Insight Brief

Ten MedTech Trends to Watch in 2025

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Every new year brings a sense of anticipation and change, but few in recent memory have signaled as much potential disruption as 2025. We believe that, in general, the MedTech industry will be among the steadiest and most sheltered from significant policy and market changes, but also that the mantra of the coming year will be to "expect the unexpected." With this in mind, here are ten MedTech trends to watch for in 2025.

1 Clinical AI — A more positive environment for much needed investment

As the use of artificial intelligence (AI) soars, its clinical utility remains narrowly focused, with imaging and cardiology capturing the greatest share of funding and development. In these fields, large amounts of accessible, clean, and clinically reliable data have allowed the development of solid algorithms with demonstrated accuracy. However, the larger clinical promise of AI remains impeded by a series of now well-documented issues, including problems with large, disconnected, and incompatible data sets whose ownership is not always clear; regulatory and reimbursement hurdles; and questions around liability, to name a few. Yet the promise is significant, particularly with wearable technologies that capture continuous data for parameters where only intermittent data was previously available. There has also been tremendous effort to clearly articulate the challenges of usable data and to propose workable solutions.

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While advancement overall is slow, each year brings accelerating progress and builds on the prior years' work. In diabetes, depression, and seizure disorders, evidence is being developed that is showing the potential for real-world medical benefits. Emerging regulatory frameworks, with common global themes around data management and monitoring, demonstrate that regulatory bodies recognize that innovative AI solutions need new approaches for evidence development and approval. Finally, the Centers for Medicare & Medicaid Services (CMS) has included new codes for AI products and services in its annual code update for 2025.

The issues around accessing and analyzing the data are multi-faceted, and unlikely to be resolved in the near-term. But now that they are understood, steps can be taken to resolve them, and we expect increasing progress every year. Pulling disparate clinical datasets together remains challenging, particularly as the interoperability of clinical data and wearable-generated data needs to be addressed. Accessing data without compromising patient privacy is well understood but needs to be carefully monitored. The sheer amount of data, particularly from wearables, is daunting, but AI tools are already helping to efficiently sort and analyze. The global regulatory maze (and U.S. state-level privacy laws) will hopefully begin to coalesce around some common parameters.

In summary, some promising clinical results, a somewhat more welcoming regulatory environment, the potential for reimbursement, and the ongoing development of AI itself should collectively help to free up investment in 2025 and bring a broader array of AI clinical solutions one step closer to reality.

2 The "Trump Effect" likely limited in 2025

With the possible exception of tariffs, the new administration's people and policies will likely have a limited impact on MedTech in its first year. President Trump has signaled that he wants to pursue tariffs as a key pillar of his trade policy, and he has called for 10% on China, and 25% on Canada and Mexico. What will actually be finalized is unclear, but with any tariffs imposed, MedTech is likely to see increased costs for offshore manufacturing, as well as for key imported materials/components. It is also possible other countries could enact retaliatory tariffs. Medical devices may be relatively insulated from retaliatory tariffs, but it is difficult to predict at this point.

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A key priority for Trump is decreased mergers and acquisitions (M&A) pressure from the U.S. Securities and Exchange Commission (SEC) on anti-trust policies, which appears largely supported by the broader Republican leadership. 2024 was a relatively strong year for MedTech M&A and included monstruous deals (such as J&J's acquisition of Shockwave Medical for $13.1B in May 2024). While MedTech did not see notable scrutiny from the SEC during the Biden administration, analysts speculate that deal appetite was lessened due to risks associated with the longer review timelines observed in the Biden administration. In addition to decreased regulatory pressures, the industry may see increased appetites for deals overall as the attitude towards the economy shifts with the transition to the Trump presidency.

