Medtech MVP – Venture & Partnering 2025

Conference Summary

Medtech MVP, *a Cambridge Healthtech Institute Event*

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Executive Overview

The Medtech MVP Venture & Partnering Conference explored how investors, operators, and healthcare stakeholders are navigating a more disciplined and complex environment for Medtech innovation and commercialization. Across sessions, speakers focused on the realities of bringing technologies to market, including higher expectations for clinical and economic evidence, evolving regulatory dynamics, and increased scrutiny from both investors and providers. Rather than rapid scaling or early exits, the emphasis was on building durable companies with clear value propositions, strong execution, and alignment across stakeholders.

Most Frequently Covered Issues

1. **Higher bar for commercialization and adoption**
   Clinical efficacy remains essential, but adoption increasingly depends on demonstrating economic value, operational efficiency, and alignment with provider constraints such as staffing and throughput.

2. **Extended timelines and capital requirements**
   Companies are staying private longer and must progress further into commercialization before attracting late-stage capital or exit opportunities, increasing the need for capital efficiency and strong syndicates.

3. **Reimbursement and market access as critical gating factors**
   Reimbursement has emerged as a primary determinant of success, often representing a greater hurdle than regulatory approval and requiring earlier, more proactive planning.

4. **Evolving investment and exit dynamics**
   The definition of "late stage" is shifting, with investors requiring greater de-risking, predictable revenue, and clear paths to scale, while companies increasingly pursue dual-track IPO and M&A strategies.

5. **Operational pressures within healthcare systems**
   Hospitals and care providers face significant staffing and capacity constraints, driving demand for technologies that improve productivity alongside clinical outcomes.

Recurring Takeaways

• Successful commercialization requires a multi-stakeholder value story that integrates clinical, economic, and operational benefits.
• Early and ongoing engagement with providers, payers, and investors improves adoption and reduces downstream risk.
• Discipline in execution, including realistic goal-setting and capital efficiency, is critical in a more selective funding environment.
• Strong culture, leadership, and decision-making speed remain key differentiators as companies scale.
• Technologies that improve productivity and fit within real-world healthcare constraints are more likely to achieve sustained success.

Successfully Scaling and Commercializing a New Medtech Product

Full Video Here

Panelists: Stacey Pugh, CEO, Endogenex (Moderator); **Jeff Peters**, OrbiMed; **Kathryn Dehn**, Fox Rothschild; **Mike Blue**, HistoSonics; **Darshana Zaveri**, Catalyst Health Ventures

The panel discussed how a more constrained funding environment is reshaping the path to commercialization. Fundraising timelines have extended, with fewer priced rounds and greater reliance on bridge financing. Investors are increasingly focused on revenue traction before committing capital, requiring companies to progress further into commercialization than in prior years. (00:02:42–00:03:19)

Early-stage investors are also adjusting their role, often supporting companies beyond initial expectations as exits take longer and capital at later stages becomes more selective. This shift is driving greater emphasis on building strong syndicates early, with the capacity to fund companies through initial commercial milestones. (00:03:40–00:05:16)

Panelists emphasized that commercialization introduces more complex decision-making, particularly around growth strategy, sales models, and exit pathways. Alignment across the board and investor group becomes critical, as differing expectations can create friction at a stage where capital deployment and strategic direction carry significant consequences. (00:06:05–00:07:49)

From an operational perspective, companies must balance investment in commercial capabilities with capital constraints. Early hiring of commercial teams can help validate demand and build investor confidence, but the approach depends heavily on product type, cost structure, and sales cycle. Clear assumptions around sales productivity and timelines are essential to avoid missteps in scaling. (00:09:09–00:12:17)

Reimbursement was highlighted as a key lever within company control, even as regulatory timelines remain uncertain. Establishing coding and payment pathways in advance, and supporting early adoption through reimbursement strategy, can strengthen commercial readiness and reduce barriers at launch. (00:20:38–00:23:01)

Key Takeaways

· Fundraising is taking longer, with greater emphasis on revenue before new capital is deployed.
· Early-stage investors are extending support further into commercialization.
· Syndicate strength and alignment are critical at the commercial stage.
· Commercial strategy must balance early investment with disciplined execution.

