NAMSA®

MEDTECH CRO

NAMSA IS THE WORLD'S LEADING MEDTECH CRO OFFERING GLOBAL END-TO-END DEVELOPMENT SERVICES

ABOUT NAMSA

Driven by our regulatory expertise and in-depth therapeutic knowledge, NAMSA has assisted thousands of MedTech Sponsors to make a positive impact to healthcare since 1967. Today, our team of global Associates delivers market-leading Contract Research Organization (CRO) services to Clients in all major markets of the world. NAMSA provides unparalleled medical device testing capabilities, strategic guidance and tactical support to fast-track market introduction and commercialization. From concept to post-market, we are proud to fully support Clients through the delivery of exceptional outcomes throughout every stage of the MedTech development continuum.

WHILE OUR ORGANIZATION HAS CHANGED, THE VALUES THAT GUIDE US TODAY REMAIN THE SAME:

- Act with integrity in everything we do
- Provide best-in-class customer experiences
- Develop superior talent and deliver expertise
- Respond with agility and provide timely results
- Embrace collaboration, diverse perspectives and ideas

NAMSA'S FULL CONTINUUM DEVELOPMENT SOLUTIONS ARE DESIGNED AROUND ONE GOAL:

Achieving Client success. From product development strategy and medical device testing to regulatory, reimbursement, quality and market research consulting, as well as clinical research services, we are committed to helping Clients overcome development hurdles, mitigate concerns and streamline market introduction efforts.

We are the MedTech industry's premier CRO partner for cost-efficient and efficacious outcomes that lead to accelerated development and commercialization success.

From preclinical to clinical and post-market, **a trusted partner** every step of the way.

OVERVIEW

PRODUCT DEVELOPMENT STRATEGY

Starting with the end in mind, we build a comprehensive strategy to “help you” fast-track development goals.

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

Our Product Development Strategy (PDS) solutions provide services to assist Clients with any development challenge, therapeutic area, reimbursement issue or regulatory environment. Our PDS Team is comprised of cross-functional scientists and strategists who support a multitude of medical device technologies, as well as In Vitro Diagnostic (IVD) and drug/device combination products. When working with our PDS Team, Clients are provided a “next steps” strategy within any stage of the development continuum.

By starting with the end in mind, NAMSA offers coordination of required development activities under one roof to achieve accelerated outcomes. We offer the following programs to meet MedTech developers where they are in their development program.

— SERVICES PROVIDED —

Product Development Strategic Summary

The Strategic Summary focuses on identifying pathways to regulatory approval or clearance, establishing a foundation for the regulatory plan and identifying milestones and efficiencies for project acceleration across various stage gates.

Product Development Get-to-Market Strategy

NAMSA’s Get-to-Market Strategy provides a strategic assessment and summary of required activities pertaining to regulatory, quality, preclinical, clinical research, reimbursement and scientific communications to achieve regulatory approval and commercialization success for a specific product and therapeutic area.

Our strategic experts are aligned to each Client’s therapeutic, regulatory and geographic areas of focus, and closely collaborate with all stakeholders to provide a detailed, actionable and achievable Product Development Plan.

Strategic Consulting

NAMSA’s cross-functional team of Product Development Strategists provides assistance to Clients when and where they need support on their path to product development and commercialization.

Our highly knowledgeable and experienced team is leveraged by Clients to provide in-house expertise to streamline costs and speed product development timelines.

— LEARN MORE —

namsa.com/product-development-strategy

MEDICAL DEVICE TESTING

NAMSA is the global leader in the medical device testing industry, providing you with precise and reliable results.

NAMSA is the pioneer of the medical device testing industry and continues to serve as the global marketplace leader for trusted testing services.

On an annual basis, our teams conduct over **100,000** tests in our state-of-the-art laboratories across the globe. We take pride in managing your testing program, supporting accelerated project timelines and delivering consistent, expert results that are highly recognized and accepted by global regulatory authorities.

Getting it right from the start translates into resource savings throughout the development continuum, allowing you to accelerate market introduction and to cost-effectively bring life-improving therapies to those who need them most.

