THE MEDTECH CONFERENCE
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Hosted by AdvaMed
The Medtech Association

# #MTC25 EVENT SUMMARY

## Insights, Themes and Takeaways from The MedTech Conference 2025

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# 1. Executive Summary

The MedTech Conference 2025 painted a vivid picture of an industry at a strategic inflection point, driven by the convergence of technological acceleration and profound structural pressures. The overarching sentiment was one of **pragmatic optimism**, as leaders expressed confidence in MedTech's transformative potential while remaining soberly aware of the immense challenges in data infrastructure, regulatory frameworks, and global market dynamics. Three macro themes defined the discourse: the imperative of AI integration, the necessity of ecosystem-wide collaboration, and the strategic recalibration required to navigate an increasingly complex and fragmented global landscape.

**Artificial Intelligence has decisively moved from a future concept to a present-day reality**, fundamentally reshaping both operational efficiency and clinical innovation. Discussions shifted from theoretical potential to tangible ROI, with leaders showcasing FDA-approved AI applications that are already reducing clinical trial sizes by up to 75%, automating back-office processes, and enabling personalized surgical planning. However, this progress is critically dependent on solving the industry's foundational data problem. The consensus was clear: without robust data governance and interoperability, the promise of AI will remain unfulfilled, making data strategy a paramount C-suite priority.

A second defining narrative was the **evolution from siloed, transactional relationships to deep, interdependent ecosystem partnerships.** This shift was evident across all domains. In finance, the venture capital funding gap is being filled by creative, risk-sharing models involving strategics, private equity, and health systems. In policy, the success of the Alzheimer's biomarker reimbursement campaign underscored that multi-stakeholder coalitions—uniting industry, patient advocacy groups, and providers—are now essential for driving meaningful change. Most importantly, the patient voice has ascended from an anecdotal input to a scientifically rigorous component of value creation, with patient preference data becoming a critical tool for regulatory submissions, HTA, and payer negotiations.

Finally, the conference highlighted a **strategic recalibration in response to a new era of geopolitical risk and market fragmentation.** The traditional US/EU-first global rollout strategy is obsolete. Companies are now adopting a "global-first" mindset, recognizing markets like Singapore and Japan as primary innovation hubs and regulatory gateways to the vast APAC region. The "China Plus One" strategy is maturing into a more nuanced approach of "rebalancing, not retreating," with a focus on localizing innovation to compete in a highly dynamic market. This global restructuring has elevated supply chain resilience from a logistical concern to a non-negotiable, board-level strategic imperative, demanding unprecedented levels of visibility, diversification, and agility.

In conclusion, The MedTech Conference 2025 revealed an industry that is simultaneously bullish on its innovative capacity and clear-eyed about the structural hurdles it must overcome. Success in this new era will not be defined by technological superiority alone, but by the ability of organizations to build collaborative ecosystems, navigate complex regulatory and reimbursement

pathways with sophisticated strategies, and place a well-governed digital and data backbone at the core of their operations. The companies that thrive will be those that master this intricate interplay of technology, policy, and partnership.

# 2. Key Themes and Trends

The discussions at The MedTech Conference 2025 converged around six interconnected macro themes that collectively define the industry's current strategic landscape. The pervasive integration of **Artificial Intelligence** has moved from a futuristic concept to a present-day imperative, fundamentally reshaping both operational efficiency and clinical innovation. This digital transformation, however, is critically dependent on solving persistent challenges in **Data, Interoperability, and Connected Care**, which remain foundational barriers to a truly integrated healthcare ecosystem.

Simultaneously, the industry is navigating an increasingly complex **Regulatory and Reimbursement Gauntlet**, where promising new collaborative pathways are emerging alongside systemic legislative and judicial uncertainties. In response, the **Ascendancy of the Patient Voice** has become a powerful force, with patient-centricity evolving from a guiding principle to a core driver of value creation, market access, and policy change.

On a global scale, MedTech leaders are recalibrating their **Global Strategy in an Era of Geopolitical Risk and Regionalization**, shifting from traditional market-entry models to more agile, resilient, and region-specific approaches. Finally, these strategic and operational shifts are profoundly influencing **The Shifting Capital Landscape**, where new M&A dynamics, creative investment models, and a renewed focus on capital efficiency are redefining the pathways to commercial success.

## 2.1. The AI Imperative: Redefining MedTech from End to End

Across The MedTech Conference 2025, no theme was more pervasive or consequential than the integration of Artificial Intelligence. Discussions have decisively moved beyond hype and theoretical potential to focus on pragmatic implementation, measurable ROI, and the profound organizational shifts required for successful adoption. The consensus is clear: AI is no longer an optional innovation but an existential imperative that is fundamentally redefining processes, products, and competitive dynamics across the entire MedTech value chain. From optimizing back-office functions and accelerating regulatory submissions to enabling next-generation clinical trials and creating entirely new paradigms in personalized patient care, AI is now a core pillar of industry strategy. However, this optimism is tempered by a deep understanding of the foundational challenges that remain, primarily concerning data governance, regulatory uncertainty, and the significant undertaking of organizational change management.

### 2.1.1. From Back-Office Efficiency to Clinical Transformation

A primary theme was the dual application of AI to drive both operational efficiency and clinical breakthroughs. Leaders emphasized that while patient-facing innovations often capture headlines, the most immediate and measurable returns on AI investment are frequently found in automating and augmenting internal processes. Sessions highlighted how AI is being deployed to streamline historically manual and time-consuming functions, thereby liberating highly skilled employees to focus on value-added work.

In the session **"AI and Automation in Promotional Review,"** panelists discussed using AI to accelerate the MLR process from weeks to days by automating routine checks for grammar, trademark usage, and claims consistency. This allows human reviewers to focus on nuanced compliance issues rather than administrative tasks. As **the CEO of a software company specializing in MLR optimization**, noted, this creates a significant commercial advantage:

> *"If I do not have an optimized process and it takes me upwards of six weeks to get the revised message into the hands of our sales reps versus seven days, which is what it really should be, or less, there's actual commercial implications for that agility."*
>
> — **Scott Rovegno**, Co-Founder & CEO, Vodori, Inc.

Similarly, in **"The Era of Agents: Transforming Medtech with AI,"** the automation of adverse event reporting and supply chain management was presented as a low-risk, high-impact application. AI agents can process customer complaints in real-time and automatically identify necessary supply chain adjustments, turning weeks of manual work into an automated workflow.

Concurrently, the conference showcased how AI is directly transforming clinical products and patient outcomes. During the **"Agents of Change"** keynote, industry leaders presented concrete examples of AI in practice:

- **Lisa Earnhardt,** Executive Vice President and Group President, Medical Devices **at Abbott,** described the Ultreon imaging platform, which uses AI to detect calcium during coronary procedures, helping physicians create more precise treatment plans.
- **Shan Jegatheeswaran, Global Head, Johnson & Johnson MedTech Digital,** highlighted the Monarch robotic bronchoscopy platform, where AI algorithms enable surgeons to navigate parts of the lung that were previously inaccessible.
- **Mick Farrell, CEO of Resmed,** introduced Dawn, an AI-powered "sleep health concierge" that personalizes therapy and coaching for sleep apnea patients.