For the U.S. Department of Health and Human Services (HHS) policies, nominee Robert F. Kennedy Jr. has signaled a strong focus on shaking up the status quo, although he will likely be slowed by tight regulations, high pressures from lobbyists, and lawsuits that have historically made significant change challenging within HHS. Additionally, most of his comments have focused on food and pharmaceuticals, with few-to-no mentions of the MedTech industry. He has stated that he wants to decouple the industry from the FDA by removing user fees, and that he will eliminate "whole departments." Which departments and how he will eliminate them are unclear, as is RFK Jr.'s plan to backfill the budget for user fees. As of this time, the most likely impact to MedTech is that FDA review timelines may slow, if budgets and staffing become challenged.

Nominee Dr. Mehmet Oz is in a position to indirectly impact the MedTech market by reshaping the care provided under CMS, but has made few overt signals on his priorities. Historically, Dr. Oz has supported Medicare Advantage, which may indicate lessened future pressures on the program, which has been drawing scrutiny for overbilling and denials. The more critical impact on CMS may come when Congress decides on the Affordable Care Act (ACA) subsidy expiration, currently set to end in 2025, which could increase premiums and eliminate coverage for millions of Americans in the coming years. Although Republican leadership has signaled an interest in reducing/cutting ACA, it remains a popular program for voters.

3 Even as it fights for survival, the FDA LDT rule will require some measure of compliance in 2025

In May of 2024, the FDA finalized a rule clarifying that Laboratory Developed Tests (LDTs) should be regulated as medical devices. This was a significant change from the FDA's prior stance which allowed LDTs to operate with minimal regulatory intervention. The new framework requires LDTs to comply with stringent regulations similar to other in vitro diagnostic (IVD) products, including medical device reporting, registration, labeling, and premarket review. The shift aims to ensure the safety and effectiveness of LDTs, providing greater confidence in their use for critical health decisions.

Almost immediately, obstacles arose. In a June 2024 ruling, the U.S. Supreme Court (in Loper Bright Enterprises v. Raimondo) overturned the "Chevron doctrine," which allowed federal agencies like the FDA to implement their interpretation of the law, including in areas where that law is silent or ambiguous. As a result, instead, courts must now exercise their independent judgement to determine the meaning of the law, even if the statute is unclear. This ruling has called into question whether the action by the FDA to implement the LDT rule was within their statutory authority. Pursuant to the ruling, in a clear signal of Congress's displeasure, Sen. Bill Cassidy (R- La.) wrote to FDA Commissioner Robert Califf as ranking member of the Health, Education, Labor and Pensions (HELP) Committee, that the FDA lacks "clear statutory authority" to implement the LDT rule. In addition, the American Clinical Laboratory Association and the Association for Molecular Pathology both sued to challenge the FDA's authority to implement the LDT Rule without prior Congressional approval through legislation.

Many of the major laboratory stakeholders have been raising awareness of the FDA's LDT rule with the new Trump administration and some have asked for Congress or the Trump administration to rescind it. However, such requests are not likely to bear fruit as they are past the 60-day window in which a federal regulation can be overturned. Congress could move to enact legislation like the Verifying Leading-edge IVCT Development (VALID) Act, or other legislation meant to provide a regulatory framework for LDTs. However, the VALID Act has been under consideration for several years and has undergone rounds of revision by Congress and the FDA, but has yet to make it to the floor for a vote.

Since the outcome of all the litigation and protest is not yet certain, laboratories that are offering LDTs will need to come into compliance, beginning with meeting the FDA's first phase of enforcement of the new LDT rule on May 6, 2025. Many are taking the pragmatic view that the writing is on the wall for some version of LDT regulation, and that, in fact, some type of regulation of LDTs is needed and overdue. The most critical 2025 actions by LDTs are likely to include:

- Regulatory requirements: Understand the FDA's regulatory framework for LDTs, including guidance documents and any proposed rules or regulations. In particular, prepare now to meet the requirements specified for the first phase of the LDT rule in May.
- Verification and validation: Begin developing rigorous analytical and clinical validation strategies to demonstrate accuracy, reliability, and clinical validity (the latter of which is not required by the Clinical Laboratory Improvement Amendments (CLIA), but is expected by the FDA).
- Regulatory: Begin mapping out regulatory strategy given the possibility of the need to submit premarket notifications (510(k)), premarket approval (PMA) applications, or other regulatory submissions as required by the FDA rule for new and significantly altered LDTs.

