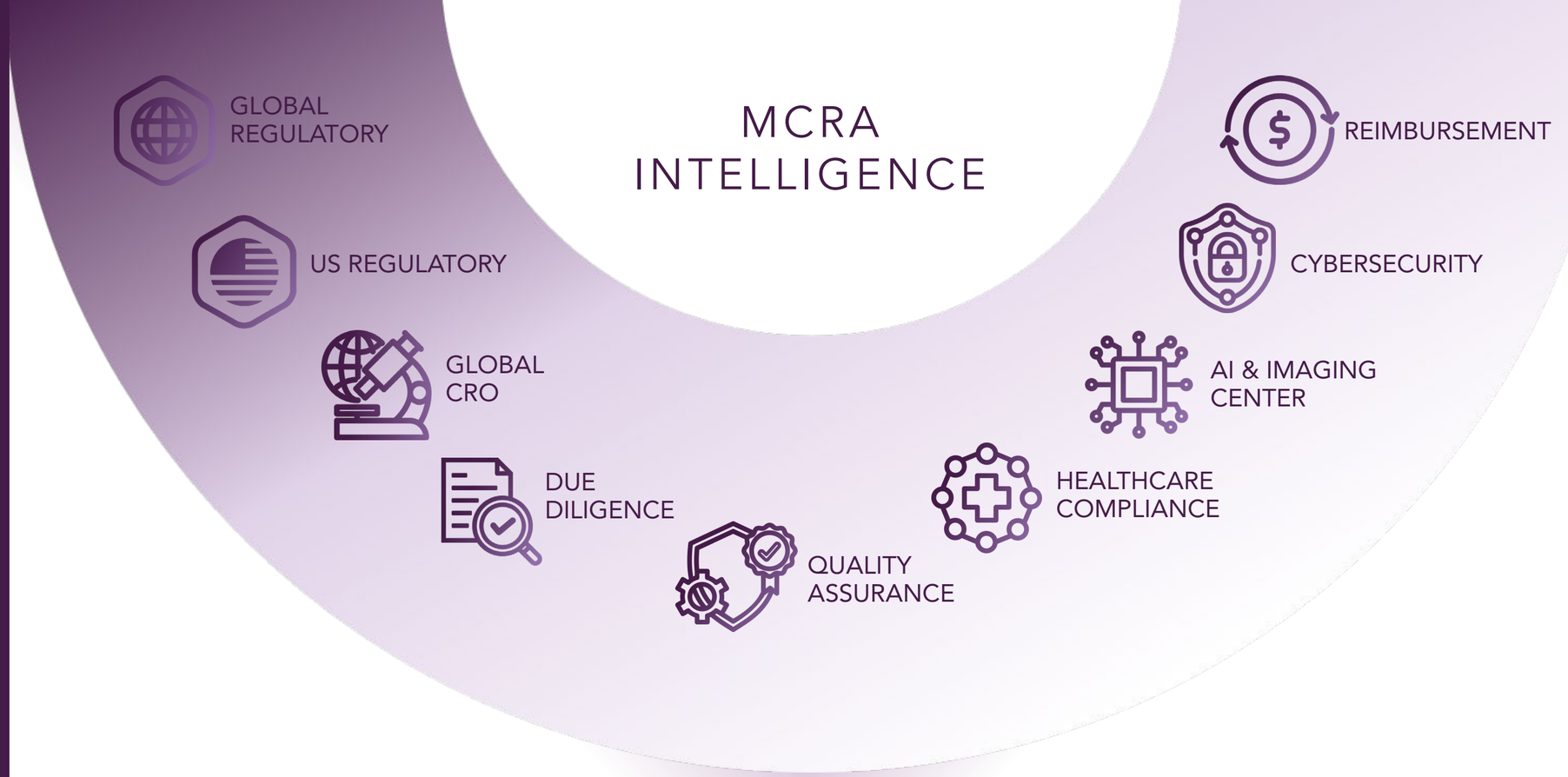
MCRA Has Assisted 500+ Start-Ups

MCRA INTELLIGENCE

MCRA Greenlight *Your* Success

A Unique Integrated Perspective for Creating the Optimal Product Pathway

WE OFFER BOTH
STRATEGY & EXECUTION



STRATEGY

- Market Opportunity Assessment
- Reimbursement & Regulatory Strategy Planning

PRE-CLINICAL

- Protocol Design with Regulatory, Clinical & Reimbursement
- Negotiations with Regulatory Authorities
- Adapting & Comparing Pre-Clinical Outcomes

CLINICAL

- Clinical Study Start-Up
- Site Contract Negotiations
- Study Execution
- Statistical Preparations & Analyses
- Clinical Trial Billing & Reimbursement Support
- Database Close-Out
- Regulatory Submission Initiation

APPROVAL

- Commercialization & Market Access Strategy
- Marketing Submissions & Negotiations
- QMS Development

COMMERCIALIZATION

- Post-Approval Study Activities
- Private Payer Negotiations
- Patient Access Programs
- Evidence Generation
QMS Audit & Remediation Support
- Compliance Program Development
DMAH Services (Japan)
Recruiting & Staffing

MCRA Therapy Specializations:

- Neurology
- Orthopedics & Spine
- Cardiovascular
- In-Vitro Diagnostic Devices
- Wound Care
- Anesthesia & Critical Care
- Digital Health
- General Surgery
- Plastics & Reconstructive Surgery
- Cell & Gene Therapy
- Radiological Health
- Biologics & Combination Devices