This dual-pronged approach, automating the back office while innovating at the clinical front line, has become the central strategy for scaling AI in MedTech.

### 2.1.2. The Data Prerequisite: Acknowledging the Foundational Challenge

A recurring and emphatic point of consensus was that the full potential of AI cannot be unlocked without first solving the industry's fundamental data challenges. The maxim "garbage in, garbage out" was a common refrain, with leaders stressing that robust data governance is no longer a technical concern for IT departments but a C-suite-level strategic priority.

During the session **"AI-Powered Healthcare: Unlocking Data, Accelerating Adoption, and Scaling Sustainable Innovation,"** survey data presented by **Oliver Richards, Managing Director at Accenture,** revealed the profound disconnect between data availability and accessibility. While healthcare generates vast amounts of data, a survey of 180 MedTech and provider executives found that providers' deep-seated concerns over patient privacy and a lack of trust are major barriers to sharing. **This point was** reinforced with a powerful statistic from the 2025 Future Health Index:

> *"More than 75% of healthcare professionals report losing clinical time due to incomplete or inaccessible patient data, with a third of them losing over 45 minutes per shift."*
>
> — **Julia Strandberg**, Chief Business Leader, Connected Care & Monitoring, Philips

This data fragmentation not only creates clinical inefficiencies but also starves AI models of the high-quality, diverse datasets required for training and validation. Speakers from Nvidia and Google Health emphasized that solutions like federated data networks and synthetic data generation are emerging to address these gaps, but the core challenge remains cultural and structural.

> *"Data is the currency of innovation going forward, full stop. The more data you have, the better you organize it. The quality of the data, how you organize it, the volume of it matters too, but the quality matters a lot. And then you take these data analytics tools like AI and you turn that data into information."*
>
> — **Geoff Martha**, Chairman and CEO, Medtronic

### 2.1.3. New Frontiers in Clinical Trials: The Rise of In Silico and Synthetic Evidence

One of the most promising applications of AI discussed was the reimagining of medical device development through computational modeling and in silico trials. The consensus was that traditional randomized controlled trials (RCTs) are often too slow, expensive, and ethically challenging for the pace of modern innovation, particularly for personalized and adaptive devices.

In the session **"Reimagining Device Development,"** panelists provided compelling real-world examples of this paradigm shift.

> *"Just recently, this year, we announced our leader trial, where we were able to take and cut the size of our clinical study from 2000 down to 500 based on virtual patients. And the key to that was actually how you integrate kind of these virtual patients into a statistical model."*
>
> — **Darrell Swenson**, Director, Engineering, Medtronic

This 75% reduction in trial size was presented not as a futuristic concept, but as a validated, FDA-accepted approach. Furthermore, **Marissa Ballesteros of Medidata** explained how synthetic data, generated from a historical database of over 36,000 trials, is being used to optimize protocols, improve recruitment, and reduce patient burden.

A critical application highlighted was the use of AI for patient selection; an existential issue for startups, where misidentifying responders can be catastrophic:

> *"There are numerous devices in the cardiovascular and other spaces that ultimately ended up having challenges in the clinic because they couldn't necessarily identify responders in advance of that procedure. That's terrifying for startups... those first patients, we did 10 of them, they might have cost us $100,000 apiece to get to that moment, maybe a quarter of a million apiece."*
>
> — **Daniel Hawkins**, Chief Executive Officer, Vista.ai

The discussion concluded with a bold prediction that regulatory agencies may soon begin to *expect*, if not require, the use of AI for patient selection to ensure trial efficiency and ethical conduct.

### 2.1.4. Sentiment Analysis

**Pragmatic Optimism:** The prevailing sentiment is one of pragmatic optimism. Leaders are highly confident in AI's transformative potential to solve systemic issues from healthcare worker burnout to surgical complications, but this enthusiasm is balanced by a sober recognition of significant barriers, including data governance, regulatory ambiguity for generative AI, and the immense challenge of organizational change management.

## 2.2. Navigating the Evolving Regulatory and Reimbursement Gauntlet

Market access remains the MedTech industry's most formidable challenge, a reality that dominated discussions across multiple sessions. The dialogue revealed a landscape of contrasts: while promising new collaborative pathways like CMS's TCET and global regulatory reliance are creating optimism, they exist alongside persistent, systemic dysfunction in both US and EU frameworks. The overarching narrative is one of determined pragmatism, as companies are forced to become increasingly sophisticated in navigating a complex patchwork of legislative uncertainties, outdated regulations, and evolving evidence requirements to bring innovation to patients.

### 2.2.1. The TCET Pathway in Practice: A Step Toward Predictability

CMS's Transitional Coverage for Emerging Technologies (TCET) pathway was a major focus, with early participants sharing valuable lessons. The program was widely praised for bringing much-needed predictability and collaboration to the national coverage determination (NCD) process. As **a key architect of the policy at CMS and now industry leader,** explained, the goal was to increase efficiency and transparency:

> *"The goals of TSET were to both increase the number of decisions that we could make each year, improve the predictability and transparency of the process so that all of the stakeholders would be better informed about exactly what CMS evidence expectations are, how to meet them, and the process for getting through to an NCD."*
>
> — **Steve Farmer**, Senior Partner, ABIG Health

Pilot companies lauded the program's collaborative nature. **Chris Brooks, VP, Market Access and Reimbursement, Impulse Dynamics,** noted that TCET is "absolutely very manageable for a small company," a critical validation for the startup ecosystem. However, significant implementation hurdles remain.

> *"We experienced many instances where Medicare Advantage plans misinterpreted the requirements of the coverage policy to think that participation in a study meant participation in a traditional trial, not a real-world data study."*
>
> — **Christine Song**, Senior Director, Global Health Economics and Reimbursement, Edwards Lifesciences

This highlights a critical need for broader education for providers and payers to ensure these innovative evidence development plans are not misinterpreted, which can lead to coverage denials and canceled cases.

### 2.2.2. Global Harmonization Gains Momentum

A strong sense of optimism emerged from discussions on global regulatory harmonization. Leaders from the FDA, UK's MHRA, and Brazil's ANVISA showcased tangible progress in streamlining cross-border approvals through reliance mechanisms. **Melissa Torres, Associate Director for International Affairs at FDA/CDRH,** reported that the International Medical Device Regulators Forum (IMDRF) has expanded dramatically, now including 29 affiliate members, fostering a broader collaborative environment.

A landmark development came with the announcement of a fundamental shift in the UK's post-Brexit strategy:

> *"We've therefore announced our intention to make recognition of CE marking indefinite in the UK... What we will then do is reinvent the specific UK market UKCA to be about an innovation-first market route rather than a duplication of CE."*
>
> — **Dr. Lawrence Tallon**, Chief Executive, Medicines and Healthcare Products Regulatory Agency (MHRA)

Furthermore, the UK is finalizing legislation to formally rely on approvals from the US, Australia, and Canada. This trend is mirrored in other regions. **Karen Noffs of Brazil's ANVISA** reported that in 2024, 64% of GMP certificates were issued based on MDSAP reports, demonstrating significant efficiency gains. This growing global consensus is reducing duplicative regulatory burdens and accelerating patient access to technology worldwide.

