CASE STUDY

Virtual Vascular Device Company Partners with NAMSA to Accelerate 510(k) Clearance by 30 Percent

Research Challenge

Peripheral Arterial Disease (PAD) is a condition that produces arterial fatty deposits and narrowed blood vessels, resulting in restricted blood flow to the arms, kidneys, stomach and most commonly, the legs. Worldwide, 14+ million people suffer from PAD with the most severe forms diagnosed as Acute Limb Ischemia (ALI) and Critical Limb Ischemia (CLI), both underserved disease states with significant morbidity and mortality rates. In the U.S. alone, over 2 million people have been diagnosed with Limb Ischemia(s), with the prevalence expected to reach 3.5 million in the coming year[4].

Coupled with the high number of Limb Ischemia complications are those that result from current treatments, delivered through drug therapy or surgical intervention—both essentially unchanged for the last 30 years. With surgical treatment, patients run the risk of bleeding and infection, while also incurring the high cost of surgical procedures and required ICU hospitalization stays. Drug delivery options also present a high financial burden to patients due to increasing pharmaceutical costs.

Observing the need for a cost-effective, yet proven, therapy for Limb Ischemias, ICHOR sought to introduce the ICHOR Panacea Vascular Embolectomy Catheter System—a non-surgical, non-drug delivery treatment that:

- Reduces ICU stays
- Decreases patient healthcare costs
- Improves patient outcomes
- Advances overall healthcare economics

Delivering Superior Outcomes

"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 efficacious 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 and
ICHOR Co-Founder

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Cost Challenges

ICHOR, operating as a virtual start-up organization, was tasked with the challenge of bringing a 510(k) device to the marketplace with limited development knowledge, restricted resources and a desire to make a timely exit following device clearance.

They required a development partner that would make the most efficient use of the firm's financial resources considering that:

- The average 510(k) product incurs expenditures of approximately **$31M** from concept to FDA clearance[7].
- The majority of medical device start-ups will need at least **$25M** in venture capital to reach exit, while others may require anywhere from **$50M—$100M+** prior to exit[1].
  - Only **one fourth** of medtech start-up acquisitions take place within **six years** of inception[1].
  - Regulatory approval is not necessarily the ultimate goal of milestones: **two thirds** of start-ups are acquired post-commercialization as opposed to pre-revenue[6].
- When conducting product development internally, leadership focus is diverted from critical start-up fundraising efforts.
- The founders of ICHOR sought to maximize ownership—the more external funds raised, the more diluted their positions would become.

Timelines Challenges

From a timeline perspective, start-ups require in excess of **5 years[1] to achieve 510(k) clearance** (inception to approval). ICHOR founders were focused on expediting development activities to achieve accelerated, yet successful, clearance.

- ICHOR founders followed a common start-up approach of funding activities with their personal resources, as well as minimzing their compensation until the start of product distribution or acquisition.
- The more quickly ICHOR was able to achieve clearance, the sooner founders, friends/family and angel investors may be rewarded for their investments.
- These factors led ICHOR to seek a development partner that could get them to market in an accelerated manner without cutting regulatory or quality corners.

Operational and Management Challenges

ICHOR, as part of their cost strategy, elected to operate as a virtual company. The organization was comprised of three founders, two of which had existing full-time careers. Since additional employees were not immediately forecast, the start-up resolved to outsource the majority of development activities.

They understood first-hand that it is often difficult and time-consuming to coordinate with multiple vendors that deliver disjointed development activities, which frequently yield unanticipated delays and additional financial burden. Therefore, ICHOR required a development partner that could provide the majority of development activities under one roof, from preclinical capabilities and biocompatibility testing to quality systems development and regulatory consulting.

Capability Challenges

While the three ICHOR founders possessed several decades of medical device expertise: an accomplished interventional radiologist, a highly-experienced corporate leader, and a skilled commercial executive, there were several development areas where they had limited knowledge and experience.

ICHOR required an expert team that had extensive expertise in successfully navigating the U.S. Food and Drug Administration (FDA) 510(k) submission pathway. They also wanted a partner who could offer consistent responsiveness and proactive solutions throughout the development effort.