MCRA Intelligence: Integration & Specialization

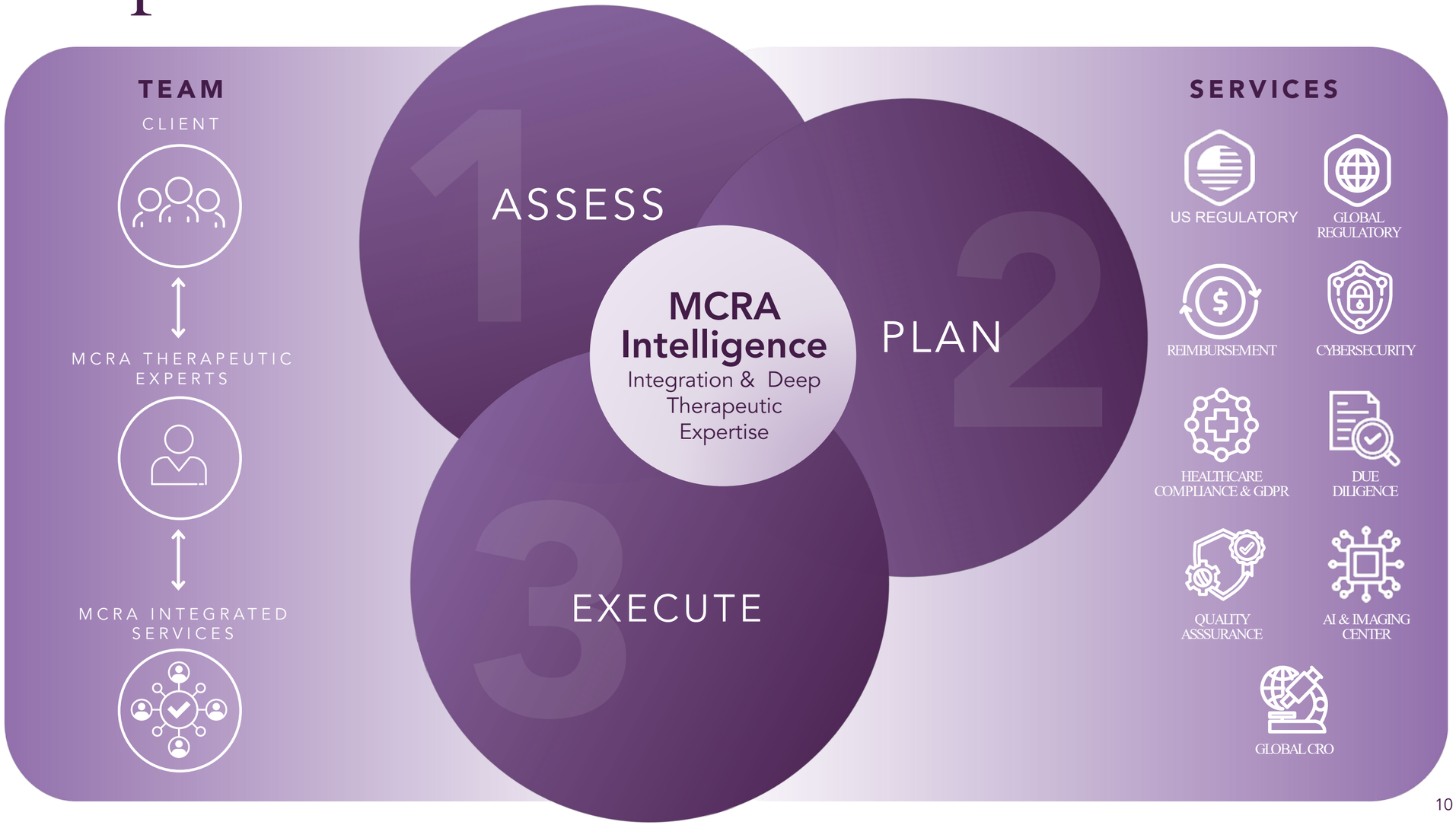
Integrated Approach

Every healthcare innovation requires an approach informed by the complete product life cycle to optimize its advantage and value.

+

Therapeutic Expertise

MCRA offers specialized therapeutic expertise across the full spectrum of medical devices and biologics. We help clients navigate the scientific complexities of healthcare innovations.



Expand Your Healthcare Distribution With MCRA Global Access

Our expansive experience in the United States, European Union, United Kingdom, Japan, Canada and other major healthcare markets enables us to help clients achieve long-term business objectives and expand into global markets. MCRA's comprehensive and integrated global services are designed to support your product throughout the entire product lifecycle, expediting successful market access and commercialization.

INCREASING GLOBAL REGULATIONS STRINGENCY DEMANDS OUR EXPERTISE

- Data Collection
- Regulatory Submissions
- Regulatory Negotiations
- Market Access
- Sites Negotiation
- Monitoring
- Marketing Submissions
- Designated Marketing Authorization Holders (DMAH)

What We Offer

MCRA Services

Global Clinical Research Organization

Full-Service Clinical Studies • Data Management • Biostatistics

Global Regulatory

Pre-Market Regulatory • Post-Market Regulatory • Breakthrough Designation Biocompatibility • CE Mark • MDR/IVDR • Strategic Regulatory • UKCA Marks • Legal Representation

Reimbursement, Health Economics & Market Access

Strategic • Health Economics • Call Center for Pre-Authorization • Coding Market Research • Evidence Generation • Reimbursement Leader Panels

Quality Assurance & Staffing

Gap Assessments • Audits & Inspection • Technical Documentation Quality Management Systems • Design Support

Healthcare Compliance & GDPR

Healthcare Compliance • Outsourced Chief Compliance Officer • Digital Health

Cybersecurity

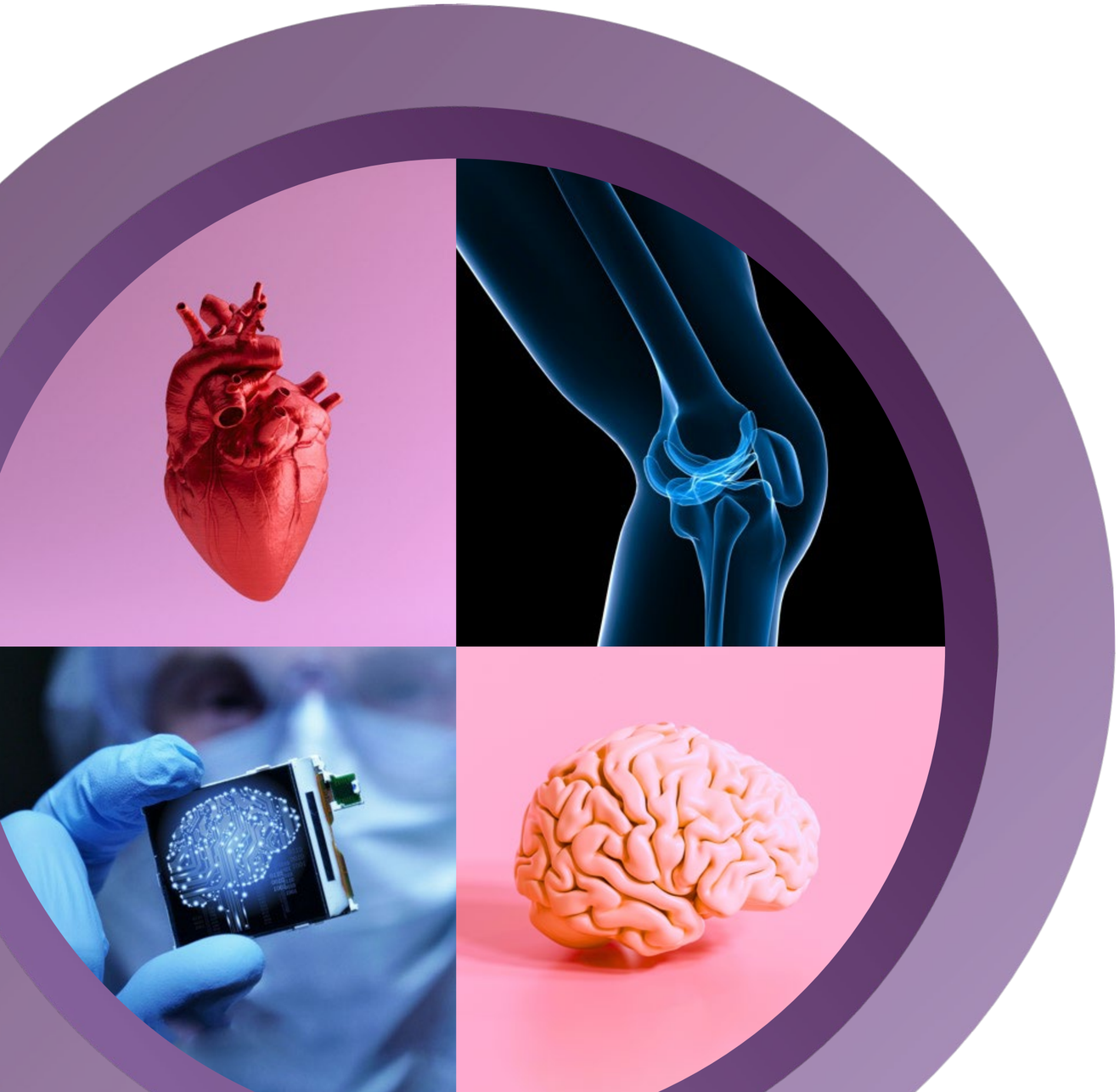
Device Security Risk Assessment • Design Control Remediation • Security Gap Analysis • Threat Modeling • Internal & External Workshops

