NAMSA®
Medical Research Organization
Consulting  Testing  Clinical
NAMSA is the only Medical Research Organization (MRO) reducing time-to-market and costs for medical device product development. We do this by providing global expertise in Consulting, Testing and Clinical services. We call this the MRO® Approach.

The MRO® Approach is designed to help clients translate great ideas into great medical products and bring their product to market, anywhere in the world. We are able to do this by leveraging our global knowledge and experience for any stage in the product development process.

Are you . . .

• A startup firm with limited resources and funds, or . . .
• Unable to leverage the knowledge your team gains on your preclinical studies to apply it to your overall strategy, or . . .
• Concerned with the time required to hire and train staff, but need the expertise today, or . . .
• Determined to shorten the amount of time it takes to identify and qualify vendors, or maybe . . .
• Looking for ways to cutback total development time and cost, and reduce burn rates before revenue starts to flow?

NAMSA’s MRO® Approach has strategies and proven solutions to help clients in all of these scenarios and more for their specific therapeutic area and device. No other contract research organization possesses the necessary services and capabilities to leverage knowledge and expertise around the globe like our Medical Research Organization. Our Associates understand that your team has unique needs, and with NAMSA’s MRO® Approach, we will support and guide you at each stage in the product development process.

To learn more, visit namsa.com/mro

“Our mission is to make a scientific contribution to every medical device in the world.”
- Dr. Ted Gorski, NAMSA Founder
Through the MRO® Approach, and our highly integrated Consulting, Testing and Clinical services, we are able to provide an all-inclusive partnership and solution to support your medical device product development goals.

**CONSULTING**
- Regulatory Strategy and Quality Systems
- Biostatistics
- Biological Safety and Validation

**TESTING**
- Preclinical Studies
- Analytical Services
- In Vivo and In Vitro Biocompatibility

**CLINICAL**
- Clinical Study Management
- Data Management
- Site Monitoring and Safety
Consulting

NAMSA's Consulting experts provide efficient and responsive regulatory, quality, biostatistics, clinical and biological safety and validation services across the full spectrum of product design and development, including post-market support. We have completed hundreds of successful submissions in a multitude of therapeutic specialties in each device class, and frequently interact with governing bodies and regulatory agencies in the US, EU, Latin America, Japan and China.

Regulatory Strategy and Quality Systems

Our Regulatory and Quality Consultants have extensive experience and knowledge in all medical device product classes to help you establish and implement the best strategy for your product. We have the capabilities to help you navigate through the increasingly complex regulatory and quality hurdles, identify the best path to market for your device and build a competitive edge. Some of the areas where NAMSA can provide Regulatory Consulting and Quality Systems support include:

- US Premarket Submissions (510(k), PMA¹, HDE², BLA³)
- International Premarket Submissions and Registrations (CE⁴ Mark, Canada, Japan, China and more)
- FDA Advisory Panel Meetings
- Notified Body Selection
- Device Classification and Predicate Device Searches
- US Designated Agent and EU Authorized Representative
- Development (ISO⁵, QSR⁶, GLP⁷)
- Audits and Gap Analyses
- Pre-Certification Assessments
- Facilitate Management Responsibility
Biostatistics

NAMSA’s Biostatisticians have a high degree of both strategic and operational expertise, and frequently interact with regulatory agencies, including participation and support of FDA pre-submissions and FDA advisory panel meetings. Our Biostatisticians and Statistical Programmers generate all analyses needed for study reports, publications and presentations—working closely with the study team, physicians and other researchers to provide data summaries that address the research questions of interest. Some of NAMSA’s Biostatisticians capabilities include:

- Strategic Statistical Support
- Regulatory Interactions
- Study Design, including Adaptive Study Design
- Data Analysis and Interpretation

Biological Safety and Validation

Our Biological Safety and Validation Consultants are able to develop evaluation programs based on currently recognized standards, industry guidance documents and industry experience to determine a successful path for moving forward in the medical device development process. These efforts do not stop with the initial device clearance, but continue through commercialization to post-market requirements. Our Biological Safety and Validation services include:

- Biological Risk Assessment
- Chemical Risk Assessment
- Equivalency Assessment
- FDA and Notified Body Response Support
- Gap Analyses
- Sterilization Validation
- Reusable Device Reprocessing Validation (Cleaning, Disinfection, Sterilization, Lifecycle Testing)
- Packaging Shelf Life Validation
- Cleanroom and Environmental Monitoring Technical Assessments
- New and Modified Product Sterilization Assessment

Additional Consulting Services

- Device Standards Assessment
- Statistical Sampling Plans and Analysis
- Internal Audit Support
- Technical Files and CERs
- Guidance on Necessary Testing, Labeling Issues and Deficiency Responses
- Complaint Handling, MDR and Vigilance Reports
- Inspection Readiness Advice, Training and Management
- Device Recall Determination and Management
- Enforcement Action Resolution (Warning Letters, Consent Decrees)

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1. PMA – Premarket Approval
2. HDE – Humanitarian Device Exemption
3. BLA – Biologics License Application
4. CE Mark – Conformité Européene Mark or European Conformity Mark
5. ISO – International Organization for Standardization
6. QSR – Quality System Record
7. GxP – General reference for Good Practices. For NAMSA this includes Laboratory, Manufacturing and Clinical.
8. CERs - Clinical Evaluation Reports
9. MDR - Medical Device Reporting
Testing

NAMSA created the medical device testing industry.

We offer all testing services in our state-of-the-art laboratories located throughout North America, Asia and Europe. Our global ISO-certified facilities and site management ensure your study meets appropriate quality standards, while our knowledge of GLP requirements support regulatory submissions. We follow methods and regulations described by the European Committee for Standardization (CEN), US Food and Drug Administration (FDA), Japanese Ministry of Health and Labor (MHLW), China Food and Drug Administration (CFDA) and other applicable guidelines. NAMSA’s MRO® Approach ensures you have a coordinated team of experts attending to your needs throughout the testing process.

Preclinical Studies

NAMSA’s translational evaluation teams consult, plan and execute preclinical studies to optimize learning potential and device design to get to a go/no go decision for your concept and feasibility work. NAMSA’s surgical suites are equipped with advanced imaging and viewing capabilities to enable advanced surgical procedures as well as physician, staff and sales training. NAMSA has everything you need in a preclinical testing and consulting partner—experience, expertise, global locations and the MRO® Approach—to prepare your regulatory and clinical strategies from your testing results. NAMSA’s preclinical capabilities include, but are not limited to:

• Tissue Engineering
• Quantitative Pathology
• Ultrastructural Pathology (SEM¹, TEM²)
• Safety Studies
• Functional and Efficacy Studies
• Cadaveric Studies
• Combination Product and Tissue Engineering
• Anatomical Preclinical Testing
Analytical Services
NAMSA's chemistry laboratories provide analytical support for the development and quality audit of medical devices, reagents and excipients. We offer a comprehensive range of services to help ensure product safety, quality and consistency during all stages of development. Our technical specialists will work with you to design and implement special studies for your product. Some of these services include:

• Material and Chemical Characterization
• Monograph Testing
• EO residuals Testing
• Reusable Device Studies
• Compendial Testing

NAMSA Characterization Matrix
Ask your NAMSA Representative for a copy today!
Or go to namsa.com/mat

In Vivo and In Vitro Biocompatibility
At NAMSA, we work with you to develop a comprehensive testing plan that is right for your product. We design the right protocols and perform testing to evaluate biocompatibility as appropriate to the intended use of the product. We also ensure that every test we perform and every protocol we design complies with current requirements and most recent interpretations of FDA and international standards. Some of the Biocompatibility tests we offer include:

• Cytotoxicity
• Sensitization
• Irritation and Intracutaneous
• Acute Systemic Toxicity
• Chronic and Subchronic Toxicity
• Genotoxicity
• Implantation
• Hemocompatibility
• Carcinogenicity
• Histopathology

Biocompatibility Matrix
Ask your NAMSA Representative for a copy today!
Or go to namsa.com/bio

