BOSTON MEDTECH ADVISORS

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June 2023 Newsletter

Recent Webinars
by the Principals of Boston MedTech Advisors, with NEIBC

Take advantage of these free webinars, which expertly blend introductory information with comprehensive analyses of modern trends regarding the U.S. Healthcare System, Regulatory Affairs, and Reimbursement Strategy.

"Introduction to the U.S. Healthcare System, the Largest and Most Complex Market," provided by David Barone.

"U.S. Healthcare Regulatory Affairs, Best Practices," provided by Zvi Ladin.

"Early Reimbursement Strategy, a Driver of Valuation," provided by David Barone.

The deadline to apply for the Massachusetts Next Generation Initiative (MassNextGen) is June 30, 2023. This program supports women and diverse entrepreneurs within Massachusetts. Ten awardees will receive up to $100,000 in non-dilutive funding along with access to executive coaching.

Recent Industry Developments of Interest

Acquiring an appropriate CPT or HCPCS code is often the first step in developing coverage for a new technology. BMTA has been following closely the new guidelines for issuing new codes for digital technologies, including AI-based devices. Our paper From "Approved" to "Covered" – What Medical Device Companies Need to Know discusses how planning for reimbursement must be an integral part of every commercialization plan of new medical technologies.

The FDA has recently published a draft guidance document - a framework for changes to medical devices that use artificial intelligence (AI) and machine learning (ML) Comments submitted by **July 3, 2023** may be considered before work begins on the final version of the guidance. The proposed policy will allow AI-enabled device modifications within the scope of "predetermined change control plans" included in the device's pre-marketing submission. Companies using AI or ML algorithms can contact BMTA to discuss the implications of this pending guideline, and other challenges affecting regulatory approvals for such technologies.

The FDA recent publication "A Risk-Based Approach to Monitoring of Clinical

Investigations, Questions and Answers" expands on its 2013 guidance, recommending risk-based monitoring enabling sponsors to better protect research participants during clinical investigations. For further information and support on implementing risk-based monitoring for clinical investigations, please contact BMTA CRO.

The American Cancer Society Cancer Action Network (ACS CAN) has launched a campaign to improve access to biomarker diagnostic testing for cancer patients. While such testing can help identify the best course of treatment, many patients do not have access to these tests due to factors such as cost, lack of insurance coverage, or lack of local services. The ACS CAN campaign aims to increase awareness of the importance of biomarker testing and advocate for policies that will improve access. To learn more, please contact BMTA.

If you know others who may benefit from our Mailing List, they can sign up here.

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
info@bmtadvisors.com

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