Boston MedTech Advisors

More Experience ►Better Results.

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Our Mission, Business and Operating Principles

Mission:

Assist medical technology companies and healthcare providers to achieve their business goals by offering ethical, result-oriented, professional and cost effective advice and services.

Business:

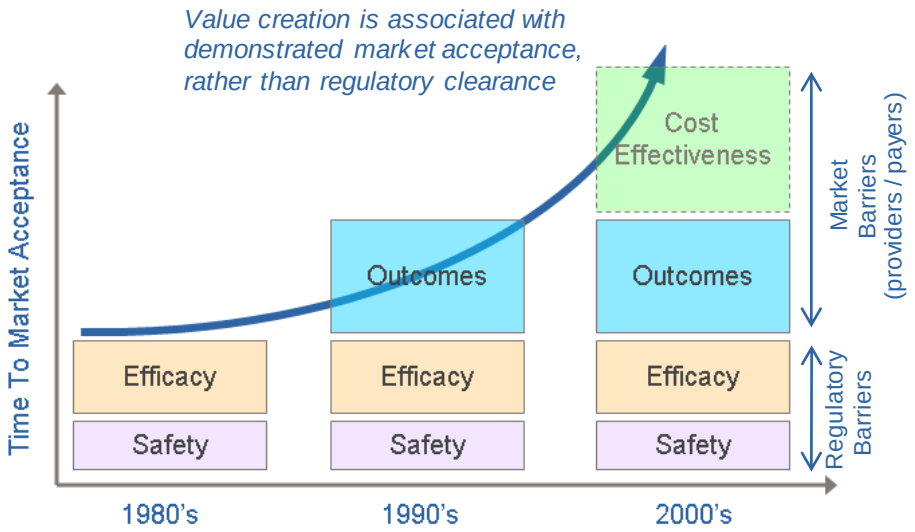
Support our clients to commercialize new products and services and to increase their market adoption, by addressing their unique and inter-dependent regulatory, clinical, reimbursement, marketing and business development requirements.

Operating Principles:

- **Provide optimal solutions** that recognize the multi-faceted aspects of today's healthcare markets and the client's unique business needs.
- **Maximize value** by delivering high quality services at a reasonable cost.
- **Leverage our own experiences**, know-how and relationships for the benefit of our clients.
- **Establish ongoing relationships** by aligning our incentives with those of our clients and partners.

Our Clients' Challenges

- **Healthcare Environment** – complex, competitive and continuously evolving
- **Regulatory Process** – intense and lengthy
- **Reimbursement** – constantly evolving rules that affect commercialization and adaptation of new technologies and procedures
- **Capital** – requires additional funding to support increased requirements for clinical evidence and marketing costs



Boston MedTech Advisors' supports companies to:

- Shorten time-to-market
- Accelerate market adoption
- Raise capital and increase enterprise value

Relevant Experiences Driving the Value to Our Clients

- Principals of Boston MedTech Advisors are entrepreneurs, founding own medtech and healthcare service companies, leveraging their extensive general management, product development, marketing, reimbursement, regulatory, clinical affairs and business development.
- We support diverse range of companies, including start-ups, pre- and post-revenue, VC-backed and public entities, enterprises based in the US, Europe, Israel and Asia, and multi-nationals.
- We provide access to an extensive network of industry, healthcare providers, academia, investors and business partners.
- We have hands-on working experience within the US and European medical technology and healthcare systems.
  - Broad industry experience, spanning over diverse and broad medical disciplines.
  - Excellent submission and communication history with the FDA and other regulatory agencies.
  - Successful record of strategizing and implementing reimbursement solutions.
  - Developing and executing marketing and business plans for new technologies and clinical services.
  - Financing of early-stage companies.