Additional Testing Services
• Microbiology
  • EO\textsuperscript{1} Single Lot and Full Sterilization Validation Studies
  • Irradiation Sterilization Validation Studies
  • Novel Modality Sterilization Validation Studies (STERRAD, H2SO4, Etc.)
  • Cleaning and Disinfectant Validation Studies
  • Antimicrobial Efficacy
  • LAL\textsuperscript{4} Testing
  • Environmental Monitoring
• Package Performance Testing
  • Validation of Packaging Process
  • Compatibility with Sterilization Process
  • Package Seal Strength
  • Package Integrity
  • Transportation Simulation
  • Accelerated Aging and Shelf Life Studies

1 SEM – Scanning Electron Microscopy
2 TEM – Transmission Electron Microscopy
3 EO – Ethylene Oxide
4 LAL – Limulus Amebocyte Lysate
NAMSA has a broad range of clinical experience with government agencies worldwide, such as the US Food and Drug Administration (FDA), Chinese Food and Drug Administration (CFDA), European National Competent Authorities (NCA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). We can lead our clients through all phases of clinical trials, from first-in-human to pivotal and post-market studies. Our global footprint gives us access to local networks of clinics to conduct effective trials on your behalf.

Based on NAMSA’s decades of experience working in clinical research, we have optimized and streamlined our processes for consistency, quality, efficiency and continued innovation.

Clinical Study Management

NAMSA’s global clinical operations include:

- Study Design and Protocol Development
- Full Study Management
- Site Selection and Qualification
- IDE¹, REC², NCA³ and CTN⁴ Submissions
- Negotiation of Contracts and Budgets
- Site Initiation and Training
- Investigator Meetings
- Trial Master File Development and Maintenance (including eTMF⁵)
- MedDRA⁶ Coding
- Site Close-Outs and Audit Preparation
Data Management

Our Data Managers are experienced in designing, building and managing clinical databases, and have participated in hundreds of database projects across multiple paper-based and EDC platforms. With backgrounds in fields such as nursing, biostatistics and clinical operations, NAMSA’s Data Management team brings a strong cross-functional understanding of how to optimally design a database and manage data for a study. Areas where NAMSA’s Data Managers can help include:

- Database Development, including Validation
- Site Training for Database Use
- Data Management Plans
- Custom Reports
- Data Review for Quality and Integrity

Site Monitoring and Safety

Experience and capabilities include:

- Site Management
- Risk-Based, Remote and Traditional Monitoring
- CEC and DMC Committee Member Selection, Charter and Procedure Development
- CEC and DMC Document Preparation (Source Documentation, Adjudication Forms, Event Narratives)
- Creation and Management of Tools to Track SAEs for Adjudication

Additional Clinical Services

Experience and capabilities include:

- Technical and Medical Writing
  - Clinical Investigation Plans and Investigator Brochures
  - CERs
  - Annual, Interim and Final Clinical Reports
  - Publications, Posters and White Papers
  - Instructions for Use
  - Gap Analysis of Clinical SOPs and Sponsor SOP Creation
  - Clinical Trial Strategy
  - Investigative Site Audits
  - Preparation and Support for FDA Site Inspections

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1 IDE – Investigational Device Exemption
2 REC – Research Ethics Committee
3 NCA – National Competent Authority
4 CTN – Clinical Trial Notification
5 eTMF – electronic Trial Master File
6 MedDRA – Medical Dictionary for Regulatory Activities
7 CEC – Clinical Events Committee
8 SAEs – Serious Adverse Events
9 SOPs – Standard Operating Procedures
10 DMC – Data Monitoring Committee
Medical Device Development Process

The development process of your medical device is made up of 5 stages.

1. Concept and Feasibility
2. Design Validation and Preclinical Testing
3. Clinical
4. Market Approval
5. Post-Market

Whether you require support in one area of your development or throughout the entire process, NAMSA has the expertise and capabilities to provide you with the services you need when you need them.

