SERVICES **BEYOND CLINICAL**

Regulatory Affairs

- Market Strategy
- Protocol Development
- Gap Assessments
- MDR/IVDR Support
- Technical File Documentation

Medical Writing

- Clinical Protocols
- Publications
- Clinical Evaluation Reports (CER)

Reimbursement Support

- Market Access
- Payor Research
- CMS Applications
- Clinical Trial Site Budgets

Quality Consulting

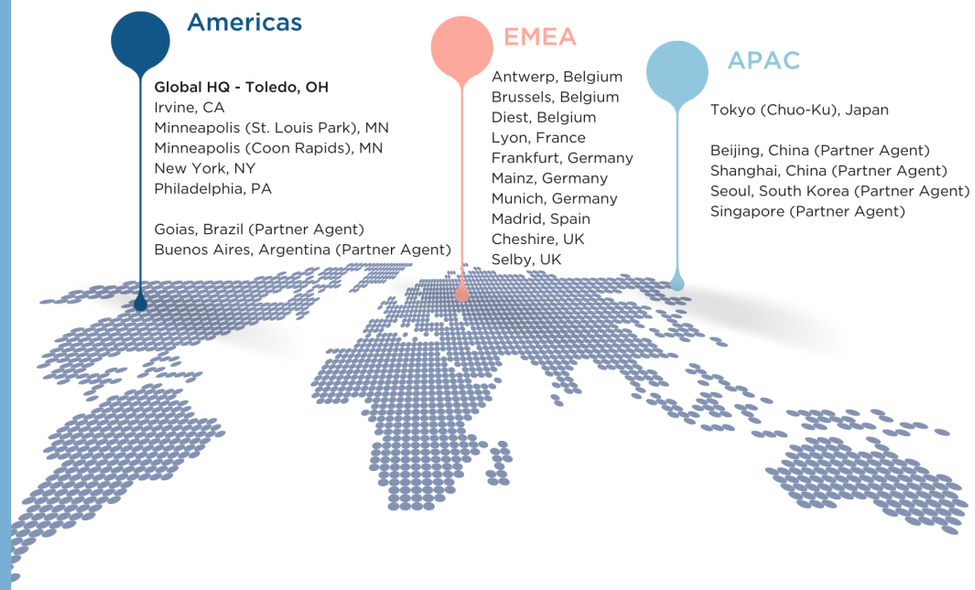
- Risk Analysis
- Audit Preparation
- Audit Support

Let us apply our long-standing expertise to your clinical trial starting now.

Scan to contact us and learn more:

NAMSA **GLOBAL LOCATIONS**

NAMSA operates 20 offices throughout North America, Europe and Asia, and employs over 1,800 highly-experienced medical device testing, clinical research, regulatory and reimbursement associates.



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+1-419-666-9455 (International)

www.namsa.com

COMPREHENSIVE **CLINICAL SERVICES**

PARTNERS ON YOUR **PATH TO APPROVAL**

The global medical device landscape is complex. Getting a new product or therapy approved requires compelling clinical evidence. At NAMSA, we know what you're up against and understand how to set you up for success.

With a dedicated focus on medical device products, we've designed and conducted trials in every area of the world to address wide-ranging client objectives—from first-in-human through post-market.

100%
Medical Device Focused

1500+
Clinical Trials Supported

270+
Global Clinical Associates

GLOBAL SERVICES **CUSTOMIZED APPROACH**

STUDY MANAGEMENT

NAMSA's Study Management solutions provide a dedicated clinical study manager in addition to a dedicated project manager to ensure success.

SITE MANAGEMENT

NAMSA's CRA and CTA team constitutes the site management group, which provides expert training, monitoring and follow-up at sites during the start-up, enrollment, follow-up and close-out phases.

BIOSTATISTICS

NAMSA's Biostatistics team works in parallel with our Study Management and Data Management teams to offer each client a custom designed program that maximizes efforts and outcomes.

DATA MANAGEMENT & DATABASE DEVELOPMENT

NAMSA's Data Management and Database Development team utilizes optimized processes and technology to design and build a customized EDC database populated with accurate data.

IMAGING CORE LAB

NAMSA's Imaging Core Laboratory utilizes expert image reviewers along with access to world-renowned physicians to ensure speed, quality and accuracy of image interpretation and analyses.

SAFETY

NAMSA offers a full service team of in-house medical monitors and MedDRA coders with expertise in clinical research to ensure that your trial runs smoothly and efficiently.

NAMSA®

AGENTS OF **ACCELERATION**

While a strong clinical study program is essential, it's only one piece of the puzzle. You also need access to informed regulatory experts to design a complete cross functional plan that can significantly shorten the time required to gain approval and propel your product inot the market place.

Because of NAMSA's expertise and time on the market, we can provide full comprehensive services across all product development needs. Sponsors can either partner with us on pieces of their product lifecycle or utilize our premier APEX program.

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