Due Diligence

Market Research • Regulatory Compliance • Risk Assessment • Clinical Data Evaluation

AI & Imaging Center

Regulatory Support • Clinical Study Design & Execution • Data Collection & Sourcing • Imaging Operations & Network of Experts • Project & Data Management • Statistical Analysis



Global CRO

BACKING YOUR INNOVATION AT THE SPEED OF SCIENCE

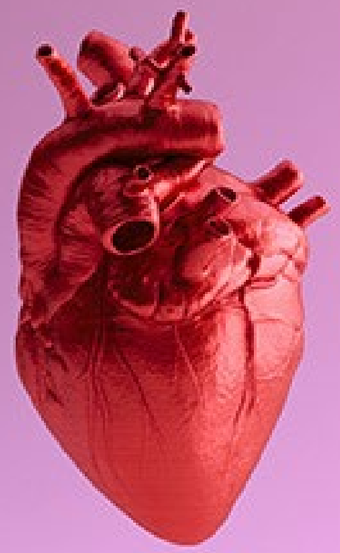
As the world's leading industry-specialized, multi-service and fully integrated CRO, we employ expertise and innovation to unlock complex barriers to success and ensure productive clinical trial outcomes.

Backing Your Innovation at the *Speed* of Science

"Things change minute to minute. This is why it is so important to build trusting relationships — to build real partnerships. MCRA is nimble and responsive. We are structured so that we can prioritize success, which enables us to bring our A game on a daily basis. Our mission is our sponsor's success."

–Abigail Allen

Vice President, Clinical Affairs



The MCRA CRO Advantage

Filling an essential gap in the healthcare innovation industry.

Large pharma CROs can be mired in bureaucracy and offer limited access to senior expertise. Smaller competitors can't offer guidance along the entire product pathway and lack a breadth of therapeutic expertise. For these reasons and more, MCRA is truly unique among its competitors.

LARGE CONSOLIDATED CRO

- Consolidated or Acquired
- Pharma Focused
- Lack of Personalized Attention
- High Turnover
- Bureaucracy and Slow Decision Making
- Limited Access to Senior Expertise
- Communication Challenges
- Less Flexibility
- Lower Company Priority
- Pharma Focused
- Siloed Study Teams

THE MCRA ADVANTAGE

- Top Talent
- Tailored Approach to Meet Client Need
- Flexible and Adaptable
- Access to Senior Expertise
- Responsiveness
- Faster Start-Up Times
- Niche Specialization
- Client Involvement
- MedTech Focused
- One Study Team for Duration of Project

SINGLE-FOCUS CRO

- Limited Resource Capacity
- Financial Restraints and Instability
- Limited Technology and Innovation
- Regulatory Compliance Concerns
- Lack of Credibility

The Fastest Spine PMA Approval on Record

MCRA Integration Means Acceleration

"Simplify Medical is so grateful for the relationship with MCRA — it's been a huge part of our success. I can't say enough great things about how they have guided us through our studies."
- **David Hovda, President and former CEO of Simplify Medical, acquired by NuVasive**

After two failed PMAs, Simplify Medical approached MCRA for help with clinical trials and PMA submissions of their two-level disc to be used in the cervical spine. Using the full scope of MCRA's integrated approach, Simplify Disc achieved the fastest-ever spine PMA approval by the FDA. This kind of acceleration is a result of MCRA's integration.

Healthcare companies across the world trust MCRA for their clinical research support needs. Our integrated process saves time and money and ensures a seamless path to success. The result is improved clinical trial rates, accelerated approvals and client satisfaction.

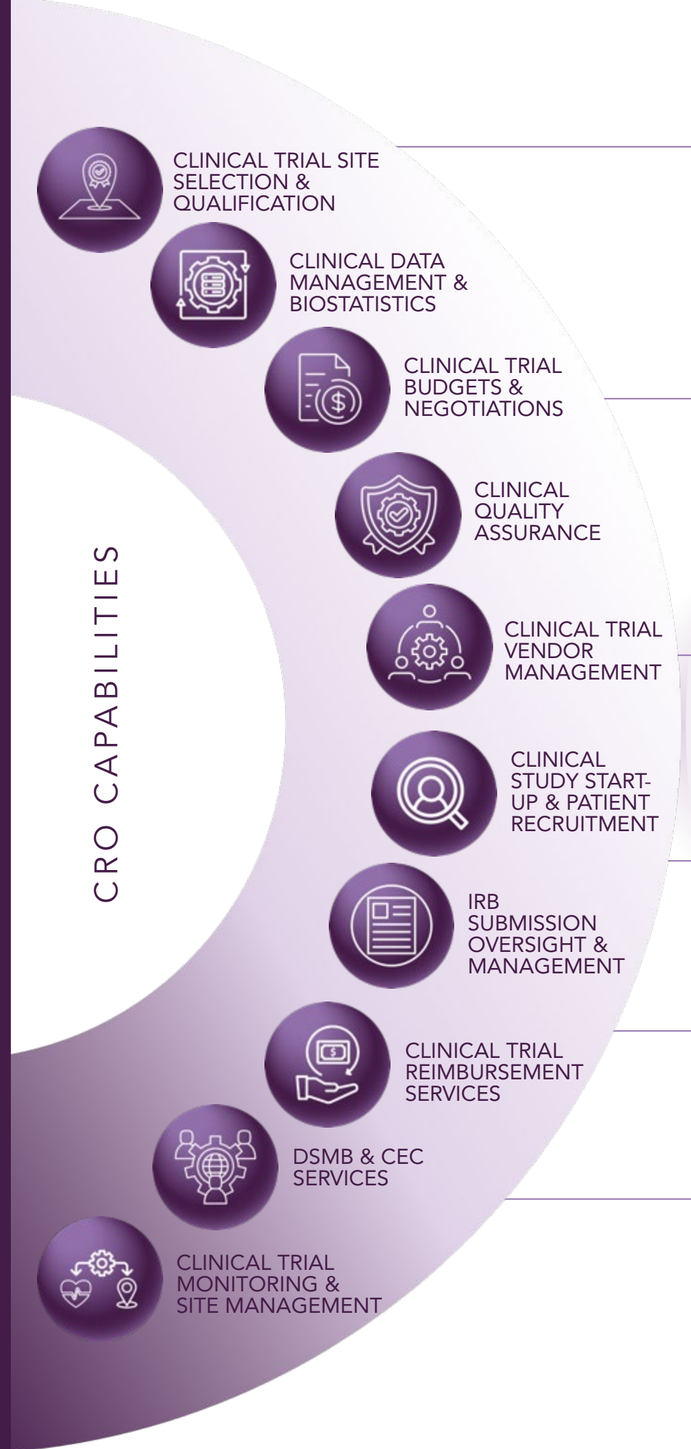
MCRA INTREGRATTED SERVICES ACTIVATED FOR SIMPLIFY MEDICAL

Regulatory | CRO | Reimbursement | Quality Assurance

50+
Studies Supported Annually

Partnering with the world's most respected medical institutions.