### 2.2.3. The PAMA and LDT Rollercoaster: Deep Uncertainty in US Diagnostics

While global harmonization showed promise, discussions in the **"D.C. Download"** town hall painted a starkly different picture for the U.S. diagnostics industry, which faces profound legislative and judicial uncertainty. The April 2025 federal court decision vacating the FDA's LDT rule was a seismic event. The ruling was not a procedural setback but a fundamental challenge to FDA's authority:

> *"The court said, no, you don't have the ability to enforce at all. You don't have the authority to enforce. Therefore, there is no such thing as enforcement discretion because you don't have the right to enforce."*
>
> — **Jamie Wolszon**, Associate Vice President, Technology & Regulatory Affairs, AdvaMed

This legal vacuum has renewed focus on legislative solutions like the VALID Act, though its path forward is unclear. Compounding this uncertainty are the persistent challenges with the Protecting Access to Medicare Act (PAMA). Efforts to reform PAMA through the Results Act are being stymied by what **Kim Zimmerman, Senior Vice President, Head of Federal Government Affairs, AdvaMed,** described as confounding changes in Congressional Budget Office (CBO) scoring, which has turned previously money-saving proposals into multi-billion-dollar costs. The ongoing government shutdown has only exacerbated the situation by halting all new FDA submissions and pausing critical policy work at CMS.

### 2.2.4. EU MDR/IVDR: A Glimmer of Hope Amidst Ongoing Challenges

Discussions on the EU's Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) revealed an industry still grappling with significant implementation burdens, though with optimism for future reforms. The most cited statisticwas the stark reality of the European market's loss of competitiveness:

> *"When we compare the timeline and how fast we can place a product on the market in the US compared to Europe, we are placing the product in the EU market four years after the US, which is definitely a challenge for patients in Europe to not have access to the last technology."*
>
> — **Michel Marboeuf**, Senior Director Regulatory Advocacy & Intelligence Global, Stryker

Panelists in **"MDR/IVDR Implementation – A Reason to Believe?"** highlighted that the clinical compliance piece—not notified body fees—represents the largest cost burden, disproportionately affecting the 90% of European manufacturers that are SMEs. However, a significant reason for optimism is the forthcoming reform proposal from the European Commission. **Petra Zoellner of MedTech Europe** announced that a proposal aimed at simplification and reducing administrative burden is expected within two months, signaling that regulators have acknowledged the system's shortcomings.

### 2.2.5. Sentiment Analysis

**Determined Pragmatism:** The overall sentiment is one of determined pragmatism. While there is palpable frustration with systemic inefficiencies and political gridlock, particularly in the US diagnostics and EU regulatory spaces, there is also a clear sense of optimism about new, collaborative pathways like TCET and global reliance. Leaders recognize that success requires

sophisticated, multi-pronged strategies and sustained advocacy, and they are actively engaging with regulators to co-create more functional frameworks for the future.

## 2.3. The Ascendancy of the Patient Voice in Value Creation

The MedTech Conference 2025 marked a definitive shift in the role of the patient, moving from a passive recipient of care to an active and essential partner in the innovation lifecycle. Discussions across multiple sessions underscored a growing consensus that patient-centricity is no longer a "nice-to-have" corporate initiative but a core driver of commercial success, regulatory approval, and market access. The dialogue has matured beyond simply "listening to patients" to a more sophisticated understanding of *how* to systematically integrate the patient voice as a form of rigorous evidence. Three dominant narratives emerged: the evolution of patient preference data into a scientifically credible tool, the strategic imperative of forging authentic, co-creative alliances with advocacy groups, and the tangible ROI of human-centered design that extends far beyond user satisfaction.

### 2.3.1. From Anecdote to Evidence: The Scientific Rigor of Patient Preference

A central theme was the formalization of the patient voice into quantifiable, regulatory-grade evidence. Speakers in the session **"Turning HTA on its Head"** went to great lengths to differentiate methodologically rigorous Patient Preference Information (PPI) from simple satisfaction surveys. The discussion highlighted that generating credible PPI is a complex, scientific endeavor rooted in economic theory.

> *"Dan McFadden, Nobel Prize winner in 2000, was the guy who came up with the random utility theory that goes into a lot of health preference research. DCE [Discrete Choice Experiment] is extremely robust in terms of the scientific rigor that goes into it. Patient preferences are not a survey monkey. You're not just putting out a Likert scale."*
>
> — **Barry Liden**, Director of Public Policy, USC Schaeffer Center

This scientific rigor is proving critical for gaining traction with Health Technology Assessment (HTA) bodies and payers. While payers make coverage decisions based on safety and efficacy, patient preference data is becoming a powerful tool for initiating technology reviews and, crucially, predicting real-world outcomes. She highlighted the direct link between what patients prefer and what they will actually adhere to, which is a primary concern for payers.

> *"One of the largest gaps between good treatment plans and outcomes is patient compliance and patient engagement. And that's very much driven by patient preference. You can have a technology that in a controlled clinical trial produces fabulous outcomes. And if patients hate it...you're not going to get those same outcomes in the real world."*

> — **Anna Wetherbee**, Director, Strategic Planning & Performance, Blue Shield of California

This reframes patient preference not as a "soft" metric but as a predictive indicator of real-world effectiveness and, by extension, economic value. The conversation demonstrated that the industry is learning to translate patient desires—like faster recovery or less invasive procedures—into the hard economic outcomes that payers value, such as reduced post-acute care costs.

### 2.3.2. Forging Authentic Alliances: The Shift from Sponsorship to Co-Creation

The conference highlighted a clear evolution in the relationship between industry and Patient Advocacy Groups (PAGs), moving from transactional sponsorships to deep, strategic partnerships. The session **"Forging Alliances"** provided a powerful case study in the successful campaign to secure appropriate CMS reimbursement for Alzheimer's biomarker tests, which would have been impossible without a coordinated, multi-stakeholder effort.

**Jennifer Pollack of the Alzheimer's Association** and **Cassie Ricci of Roche Diagnostics** detailed how their organizations, alongside AdvaMed, presented a unified voice to CMS. This collaboration was not a last-minute appeal but the result of a long-term, trust-based relationship. Panelists stressed that the most effective alliances are built on a foundation of shared purpose, not short-term projects.

> *"You should start with a purpose, not a project. Our purpose is how we can reach these communities, how we can help diagnose earlier in the disease, rather than I have this one test and now I'm going to do the things I need just for this test."*
>
> — **Jennifer Pollack**, Director, Access Policy, Alzheimer's Association

Authenticity was a recurring keyword. In the session **"Driving Payer Coverage Decisions," Lee Fleisher, former CMS Chief Medical Officer,** provided a candid view from the payer side, warning that advocacy heavily funded by industry is often discounted. He emphasized the critical importance of identifying and empowering independent, trusted patient voices.