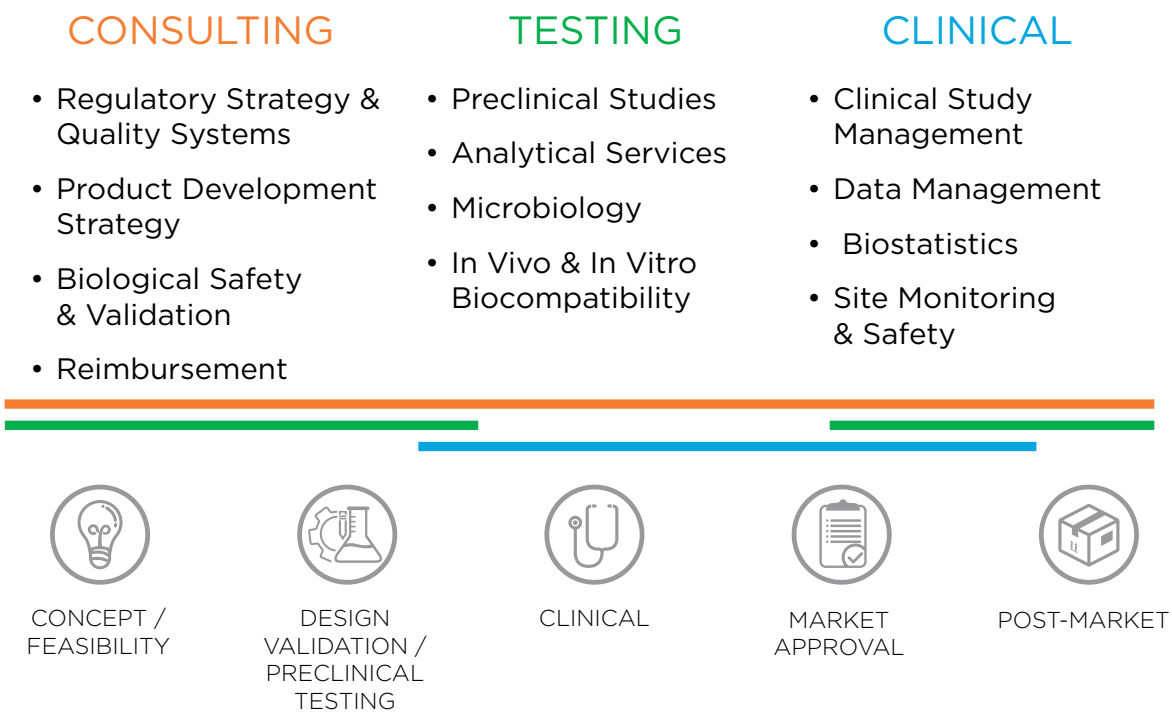
The Solution

Upon completion of ICHOR's Contract Research Organization (CRO) qualification process, NAMSA was selected as their medical device development partner of choice based on the following criteria:

- Existing relationship with NAMSA and familiarity with the organization's Medical Research Organization (MRO® Program): a unique strategic process that provides guidance and tactical support for the full development continuum, including medical device testing; preclinical/clinical research services; and quality, regulatory and reimbursement consulting.
- NAMSA's positive working relationships and established experience with the U.S. FDA, including (cumulative):
  - ✓ 300+ 510(k) submissions
  - ✓ 100+ Premarket Approval (PMA) submissions
- One dedicated point-of-contact (NAMSA MRO Program Director) who possessed extensive product development experience, applicable vascular device knowledge, and relevant regulatory expertise with FDA processes, including pre-submission meetings and 510(k) regulatory submissions.
- Proven track record of judiciously utilizing client resources to achieve expedited timelines and decreased costs, while delivering proactive, timely communications surrounding program progress.

> "None of this would have been possible without the consistent and thorough partnership of NAMSA, virtually from our beginning and continuing today. Our development program benefited greatly from having one point-of-contact at every turn vs. managing multiple vendors at once."
>
> — Jeff Blair
> Co-Founder and Chairman
> ICHOR

Figure 1: NAMSA MRO® Program Methodology



Implementation

Upon program kick-off, NAMSA's dedicated MRO Program Director worked closely with ICHOR's virtual team to discuss program requirements and how these would be managed to deliver optimal outcomes. Soon thereafter, the NAMSA / ICHOR Team created a full Product Development Plan (PDP), established how program updates and communications would be distributed, identified milestones whereby success would be gauged, and laid out a clear budgetary plan to achieve all activities.