MCRA Is the Largest Organically Built Medical Device–Focused CRO



MCRA

CLINICAL TRIAL EXPERIENCE

- Supporting > 50 studies annually
- 90% team retention rate v. 25% turnover rate in CRO industry
- Medical device, biologics & IVD focused

DEEP THERAPY EXPERIENCE

Orthopedics & Spine • Cardiovascular • Neurology • Digital Health • Anesthesia & Critical Care • General & Plastics Surgery • Wound Care • Biologics & Combination Devices • In-Vitro Diagnostic Devices • Other Medical Devices

INTEGRATED SERVICE SPECIALIZATION

Only firm with integrated Clinical Trial, Regulatory, Quality, Reimbursement, Compliance, and Cybersecurity services

INVESTIGATOR & SITE FAMILIARITY

Established relationships with 1000+ investigators & sites around the world

WORLD-CLASS CLINICAL QUALITY

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

FULL-SERVICE CRO WITH BOUTIQUE ADVANTAGES

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

MCRA: Your Partner for Custom Workforce Solutions

From staffing to full-service CRO, we can cover all your clinical needs.

We understand the complexities involved in finding the right talent to meet your specific needs — from a single study coordinator at a remote site, to deploying an entire team of experts.

ON-DEMAND RESOURCING & PROJECT-BASED STAFFING

Addressing specific resourcing gaps, changing workloads and critical talent requirements.

CONTRACT-TO-HIRE

Adding talent to support your team on a temporary or contract basis. Transition talent to fulltime, permanent members of your team when/if you are ready.

DIRECT HIRE & PERMANENT PLACEMENT

Allow MCRA's Talent Solutions Team to be your staffing partner. We can identify and place a candidate directly into a permanent position on your team

RECRUITMENT PROCESS OUTSOURCING

A strategic partnership in which MCRA's Talent Solutions team serves as an extension of your company's HR or talent acquisition team to take over certain processes and/or recruiting efforts

Global Regulatory

EXPAND YOUR INTERNATIONAL IMPACT

MCRA helps clients around the world achieve their long-term business objectives and expand into global markets. We offer expansive regulatory affairs experience in the United States, European Union, United Kingdom, Japan, Canada and other countries.

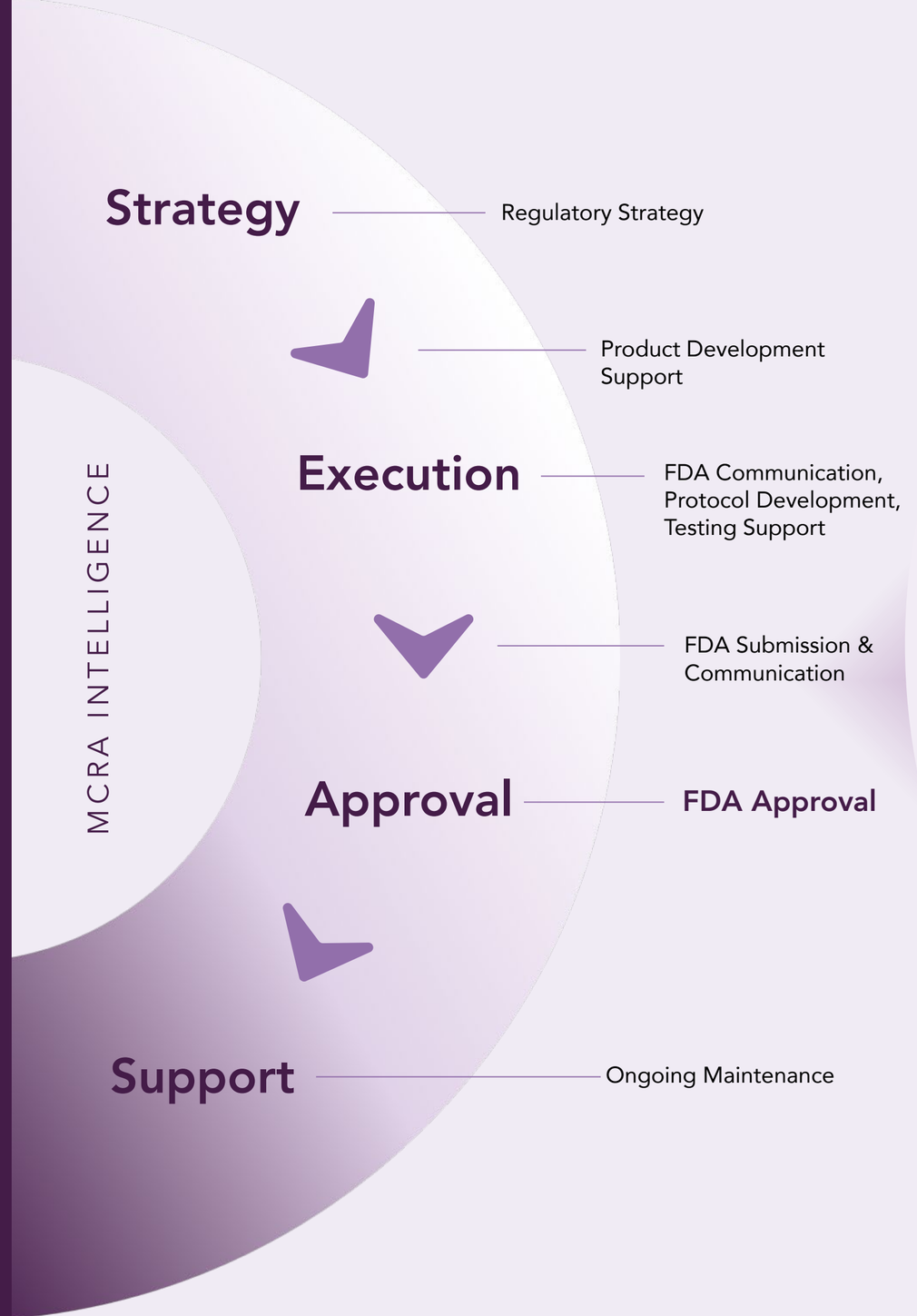
MCRA Has Supported Product Approvals in More Than 30 Countries Around the World.