> *"When we see certain patient advocate groups come to us, we try to understand who's supporting that patient advocate. Like 95% is coming from pharma, that is discounted. Finding those patient advocate groups...that are really the trusted voice of the patient is really important."*
>
> — **Lee Fleisher**, Principal and Founder, Rubrum Advising

This underscores the need for industry to foster genuine, long-term partnerships where patient groups are treated as expert equals, not as marketing channels.

### 2.3.3. Human-Centered Design as a Competitive Differentiator and ROI Driver

The conversation around patient-centricity extended deep into product development, with the session **"From Device to Experience"** exploring how human-centered design (HCD) has become a powerful driver of both patient outcomes and business value. Panelists argued that the focus must expand beyond just the patient to include the entire ecosystem of users—nurses, sterilization staff, and family caregivers—as any one of them can be a barrier to adoption.

> *"In diabetes, patient choice is really at the forefront. It's not your healthcare provider necessarily saying this is what you'll use. Patients are coming in and looking at an array of options and they're choosing."*
>
> — **Madison Smith**, Therapy Chief Engineer, Smart MDI Systems, Medtronic

This power of choice means that intuitive, lifestyle-integrated design is no longer a luxury but a competitive necessity. The session provided tangible examples of how good design translates to ROI. **Madison Smith** explained that intuitive devices reduce the need for costly training and support calls. **Josh Makower of Stanford Biodesign** provided a powerful anecdote about quantifying the value of a design choice to a skeptical commercial team, demonstrating how a seemingly small decision about a training needle had a net present value of $32 million.

A crucial insight was the need to observe user behavior rather than just listen to user requests. **Amy Kerdok, a consultant with experience at Intuitive Surgical,** emphasized that watching how users "hack" or modify their devices reveals unmet needs far more effectively than focus groups. This deep, empathetic observation, conducted by cross-functional teams, is the cornerstone of breakthrough innovation.

### 2.3.4. Sentiment Analysis

**Empowerment and Validation:** There was a strong, palpable sense of empowerment and validation among patient advocates and design leaders. The dialogue has clearly shifted from "why should we listen to patients?" to "how can we best integrate patient insights to drive value?" The increasing adoption of rigorous methodologies for PPI and the tangible successes of patient-led advocacy campaigns have given the patient voice a new level of credibility and influence within the industry. This has fostered a sense of optimism that patient-centricity is finally becoming institutionalized as a core business practice.

## 2.4. Global Strategy in an Era of Geopolitical Risk and Regionalization

Discussions at The MedTech Conference 2025 painted a picture of a global landscape in flux, forcing a fundamental reassessment of international strategy. The era of straightforward globalization, characterized by centralized manufacturing and sequential market rollouts, is over. In its place is a more complex, multipolar world defined by geopolitical tensions, regional trade blocs, and the strategic necessity of supply chain resilience. The sessions revealed that leading MedTech companies are no longer treating international markets as secondary extensions of their US or EU operations. Instead, they are adopting sophisticated, region-specific strategies that balance local manufacturing and innovation with global scale. Key themes included the strategic recalibration of engagement with China, the emergence of new innovation and regulatory hubs in Asia, and the urgent, board-level focus on building resilient, adaptable supply chains.

### 2.4.1. The "China Plus One" Reality: Rebalancing, Not Retreating

The dialogue around China has matured significantly, moving from a narrative of unbridled growth to one of strategic rebalancing. While acknowledging the immense and growing market opportunity, leaders in the session **"China From the General Manager Lens"** spoke candidly about the challenges of volume-based procurement (VBP), rising local competition, and geopolitical headwinds. The consensus was not to retreat from China, but to evolve the model from "importing innovation" to building end-to-end local capabilities.

It was emphasized that the fundamental market drivers remain powerful, making a long-term commitment essential:

> *"When I look at the Chinese market, I think the fundamentals remain quite powerful. The business case that supports a long-term view for China stays. When you look at the demographics, epidemiology in terms of the aging population... that's a tailwind that's going to stay."*
>
> — **June Chang**, President of Greater China, Boston Scientific Corporation

However, success now requires a "China for China" approach, which includes local R&D and manufacturing. This is no longer just a strategy for cost reduction but a necessity for market

access. As **Iris Lin, Head of JAPAC at QuidelOrtho,** explained, localization is now a prerequisite for participating in government tenders. Furthermore, speakers warned that local Chinese competitors are no longer just "fast followers." With over 80% of new NMPA device approvals now going to local players, these companies are becoming global innovators themselves.

> *"If we don't commit ourselves to this market, my worry is that the locals will get stronger and will get scaled up faster. Ceding the market over to those local competitions might mean that they get scaled up quickly and that they might turn back and compete with us even more globally."*
>
> — **June Chang**, President of Greater China, Boston Scientific Corporation

This sentiment was echoed in **"Emerging Geopolitical Risks,"** where panelists described the strategic "rebalancing" of supply chains—diversifying away from sole reliance on China while still serving its massive domestic market.

### 2.4.2. The Rise of APAC Innovation Hubs: Singapore and Japan as Strategic Gateways

A significant shift in global strategy is the recognition of Asia-Pacific (APAC) countries not just as end-markets, but as strategic hubs for innovation, manufacturing, and regional regulatory access. The sessions **"From Manufacturing to Innovation: Asia's Untapped Opportunities"** and **"Japan's Medical Device Landscape Progress"** showcased how Singapore and Japan have become critical gateways to the broader region.

**Cindy Koh of the Singapore Economic Development Board (EDB)** highlighted that Singapore's MedTech manufacturing output has tripled to $15 billion over the last decade. More importantly, Singapore's regulatory body, the Health Sciences Authority (HSA), has established mutual reliance programs with neighboring countries.

> *"Once you get an HSA approval actually, you're not just talking about 6 million; we are talking about more than 270 million population size and hopefully, with that, it will get the industry to reconsider filings into Singapore as a first stop for the medical device authorities."*
>
> — **Dr. Raymond Chua**, Chief Executive Officer, Health Sciences Authority

Similarly, Japan was presented as a highly attractive and predictable market. Its universal health insurance system provides clear reimbursement pathways, and its regulatory agency, the PMDA, offers predictable review timelines and multiple fast-track options. The recent opening of a PMDA office in Washington, D.C., as detailed by **Akihiro Ishiguro, Head of PMDA Washington, D.C. Office, PMDA,** further signals Japan's commitment to global collaboration and supporting foreign companies entering its market. This evolution is changing the traditional go-to-market sequence.

> *"Go back 10 or 15 years ago, there was a pretty well-trodden pathway of going to Europe first, getting your CE mark... and then figuring out the rest of the world. It's a totally different mindset now."*
>
> — **Chas McKhann**, Board Director, Exagen Inc.