Further, the PDP and financial plans were utilized as part of ICHOR's investor presentation for subsequent fundraising efforts, creating further credibility and confidence for investors given NAMSA's track record of efficiently and cost-effectively bringing 510(k) products to the market.

Results

The NAMSA Team quickly ramped up to execute the agreed-upon PDP, conducting the majority of development initiatives concurrently, while also providing contingency plans to proactively meet unforeseen challenges head-on:

In summary, ICHOR achieved significant time and cost efficiencies, based on the following key factors:

- NAMSA served a key partnership role while involving ICHOR stakeholders during critical development meetings and milestones. This allowed the ICHOR Team to focus on important fundraising efforts and start-up tasks.
- ICHOR eliminated costly administrative overhead expenditures by operating as a virtual company and allowing NAMSA's MRO Program Director to lead the program from kick-off to closeout. This provided the ability for ICHOR to utilize start-up investment dollars for only the most value-added tasks and processes.

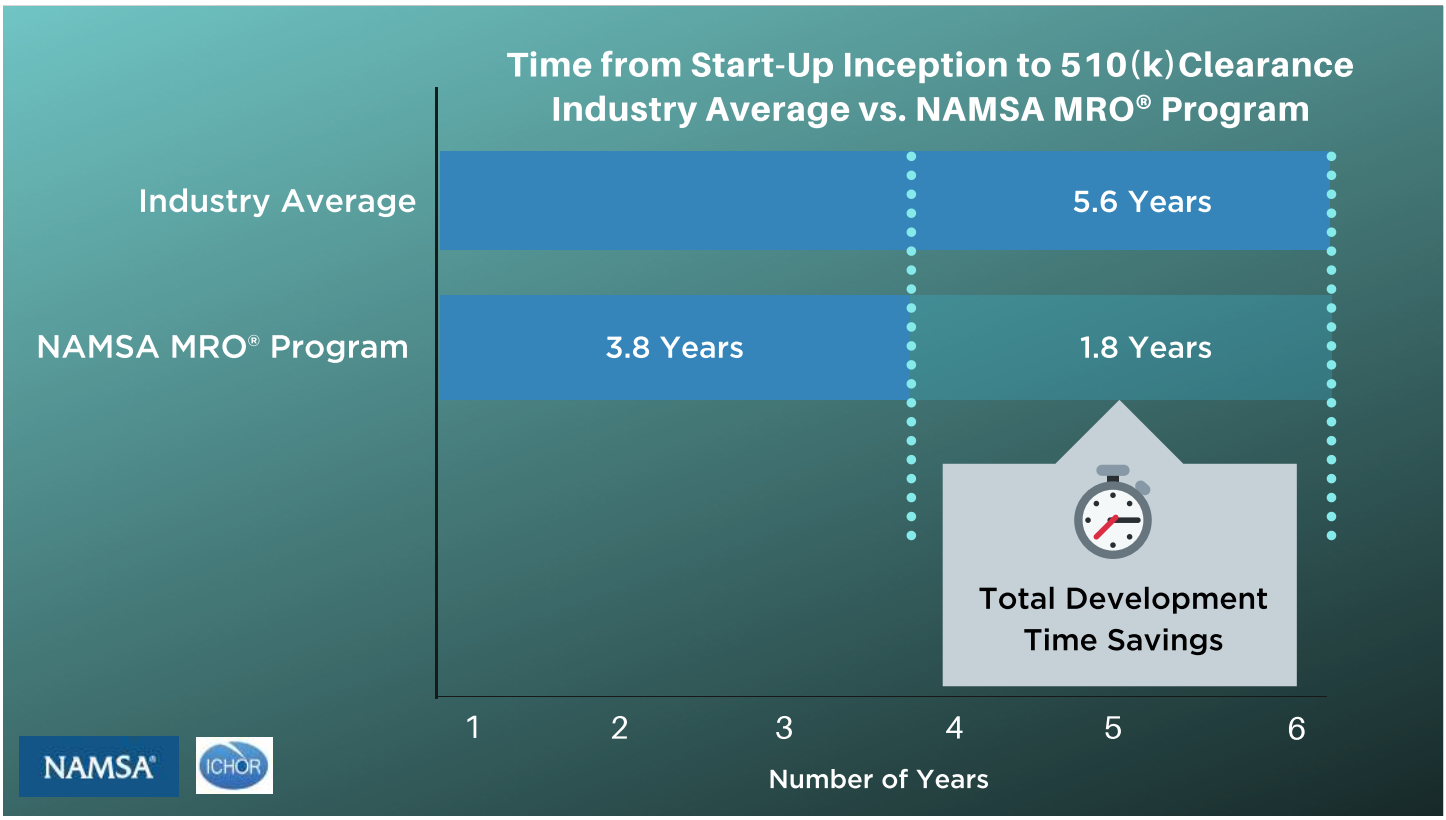
- Based on NAMSA's experience with over 300+ 510(k) submissions, the internal team of regulatory experts identified historical, potential risks that would likely be of concern for the government agency. To prepare for these risks, NAMSA pre-emptively prepared applicable information and test methods to properly confront all issues of concern.
- NAMSA was able to pivot the program and provide further support when ICHOR encountered a contract manufacturing transition. While this caused a 9-month delay in the project, NAMSA was able to identify the need for significant design changes to allow for improved product performance and efficacy. This process necessitated a repeat of all bench testing (and a further delay in development). However, NAMSA leveraged use of prior designs for preclinical studies, biocompatibility and sterilization, which ultimately reduced overall program costs.
- ICHOR was equipped to fund the business with improved terms by achieving key milestones on time and on budget. Specifically, 510(k) clearance was granted well in advance of expected timelines, which provided ICHOR and potential investors tremendous confidence.

