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April 2024 Newsletter

Breaking News: The U.S. Food and Drug Administration (FDA) has unveiled its much-anticipated final rule to regulate laboratory developed tests (LDTs) as medical devices. The full FDA press release can be found [here](#).

Industry News

Challenges of Integrating AI into Healthcare

Growing interest in the use of AI to improve diagnosis, support clinical decisions, and optimize healthcare operations is tempered by certain **challenges** of AI algorithm development, including:

- Minimizing potential biases and errors in the datasets used for the development of the algorithms.
- Determining requirements for optimal interoperability with healthcare applications, such as the electronic medical record.
- Adhering to HIPAA privacy and security requirements.
- Ensuring that the AI applications enhance providers' workflow rather than create new operational barriers.

While there is a growing interest in AI-based products and services, their adoption is affected by lack of appropriate policies and regulations (e.g., from the Office of the National Coordinator for Health Information Technology) The recent release of [U.S. health-tech AI rules](#) highlights this dynamic.

[BMTA](#) assists developers of AI solutions to analyze market requirements,

New BMTA Blog



Implant Devices Performance Requirements

FDA offers a [new guide for developers](#) of implant devices, which clarifies the performance data needed to receive 510(k) clearance for implants. The required data depends on the implant's 'indications for use' (IFU) and how long the device stays in the body. The guide also recommends specific tests (e.g., biocompatibility) and emphasizes the importance of considering, during design and testing, both patients' and physicians' experiences.

For a thorough analysis of regulatory requirements that may pertain to implantable devices, please contact [BMTA](#)

understand regulatory requirements, identify reimbursement opportunities, and develop optimal go-to-market strategy.

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About Boston MedTech Advisors

Since 2004, BMTA's multidisciplinary team of highly experienced consultants has supported more than 400 medical technologies and life sciences companies around the world to achieve their business goals. BMTA offers valuable, ethical, result-oriented, professional, and cost-effective insights that recognize the multi-faceted aspects of today's healthcare markets and the client's unique business needs.

- [Market Analysis and Business Strategy](#)
- [Business Development](#)
- [Regulatory Affairs and Clinical Trial Management](#)
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Boston MedTech Advisors provides practical business services to:

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

More Industry News

Geisinger Acquired by Kaiser's Risant Health

[Geisinger Health](#), a Pennsylvania integrated delivery network (IDN), is the first health system to be acquired by Risant Health. Created by Kaiser Foundation, [Risant Health](#) aims to expand and accelerate the adoption of value-based care in diverse, multi-payer community-based health systems. IDNs combine health coverage and patient care into a single coordinated delivery system. Companies introducing new medical technologies should consider including IDNs in their product adoption strategy, potentially enabling them to gain earlier adoption while pursuing coverage by third-party payers.

[BMTA](#) has successfully supported manufacturers of medical devices to establish early markets within IDNs and government healthcare systems.

Physicians and Medical Device Purchasing

According to a report published by the Physicians Advocacy Institute, nearly [78% of U.S. physicians are now employed by hospitals and/or corporate entities](#). This trend highlights a departure from the traditional models of independent practices, shifting decisions about adopting new technologies from physicians to shared decision-making including non-clinical areas, such as finance, purchasing, and risk management. [BMTA](#) supports companies commercializing new products to understand the complexities for different products and to plan optimal commercialization plans.

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please visit our website at
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