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4 The RWE train shows no signs of slowing

The use of real-world evidence (RWE) continues to expand, evidenced by the 35% annual growth rate in 2018-2023 from a review of FDA records as compared to the 10% growth seen in more traditional clinical trial publications. The difference reflects challenges in executing clinical trials through the pandemic and the increasing availability of high-quality real-world datasets. The emerging use cases and benefits of RWE are also major contributors, including more efficient study execution (time and cost), data that reflects actual device utilization (outside the well-controlled clinical trial setting), and inclusion of diverse patient populations. In addition, there has been a steady uptick in acceptance by regulators, payers, physicians, and other healthcare stakeholders.

Regulators have shown leadership in opening the door for RWE. In December 2023, the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) published draft guidance on the use of RWE in medical device regulatory decision making. The FDA has been committed to advancing RWE since the passage of the 21st Century Cures Act of 2016 and has published more than 10 RWE guidance documents across drug and device centers. These documents provide important context on the use of real-world data, study design, data standards, and submission.

Payers are also increasingly open to RWE, with a noteworthy example being the CMS Coverage with Evidence Development (CED) program which is part of National Coverage Determinations (NCD). This program provides coverage for innovative medical technologies but mandates real-world post-market data collection. It has been utilized for devices ranging from positron emission tomography scanners to transcatheter aortic valve replacement.

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Public/private partnerships are key to supporting the momentum with RWE. One example is the National Evaluation System for Health Technology (NEST), a research network to advance RWE and foster collaboration of stakeholders. NEST published a review of RWE in 21 test cases in 2022, and NEST data has recently supported labeling modification for surgical robots.

Finally, it is important to highlight the natural convergence of artificial intelligence and RWE. AI enables RWE through enhanced data collection capabilities such as the extraction of unstructured data from the Electronic Medical Record (EMR). Real-world data sets are also critical inputs for AI training and algorithm development.

In 2025, medical technology manufacturers who actively incorporate RWE into their clinical planning can do so with confidence that it will contribute to successful achievement of critical commercial, regulatory, and market access objectives.

5 Cybersecurity continues to demand attention and investment

Multiple high-profile cyberattacks in the healthcare space gained national attention in 2024, and the frequency and intensity of ransomware and other cyber threats is expected to continue or accelerate in 2025. While cybersecurity as a product requirement has become normalized within the medical device sector, the market as a whole has yet to address broader cybersecurity and interoperability issues. One survey by the Healthcare Information and Management Systems Society found that 73% of healthcare provider organizations use legacy IT systems, which are costly to support and often rife with gaps in security. In November 2024, the U.S. Government Accountability Office (GAO) issued a report with findings that HHS has yet to meet critical cybersecurity goals, leaving healthcare organizations vulnerable to increasingly complex cyber threats. In addition, the U.S. Cybersecurity and Infrastructure Security Agency (CISA), issued 13 reports in 2024 warning about vulnerabilities in medical Industrial Control System (ICS) devices.