Offices in New York, Europe, DC, & Japan

US Regulatory Affairs Services

Where All Pre-Market Activities Converge

MCRA DELIVERS THE BEST PMA TRACK RECORD IN THE MEDICAL DEVICE INDUSTRY



100%
PMA SUCCESS RATE

10+
APPEALS

65+
PMA APPROVALS

25+
FORMER FDA BRANCH CHIEFS & REVIEWERS

17
DE NOVOS GRANTED

5
PANEL MEETINGS SUPPORTED

80+
BREAKTHROUGH DESIGNATIONS

Success Breeds Success

Meet the Largest Team of Former FDA Experts in the Industry

MCRA

Name:	**Glenn Stiegman, MS**
FDA Position:	Former FDA Branch Chief Orthopedic Devices
Years at FDA:	6 Years

Name:	**Michael John, M.S.**
FDA Position:	Former FDA Branch Chief, Interventional Cardiology Devices
Years at FDA:	10 Years

Name:	**Fernando Aguel, M.S.**
FDA Position:	Former FDA Branch Chief, Circulatory Support Devices
Years at FDA:	15 Years

Name:	**James Mullally, Ph.D**
FDA Position:	Former FDA Assistant Director Chemistry Toxicology Devices
Years at FDA:	9 Years

Name:	**Tim Marjenin**
FDA Position:	Former FDA Branch Chief, Neurostimulation Devices
Years at FDA:	16 Years

Name:	**Todd Courtney, M.S.**
FDA Position:	Former FDA Assistant Director / Branch Chief Anesthesia Devices
Years at FDA:	11 Years

Name:	**Carolyn Yong, Ph.D**
FDA Position:	Former FDA Chief of Policy & Special Projects, Office of Therapeutic Products (CBER)
Years at FDA:	11 Years

Name:	**Iris Marklein, Ph.D**
FDA Position:	Former FDA Associate Director for Policy, Office of Therapeutic Products (CBER)
Years at FDA:	8 Years

Name:	**Alex Cadotte, Ph.D**
FDA Position:	Former FDA Team Lead, Mammography, Ultrasound & Imaging Software
Years at FDA:	6 Years

Name:	**John Doucet, Ph.D**
FDA Position:	Former FDA Policy Lead, Breakthrough Devices & Lead Reviewer, Neurostimulation Devices
Years at FDA:	12 Years

Name:	**Dave McGurl**
FDA Position:	Former FDA Senior Lead Reviewer, Orthopedic & Joint Devices
Years at FDA:	7 Years

Name:	**Hollace Rhodes**
FDA Position:	Former FDA Lead Reviewer, Orthopedic & Joint Devices
Years at FDA:	17 Years

Name:	**Justin Eggleton**
FDA Position:	Former FDA Lead Reviewer, Spine Devices
Years at FDA:	2 Years

Name:	**Nima Akhlaghi, Ph.D**
FDA Position:	Former FDA Lead Reviewer, Radiological Health
Years at FDA:	5 Years

Name:	**Robert Hermann, Ph.D**
FDA Position:	Former FDA Team Lead Reviewer, Neurointerventional Devices
Years at FDA:	6 Years

Name:	**Rob Allen, Ph.D**
FDA Position:	Former FDA Lead Reviewer and Biocompatibility Reviewer, Cardiovascular Devices
Years at FDA:	3 Years

Name:	**Mehdi Kazemzadeh-Narbat, Ph.D**
FDA Position:	Former FDA Biomedical Engineer & Scientific Lead Reviewer, Dental & Orthopedic Devices
Years at FDA:	4 Years

Name:	**Veronica Downen, M.S.**
FDA Position:	Former FDA Reviewer, Joints & Fracture Fixation
Years at FDA:	3 Years

Name:	**Eric Sussman, Ph.D**
FDA Position:	Former FDA Biomedical Engineer & Regulatory Reviewer
Years at FDA:	10 Years

Name:	**Devjani Saha, Ph.D**
FDA Position:	Former Policy Analyst & Scientific Reviewer
Years at FDA:	6 Years

Name:	**Alvin Cutler Van Orden, M.S.**
FDA Position:	Former FDA Mathematical Statistician
Years at FDA:	15 Years

Name:	**Chava Zibman, Ph.D**
FDA Position:	Former FDA Mathematical Statistician
Years at FDA:	11 Years

