BOSTON MEDTECH ADVISORS

More Experience ▸ Better Results

April 2023 Newsletter

2022 was another productive year for Boston MedTech Advisors. We worked during the year with over 30 companies on a wide range of activities, including (partial list):

- Developing regulatory strategies, holding meetings with the FDA, and obtaining approvals for diverse products.
- Helping companies navigate the complex reimbursement landscape in the U.S., including the development of new reimbursement codes.
- Conducting market research and advising companies on go-to-market and market expansion strategies.
- Developing clinical studies protocols and supporting the execution of multi-center clinical studies through BMTA CRO operations.
- Developing complete business plans supporting fundraising and business development initiatives.
- Developing financial pro-forma and valuations analysis.
- Supporting due diligence activities.

Our clients last year included companies in the U.S., Europe, Israel, and Asia, in all stages of development, from start-ups, incubators and research institutions, to VC-backed, publicly traded (pre and post revenue), and Fortune 500 companies.

Boston MedTech Advisors Welcomes New Members

Whitney Herchek, Senior Consultant
B.Sc. in Biomedical Engineering and a M.Sc. in Innovation Management and Entrepreneurship Engineering from Brown University. Whitney's prior experience includes technology licensing, seed stage fundraising activities and directing preclinical development of new medical technologies. Whitney is also a member of the board of directors for SynCell Biotechnology. Presently, Whitney activities focus on market research, GTM strategy, and reimbursement activities.

Sara Little, Ph.D., Senior Consultant
B.Sc. in Biology from Amherst College, and Ph.D. in Biomedical Sciences from Texas A&M University (primary areas - bioinformatics, antibiotic resistance, and quorum sensing). Previous experiences include research and coordination of clinical trials. Sara's current activities focus on the development of regulatory strategies, clinical research design and implementation.

Melissa Severson, Office Administrator
B.A. from the University at Albany. Prior to joining BMTA, Melissa worked as an Ophthalmic Clinical Assistant for a large ophthalmic practice, and as a Project Coordinator for a consulting firm.

Principals of BMTA participated in multiple workshops, discussing issues affecting the development and commercialization of innovative technologies. Recent presentations included webinars sponsored by MassMedic, the California-Israel Chamber of Commerce (CICC), Arnon Tadmor-Levy & Co. (Israel), and Swissnex

(Switzerland). The latest webinar is available at: Earlier Reimbursement as a Driver of Valuation.

Join the New England Israel Business Council (NEIBC) for three upcoming webinars offered by the Principals of BMTA:

Introduction to the US Healthcare System
Speaker: **David Barone**
When: Tuesday, April 25, 2023 @ 10:00am ET

RSVP

US Regulatory Affairs, Best Practices
Speaker: **Zvi Ladin, Ph.D.**
When: Tuesday, May 16, 2023 @ 10:00am ET

RSVP

Early Reimbursement Strategy, a Driver of Valuation
Speaker: **David Barone**
When: Tuesday, June 6, 2023 @ 10:00am ET

RSVP

Industry News

A policy brief from the Journal of Science Policy & Governance warns that AI-driven software as medical devices (SaMDs) "have the potential to codify bias in healthcare settings", further highlighting the need to include all relevant considerations when planning clinical studies. Boston MedTech Advisors can help companies develop protocols for clinical studies that will provide data requested by the FDA, as well as clinical evidence supporting coverage of new technologies by health plans.

The "Strategy First, Execution Second: Why Life Science Entrepreneurs Should Adopt a Top-Down Mindset Early" article discusses the importance of developing a market-aligned strategy that caters to each unique sector dynamics. "Savvy management should adopt an external, market-driven evaluation and analysis rather than inward-looking and uniformed biased judgment. Crafting a mature, market-aligned strategy will increase the probability of success." To learn more, please contact BMTA.

FDA's Breakthrough Device Designation (BDD) and the Safer Technologies Program (STeP) can offer important benefits for developers of innovative medical devices. In 2022, CDRH has granted 135 BDD designations and 14 SteP designation (the first year of the program). Recently, the FDA has proposed updates for the Breakthrough Devices Program Guidance, which may potentially broaden the range of devices eligible for this status. To discuss the suitability of your device for either BDD or STeP, contact info@bmtadvisors.com.

A bipartisan bill introduced recently in the House would require Medicare to temporarily cover breakthrough medical devices (including digital therapeutics) for four years while the CMS would be required to make a permanent coverage

determination. Favorable coverage policies are essential for the success of new medical technologies. Boston MedTech Advisors has assisted numerous companies to develop an integrated reimbursement, regulatory, and marketing strategy. To learn more about reimbursement coding and coverage, read the popular From "Approved" to "Covered" – What Medical Device Companies Need to Know.

About Boston MedTech Advisors

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

- Market Analysis and Business Strategy
- Business Development
- Regulatory Affairs and Clinical Trial Management
- Reimbursement and Contracting Strategies
- Financing Support
- Other Services

Boston MedTech Advisors provides practical business services to:

- Established and growing medical technology companies
- Healthcare providers
- Startups and entrepreneurs
- Private and institutional investors

To learn more about our organization and services
please visit our website at
www.bmtadvisors.com and www.bmtCROgroup.com.
You can also contact us by phone at 781-407-0900, or email
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