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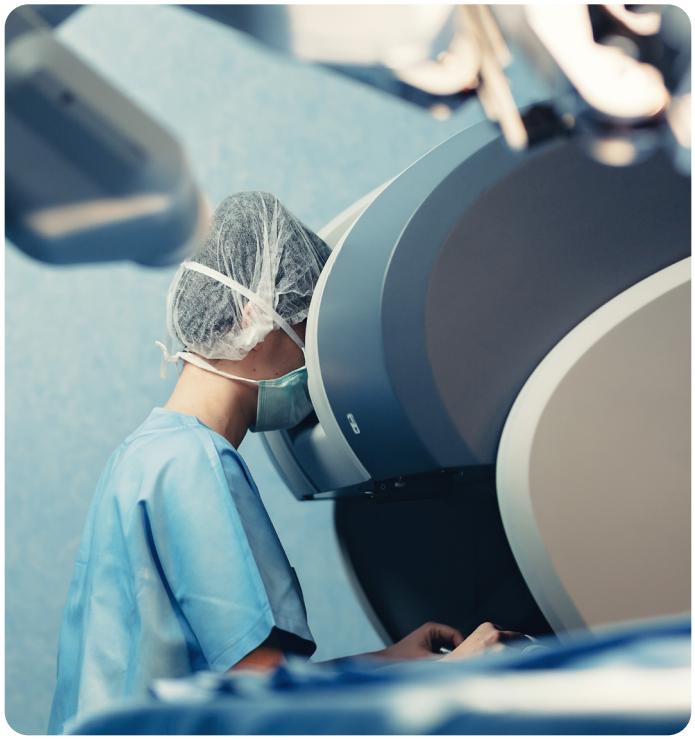
The FDA's latest guidance for medical device manufacturers dates from September 2023. It focuses on the importance of integrating cybersecurity considerations into Quality System Regulations (QSR) and premarket submissions, and requires that security measures should be built directly into device design and labeling to ensure that medical devices are resilient to cybersecurity threats. Beyond design elements, however, the FDA now requires that manufacturers also document a comprehensive risk management approach that includes threat modeling, vulnerability assessments, and continuous monitoring throughout the device lifecycle. These measures also need to take into account human factors, which still account for the vast majority of data breaches that result in lost information or access.

In Q4 2024, CDRH made public the list of documents it proposes to publish in 2025. Key documents include final guidance on Quality System Considerations and Content of Premarket Submissions, updates to the Premarket Cybersecurity Guidance, and recommendations for AI-enabled device software functions. The list also features proposed draft guidance on lifecycle management for AI-enabled software and the regulatory status of device software functions.

This combination of additional regulation, legacy system vulnerabilities, and the continued value of healthcare data will ensure that cybersecurity will only increase in importance for the MedTech sector. Medical device manufacturers will not only need to stay abreast of continuing regulations, but they will also need to proactively deploy such tactics as AI and Blockchain tools specifically for privacy and security, Zero Trust model approaches for device security, and enhanced protocols to include biometric security measures.



6 3D printing steps up

According to one market research study (Verified Market Research), the 3D printing (also known as additive manufacturing) medical market is expected to grow at a CAGR of 17.18% from 2024 to 2031. Since its introduction into medical technologies, each new use application seems to generate several more potential uses within the healthcare space. Further, as 3D printing technology evolves to incorporate new materials, new applications become possible, resulting in exponential growth.

In the immediate term, there are several drivers of healthy growth. One is the creation of anatomical prototypes for education and clinical practice. These can be printed onsite using patient images (e.g., MRI, X-ray, CAT scan) and are particularly useful in complex pediatric, brain, and heart surgeries. According to one survey, among surgeons who have used 3D-printed models in the U.S., 94% said the model was a valuable tool for presurgical planning. 3D printing is also used to create surgical cutting and drilling guides specifically designed for a particular patient and surgery. Academic centers are likely the primary users of these applications, and usage has grown from just a few hospitals with localized 3D printing labs to well over 100. In fact, it has expanded to such a degree that centralized 3D print labs are becoming more common.

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Orthopedic and maxillofacial implants are increasingly being fabricated using 3D technology to fit exact patient specifications when traditional implants fall short. In 2024 for instance, a 3D-printed, patient-specific cranial implant system, the first to use polyetheretherketone (PEEK), was granted FDA 510(k) clearance. Advances in materials, experience, and capacity are exponentially expanding the use cases for custom implants.

The FDA is attempting to keep up with this sea change as manufacturing moves from factories following "good manufacturing processes" to provider facilities. In 2021, it issued a call for comment on a future-proof regulatory framework designed to ensure the quality of 3D-printed medical devices. The draft guidance provides manufacturers with recommendations for device design, manufacturing, and testing considerations when developing 3D-printed devices. However, it has not been finalized.