### 2.4.3. Supply Chain Resilience as a Non-Negotiable Imperative

The fragility of global supply chains, exposed by the pandemic and exacerbated by geopolitical events, has elevated supply chain resilience from an operational concern to a C-suite and board-level strategic imperative. In the session **"Emerging Geopolitical Risks & Cross-Border Supply Chain Uncertainty,"** leaders from Medtronic, Baxter, and Roche Diagnostics and Integer Holdings shared strategies for navigating this new reality.

A key theme was the shift from single-sourcing and just-in-time inventory to multi-sourcing and risk-based inventory management. **Sejla Holland, Chief Procurement Officer, Planning and Strategy at Baxter,** described how her company now segments its 40,000+ products based on their criticality to healthcare, applying different safety stock levels to protect the most essential supplies. This move reflects a broader industry recognition that resilience is non-negotiable.

Panelists emphasized that true resilience requires end-to-end visibility and horizontal integration across the value stream. Panelists also stressed the need to understand risks not just with tier-1 suppliers, but across the entire multi-tier supply network. This requires new digital tools and a cultural shift toward cross-functional collaboration. The discussion also highlighted the critical importance of master data governance as the foundation for any advanced supply chain system.

> *"Master Data. The relevance of Master Data... Whether it's AI, whether it's machine learning, whatever it might be, if your data is not right, the blood in your body's corrupt, you have trouble in the decathlon."*
>
> — **Greg Smith**, EVP Enterprise Operations, Medtronic

### 2.4.4. Sentiment Analysis

**Calculated Urgency:** The sentiment was one of calculated urgency. Leaders conveyed a clear understanding that the global landscape has fundamentally and irrevocably changed. The era of complacency is over, and there is a strong sense that companies must act decisively to restructure their global strategies and supply chains. This urgency is not panicked, but rather a strategic recognition that proactive adaptation is essential for long-term survival and competitiveness in a more fragmented and unpredictable world.

## 2.5. Building the Digital Backbone: Data, Interoperability, and Connected Care

The vision of a fully connected healthcare ecosystem—where data flows seamlessly from wearable sensors in the home to integrated systems in the hospital—was a central and recurring theme at the conference. Discussions highlighted the immense potential of digital health to improve patient outcomes, enhance clinical efficiency, and enable new care models like Hospital at Home. However, the dialogue was firmly grounded in the formidable structural barriers that continue to impede this vision. The prevailing sentiment was one of impatient optimism: while the technological building blocks are largely in place, the industry is still grappling with the foundational challenges of data governance, system interoperability, and misaligned financial incentives.

### 2.5.1. The Interoperability Impasse: A Persistent Barrier to Progress

Despite years of industry effort, the lack of interoperability remains the single greatest obstacle to scaling connected care. This was starkly illustrated in the session **"Interoperability, Integration and Interpretation,"** where a survey of 180 executives revealed a critical disconnect:

> *"According to medtech executives, top adoption challenges for health care providers includes lack of interoperability with EHR (45%), data privacy and security (32%), and integration with existing workflows (31%)."*
>
> — **Ryder Riess**, Principal, Deloitte

Panelists described the current state as a "messy" patchwork of siloed systems, where valuable data remains trapped and inaccessible. **Julia Strandberg of Philips Healthcare** noted that this fragmentation has a direct impact on clinical efficiency, with a recent study showing over a third of healthcare professionals losing more than 45 minutes per shift due to inaccessible data.

The solution, speakers agreed, lies in a combination of industry-led standards development and the strategic adoption of integrated platforms. **Julia Strandberg** highlighted Philips' work with IEEE on a new "Service Device Connectivity" standard, akin to HL7 FHIR but specifically for medical devices. Simultaneously, health systems are increasingly favoring "mega-vendors" like Epic and Microsoft, whose integrated platforms simplify connectivity. As **Maria Liu, Director of Data Governance and Interoperability at Sharp HealthCare,** explained, this platform consolidation is accelerating the adoption of connected care applications by reducing the integration burden for both providers and MedTech companies.

### 2.5.2. From Wearables to Clinical-Grade Monitoring: The Consumerization of HealthTech

The line between consumer wellness devices and regulated medical technology is rapidly blurring, creating both opportunities and regulatory challenges. In **"The Future of Healthtech and Wearables,"** leaders from Apple, Dexcom, Oura, and Nanowear showcased a future where continuous, real-world data from wearables becomes a cornerstone of clinical care.

A key trend is the convergence of different data streams through strategic partnerships. **Ricky Bloomfield, Chief Medical Officer at Oura,** described a collaboration with Dexcom that allows users to see their continuous glucose monitoring (CGM) data within the Oura app, enabling them to directly correlate lifestyle factors like sleep and activity with their metabolic health. He shared a personal anecdote that illustrated the power of this integration for driving behavioral change:

> *"I learned so much in the first week just by looking at what I put into my mouth, how that impacted my glucose. Eating late is not good for you because your body's still digesting that food well after you're asleep, and what that does is it keeps your resting heart rate much higher, which impacts your ability to have deep sleep."*
>
> — **Ricky Bloomfield**, Chief Medical Officer, ŌURA

However, this rapid innovation is also creating regulatory friction. **Venk Varadan, CEO of Nanowear,** pointedly referenced the FDA's recent warning letter to Whoop regarding its blood pressure monitoring claims, signaling stricter enforcement. This underscores the need for companies to proactively engage with regulators. **David Amor from Apple** described his company's approach as defining the intended use first, then determining the appropriate regulatory pathway, a strategy that has allowed them to successfully bring features like hypertension notifications to market with FDA clearance.

### 2.5.3. The Hospital at Home Model: A Promising but Fragile Frontier

The Hospital at Home model, born out of necessity during the COVID-19 pandemic, was presented as a transformative opportunity to deliver acute-level care more effectively and equitably. In the session **"Hospital at Home," Lee Fleisher, former CMS official,** recounted how the emergency waiver was created in just seven days to address looming hospital capacity shortages. The model has since proven its clinical value, with providers like **Marybeth McMahon of Christiana Care** reporting high patient satisfaction and improved outcomes, especially for conditions like dementia where the home environment is less disruptive.

Despite its success, the model's future is precarious. The CMS waiver is currently suspended due to the government shutdown, highlighting its fragile regulatory foundationand suggesting the industry needs long-term policy certainty to justify investment:

> *"The certainty around payment reimbursement, whatever that is, is absolutely necessary in any way that we move forward... We really have to get clarity to truly*

*encourage the folks who are doing this on the ground to have that certainty in adopting these models and putting that investment up front."*

— **Amanda von Leer**, Vice President, Global Government Affairs & Policy, Resmed

Furthermore, panelists identified significant logistical and technological gaps that are hindering scalability. **Maulik Majmudar, Chief Medical Officer at Biofourmis,** described the "dirty secret" that hospitals are reluctant to scale these programs when their inpatient bed capacity drops below 90%, due to financial disincentives. He also highlighted the need for an "Uber model" for coordinating in-home services to avoid logistical chaos. These challenges underscore that realizing the full potential of Hospital at Home requires not just technological innovation but also fundamental reform of payment models and care delivery logistics.