OUR UNMATCHED EXPERTISE ENSURES ACCURATE TESTING AND STREAMLINED TIMELINES, GUARANTEEING EXCEPTIONAL RESULTS

— SERVICES PROVIDED —

- Antimicrobial/Antibacterial/ Antifungal/Antiviral Testing
- Bacterial Endotoxin Testing (LAL)
- Biocompatibility Testing
- Biofilm Testing
- Biological Safety Consulting
- Chemical Characterization & Analytical Services
- Cleaning Studies & New Single Use Devices
- Custom In Vitro Cell Models
- Custom Ex Vivo Tissue Models
- Environmental Monitoring
- Histopathology
- Long-Term & Accelerated Shelf-Life Testing (ICH)
- Materials Testing (EN 13726)
- Method Development & Validation
- MMP Modulation
- Packaging Validation Services
- Particulate Analysis
- Sterilization Validation
- Validation for Reprocessed Medical Devices
- Viral Testing
- Yeast and Spore Forming Bacteria Testing

— LEARN MORE —

namsa.com/medical-device-testing

INTERVENTIONAL AND SURGICAL PRECLINICAL RESEARCH

State-of-the-art surgical instrumentation and certified medical experts to support your preclinical research needs.

When conducting medical device research, expertise and know-how matter. NAMSA is proud to serve as the CRO industry's premier destination for preclinical, interventional and surgical research. Combining decades of knowledge in multiple therapies, delivery systems and implantable research, we distinctively understand how to achieve cost-efficient outcomes for your unique program requirements and market introduction goals.

NAMSA's team of experts offers support for a wide-variety of model types, treatments, therapeutic areas and implant objectives. Cutting edge imaging technology is at the heart of all research processes, including diagnostic imaging for visualizing implants, diagnosing defects or disease and documenting research outcomes. Our surgical staff are equipped to support entire procedures or partner with your physicians during implant or treatment procedures.

— SERVICES PROVIDED —

NAMSA is proud to offer the following preclinical research support in multiple locations across the globe:

- Bioskills Cadaver & Simulation Laboratories
- Interventional Research
- Multiple Imaging & Data Collection Modalities
- Pathology
- Pharmacology & Toxicology
- Physician Training
- Surgical Research

NAMSA OFFERS SUPPORT FOR A WIDE-VARIETY OF MODEL TYPES, TREATMENTS, THERAPEUTIC AREAS AND IMPLANT OBJECTIVES

— LEARN MORE —

namsa.com/preclinical

CLINICAL RESEARCH

Comprehensive services, customized approach: personalized programs to help meet your unique clinical research endpoints.

The global MedTech landscape is complex and 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.

NAMSA, highly recognized for its clinical expertise in the areas of Cardiovascular, IVD, Neurology and Orthopedics, also has experience in working with nearly every manner of technology, therapy, indication and geography. This broad range of experience allows us to successfully lead our Clients through all stages of clinical research: from first-in-human to pivotal and post-market studies. NAMSA's global footprint also provides Clients direct access to our local networks to conduct safe, effective and efficient clinical trials, optimized to achieve clinical endpoints, regulatory approval and continued innovation.

— SERVICES PROVIDED —

- Biostatistics & Statistical Programming
- Clinical Evidence & Post-Market Studies
- Clinical Study Management
- Clinical Trial Safety
- Data Management & Electronic Data Capture (EDC)
- Data Safety Monitoring Board (DSMB) Services
- Field Clinical Engineering Staffing
- Imaging Core Laboratory
- Medical Writing
- Physician Consulting
- Safety Reporting & Clinical Events Committees

SUCCESSFULLY LEADING CLIENTS THROUGH EARLY FEASIBILITY TO POST-MARKET CLINICAL RESEARCH

— LEARN MORE —

namsa.com/clinical-research

REGULATORY & QUALITY CONSULTING

Getting you to market faster, so you may make a more immediate impact on patient safety and healthcare.

NAMSA is the industry leader in driving successful regulatory submissions and outcomes through near-daily interactions with international authorities and regulatory entities.

Many of our Associates have held positions within these organizations, which provides you the benefit of a clear understanding of how to proactively plan for domestic and international requirements and expectations.

We provide a wide range of regulatory and quality consulting services across product design, device development and post-market support. From Medical Device Regulation (MDR) and CE Mark guidance to 510(k), Premarket Approval (PMA) and De Novo support, our experts develop and implement global regulatory and quality strategies to fast-track your commercialization goals—ultimately getting you to market faster so you may make a more immediate impact on patient safety and healthcare.