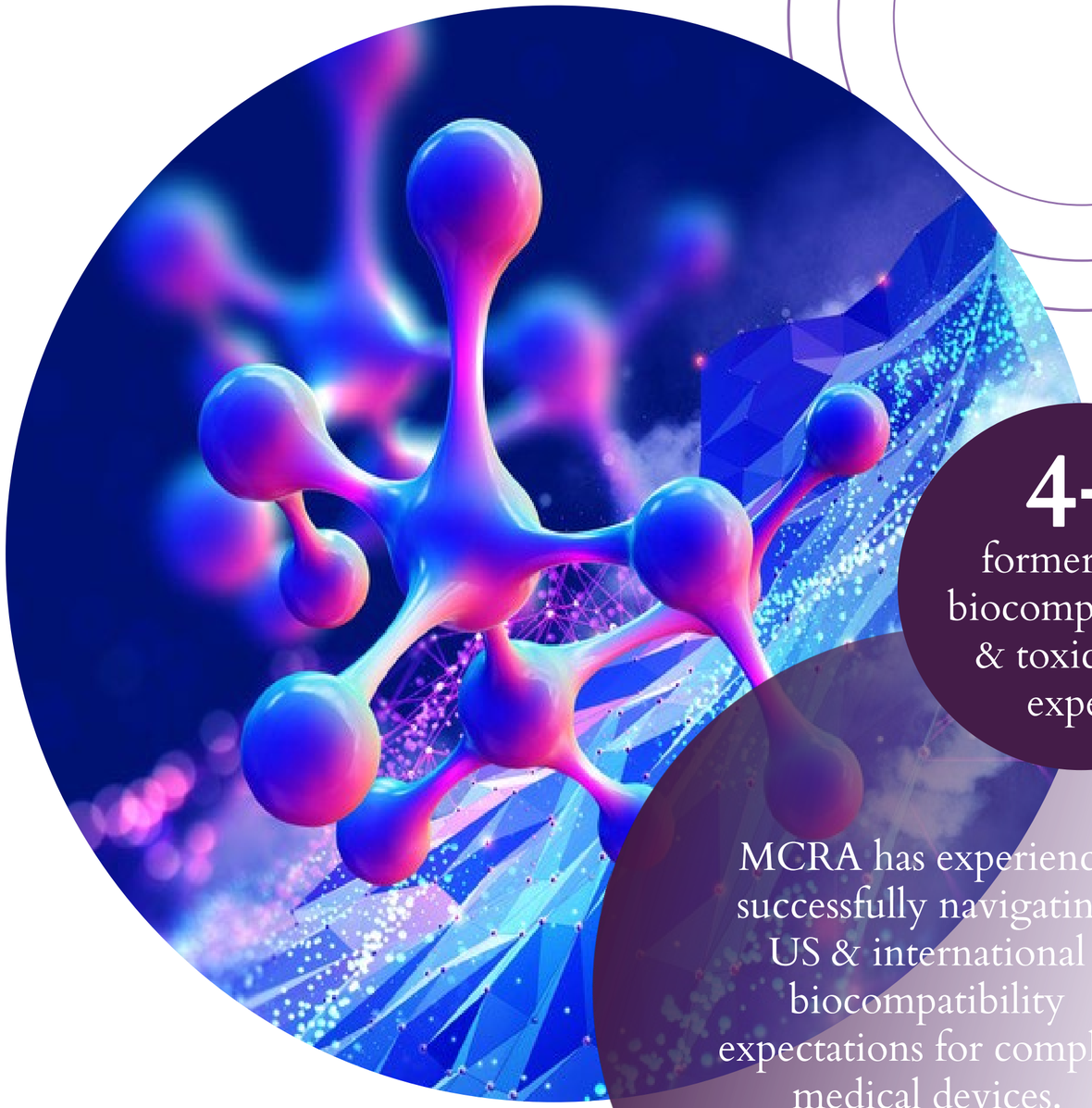
Biocompatibility

Ensure Your Device Is Safe and Effective For Clinical Use

Because medical technology is a highly regulated industry, each new device must be thoroughly vetted to ensure it is safe and effective for clinical approval. MCRA's biocompatibility evaluation and extensive FDA expertise helps guide clients in creating sound strategies poised for regulatory success.

KEY SERVICES

- Global clinical trials
- Response to deficiencies / nonconformities
- Biocompatibility strategy for new devices, combination products, device changes, material supplier changes
- Biological evaluation plans (BEP) & reports (BER)
- Chemical characterization (extractables & leachables testing) design and remediation (ISO 10993-18:2020)
- Toxicological risk assessment (TRA) planning and remediation
- Gap assessments to ISO 10993 series
- Rationales based on materials and manufacturing in lieu of biocompatibility testing
- Test report review
- Device materials selection
- Risk mitigation strategies for impurities and degradants



4+ former FDA biocompatibility & toxicology experts

MCRA has experience successfully navigating US & international biocompatibility expectations for complex medical devices.

MCRA Global Access: Europe & Japan

Our global approach integrates regulatory strategies across the top medical markets in the world.

30+
Countries with Global Regulatory Approvals

END-TO-END SOLUTIONS FOR SUCCESS IN EUROPE'S MEDICAL MARKET

MCRA's European team has extensive experience across all therapies in the medical device industry and is led by former BSI Notified Body decision makers. Services offered include regulatory, clinical, quality assurance, compliance and cybersecurity.

- Two former BSI Notified Body Decision Makers
- Medical Device Regulation (MDR, (EU) 2017/745) and IVD Regulation (IVDR), (EU) 2017/746
- Regulatory Strategy
- Technical Documentation Development & Review
- Clinical Performance Evaluation Reports
- Post-Market Surveillance

END-TO-END SOLUTIONS FOR SUCCESS IN JAPAN'S MEDICAL MARKET

- Japan is the 2nd largest MedTech market with a large, aging population and favorable reimbursement landscape as part of the nationalized healthcare system.
- PMDA's conservative approach and the cultural/language barrier can create a challenging regulatory barrier to navigate.
- Based in Tokyo, MCRA's dedicated team is comprised of RA/CA/DMAH experts with decades of experience helping foreign manufacturers enter Japan without the need for subsidiary or exclusive partnership with distributor.
- **MCRA Japan is the leader in new, complex regulatory approvals** with more regulatory approvals than any other consulting firm in Japan over the last two years.
  - 55+ lifetime regulatory approvals with the majority being Class III and IV products
  - 6 new premium reimbursement categories
- Market Landscape Assessments
- Clinical Development and Operations
- Regulatory Strategy, Submission & Approval
- Reimbursement / Market Access
- D-MAH (Designated Marketing Authorization Holder) for in country representation
- Distributor and Local Subsidiary Support

Reimbursement, Health Economics & Market Access

STREAMLINE THE PROCESS OF HEALTHCARE COMMERCIALIZATION

With more than 50 years of combined healthcare policy and finance services experience, our medical device reimbursement consultants guide leading healthcare companies through the complex, ever-evolving dynamics of medical technology commercialization.

EVIDENCE DEVELOPMENT

Early Strategic Reimbursement & Market Access Services

- Landscape assessments – coverage, coding and payment assessment
- Strategic reimbursement and market access plan development
- CMS engagement and policy analysis
- Reimbursement submissions – NTAP, Transitional Pass-Through Payment
- Coding strategy and applications – CPT, HCPCS, ICD-10-PCS
- Evidence landscape assessment and evidence generation plan development
- Market and evidence gap assessments
- Value proposition development

Clinical Trial Reimbursement Services

- Commercial payer clinical trial policy review and assessment
- Clinical trial contract support – contract development and negotiations, management, coding recommendations
- Site education (clinical trial billing guide, clinical trial billing trainings)
- Trial-generated claims/payment data collection and reporting
- Patient Access Program (PAP) to address individual patient access, support coding and coverage strategies, and establish value proposition

Strategy Execution

- Establish codes and new technology payment
- Stakeholder engagement
- Patient Access Programs (PAP) post commercialization
- Reimbursement and market access asset development – economic models, value briefs, billing guides
- C-suite, provider and field sales training
- Study execution – clinical and economic, prospective and retrospective
- Clinical trial protocol development and review