### 2.5.4. Sentiment Analysis

**Impatient Optimism:** The sentiment is one of strong optimism about the transformative potential of a fully connected digital health ecosystem, but this is coupled with a deep-seated impatience regarding the slow pace of structural change. Leaders are confident that the technology is ready, but are acutely aware that overcoming entrenched barriers like data silos, misaligned payment models, and regulatory inertia requires a level of industry-wide collaboration and will that has yet to fully materialize.

## 2.6. The Shifting Capital Landscape: M&A, Investment, and Public Market Dynamics

Discussions on the MedTech capital markets at the conference painted a picture of an industry in a state of cautious recalibration. After an unprecedented three-year IPO drought and a period of intense macroeconomic pressure, a fragile sense of optimism is returning. However, the landscape has been fundamentally altered. The bar for both public offerings and strategic acquisitions has been raised significantly, and the venture capital ecosystem has consolidated, creating a funding gap for many early-stage companies. In response, the industry is embracing a new era of financial creativity, with alternative funding models, strategic partnerships, and a renewed focus on capital efficiency becoming essential for survival and success.

### 2.6.1. The Post-Drought IPO and M&A Outlook: A Selectively Open Window

The most significant market signal discussed was the partial reopening of the IPO window after a complete shutdown from October 2021 to October 2024. While the eight MedTech IPOs in the past year were seen as a positive sign, panelists in **"Forecasting MedTech"** and **"MedTech M&A 2025"** were quick to temper expectations. The market is "selectively open" at best.

> *"What you really have right now in the IPO marketplace, there's only about 12 people buying these deals. It sounds insane, but I'm telling you, there's about 12 to 15 people looking at device IPOs. That's just not enough people to build a syndicate."*
>
> — **David Lewis**, Founder and Managing Partner, Gilmartin Capital

This has dramatically raised the bar for companies aspiring to go public. The old benchmark of $50-80 million in revenue is no longer sufficient; investors now demand greater scale, multiple quarters of predictable growth, and a clear path to profitability. The focus has shifted from "growth at all costs" to demonstrating a "profitable algorithm," as **David Lewis** termed it—a clear model for achieving operating leverage.

On the M&A front, strategics remain active but are also more discerning. **Jennifer Kozak of Johnson & Johnson** and **Chris Eso of Medtronic** both emphasized a disciplined focus on high-growth areas like cardiovascular, robotics, and digital solutions. Despite the challenges, M&A remains the dominant exit path, accounting for approximately 90% of MedTech exits, a statistic highlighted by **Zack Scott of Norwest.**

### 2.6.2. The Art of Early-Stage Fundraising: Navigating a Consolidated VC Landscape

For early-stage companies, the fundraising environment is more challenging than ever. Panelists in **"Dos and Don'ts of Fundraising"** and **"Finding the Right Match"** described a venture landscape that has consolidated around large, multi-billion-dollar funds. This creates a structural problem:

> *"With all the capital being at the large VCs, they need to write very big checks and they need exits of say 1 to 2 billion dollars, which puts all of us who are innovating in companies that would sell for say less than $500 million in a tough spot because there's not a ton of capital to invest in us."*
>
> — **Adam Rosenwach**, Partner and Chief Business Officer, Coridea

In this environment, the "dos and don'ts" of fundraising have become even more critical. The consensus was unequivocal: **cold outreach is dead. Andrew El Bardissi of Deerfield Management** stated that his firm receives five cold emails a day, making warm introductions through a trusted network (such as clinical advisors or portfolio company CEOs) the only reliable way to get a meeting.

Furthermore, entrepreneurs were advised to prioritize clean terms and the right partners over chasing the highest valuation. As **Justin Klein of Vensana Capital** warned, "ugly terms that can misalign your current investors, your new investors, your future investors, [and] your management team" create long-term damage that far outweighs a short-term valuation bump.

### 2.6.3. Creative Deal Structures and Alternative Funding Models

In response to the early-stage funding gap, the industry is seeing a surge in creative financing structures and alternative capital sources. The sessions highlighted three key models:

1. **Build-to-Buy and Strategic Partnerships:** Large strategics are engaging with startups earlier through structured partnerships that de-risk innovation. **Jennifer Kozak** described how Johnson & Johnson uses "build-to-buy" structures to invest in and co-develop technology over time, ensuring it meets their specifications before a full acquisition.

2. **Private Equity as a Strategic Partner:** Private equity is no longer just a buyer of mature, profitable assets. **Chris Eso of Medtronic** detailed an innovative partnership with Blackstone, where the private equity firm funds specific R&D programs within Medtronic in exchange for future royalties. This allows Medtronic to pursue more innovation without an immediate P&L impact.

3. **Health System Venture Arms:** Institutions like Mayo Clinic are becoming active investors and even company creators. As **Nir Goldenberg of Mayo Clinic Ventures** described, their "Practice Transformation Ventures" initiative identifies unmet clinical needs from their own physicians and builds companies to solve them, often without pre-existing IP.

These models represent a fundamental shift toward more collaborative, risk-sharing approaches to innovation, providing new lifelines for early-stage companies.

### 2.6.4. Sentiment Analysis

**Cautious Resilience:** The sentiment is one of cautious resilience. While acknowledging the harsh realities of a consolidated venture market and a selective IPO window, leaders expressed

strong confidence in the underlying value of MedTech innovation. There is a clear belief that high-quality companies with strong clinical data, clear market needs, and disciplined execution will always find capital. The industry has weathered such cycles before, and the current environment is seen as a forcing function for greater creativity, collaboration, and financial discipline.

# 3. Opportunities and Challenges

The MedTech Conference 2025 highlighted a landscape of significant transformation, presenting both remarkable opportunities and ongoing systemic challenges. While rapid technological advancements in areas like AI, digital health, and robotics are opening new possibilities for patient care, the industry's full potential is hampered by structural hurdles in regulation, reimbursement, and data infrastructure. The following summarizes the main opportunities and challenges discussed, which are central to the MedTech narrative.

## 3.1. Key Opportunities

- **AI-Driven Efficiency and Clinical Excellence:** A clear and immediate opportunity lies in deploying AI to automate back-office functions (e.g., promotional review, supply chain management, regulatory documentation), which can unlock significant cost savings and free up human capital for higher-value work. Clinically, AI is enabling breakthroughs in diagnostic accuracy, personalized surgical planning (as seen with **Johnson & Johnson's** Monarch platform), and real-time patient monitoring that dramatically improves outcomes, such as the 80-90% rescue rates cited by **Katie Szyman of Masimo.**

- **Accelerated Innovation Through In Silico and Synthetic Trials:** The validation of computational modeling and synthetic data, exemplified by **Medtronic's** 75% reduction in clinical trial size, represents a paradigm shift in device development. This opportunity allows companies to de-risk innovation, reduce time-to-market, and explore therapies for underserved populations (e.g., pediatrics) where traditional RCTs are ethically or logistically prohibitive.