Proactive Compliance in the Age of FDA AI-based Submissions & Inspections

Full Video Here

Adam Foresman, Ryden Solutions

The presentation explored how regulatory oversight in Medtech is evolving, with increased complexity driven by both policy changes and the growing use of AI by regulators. Recent FDA announcements indicate that AI will be incorporated into premarket review processes and inspections, increasing the depth and speed of document and data evaluation. This shift, combined with ongoing global regulatory pressures such as EU MDR and emerging AI-specific requirements, is raising the bar for compliance across the industry. (00:01:10–00:02:25)

As regulatory expectations expand, companies face growing challenges in managing compliance across multiple regions and frameworks. The volume of applicable regulations, combined with the need to maintain alignment across quality systems, clinical data, and internal processes, makes manual approaches increasingly difficult to sustain. Organizations must ensure not only adherence to external requirements but also consistent execution of their own internal policies and procedures. (00:02:25–00:02:59)

The speaker emphasized the need for a more proactive approach to compliance, shifting from periodic audits to continuous monitoring. By integrating across quality management systems, clinical platforms, and document repositories, companies can assess compliance in real time, identify gaps, and respond more quickly to regulatory changes. This approach enables organizations to remain inspection-ready while reducing the time and cost associated with traditional compliance processes. (00:02:59–00:03:46)

Continuous compliance also supports global expansion by enabling companies to assess readiness for new markets and understand regulatory gaps across regions. Automated analysis of evolving standards and requirements allows teams to focus on remediation and strategic priorities, rather than manual tracking. As regulatory bodies increasingly adopt AI-driven review processes, aligning internal systems with this level of scrutiny will become essential for maintaining competitiveness and reducing risk. (00:03:46–00:04:53)

Key Takeaways

· Regulatory oversight is increasing, with AI accelerating review and inspection processes.
· Global compliance requirements are expanding, adding complexity across regions.
· Continuous monitoring can replace periodic audits and improve inspection readiness.
· Proactive compliance strategies help reduce cost, risk, and time to market.

Evaluating Medtech Innovation: How Providers Balance Clinical Value, Economics, and Adoption

Full Video Here

Panelists: Karen Ruszkoski, Volta Medical (Moderator); **Steven Manoukian, MD,** HCA Healthcare; **Lori Chmura,** Nyra Medical; **Andy Danielsen,** Mayo Clinic; **Scott Anseth,** Twin Cities Orthopedics

The panel explored how hospitals and ambulatory surgery centers evaluate new medical technologies, emphasizing that clinical efficacy remains the initial gate but is rarely sufficient on its own. Technologies are assessed not only for safety and effectiveness, but also for whether they represent incremental improvement or meaningful change in care delivery. Increasingly, secondary factors such as efficiency, procedure time, and resource utilization play a central role in adoption decisions. (00:08:07–00:09:29)

Panelists highlighted the importance of physician engagement in the evaluation process, while noting that adoption is rarely driven by a single stakeholder. Organizations often seek consensus among clinicians, supported by broader exposure to new technologies through trials, labs, and pilot programs. However, even when physicians recognize value, willingness to change established practices can remain a significant barrier. (00:06:47–00:07:50)

Economic considerations are central to decision-making, particularly as health systems balance rising demand with staffing shortages and infrastructure constraints. Administrators evaluate not only direct costs, but also downstream impacts such as throughput, length of stay, and overall resource utilization. In many cases, operational and financial benefits can outweigh purely clinical advantages, particularly when systems are under pressure to improve efficiency. (00:09:29–00:11:02)

From a commercialization perspective, panelists emphasized the need to build a comprehensive value story that addresses multiple stakeholders. Successful adoption requires aligning clinical data with economic and operational benefits, often tailored to each organization's priorities. Early engagement with providers, including participation in clinical trials and data generation, can help validate value and reduce barriers to adoption. (00:24:36–00:25:40)

Key Takeaways

· Clinical efficacy is necessary but must be paired with operational and economic value.
· Physician support is critical, but adoption requires alignment across multiple stakeholders.
· Efficiency, staffing, and throughput are increasingly important in decision-making.
· Early engagement with providers strengthens adoption and value validation.

Late-Stage Medtech Investment: Evolving Definitions, Higher Barriers, and Exit Strategy Tradeoffs

Full Video Here

Panelists: Jonathan Demchick, Gilmartin Capital (Moderator); **Jan Garfinkle,** Arboretum Ventures; **Kate Hobbs,** T. Rowe Price; **Jennie N. Xue,** Guggenheim Partners; **Joe Biller,** American Century

The panel examined how the definition of "late stage" in Medtech has shifted, with timelines extending as companies remain private longer and require greater de-risking before exit. While historically tied to proximity to IPO, late-stage companies are now often expected to demonstrate meaningful revenue, regulatory clarity, and a clear path to commercialization. As a result, companies that were once considered early commercial are increasingly viewed as still carrying early-stage risk. (00:01:29–00:03:09)

Despite macro uncertainty, including geopolitical risk, tariffs, and regulatory changes, panelists described the investment environment as largely stable, with continued focus on long-term fundamentals. Strategic buyers remain active, and M&A interest has persisted, though timelines and processes have become more complex. At the same time, uncertainty around regulatory agencies and reimbursement remains an ongoing area of concern, particularly as companies plan development and submission strategies. (00:06:47–00:10:00)

