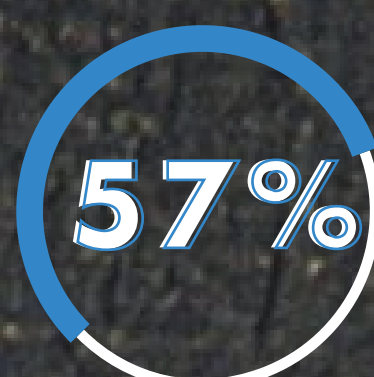


5 MEDICAL DEVICE TRENDS IN 2019

1. DE NOVO DEVICE PATH TO MARKET GROWTH

De novo pathways to market have been around since the end of the 1990s but use by device companies has been growing more significantly in the last 5 years. Cutting edge technologies, simplification of the application process, and increasing emphasis on patient engagement have fueled novel device creation and the use of this previously underused pathway. Properly leveraging this channel can significantly reduce the cost to market for new medical devices. Inherently, de novo classification typically carries a “high-risk” categorization so device makers must be prepared to submit a highly detailed explanation of risk to avoid that high-risk label.

228
clearances/approvals since 1998



coming since 2014

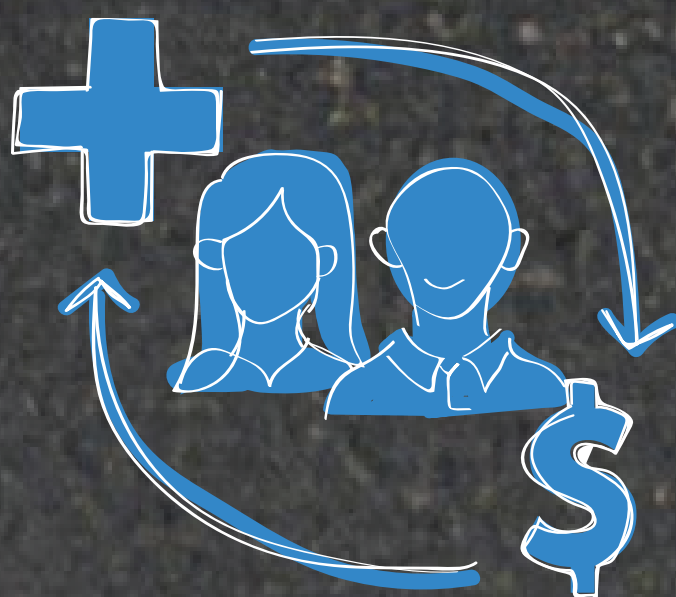
2. INCREASING USE OF SMART DEVICES AND INTERNET OF THINGS



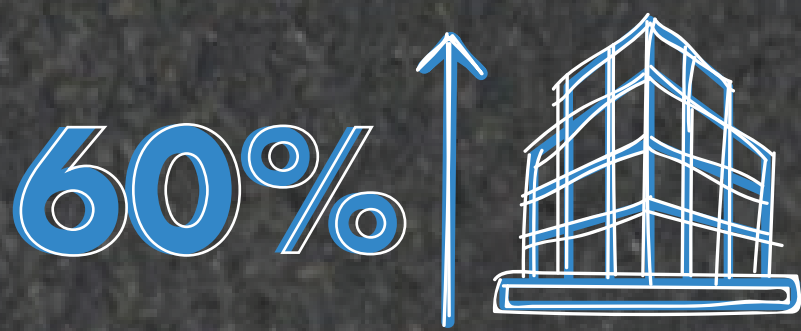
IOT-connected smart devices are feeding medical device makers a wide range of new data sets with potential applications across their business. Tracking performance metrics, maintenance, and compliance can provide benefits for patient and manufacturer alike. With the growing awareness and role that patients are playing in their own healthcare, being able to actively provide data and information on the benefits created by a device can set you apart from competitors. Beyond that, companies can use these metrics to develop new features and optimize performance based on consumer interactions recorded by the device, rather than relying on outdated collection methods such as focus groups and surveys. The proactive application and use of this data can lead to a better consumer experience in an increasingly patient-centric industry.

3. VALUE-BASED HEALTHCARE CHANGING PAYER BEHAVIOR

Value-based care has been a trend growing in the life sciences space for several years now. In 2018, the Centers for Medicare and Medicaid Services (CMS) introduced the Bundled Payments for Care Improvement (BCPI) model to reduce the cost to the patient for some clinical procedures. One of the biggest impacts of this program evident from the pilots is the spend on medical devices within these procedures. While these costs aren't typically isolated to a single vendor's products, this change in payment will impact the revenues realized by medical device companies. This will also increase pressure on manufacturers to reduce cost in producing the devices while maintaining or ideally increasing the quality of the devices. Payers will increasingly focus on the “proof-of-value” for each device, changing the way manufacturers compete and communicate value.



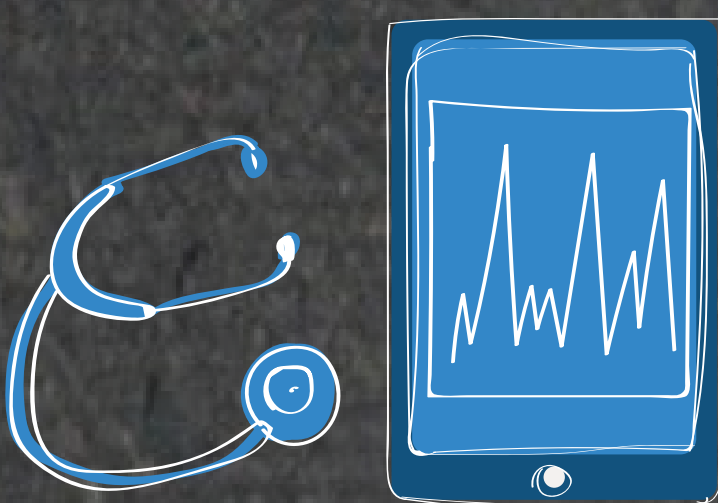
4. MERGERS AND ACQUISITIONS DRIVING BUSINESS EXPANSION



As ever, the industry continues to leverage M&A for growth. The small and midsize players are attempting to compete with industry leaders by consolidating, while industry leaders continue to reach new markets through smaller, niche acquisitions. In spite of decades of industry M&A, medical device leaders continue to face consistent and persistent challenges to value realization. In 2019, medical device makers must take a proactive approach to how they select and implement new technologies and solutions, collect and manage their data, and organize their business.

5. EMERGENCE OF MACHINE LEARNING AND ARTIFICIAL INTELLIGENCE

There are still barriers to full use of advanced machine learning and artificial intelligence in care decisions but those next-generation competencies are already impacting device development. Devices focused on diagnostics are using machine learning algorithms to supplement and eventually replace requirements for clinician review in diagnoses. The increasing accessibility and volume of health data lends itself well to opportunities for earlier diagnosis and more accurate monitoring of impactful symptoms or precursors. Beyond the device itself, these analytic techniques have the potential to improve R&D by automating discovery, increasing the pace of development, and reducing time to market. Moving forward, leaders in medical device should closely monitor the constantly evolving regulatory landscape as regulators and legislators look to understand more on validation and oversight as it relates to artificial intelligence and machine learning.



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