The current uses of 3D printing will continue to drive healthy growth and expansion through 2025, while a number of new innovations will exponentially spur growth through the next decades.

7 A small but interesting potential end run around VBP in China emerges

Since 2019, the introduction and subsequent expansion of Volume Based Procurement (VBP) in China has limited the ability of global MedTech manufacturers to participate profitably in the market. Designed in part to encourage domestic production, the policy has had the intended effect of limiting the availability of both pharmaceuticals and medical devices from leading global manufacturers.

There is anecdotal evidence that this rule is frustrating to Chinese citizens who can afford more expensive healthcare. Further, as China's economic growth has slowed in recent years, the country is now looking for ways to encourage greater foreign investment. In June of 2024, China's cabinet called for greater efforts to attract foreign investment, including lifting all restrictions on outside investment in manufacturing and rolling out a new round of trial measures to expand opening of the services sector. In September of 2024, China turned its attention to the healthcare segment and announced

that it would permit wholly owned foreign hospitals to be set up in nine trial regions (Beijing, Tianjin, Shanghai, Nanjing, Suzhou, Fuzhou, Guangzhou, Shenzhen, and Hainan) as part of efforts to open up the healthcare sector. The announcement, issued jointly by the Ministry of Commerce, the National Administration of Traditional Chinese Medicine, and the National Disease Control and Prevention Administration, was described as a way to deliver diversified healthcare services for foreigners working, studying, and living in China, as well as Chinese people with special needs.

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This year's government work report proposed that market access for medical and other service industries will be relaxed. Although expectations of suspended or significantly reduced VBP is unlikely, the Chinese National Government gave a strong signal that VBP will not be the only solution for the public healthcare system. The majority of the population will stay within the public healthcare sphere where they are provided with basic and cost-effective medical support. However, those who are able to afford more expensive healthcare will have options, such as the approximately 200 clinics and outpatient departments and just over 100 hospitals that are funded by foreign organizations, including the first Mayo Clinic office in China which opened May 2024. Currently, the market share of foreign-invested medical institutions remains small compared with the total of more than one million medical and health institutions in the country. However, these new initiatives from the National Government could allow both MedTech and pharmaceutical manufacturers to achieve more favorable pricing in this small, but potentially growing, segment of China's healthcare market.

8 Supply chain vulnerabilities remain

Weather events, increasing in frequency and intensity, are challenging all types of manufacturers, but no one's health is put at risk if, for instance, a new car is delayed by a couple of months. MedTech manufacturers have made great strides in supply chain resiliency, learning from both the COVID-19 pandemic supply chain issues and an almost constant stream of weather events. The saline bag shortage that followed a manufacturing plant shutdown in North Carolina after Hurricane Helene in 2024 was similar to a crisis following Hurricane Maria in 2017, and shows how vulnerable supply chains continue to be.

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Manufacturers are caught between two fundamentally competing pressures. On one hand, they need to pursue strategies that can reduce supply chain risk, like moving manufacturing closer to customers, securing materials, and increasing inventory levels. On the other hand, to meet their customers' ever-increasing demand for lower prices, they need to implement cost reduction strategies like moving manufacturing to low-cost geographies and concentrating production to fewer facilities to drive efficiency.

These competing pressures are unlikely to ease in 2025. The number of billion-dollar weather and climate events in 2024 climbed to 19, putting it in second place to 2023 for the most to occur from January through the end of July. At the same time, the American Hospital Association (AHA) reports that hospitals and health systems will

continue to experience significant financial pressures in 2025. They are facing substantial challenges due to higher costs for labor, drugs, and supplies, while reimbursement increases from Medicare and Medicaid are falling far short of inflation.