- **The Rise of Strategic, Value-Driven Partnerships:** The current capital-constrained environment is fostering an era of unprecedented collaboration. Opportunities abound for startups to engage in creative "build-to-buy" deals with strategics, for large companies to partner with private equity on R&D funding (like the **Medtronic-Blackstone** model), and for MedTech to collaborate with Big Tech on foundational platforms, shifting the industry from a competitive to an ecosystem mindset.

- **Global Market Expansion Through Regulatory Harmonization:** The momentum behind regulatory reliance and harmonization (e.g., IMDRF, MDSAP, UK's recognition of FDA approvals) is creating more efficient pathways for global market access. Companies can now leverage a single regulatory approval in a trusted jurisdiction like Singapore or Japan to gain expedited access to entire regions, representing a significant opportunity to scale internationally with reduced friction.

- **New Frontiers in Patient Care Delivery:** Emerging models like Hospital at Home and decentralized diagnostics are creating entirely new markets. Driven by patient demand for convenience and the need to alleviate pressure on traditional healthcare facilities, these models offer MedTech companies the opportunity to develop integrated technology platforms that support the entire continuum of care, from the hospital to the home.

## 3.2. Persistent Challenges

- **The Data and Interoperability Impasse:** The single most cited barrier to progress is the lack of a connected data backbone. Data remains siloed in incompatible EHRs, proprietary device ecosystems, and disparate hospital systems. Until industry-wide standards for data governance, security, and interoperability are established and adopted, the full potential of AI and connected care will remain unrealized.

- **Outdated Reimbursement and Regulatory Frameworks:** Payment and regulatory systems are struggling to keep pace with innovation. The ongoing uncertainty surrounding the FDA's LDT rule and CMS's PAMA reform for diagnostics, the temporary nature of the Hospital at Home waiver, and CMS's outdated policy of classifying software as an indirect expense all create significant commercial risk and stifle investment in breakthrough technologies. As **Robert Jarrin of Resmed** noted, this is a "huge, huge obstacle."

- **The Early-Stage Funding Gap:** The consolidation of venture capital into large funds seeking billion-dollar exits has created a "capital desert" for early-stage MedTech companies with viable but smaller-scale exit potential. This threatens the long-term innovation pipeline, as promising technologies may fail to secure the necessary funding to reach critical development milestones.

- **Navigating Geopolitical and Supply Chain Volatility:** The era of predictable, globalized supply chains is over. Companies now face a complex web of geopolitical risks, including tariffs, regional conflicts, and the strategic imperative to re-shore or near-shore manufacturing. Building resilient, agile, and regionalized supply chains is a capital-intensive and logistically complex challenge that has become a board-level priority.

- **The Change Management Imperative:** The technology itself is often not the hardest part of digital transformation; changing human behavior and organizational processes is. As highlighted in multiple sessions, successful AI adoption is a "change program" that requires C-suite sponsorship, extensive workforce upskilling, and a fundamental reimagining of clinical and operational workflows. Resistance to change remains a significant barrier to realizing the full value of new technologies.

# 4. Evolving Narratives

The MedTech Conference 2025 served as a pivotal platform, transforming industry discussions rather than merely showcasing existing ideas. A distinct progression in dialogue was evident throughout the sessions, shifting from abstract theories to practical applications, from isolated viewpoints to integrated ecosystem approaches, and from reactive solutions to proactive strategies. The conference was characterized by three significant narrative changes: the evolution of AI discussions from mere hype to practical implementation, the move from a US/EU-centric global strategy to a genuinely global-first mindset, and the intensification of partnership discussions from simple transactions to interdependent, ecosystem-driven collaborations.

## 4.1. From AI Hype to Pragmatic Implementation and ROI

The conversation around Artificial Intelligence has matured dramatically. In previous years, discussions often centered on the futuristic potential of AI. At MTC25, the narrative shifted decisively to the practical realities of implementation, governance, and measurable return on investment. The focus was less on "what AI could do" and more on "what AI *is doing* and *how* we are scaling it responsibly."

Leaders from companies like **GE HealthCare**, **Abbott**, and **Johnson & Johnson** in sessions such as **"Agents of Change"** and **"Beyond the Hype"** moved beyond conceptual discussions to showcase FDA-approved, market-ready AI products that are already impacting clinical workflows. The dialogue was replete with specific use cases—from automating promotional review to guiding robotic surgeries—grounded in tangible metrics. It was emphatically stated, the industry must "stop talking about technology" and start talking about outcomes:

> *“Nobody cares about investing 200 billion dollars in tech. What they care about is outcomes. Did you lower the labor cost of setting a patient up on therapy by 50%? We're not talking about tech, we're just increasing adherence to 87%.”*
>
> — **Mick Farrell**, Chairman & CEO, Resmed

This shift was also evident in the frank acknowledgment of AI's limitations and risks. Instead of glossing over challenges, panels delved into the complexities of data governance, the dangers of AI "hallucinations" (even with curated data), and the critical necessity of "human-in-the-loop" validation. The conversation has evolved from a purely technological one to a socio-technical one, where change management, workforce upskilling, and ethical governance are now considered co-equal pillars of a successful AI strategy.

## 4.2. From US/EU-First to Global-First Market Strategies

A second significant narrative shift was the re-evaluation of global market strategy. The long-standing, sequential approach—launch in Europe, then the US, then consider the "rest of the world"—was repeatedly declared obsolete. The dialogue has moved toward a more nuanced,

"global-first" mindset where international markets, particularly in the Asia-Pacific region, are considered primary strategic priorities from the outset.

The sessions **"From Manufacturing to Innovation: Asia's Untapped Opportunities"** and **"China From the General Manager Lens"** were emblematic of this shift. Speakers portrayed markets like Singapore and Japan not as secondary end-markets but as sophisticated regulatory and innovation hubs that serve as strategic gateways to a region of 270 million people. **Dr. Raymond Chua, CEO of Singapore's Health Sciences Authority,** made a compelling case for flipping the traditional launch sequence by highlighting the market access multiplier effect of a single HSA approval.

Simultaneously, the narrative around China has become more pragmatic and multifaceted. While acknowledging significant headwinds from VBP and local competition, leaders universally rejected the notion of retreat. Instead, the conversation focused on a deeper commitment to localization—"China for China"—and the strategic imperative of competing in what **June Chang of Boston Scientific** called a "fitness gym" for global operations. The narrative has evolved from viewing China as a simple growth market to seeing it as a complex, competitive arena where success is critical for maintaining global leadership. This pragmatic view was also reflected in supply chain discussions, where the strategy is now "rebalancing" and diversification, not wholesale decoupling.

## 4.3. From Transactional Relationships to Ecosystem Partnerships

Perhaps the most profound narrative evolution was the move away from discussing stakeholders in transactional terms (vendors, customers, sponsors) toward a vision of an interdependent "ecosystem." This was evident in conversations spanning M&A, regulatory affairs, patient engagement, and technology development.

In the financial realm, the dialogue in **"Beyond the Headlines"** shifted from traditional funding rounds to creative, collaborative structures like build-to-buy deals and co-development partnerships between strategics, health systems, and startups. **Nir Goldenberg of Mayo Clinic Ventures** spoke of "joint forces between health systems, investors, entrepreneurs, and physicians," framing innovation as a collective endeavor.