Aesthetic Medicine
Ambulatory monitoring
Anesthesiology
Cancer Therapies
Cardiology
Critical Care
Cryosurgery
Dermatology
Emergency Medicine
General Surgery
Health IT
Hepatology
Home care
Interventional Cardiology
In-Vitro Diagnosis
Interventional Radiology
Neurology
Orthopedic
Patient Monitoring
Pulmonary
Radiology / Imaging
Rehabilitation Medicine
Sleep Medicine
Spine Surgery
Vascular Medicine

Engagements *(sample)**

- Start-ups through Fortune 500 companies
  - Diagnostic, therapeutic and monitoring technologies
  - Healthcare providers - medical practices, clinics and hospitals
  - Consumer medical products and services
  - US and non-US companies
- Technology incubators
- Technology transfer and licensing offices
- Investors (private, institutional)

* Including advisors' prior relationships

When Working with Boston MedTech Advisors…

- You benefit from active involvement by an experienced US and European team, dedicated to helping your company to successfully develop and execute its plans.
- You receive comprehensive support, tailored to the specific needs of the organization, whether an early-stage or an established medical technology company.
- You can recognize significant efficiencies by working with a single entity offering vertically integrated strategy development, planning and execution services.

Expertise, practical solutions and execution in the following areas:

- Regulatory Affairs
- Clinical Trials and Evidence Development
- Technology Assessment, Market Analysis and Business Strategy
- Reimbursement and Contracting Strategy
- Business Development
- Business Plans and Financing Support

Regulatory Affairs

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Analyze the impact of FDA regulatory guidelines on product development, clinical studies and marketing plans.
- Develop rational regulatory strategies and plans, addressing short and long term corporate objectives.
- Solidify regulatory strategies by conducting pre-submission review meetings with the FDA and other regulatory agencies.
- Prepare and facilitate regulatory filings, including 510(k), PMA and IDE applications. Provide an overall management and oversight in order to reduce time-to-approval.
- Coordinate and "harmonize" FDA and CE efforts in order to increase efficiencies of regulatory activities.
- Serve as a registered 'US Agent' for foreign medical device manufacturers.

Clinical Trials Planning and Evidence Development*

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Develop clinical study plans and protocols in support of regulatory submissions, marketing and reimbursement activities.
- Identify appropriate sites and principal investigators for clinical studies and negotiate study agreements.
- Prepare IRB, enrollment plans and pother study documentation.
- Provide technical, clinical and management oversight during clinical studies
  - ✓ Project / trial management
  - ✓ Clinical site and patient monitoring
  - ✓ Database development, data acquisition and analysis
  - ✓ Logistical and operational support
- Prepare summaries of clinical trials for presentation to regulatory agencies, customers, business partners and investors.

* Through Boston MedTech CRO Group

Reimbursement and Contracting Strategies

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Review pertinent reimbursement codes and coverage guidelines for new products and services.
- Analyze reimbursement impact on product design, sales, marketing and business strategy.
- Develop a strategy and plans for solidifying new reimbursement codes, favorable coverage policies and adequate payments for new technologies and corresponding clinical procedures.
- Evaluate the multi-facet effects of regulatory, clinical evidence and marketing initiatives on reimbursement and identify steps to mitigate the effects of payment barriers.
- Manage the application process for new reimbursement codes and/or expansion of coverage guidelines.
- Develop reimbursement support services for end-users.
- Provide guidance for contracting with third-party payers.

Technology Assessment, Market Analysis and Business Strategy

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Assess market potential for new technologies and services.
- Conduct competitive market research and analysis.
- Analyze clinical and technical requirements, regulatory and reimbursement environments for new technologies, products and services.
- Identify new market opportunities for medical technologies and services, and identify optimal clinical applications for 'platform' technologies.
- Evaluate marketing strategies and develop marketing plans – pre and post launch.
- Evaluate new markets for existing products and services.

Business Development

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Identify complementary business opportunities and potential strategic partners.
- Analyze alternative sales channels.
- Initiate and facilitate business relationships, supporting product development, marketing and financing.
- Create early US or European presence, including marketing and business development arm for emerging companies.*
- Introduce larger companies seeking to augment their product or technologies portfolio to appropriate early stage players.