Adding to these challenges are new concerns for 2025 as the new U.S. administration is considering policies that will exacerbate the situation. First, it is publicly discussing tariffs on goods from Mexico and Canada, where manufacturing for MedTech destined for North America is concentrated. Second, the newly proposed Department of Government Efficiency (DOGE) is unlikely to be generous with federal healthcare funds, starting with funding of state Medicaid budgets. So MedTech supply chain executives can expect another challenging year as they work to get life-saving technologies to the patients that need them.

9 Glimmers of hope in market access

2025 brings a few helpful developments in the market access space, and while they do not represent enormous change, any positive change in an area usually marked by negative trends is worth noting. Transitional Coverage of Emerging Technologies (TCET), which IQVIA MedTech has written about in a prior trends article, has finally become a reality with a pilot program. TCET is designed to provide a pathway to coverage for devices which achieve the FDA's breakthrough designation to encourage early utilization and evidence development. There are currently two products in the program, with two more promised for March. The announced target is to bring five to six products into the program per year. However, with approximately 900 devices currently designated as breakthrough, the TCET program — as currently formatted — is not going to make a significant difference for most of them.

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The New Technology Add-On Program (NTAP), another program designed to encourage utilization of new technology, albeit in hospitals, has seen some positive changes that will become evident in 2025. Historically, to qualify for NTAP, a device had to be new, cost enough so that the associated DRG reimbursement rate is inadequate, and demonstrate a substantial clinical improvement over existing services or technologies. The add-on payment was capped at 50%. In 2024, NTAP coverage was extended for 11 technologies and eight new applications were approved. Further, the add-on payment for most NTAP products has been increased to the lower of either 65% of the technology costs, or 65% of the excess costs above the standard DRG payment. In the most significant development, certain new medical services and technologies may be eligible to apply for NTAP under an alternative pathway. Under the alternative pathway, a Breakthrough Device-designated technology is considered not to be substantially similar to an existing technology for the purposes of NTAP, and will not need to meet the substantial clinical improvement criterion.

Finally, AI products and services have traditionally struggled to chart a path to reimbursement. In a positive step forward, CMS included new codes for AI products and services in its 2025 code update. The seven new codes build on the American Medical Association's guidance developed in 2023 taxonomy for classifying various AI applications for medical services and procedures into one of three categories: assistive, augmentative, or autonomous. They cover AI augmentative data analysis involved in electrocardiogram measurements, medical chest imagining, and image-guided prostate biopsy. It is worth noting, however, that these are category III codes, so coverage and reimbursement payment rates are not guaranteed. Nevertheless, they represent progress in an area where access has lagged behind innovation.

10 Prepare now for EU health technology assessments

The European Union (EU) centralized Health Technology Assessment (HTA) will harmonize processes across the EU and hopefully lead to more consistent and predictable market access pathways. This consistency will benefit both the industry and healthcare providers by reducing the administrative burden and facilitating the adoption of new technologies.

While the full implementation of the system for MedTech and IVDs is still some time away (2030), 2025 will be a critical year for MedTech companies to observe and learn from the ongoing pharmaceutical technology assessments, particularly in oncology and high-tech procedures, which began in January 2025. This proactive observation will be essential for navigating the complex market access landscape and ensuring that new medical devices and diagnostics meet the stringent requirements set by the EU.

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A key step will be to align development processes with the forthcoming Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC). The European Commission's recent public consultation on the draft implementing act for JSCs for medical devices and IVDs, which closed in November 2024, asks for the industry's commitment to early engagement on JCA, but also country-specific HTA systems.

One can expect that the upcoming JSC/JCA for MedTech and IVD products will involve similar guidance to the JSC for medicinal products, including:

- Streamlined advice that meets the evidence requirements for HTA bodies
- Early engagement with both regulatory and HTA bodies during the development phase of their products
- The importance of providing actionable and practical recommendations that can be realistically implemented

MedTech companies that lay the groundwork now for the eventual implementation of EU HTA regulations through proactive engagement and alignment with market access requirements will not only facilitate compliance and market access for themselves, but also drive innovation and improve patient outcomes, ultimately benefiting the entire healthcare ecosystem.

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