This ecosystem narrative was equally strong in technology discussions. In **"Health Tech Convergence,"** leaders from **Medtronic**, **Stryker**, and **NVIDIA** agreed that no single company can build the future of digital health alone. The conversation was about creating platforms and standards that enable others to innovate.

Finally, the relationship with patients has been reframed. The narrative in the **"Patient Engagement and Experience Summit"** moved beyond extracting "insights" to building authentic, co-creative partnerships. As **Cameron Kit, founder of You Own Your Own Stories,** emphasized, the goal is to tell stories *with* patients, not *about* them. This shift from a hierarchical to a collaborative model reflects a broader industry recognition that solving healthcare's most

complex challenges requires breaking down silos and fostering deep, trust-based partnerships across the entire ecosystem.

# 5. Strategic Recommendations

The insights gathered from The MedTech Conference 2025 translate into a clear set of strategic imperatives for leaders across the industry. The prevailing themes of AI integration, regulatory complexity, patient empowerment, and global rebalancing demand proactive and adaptive strategies. The following recommendations are tailored for key stakeholder groups—Technology and Innovation Leaders, Finance and Investment Leaders, and Regulatory and Policy Leaders—to help them navigate the evolving landscape and capitalize on emerging opportunities.

## 5.1. For Technology and Innovation Leaders (CTOs, CPOs, R&D Heads)

- **Prioritize Data Governance as a Foundational Prerequisite for AI.** The consensus is unequivocal: successful AI implementation is impossible without a clean, well-governed data infrastructure. Leaders must champion C-suite investment in breaking down internal data silos and establishing robust master data management frameworks. As emphasized in **"AI-Powered Healthcare,"** this is no longer just an IT issue but a core strategic enabler for all future innovation. A crucial first step is to **launch a cross-functional data governance initiative with executive sponsorship** to create a unified, enterprise-wide data strategy before attempting to scale further AI projects.

- **Adopt a "Human-in-the-Loop" and "Crawl-Walk-Run" Approach to AI Deployment.** Avoid the temptation of pursuing large-scale, fully autonomous AI systems from the outset. Instead, focus on augmenting human capabilities by **starting with deterministic, low-risk back-office applications** (e.g., promotional review, supply chain analysis) to build organizational confidence and demonstrate measurable ROI, as advised in **"The Era of Agents."** For all clinical AI tools, ensure a "human-in-the-loop" is maintained for validation, a non-negotiable step to ensure patient safety and build clinician trust.

- **Embed Human-Centered Design (HCD) and Patient Co-Creation into the Product Lifecycle.** Shift from treating patient feedback as a late-stage validation step to making it a core component of the initial design process. Establish dedicated, cross-functional teams responsible for the end-to-end user experience, as described in **"From Device to Experience."** An immediate, high-impact action is to **create a formal Patient Advisory Board with equity participation**, as suggested by **Heidi Dohse on “Driving Payer Coverage Decisions Through Collaborative Engagement”**, to provide continuous, authentic input from the earliest stages of development and ensure products are designed *with* patients, not just *for* them.

- **Embrace Open Platforms and Ecosystem Partnerships.** The future of digital health is collaborative, not proprietary. Technology leaders should shift their mindset from building closed, end-to-end solutions to creating platforms that can integrate with other devices and systems. **Actively seek partnerships with Big Tech for non-differentiating**

**infrastructure** (e.g., cloud, compute) to accelerate development and focus internal resources on core clinical innovation and unique value propositions.

## 5.2. For Finance and Investment Leaders (CFOs, VCs, Corporate Development)

- **Re-evaluate Investment Theses for a Consolidated Market.** With the VC landscape dominated by large funds and the IPO window remaining selectively open, investors must adapt. VCs should consider creating smaller, specialized funds for sub-$500M exit opportunities or focus on providing later-stage crossover capital. Corporate development leaders should **formalize "build-to-buy" and other creative partnership structures** to secure their innovation pipeline, as discussed in **"Beyond the Headlines,"** providing a clear pathway for both startups and strategics.

- **Prioritize Capital Efficiency and a Demonstrable "Profitable Algorithm."** In the current market, "growth at all costs" is no longer a viable strategy. Investors should demand clear evidence of strong unit economics and a scalable path to profitability. As **David Lewis of Gilmartin Capital** noted, the market will not tolerate businesses with a linear relationship between revenue and operating expenses. For portfolio companies, this means leadership must **enforce disciplined spending and require that every dollar invested be tied to a measurable value-inflection milestone.**

- **Incorporate Geopolitical and Supply Chain Risk into Due Diligence.** Investment and M&A models must be updated to account for the new realities of geopolitical instability and supply chain fragility. Due diligence processes must now **include a thorough assessment of a target's manufacturing footprint, supplier diversification strategy, and resilience to tariffs and regional conflicts** to provide a complete picture of long-term risk.

- **For Entrepreneurs: Prioritize Clean Terms and the Right Partners Over Valuation.** In a competitive fundraising environment, founders should recognize that the quality of their investor syndicate and the cleanliness of their term sheet are more critical for long-term success than a headline valuation. As advised in **"Dos and Don'ts of Fundraising,"** misaligned investors can destroy a company. Therefore, entrepreneurs should **conduct reverse due diligence on potential investors to ensure alignment on vision, timeline, and exit strategy** before accepting a term sheet.

## 5.3. For Regulatory and Policy Leaders (Heads of RA/QA, Government Affairs)

- **Engage Early and Collaboratively with Regulators.** The success stories from the TCET pathway and De Novo submissions all shared a common thread: early and frequent communication with regulatory agencies. Leaders should make it standard practice to **utilize pre-submission meetings and other informal channels to de-risk their regulatory strategies,** especially for novel technologies without precedent, thereby building a collaborative relationship with reviewers from the outset.

- **Build Multi-Stakeholder Coalitions to Drive Policy Change.** The successful Alzheimer's biomarker reimbursement campaign demonstrated that policy change requires a unified voice. Regulatory and government affairs teams must **proactively partner with patient advocacy groups and medical societies to build broad coalitions** that can effectively engage CMS and Congress on critical issues like PAMA reform and breakthrough device coverage.

- **Champion Global Harmonization and Leverage Reliance Pathways.** The momentum toward regulatory convergence is a significant opportunity to reduce costs and accelerate global market access. Regulatory teams should **designate a team member or small group to explicitly track developments in IMDRF and MDSAP, and to assess how to integrate reliance pathways into the company's global registration strategy**, ensuring the organization is prepared to capitalize on these efficiencies.

- **Develop a Proactive Stance on Cybersecurity Compliance.** With FDA's Section 524B turning cybersecurity guidance into law, compliance is no longer optional. Regulatory and quality teams must work together to **embed "security by design" into the product development lifecycle and establish robust post-market vulnerability management plans.** As discussed in **"Navigating the Regulatory Maze,"** cybersecurity should be framed internally and externally as a market differentiator, not just a compliance burden.