The discussion highlighted a higher bar for late-stage investment, particularly for companies targeting public markets. Investors are increasingly looking for strong revenue visibility, predictable growth, and clear pathways to scale. In many cases, this includes line of sight to $100 million in revenue and sustainable margins, along with the ability to consistently meet or exceed expectations. Companies that fail to demonstrate predictability or overpromise on performance risk losing investor confidence early. (00:17:40–00:20:40)

Panelists also emphasized the importance of maintaining flexibility in exit strategy, with many companies pursuing dual-track approaches across IPO and M&A. While IPOs offer long-term growth potential, they introduce greater scrutiny and ongoing performance pressure, making them a beginning rather than an endpoint. In contrast, M&A remains the more common path to liquidity, with increasing use of structured deals and earlier strategic engagement to manage risk and secure pipeline assets. (00:22:00–00:25:15)

Key Takeaways

· The definition of late stage is shifting, with greater emphasis on revenue and de-risking.
· Macro uncertainty has raised the bar but not slowed long-term investment activity.
· Public market investors expect predictable growth, scale, and disciplined execution.
· Maintaining flexibility across IPO and M&A pathways is critical to maximizing outcomes.

Advancing Women's Health: A New Approach to Managing Stress Urinary Incontinence

Full Video Here

Allison Watkins, Watkins-Conti Products

The presentation introduced a novel approach to addressing stress urinary incontinence (SUI), a condition affecting millions of women and often managed with absorbent products or surgical interventions. Despite available treatments, many women continue to rely on passive solutions that do not address the underlying issue, highlighting a gap in the continuum of care for non-invasive, user-controlled options. (00:00:02–00:01:14)

The speaker presented Yoni.Fit, a medical-grade silicone vaginal insert designed to prevent involuntary urine leakage during everyday activities. Positioned as an alternative to absorbent products and a complement to clinical interventions, the device allows for episodic or continuous use without interfering with normal function. Early user feedback emphasized ease of use, discretion, and meaningful improvements in quality of life. (00:01:14–00:02:25)

Clinical validation was a key focus, with results from blinded, sham-controlled trials demonstrating significant reductions in leakage and high patient-reported improvement. All participants in the study were successfully fit with the device, supporting its usability across a broad patient population. Physician feedback highlighted the simplicity of prescribing and the potential to expand treatment access across multiple provider types. (00:04:13–00:05:46)

The company is currently commercializing the product in the U.S., supported by established distribution channels, a clean FDA audit, and an expanding reimbursement strategy. With a growing product ecosystem and a strong intellectual property portfolio, the company is positioning itself for broader market adoption and future innovation within women's pelvic health. (00:08:41–00:10:15)

Key Takeaways

· Stress urinary incontinence remains underserved by existing non-invasive solutions.
· User-controlled devices can complement surgical and absorbent treatment options.
· Clinical data and physician adoption support broader accessibility and use.
· Early commercialization is focused on distribution, reimbursement, and product expansion.

Executive Insights on Leadership and Success

Full Video Here

Michael Mahoney, Boston Scientific; **Interviewed by: Justin Klein, MD, JD**, Vensana Capital

The discussion explored how sustained performance in Medtech requires consistent execution, disciplined communication with investors, and a long-term view of growth. Building credibility with shareholders is achieved over time through setting realistic expectations and consistently delivering against them. Maintaining financial discipline, even when pursuing acquisitions or new investments, reinforces trust and enables companies to balance short-term performance with long-term strategic growth. (00:01:53–00:03:06)

The speaker emphasized the importance of continuous reinvestment in innovation and portfolio development, particularly as companies scale. Rather than focusing solely on near-term results, leadership must prioritize future growth opportunities, often investing in initiatives that may not deliver returns for several years. This requires making deliberate tradeoffs across the business while maintaining a clear strategic direction. (00:05:56–00:08:04)

Organizational culture and decision-making were highlighted as critical differentiators. As companies grow, bureaucracy can slow progress, making it essential to actively simplify processes and empower leaders who are willing to make decisions and take calculated risks. Creating an environment where teams can share both successes and challenges openly supports better outcomes and stronger execution. (00:09:34–00:12:25)

From an industry perspective, the speaker pointed to productivity as an increasingly important factor in Medtech innovation. Beyond clinical efficacy, new technologies must address operational constraints within healthcare systems, including staffing shortages and capacity limitations. Solutions that improve efficiency and throughput, while maintaining strong clinical outcomes, are more likely to achieve broad adoption. (00:27:49–00:29:36)

Key Takeaways

· Credibility with investors is built through consistent execution and disciplined communication.
· Long-term growth requires ongoing investment beyond near-term financial performance.
· Culture and decision-making speed are critical to sustaining performance at scale.
· Productivity is becoming as important as clinical efficacy in driving adoption.