100+
Coding & Payment Applications

MCRA Reimbursement: Pre-Commercial

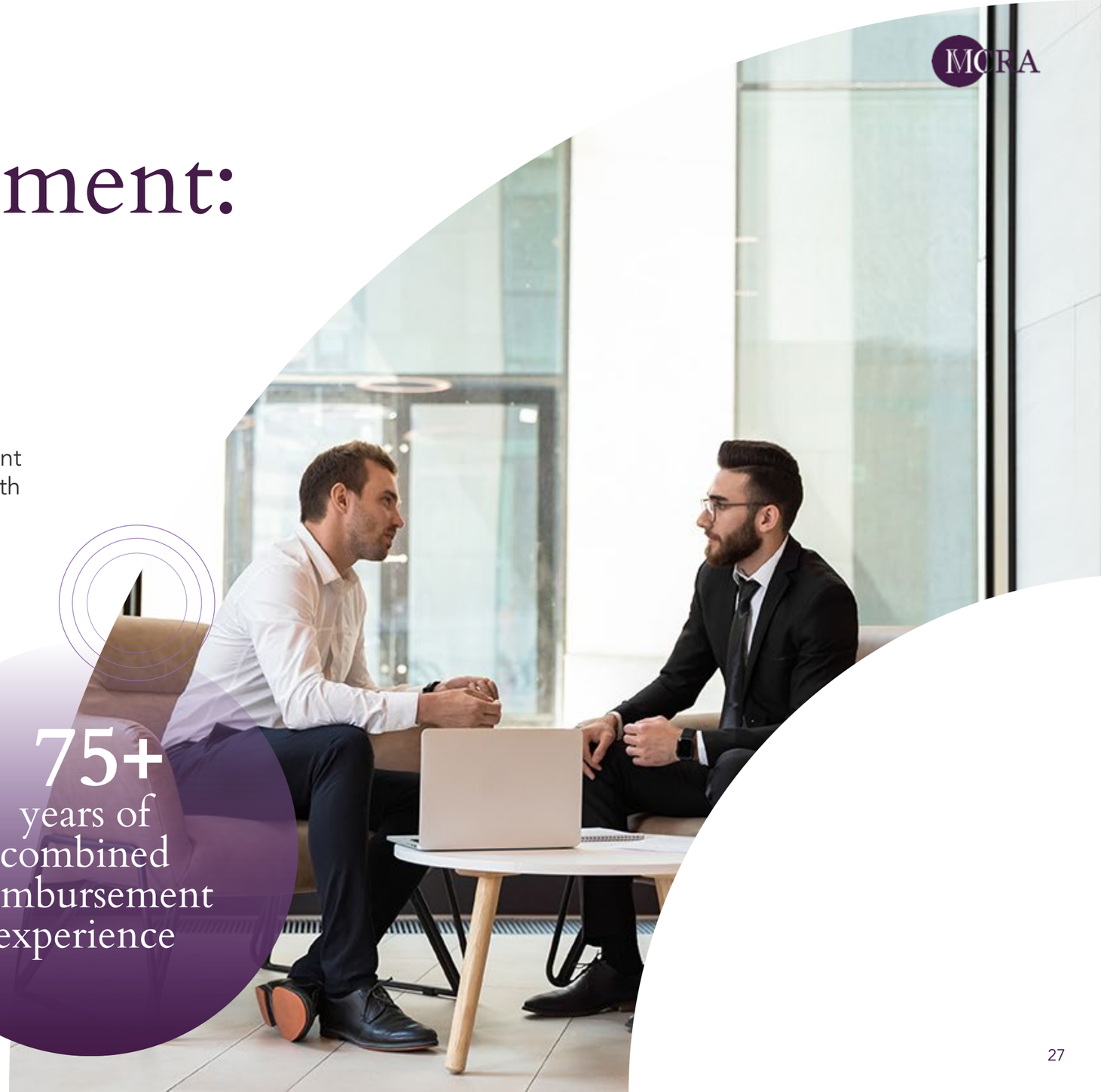
LSEAP: Optimize your Innovation for Commercial Success

Years of experience prove that it's never too soon to start reimbursement planning. By developing a sound reimbursement strategy in parallel with your regulatory strategy, you'll save time and money while ensuring commercial acceptance.

The MCRA Life Sciences Advisory Panel (LSEAP) offers clients valuable stakeholder feedback to accelerate market adoption. Our expert panel includes:

- Former payer medical directors
- Hospital value analysis committee members
- PT coding advisors
- Other experts in the field

Clients can engage LSEAP to assess how strong their hospital adoption plan will be — a critical part of achieving market success. LSEAP is the only way clients can receive expert payer director feedback to set their products up for commercialization.



75+
years of combined reimbursement experience

MCRA Reimbursement: Post-Commercial

Ensuring Utilization with a Top-Down/Bottom-Up Approach

A successful reimbursement strategy must establish coverage, coding and payment. MCRA employs a top-down/bottom-up approach to ensure broad coverage and adoption of your healthcare innovation.

TOP-DOWN

Our top-down strategy takes the form of market-access efforts focused on direct payer education and a discussion of published clinical outcomes data.

BOTTOM-UP

Bottom-up efforts demonstrate patient and provider demand (utilization). Our case managers work directly with patients and insurance companies on approvals and appeals.

Quality Assurance & Staffing

ENSURE QUALITY STANDARDS & MARKET PRESENCE

Healthcare companies rely on MCRA to help them meet the quality assurance standards set by the FDA and other regulatory bodies. Leveraging our deep experience, we guide clients through product review, approval and regulatory compliance. Once a device is brought to market, we support quality assurance requirements to ensure uninterrupted market presence.

Quality Assurance

Specialized Consulting Model

QUALITY SYSTEMS & PROCESSES

- QMS development & updates
- QMS software validation
- FDA medical device reports, unique device identification and recalls

DESIGN SUPPORT

- New device design, development and manufacturing
- Significant changes to device designs
- Medical device software validation
- DHF, DMR, and DHR remediations
- Equipment qualification

GLOBAL MARKET SUPPORT

- 13485:2016 and MDSAP certification
- Country-specific technical documentation
- Upgrades from the EU MDD to the EU MDR

AUDITS

- Internal and external
- FDA inspections

Quality Operations

Temporary Staffing Model

QUALITY SYSTEMS & PROCESSES

- Quality engineering
- Risk management
- Supplier quality
- Process validation
- Corrective and preventive action
- Complaint handling
- Design controls
- Document controls

VALIDATION

- Process validation
- Software and computer system validation
- Test method validation
- Equipment qualification

AUDITS

- Internal and external
- FDA inspections

Healthcare Compliance

SAFEGUARD YOUR COMPANY FROM RISK AND LIABILITY

MCRA's Compliance Program was designed to identify vulnerabilities and protect our clients from punitive fines, reputational damage and financial loss.

Change is a Constant in Healthcare Compliance

THE MCRA SEVEN-POINT COMPLIANCE PROGRAM

The MCRA Compliance Program was developed to safeguard your company's directors, officers, employees and other constituencies against the risks and liabilities of healthcare compliance violations.

As a medical device company, some of the greatest threats to healthcare compliance include regulatory changes, data security, staff training, billing and coding errors, healthcare fraud, patient privacy, anti-kickback laws and third-party vendor compliance. The consequences for non-compliance include punitive fines, criminal proceedings, reputational damage and sanctioning.

1. **Standards, Policies & Procedure**
2. **Oversight**
3. **Open Communication**
4. **Training & Education**
5. **Monitoring & Auditing**
6. **Enforcing Standards**
7. **Response & Action**

"After MCRA's Compliance Assessment, we realized we had real vulnerabilities…. the MCRA team stepped in and ensured we were ready for commercialization."

MCRA CAN SERVE AS YOUR CHIEF COMPLIANCE OFFICER

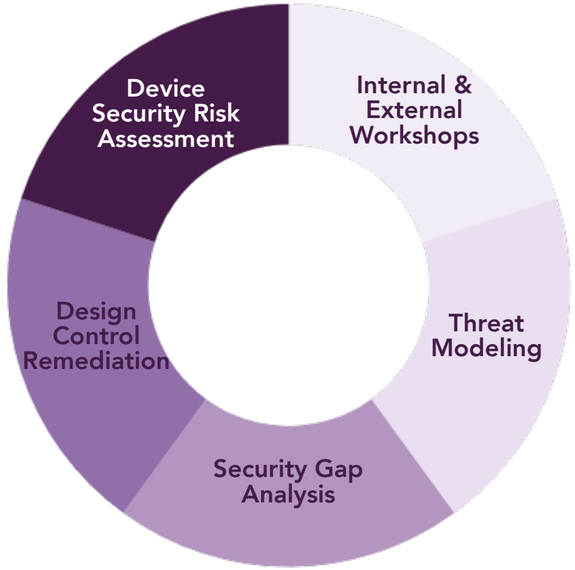
- Demonstrates an organization's commitment to honest and responsible corporate conduct
- Increases likelihood of preventing, identifying and correcting unlawful and unethical behavior at an early stage
- Encourages employees to report potential problems for appropriate internal investigations and corrective actions
- Minimizes financial loss to the organization through early detection and reporting
- Eliminates the need and expense of hiring a full-time Chief Compliance Officer — MCRA will manage the risk

Cybersecurity

SECURE & PROTECT YOUR MEDTECH INVESTMENT

MCRA's cybersecurity experts provide fully integrated services to secure and protect our client's medical device, software as a medical device and organization by leading discussions and delivering risk assessments, strategy and advisory services. Learn about MCRA SAFEGUARD, your path to Cybersecurity security.