— SERVICES PROVIDED —

- Biological Safety & Validation Consulting
- Global Regulatory Strategy & Compliance
- International Medical Device Registration Consulting
- Medical Writing
- Quality Systems & Compliance
- U.S. FDA Agent Services

EXPERTS AT FACILITATING SUCCESSFUL INTERACTIONS WITH:

U.S. FDA (510K, PMA, DE NOVO)

JAPAN PMDA (MHLW)

EU NOTIFIED BODIES (CE MARK & MDR COMPLIANCE)

CHINA NMPA

AUSTRALIA TGA

— LEARN MORE —

namsa.com/regulatory-and-quality

REIMBURSEMENT & MARKET ACCESS

Helping you remove reimbursement barriers on your path to coverage and market adoption.

Healthcare payment and reimbursement systems throughout the world are complex and vary widely from one country to another. This makes it critical to understand potential reimbursement barriers and the means by which devices are compensated.

As a result of these intricacies, global MedTech Clients sometimes lack the proper context and contacts when distinguishing effective reimbursement and commercialization strategies—that's where NAMSA's international team of reimbursement experts put their knowledge to work for you.

NAMSA offers reimbursement services and solutions for new and existing medical technologies. Our teams are expert in all aspects of reimbursement strategy, including: payer relations, medical policy research, coverage advocacy, HCPCS and CPT code analysis/applications and health economic analysis.

— SERVICES PROVIDED —

- Code Analysis & Applications
- Health Economic Analysis
- Market Access Roadmaps
- Medical Advisory Board Development
- Medical Policy Research & Coverage Advocacy
- Product Adoption Support
- Reimbursement Guides
- Reimbursement Landscape Assessments
- Reimbursement Strategy

HELPING YOU ENSURE COVERAGE FOR YOUR NOVEL MEDICAL DEVICE

— LEARN MORE —

namsa.com/reimbursement

IN VITRO DIAGNOSTICS

A dedicated IVD Team that takes the guesswork out of clinical research and regulatory compliance.

NAMSA's dedicated IVD Team is focused on meeting the unique product development, regulatory and clinical research needs of IVD manufacturers.

We not only understand how to accurately interpret the complicated regulatory challenges that IVD manufacturers sometimes face, but we also help you simplify the design and implementation of effective clinical strategies across all development phases.

Whether supporting IVD regulatory assessments and submissions, developing IVDR-compliant technical files, designing and managing clinical trials or building ISO 13485:2016 and 21 CFR Part 820-compliant quality systems, we've got you covered.

— SERVICES PROVIDED —

- In Vitro Diagnostic Clinical Research, Biostatistics & Data Management
- In Vitro Diagnostic Regulatory Consulting
- In Vitro Diagnostic Reimbursement Support
- In Vitro Diagnostic Quality Systems Support
- In Vitro Diagnostic Regulation (IVDR) Consulting Services

DELIVERING SUPPORT TO HELP YOU MEET THE UNIQUE NEEDS OF IVD DEVELOPMENT HEAD-ON

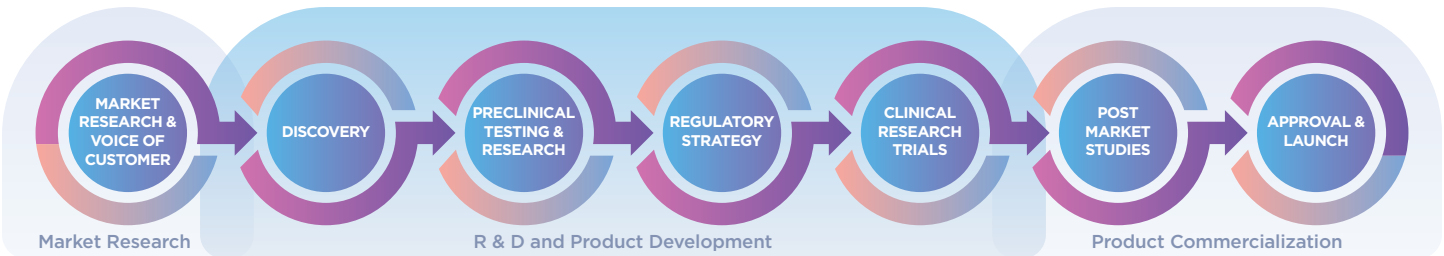
— LEARN MORE —

namsa.com/ivd

MARKET RESEARCH CONSULTING

An experienced partner in customized MedTech market research to help you effectively bring your novel device to market.

NAMSA's market research consulting services provide actionable results through extensive data analysis and expert insights. Leveraging in-house databases, customized research interviews and thorough data analysis, we deliver clear, meaningful results with actionable recommendations to transform your business strategy.