NAMSA's MRO Program delivered ICHOR significant time and cost savings in contrast to industry averages for 510(k) development timelines and expenditures.

Timelines

The average time from company inception to 510(k) approval is more than **67 months**[6]. NAMSA, with proven solutions for the complete continuum of development activities, assisted ICHOR in achieving clearance in just **46 months**[6], cutting more than **30 percent** off average development timelines.

Figure 2: Time from Start-Up Inception to Clearance—Industry Average vs. NAMSA MRO® Program

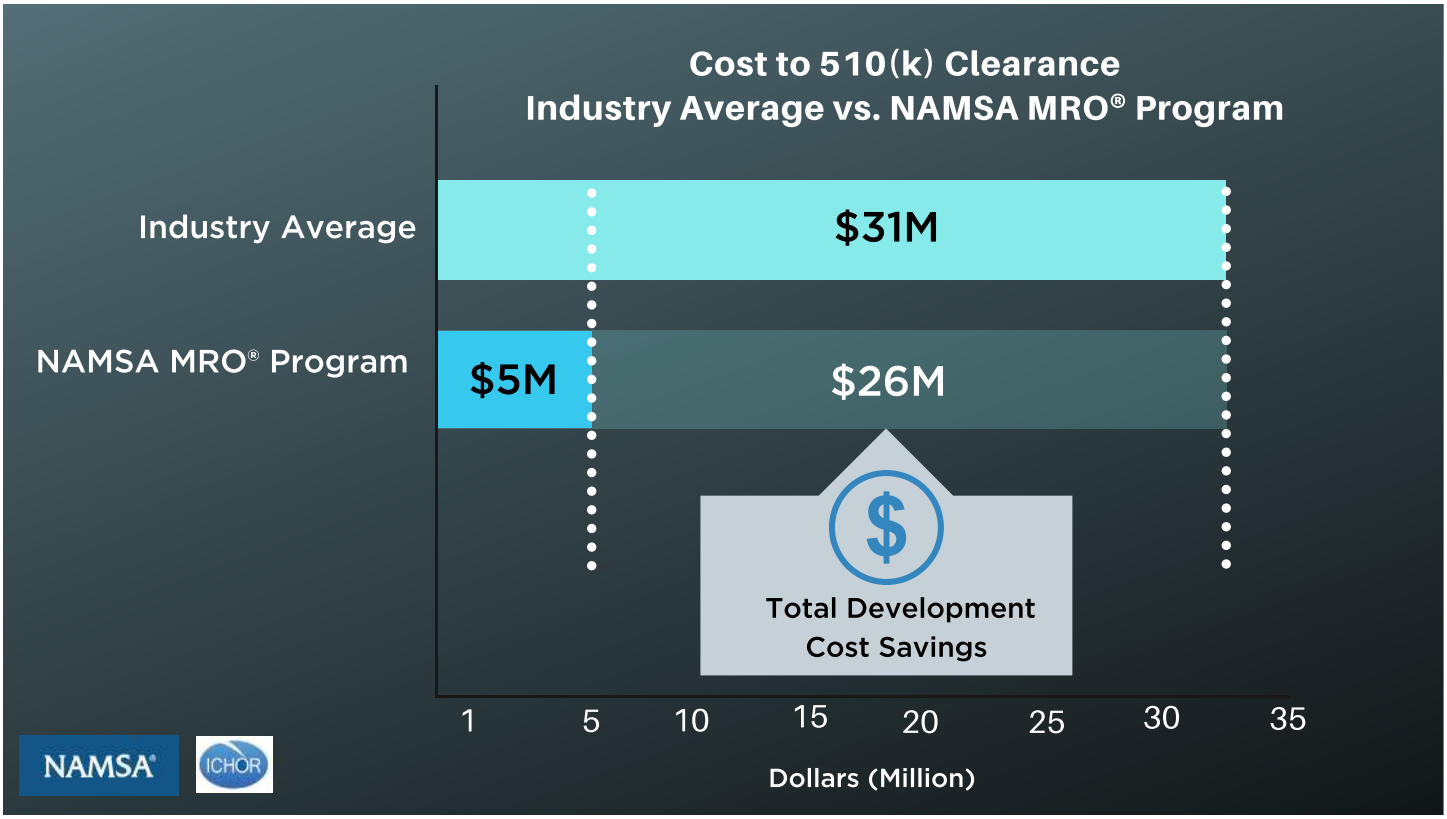


(Source: "How Long it Takes the U.S. FDA to Clear Medical Devices via the 510(k) Process"[6])

Expenditures

Furthermore, the average cost of bringing a 510(k) to the U.S. market is approximately **$31M**[1]. With NAMSA's expert services and solutions, ICHOR achieved 510(k) clearance for less than **$5M**[5].

Figure 3: Cost to Achieve 510(k) Clearance—Industry Average vs. NAMSA MRO® Program



(Source: "The Medical Deice Milestone Gap"[1] and "NAMSA and ICHOR Company Records"[5])

Key Benefits

- Accelerated Timelines
- Reduced Expenditures
- Trusted Partnership
- Greater Device Adoption and Market Share
- Positive Investor Return and Growing Company Valuation
- Increased Positive Patient Outcomes

About NAMSA

Helping medical device Sponsors improve healthcare since 1967, NAMSA is the only 100% medical device-focused, full continuum Contract Research Organization (CRO) in the world. Driven by our global regulatory expertise and in-depth therapeutic knowledge, NAMSA is dedicated to accelerating medical device product