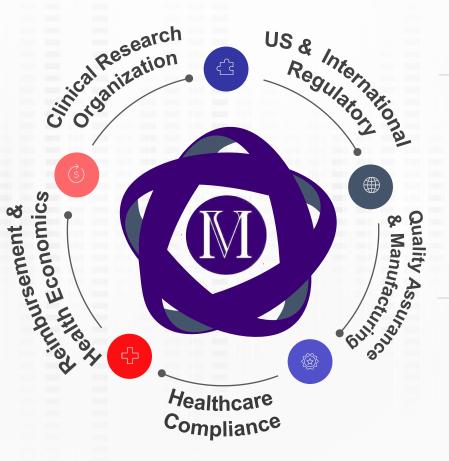
MCRA Overview



World-renowned neuro-musculoskeletal device and biologics consulting firm

- ☐ Founded in 2004
- ☐ 100+ employees & consultants
- ☐3 offices (Washington, DC New York | Connecticut)
- Significant global expertise

- ☐500+ clients worldwide since inception
- >100 Projects Annually
- □Worked w/: >150 Clients Annually

Clients Includes:

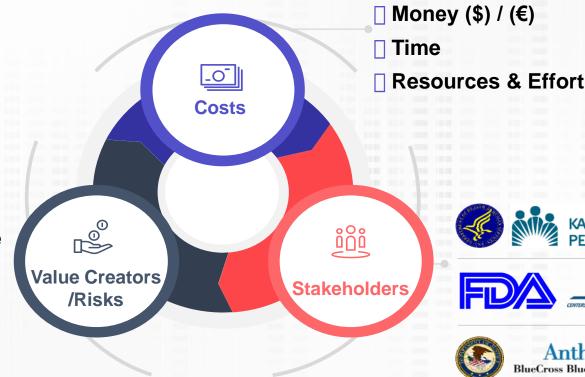
- ☐ Academic Centers
- **□Law Firms**
- Private Equity Firms
- ☐ Technology Companies ☐ Emerging MedTech Companies
 - ☐ Contract Research Organizations
 - Ortho Original Equipment Manufacturers



Key to Our Business Model

Expertise & Integration is Strategic Advantage

- **Full Service CRO**
- ☐ FDA Approvals, Registrations, Clearances
- ☐ Codes & Insurance Coverage
- **Clinical Studies**
- Surgeon Ethics/ Compliance
- **Policies & Procedures**











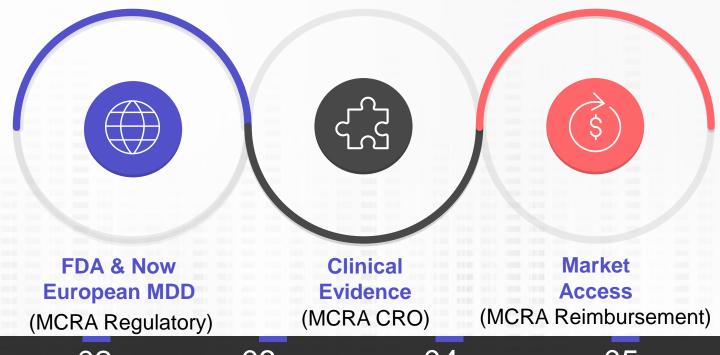








MCRA Industry Growth Thesis



01.

02.

03.

}

04.

05.

Regulatory
Pathway Will
Become
Longer

Clinical Spending is Rising

Reimbursement
Becoming
Primary Due to
the Formation of
a US Single
Payor System

Quality System Requirements becoming more Intense Healthcare
Compliance Must
Be Executed
Throughout All
Aspects of
Clinical Trial

↑ Risk at Every Time Point & It Cannot Undo a Path Already Forged

MCRA Experience & Value Proposition

 MCRA Assists SANUWAVE with **Medical Device MCRA** Leads Successful De **Quality: Why Innovation Novo Decision:** Software Is Training with **3rd Wound Care** FDA as Part of More **De Novo Since** Challenging its Experiential 2010 **Than Hardware** Learning Program (ELP) MCRA Assists **IlluminOss Medical** with Successful De **Novo Decision** 2017 2018 **MCRA MCRA Offers** The Hidden The Impact Releases New Informational Of U.S. Costs of White Paper **Presentation** Regulation Clinical Analyzing the on Medical on Medical Trial Industry **Device Device** Agreement Impact of the Regulation to Innovation **Negotiation** Federal Budget the Chinese Request on **FDA** FDA