Through a variety of methodologies, we can support you with market sizing and segmentation, brand perception, personas, patient pathways, competitive assessment and monitoring, VOC and customer needs, reimbursement landscapes and more. We also offer customized intelligence to help you optimize your product launches and post-launch tracking in medical devices, IVDs, pharmaceuticals, diagnostics and health IT.

Market Research

- Brand Awareness
- Brand Strategy
- Pricing
- Segmentation
- Market Needs

Product Research

- New Product Introduction
- Value Proposition
- Usability Testing

Test Marketing

- Concept Testing
- Message Testing
- Website Testing
- Advertisement & Marketing Testing

Competitive Research

- Win/Loss Analysis
- Sell Against Info
- Mergers & Acquisitions
- SWOT Analysis

Consumer Research

- Customer Experience & Insight
- Net Promoter Score (NPS)
- Patient Studies
- Patient Centricity
- Consumer Studies

NAMSA APEX PROGRAM™

ASSESS | PLAN | EXECUTE: Predictable development outcomes for successful regulatory approval and market adoption.

Medical device development is complex. In today's value-based environment, the commercial challenges are more numerous than ever as regulatory approval does not guarantee market adoption. To mitigate risk, preserve capital and ensure the most efficient path to commercial success, development functions must be aligned with an integrated strategy that considers multiple factors and stakeholders.

The NAMSA APEX Program™ is designed with the above objectives in mind. We help you achieve success through our people—the top Subject Matter Experts in the MedTech industry—and our processes—proven, integrated services and tools that deliver predictable planning, phase overlap and vertical integration of all product development phases. This ultimately delivers Sponsors significant time savings, cost reduction and accelerated commercialization.

How Does it Work?

Starting with the end in mind, a dedicated Program Director initiates the process to build a strategy and execution plan for market approval and adoption. This includes best-fit strategies for market access, reimbursement, clinical and regulatory objectives—all while optimizing timelines and costs as effectively and efficiently as possible.

Learn more about the APEX Program™ at namsa.com/apex-program

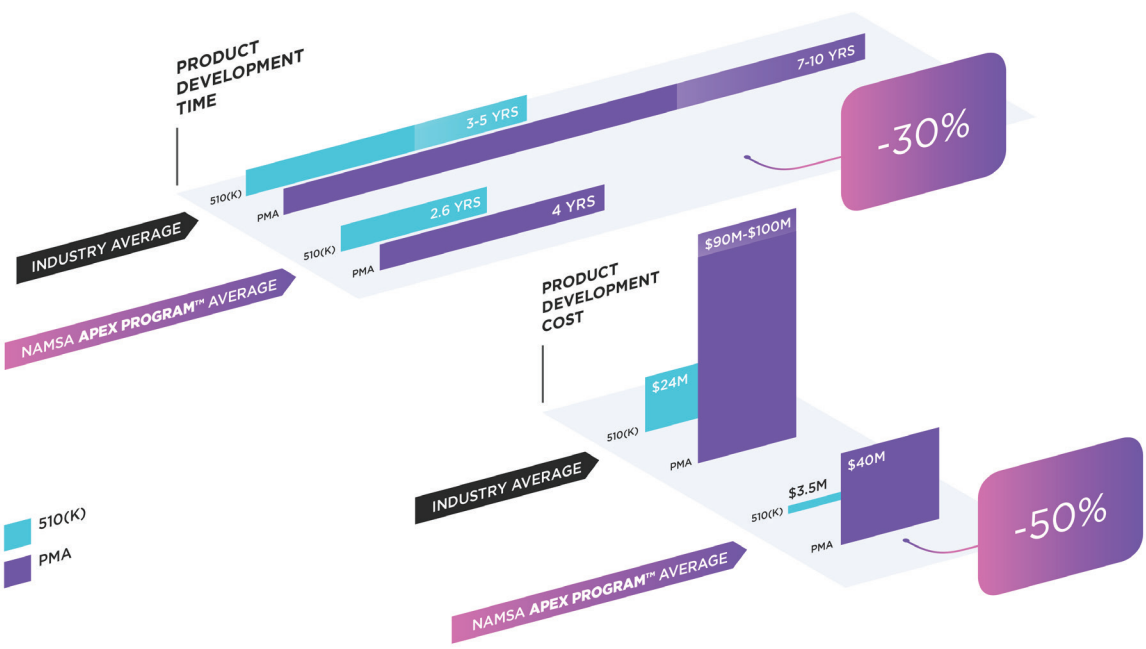
The NAMSA APEX Program™ provides

- Integrated support across multiple services and phases of product development
- A large depth and breadth of global strategic expertise and Subject Matter Experts at your fingertips
- A dedicated, expert Program Director for easy communication, Sponsor advocacy and effective management of any outside suppliers and internal stakeholders
- Guidance for challenges, opportunities and communication to all stakeholders in the development continuum—because we understand that regulatory strategy is only part of the success story
- Real-time progress updates via customized dashboards: understand where you are in the development process anytime, anywhere