Learn how NAMSA can save you TIME and MONEY with your medical device development:

namsa.com/compare

Concept and Feasibility
While the concept and feasibility stage in product design and development processes are not required by regulations or harmonized standards, the processes undergone in this stage help minimize risk during product development, and can prevent unexpected failures during design verification and validation testing. Some of these processes include:

- Defining Customer Requirements, Market Analysis and Competitive Assessment
- Developing Concepts, Plans, Schedules and Models
- Early Risk Assessment
- Non-GLP Functional and Efficacy Studies
- Initial Regulatory, Clinical and Reimbursement Strategy

Design Validation and Preclinical Testing
This is the stage of the development process in which the design of the product is set, such as functionality and safety aspects, and validation of the selected materials and processes begins. Additional operations that occur during this stage include, but are not limited to:

- Regulatory Strategy, Reimbursement Strategy and Competitive Assessment Updates
- Pre-Submission Meeting Preparation and Documentation Development
- Quality System Development (Manual, SOPs)
- Risk Analysis (FMEA¹, FTA²), HA³ and Process FMEA Design
- Clinical Plan and Preliminary Protocol Development
Clinical

The clinical stage is where you prove your product’s efficiency through human studies. This stage can be the most time consuming, least predictable and most expensive part of your product’s development. Processes addressed during the clinical stage include:

- Clinical Study Set-Up and Conduct
- Product Branding
- Optimizing Design
- Initiating Trace Matrix
- Technical File Development

Market Approval

This is the time of the development process when your device is submitted for approval by the appropriate governing regulatory body. A few of the steps that can be expected to occur during this stage include:

- Customer Training Plan Development
- Establishment of Commercialization and Product Launch Plan
- Market Approval Application
- Finalization of Risk Management Report
- Statistical Analysis and Presentation of Results

Post-Market

Once your product has been approved and is out on the market, post-market surveillance should be constant. This stage is focused on continued commercialization and monitoring the safety of your product. Some of the operations that take place during the post-market stage are as follows:

- Physician Training and Continued Promotion Efforts
- Product Release Testing
- Update Design Control Documents
- Quality Audits
- Post-Market Clinical Studies to Support Long-Term Safety/Effectiveness and Reimbursement

1 FMEA - Failure Modes and Effects Analysis
2 FTA - Fault Tree Analysis
3 HA - Hazard Analysis
NAMSA's medical device experts have a deep breadth of industry and applied knowledge across a multitude of therapeutic areas. By utilizing the combined experiences of our cross-functional team of specialists, we are able to customize quality system development, design validation, testing and clinical studies for specific therapeutic disciplines.

**Cardiovascular**

From pacemakers to coronary stents and mitral valves, NAMSA has a broad range of experience within the cardiovascular space.

**Peripheral Vascular**

We have supported numerous medical devices specific to peripheral vascular therapies. Some of these devices include peripheral arterial stents, drug-coated balloons, embolic protection and atherectomy devices.
IVD and Companion Diagnostics
One of NAMSA’s specialties is the design and conduct of IVD clinical studies. We have focused teams of IVD experts who understand IVD clinical protocols, and routinely customize data collection and management methods along with monitoring plans to accommodate the unique requirements of IVD studies.

Orthopedic
NAMSA has experience with Class II and orthopedic devices. A few of these projects have included large and small joint replacement devices, cartilage repair systems, fixation devices and biologics, such as bone morphogenic proteins (BMP), allografts and demineralized bone matrix products.

Transplant
Gastroenterology and Bariatrics
Endocrinology
General and Plastic Surgery
Urology and Renal
Oncology and Hematology
Obstetrics and Gynecology
Dental
Anesthesia and Respiratory
Regenerative Medicine
Wound Care and Dermatology
A US West Coast medical device start-up was preparing to market their wearable glucose monitor. The firm’s CEO raised enough capital to cover operational costs for two years beyond the anticipated approval date, and had gathered a team with a thorough understanding of both the product technology and a working knowledge of the FDA approval process. The company had set up a series of FDA Pre-Sub meetings to address premarket concerns and ensure their clinical strategy was in line with FDA’s requirements and expectations based on the risk determination of the product. Despite these preparations, application approval was delayed, and revenue generated was much lower than expected.