* In collaboration with Boston MedTech Advisors' strategic partners.

Business Plans and Financing Support

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Work with entrepreneurs and management teams to develop 'fundable' business plans and to optimize financing campaigns.
- Introduce entrepreneurs to VCs and private investors active in the healthcare field.
- Identify prospective strategic partners, prepare companies to appropriately explore opportunities and support all phases of the process.
- Support fundraising activities.
- Conduct due-diligence evaluations of new technologies and services.

Senior Team

David Barone, Principal

Over 25 years experience including general, technical and operations management, strategic planning, marketing and business development. Current activities focus on advising and assisting US and off-shore medical technology organizations, ranging from start-ups to Fortune 500 companies, in areas ranging from opportunity analysis, marketing strategy and market development, reimbursement strategies, business development and financing. Prior to co-founding Boston MedTech Advisors, David held senior management positions in a number of medical device companies and has founded, financed and developed a number of healthcare companies. B.Sc., Electrical Engineering, Technion, Israel Institute of Technology, M.Sc., Bio-Medical Engineering and Master, Business Administration, both from Rensselaer Polytechnic Institute, NY.

Zvi Ladin, PhD, Principal

Over 20 years of experience in the medical industry, government and academia, focusing on developing and managing clinical, regulatory affairs and reimbursement initiatives. A co-founder of Boston MedTech Advisors, focusing on establishing regulatory strategies for therapeutic and diagnostic medical device companies, submission of regulatory applications, including 510(k) and PMAs for products in Class I-III and drug-device combination products and representing companies in negotiations with the FDA and other regulatory agencies. Dr. Ladin taught mechanical and biomedical engineering at MIT and Boston University and served as a scientific advisor to the FDA. B.Sc., Aeronautical Engineering and M.Sc., Biomedical Engineering, Technion, Israel Institute of Technology; Ph.D., Medical Engineering, MIT-Harvard Medical School Division of Health Science and Technology.

Michael Imhoff, MD, PhD, Senior Advisor

Board certified in surgery and intensive care medicine, with over 15 years of clinical experience in large medical centers and strategic consulting for leading companies in the global medical technology markets, as well as start-ups in the US and Europe. Research areas include trauma surgery, intensive care medicine, patient monitoring, clinical data management, artificial intelligence in medicine and health economics. Dr. Imhoff is a professor in Medical Informatics and Statistics at Ruhr-University Bochum, Germany, a reviewer for the German Research Foundation, a member of the editorial boards of and reviewer for several international biomedical journals, and author of over 300 publications and scientific presentations. Medical school: Universities of Bochum and Munster, Germany; PhD, Ruhr-University, Bochum, Germany. 1991 Recipient of the Lederle Prize for Research.

Bios *(cont.)*

Yossi Elaz, Senior Advisor

Background includes senior executive positions in large global medical device organizations, including Siemens Medical Systems, and most recently, a member of Draeger Medical's Global Management Team. Experience includes overseeing large R&D organizations, product requirements management, operations and business development activities encompassing a diverse range of medical disciplines, including platforms for patient monitoring system, therapy devices and critical care information management systems. Developed a large number of clinical partnerships with leading medical institutions and opinion leaders in US and Europe and has been involved in the evaluation of numerous medical device technologies. B.Sc., Electrical Engineering, Technion, Israel Institute of Technology.

Andrea Nadai, Manager, BMT CRO Group

Seasoned health care professional with clinical background in physical therapy and clinical teaching. Prior experiences include the development of corporate compliance program, risk management, grant writing, searching state and federal regulations and supporting accreditations. Managed clinical support services in sponsored clinical studies, managed rehabilitation clinic operations, including physical, occupational and speech therapists, and provided direct care of patients with neurologic and orthopedic disorders in outpatient, inpatient and home-based settings. Led continuing education seminars in diverse areas, including pediatrics, gait analysis, manual therapy techniques and more. B.Sc., Physical Therapy, State University of New York, and Master, Health Professions, Northeastern University, MA.