Benefits

Sponsors experience the benefits of reduced timelines and costs, in addition to:

- Simplifying an often complicated development process
- Delivering predictability and 24/7, easy access to project status
- De-risking product development with early identification and mitigation plans
- Eliminating the need to engage with multiple vendors
- Helping tell the "right" story to the each stakeholder



THERAPEUTIC EXPERTISE

Established, trusted therapeutic expertise to help you achieve your development objectives.

At NAMSA, we believe that therapeutic experience is one of the main components of successful scientific, regulatory and market introduction success. We take great care to support your specific goals by appointing a project team comprised of experts with relevant therapeutic experience. A team that understands the nuances of your particular medical device, providing best practices and proven strategies to help you achieve desired clinical outcomes.

The Largest Depth and Breadth of Therapeutic Expertise in the MedTech CRO Industry

* Core Therapeutic Expertise

— LEARN MORE —

namsa.com/therapeutic-expertise

DEDICATED TO CLIENT SUCCESS

— A TRUSTED PARTNER —

"From preclinical testing, clinical trial management and regulatory strategy, NAMSA is truly expert at delivering high-quality outcomes throughout the entire medical device development continuum. Start to finish, NAMSA understood the required activities for accelerated development and efficacious market introduction.

Undoubtedly, NAMSA played a critical role in Solvay's successful product commercialization, all while providing significant cost savings throughout our program. I would highly recommend NAMSA to any medical device Client that is looking to achieve expedited, cost-efficient development outcomes."

Shawn Shorrock
Global Director
Solvay Dental 360®

12 MONTHS TIME SAVINGS | **$7.5 M** COST SAVINGS

— EXTENSIVE CLINICAL EXPERTISE —

Elizabeth Galle
Vice President of Global Clinical Research
CVRx™

"CVRx was fortunate to select NAMSA as its preferred clinical research partner—they were with us throughout the journey, continually providing their extensive statistical expertise and overall development support."

"At the time of our CRO search, CVRx was a small, privately-funded medical device company. Resources within the organization were limited, resulting in substantial reliance on outside experts to assist with CVRx's BAROSTIM NEO™ product—the world's first neuromodulation device for the treatment of heart failure.

As a start-up organization, CVRx had to secure the right partnerships to obtain clinical safety and effectiveness evidence required for U.S. FDA approval.

Today, CVRx is a successful, publicly traded company bringing much-needed, life-saving technology to heart failure patients throughout the U.S.

Undoubtedly, NAMSA played an integral role in this success and I would highly encourage any start-up organization seeking an experienced clinical CRO to consider NAMSA as their trusted partner."

— SIGNIFICANT DEVELOPMENT SAVINGS —

"NAMSA's knowledge and expertise with the U.S. FDA was a critical factor in helping us achieve unparalleled, accelerated results for our 510(k) device. This, coupled with their consistency, responsiveness and proactive nature, provided our firm the confidence we were making the right development decisions for long-term commercialization success.

When operating as a virtual organization, the importance of having a development leader who can drive activities as promised cannot be overstated. Not only is this key to achieving company milestones, but also to fundraising and driving company value.

Any medical device organization seeking superior development results should have the confidence to select NAMSA as their trusted partner on the path to successful commercialization."

Dr. Troy Long
Interventional Radiologist
Co-Founder
ICHOR Vascular

20 MONTHS TIME SAVINGS | **$26 M** COST SAVINGS

VISIT US

NAMSA®

MEETING YOU WHERE YOU ARE...

ANYWHERE IN THE WORLD.

AMERICAS

- **GLOBAL HEADQUARTERS**
  Toledo, Ohio, USA
- **Minneapolis, Minnesota, USA**
- **New York, New York, USA**
- **Philadelphia, Pennsylvania, USA**
- **Irvine, California, USA**

EUROPE

- **Antwerp, Brussels & Diest, Belgium**
- **Lyon, France**
- **Frankfurt, Munich &**
  Rheinland-Pfalz, Germany
- **Cheshire & Selby, United Kingdom**
- **Madrid, Spain**

ASIA PACIFIC

- **Tokyo, Japan**

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