development, offering only the most proven solutions to move clients' products through the development lifecycle efficiently and cost-effectively. From medical device testing; regulatory, reimbursement and quality consulting; and clinical research services, we are the industry's premier, trusted partner for successful development and commercialization outcomes.

About ICHOR

ICHOR Vascular, Inc. received 510(k) clearance from the U.S. Food and Drug Administration (FDA) in Q4 of 2018 for its percutaneous embolectomy / thrombectomy system to treat a wide range of arterial and venous occlusions. Acute clot, thrombosed bypass grafts, occluded stents, organization thrombus, embolic events, and post-atherectomy tibia occlusions have been successfully performed using ICHOR's Panacea technology.

References

1. Hirsch, R.; The Medical Device Milestone Gap (December, 2013)
2. Centers for Disease Control and Prevention; Division for Heart Disease and Stroke Prevention; Peripheral Arterial Disease (PAD) Fact Sheet
3. Vascular News; Major Amputation Over Utilized Globally for Critical Limb Ischemia (July 2016)
4. Baser O., Verpillat P., Gabriel S., Wang L.; Prevalence, Incidence, and Outcomes of Critical Limb Ischemia in the US Medicare Population (February 2013)
5. NAMSA and ICHOR Company Records (November 2019)
6. How Long it Takes the U.S. FDA to Clear Medical Devices via the 510(k) Process; Emergo (March 2017)
7. FDA Impact on U.S. Medical Technology Innovation; Stanford University, Medical Device Manufacturers Association (MDMA); National Venture Capital Association (2010)

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