Cybersecurity



MCRA CYBERSECURITY SAFEGUARD PLAN

We establish cybersecurity protocols across your organization to prevent costly data breaches.

OUR EXPERTISE

- Cybersecurity Strategy for Medical Devices and Risk Assessment
- HIPAA & GDPR Security Compliance
- Medical Device Cybersecurity Plan
- Organizational Cybersecurity Plan

ADVISING & SERVICES

- Device Security Risk Assessment
- Design Control Remediation
- Security Gap Analysis
- Threat Modeling
- Internal & External Workshops

$9.23M

THE AVERAGE COST OF A HEALTHCARE DATA BREACH

58%

OF HEALTHCARE ORGANIZATIONS EXPERIENCE A DATA BREACH

Due Diligence

MITIGATE RISK TO MAXIMIZE SUCCESS

MCRA provides rigorous due diligence support for investors, lenders and strategic buyers. Our team of experts help mitigate risks and maximize the chances of a successful investment in the dynamic and highly regulated medical device and biologics industry.

Due Diligence

Rigorous Due Diligence Support

"MCRA was a dedicated and diligent partner in our evaluation of Envoy Medical, and we are grateful for their perspective on the pathways to FDA approval and Medicaid/Medicare reimbursement."

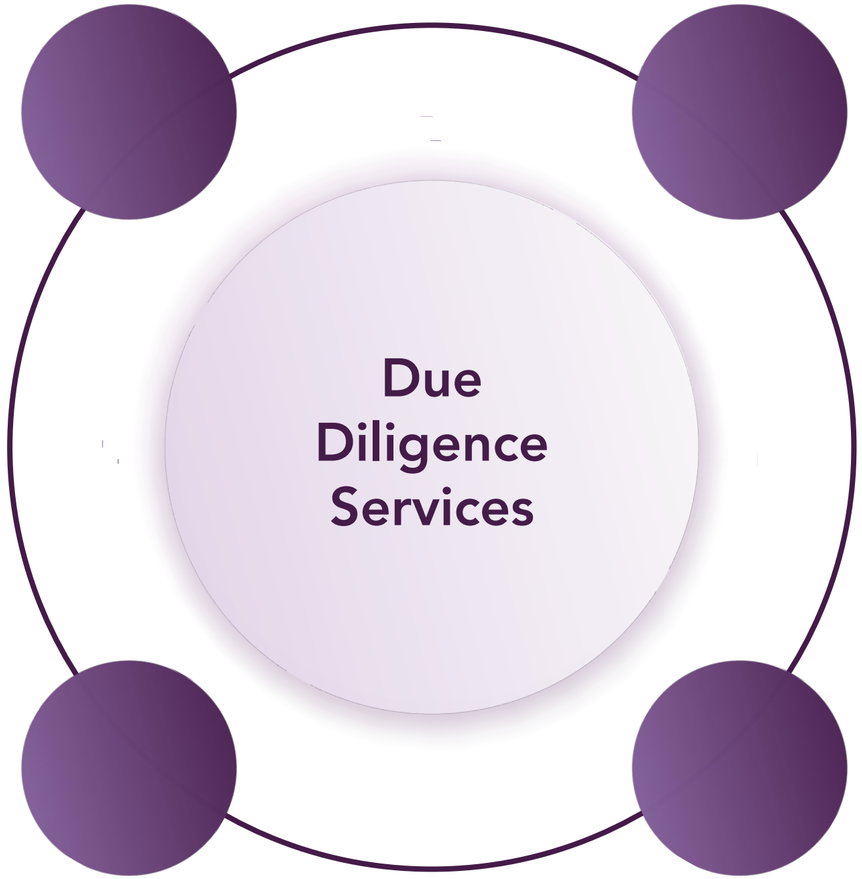
WHITNEY HARING-SMITH
Former CEO of Anzu Special Acquisition Corp 1

MARKET RESEARCH

We conduct in-depth market research to evaluate the competitive landscape, market trends and potential for growth in the medical device and biologics sectors. This helps investors gauge the company's positioning and market share.

REGULATORY COMPLIANCE

We assess the company's adherence to regulatory requirements, quality control processes and compliance with industry standards. This crucial step identifies any potential legal or regulatory risks.



RISK ASSESSMENT

We provide an overall risk assessment, highlighting potential challenges, liabilities, and opportunities that could impact the investment.

CLINICAL DATA & TRIALS

We evaluate the clinical study design or data collected to assess the potential for product success and market acceptance.

Due diligence is a crucial piece of the puzzle for healthcare investors. Our due diligence process involves a comprehensive evaluation of a company's viability and potential risks.

AI & Imaging Center

ACCESS EXPERTISE TO BRING YOUR INNOVATION TO MARKET

MCRA combines our extensive knowledge about how the FDA views AI with our fully integrated process to more quickly deliver a best-in-class product to the marketplace.

AI & Imaging Center and Digital Health

Guiding Your Innovations Into the Future

DIGITAL HEALTH SERVICES & KEY DIGITAL DIAGNOSTICS THERAPEUTICS SERVICES

- Predictive and Diagnostic Algorithms
- Remote Patient Monitoring Solutions
- VR-Enabled Technology
- Therapeutic Apps
- Clinical Decisions Support
- Robotic Systems
- Wearable Technology
- Hardware-Software Interfaces

Nima Akhlaghi,
Head of AI & Imaging Center at MCRA

"With deep FDA knowledge about how the agency views AI, and MCRA's integrated approach as the foundation, the AI & Imaging Center allows MCRA to be more innovative and deliver a best-in-class product to the marketplace."

ABOUT THE AI & IMAGING CENTER

Led by FDA experts, the MCRA AI & Imaging Center is an integrated hub that supports the entire product lifecycle. We combine our extensive knowledge about how the FDA views AI with MCRA's fully integrated process to more quickly deliver a best-in-class product to the marketplace.

AI & IMAGING CENTER SERVICES

Experience includes:

- Data Collection & Sourcing
- Expert Selection & Training
- Performance Testing
- Ground Truthing
- Standalone Testing
- MRMC Analysis
- CADe, CADx, CADt
- Quantitative Imaging
- Segmentation & Image Analysis Tools
- Computer-Aided Detection, Diagnosis & Triage
- Computer-Aided Algorithms

100%
FDA Approval Rate Success

Propelling AI Imaging & Applications with FDA Expertise


The journey is long,
pick the right partner
MCRA