The CEO had hired a regulatory partner with solid experience in the pharmaceutical industry but less experience within the medical device space. They were adequate in ensuring appropriate regulatory paperwork was filed for the device but didn’t realize that updates to the device software meant a separate update would be required for the component that received the data from the monitor. This caused significant and unnecessary delays. Additionally, the company’s marketing plan did not focus enough on adoption/reimbursement gatekeepers such as pharmacies and managed care organizations, who care less about features and more about bottom line costs. Lastly, unexpected “human factor” costs—e.g., technical support personnel and training, customer support, user training, etc.—had not been sufficiently built into the original price of the product, so it took a much longer time for the company to begin generating revenue.

It is imperative to work with a partner who is familiar with medical devices and who can best identify processes in clinical and regulatory plans that are most at risk for developing delays. Having a good sense of downstream costs during the early phase of product development is also crucial to help set a realistic price point for your product.

“Despite these preparations, application approval was delayed, and revenue generated was much lower than expected.”

Finally, even the best marketing strategies can fail to yield results if they fail to reach the audience with the most influence. Delays in approval and market visibility issues for a new product may be inevitable, especially for start-ups, but partnering with a medical research organization like NAMSA can help you avoid some of the common pitfalls in the device development and marketing process.
A large medical device company made the decision to market internationally a prescription-based Class II home-use device for patients with a specific sleep disorder. Company executives were aware of the potential for revenue growth offered by overseas markets, and the company had experience in marketing devices internationally as well as the infrastructure to do so efficiently. For this product, funding was in place, coordination (and additional hiring) across departments was planned for, the supply chain was strengthened to account for additional strains and trusted in-country affiliates with regulatory expertise were identified. The staff knew what to do next. Testing and clinical study data were able to be repurposed. Regulatory submissions went smoothly, and expected approvals were granted. And still, funding outlay was greater than expected and revenue slower to come in.

The regulatory expertise of the in-country affiliates proved invaluable in alerting the home company to recent changes in regulatory processes and requirements in the target market. However, for all the affiliate’s regulatory strength, they were short on personnel in the areas of translation and post-approval marketing. Translation of technical documents was fairly straightforward and had been handled by a translation vendor, but bilingual packaging, user materials and promotional materials underwent detailed re-review by a team familiar with the product, the language and the culture. Additionally, an alternate-language version of the company/product website had consumed 20% more resources than projected.

The biggest issue was that the market was slower than projected to take up the product, even though its design had several potential advantages over predicate devices already on the market, including newer materials that minimized bacterial growth. How could this company have planned to eliminate these setbacks? In what areas could NAMSA have helped them to avoid some of the issues above?

"And still, funding outlay was greater than expected and revenue slower to come in."

NAMSA’s MRO® Approach involves Regulatory and Clinical strategies up front in the medical device process to help determine where to go and how to get there, including pre-market and post-market clinical data collection, to support market adoption. We offer reimbursement strategy to determine realistic pathways in each country to ensure profit once the product is approved, and our global experts work with you to develop a key market strategy to determine how to present the device to key stakeholders.
NAMSA upholds several accreditations and certifications, and strives diligently to maintain the highest industry standards.

To view the most up-to-date locations, visit namsa.com/locations.
Not only has NAMSA been a key contributor to the development of the test methods used to govern the medical device industry today, but our scientists continue to actively participate in domestic and international standard setting committees to help shape the future of testing guidelines and protocols.

Additionally, NAMSA aspires to increase the understanding of industry regulations, trends and product development best practices for our clients. Our efforts include:

• Hosting global in-person and remote training seminars on consulting, testing and clinical topics;
• Administering Physician Training at our facilities or a location of your choosing;
• Exhibiting and presenting on consulting, testing and clinical topics at Tradeshows around the world; and
• Distributing detailed clinical, testing and consulting materials and experiences through on-line webinars.

NAMSA delivers high-quality services and expertise to our Clients so they can provide patients with the product they need, when they need it.
MRO
Medical Research Organization
No matter where your product is in its development process, NAMSA has the expertise and services to support your medical device, IVD or combination product. We have several global laboratories, offices and geographically strategic agencies ready to provide you the services you need, when and where you need them.

Our expert cross-functional teams comprising of numerous in-house Consulting, Testing and Clinical specialists provide the foundation of NAMSA’s proven MRO® Approach, which can save you time and money.

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