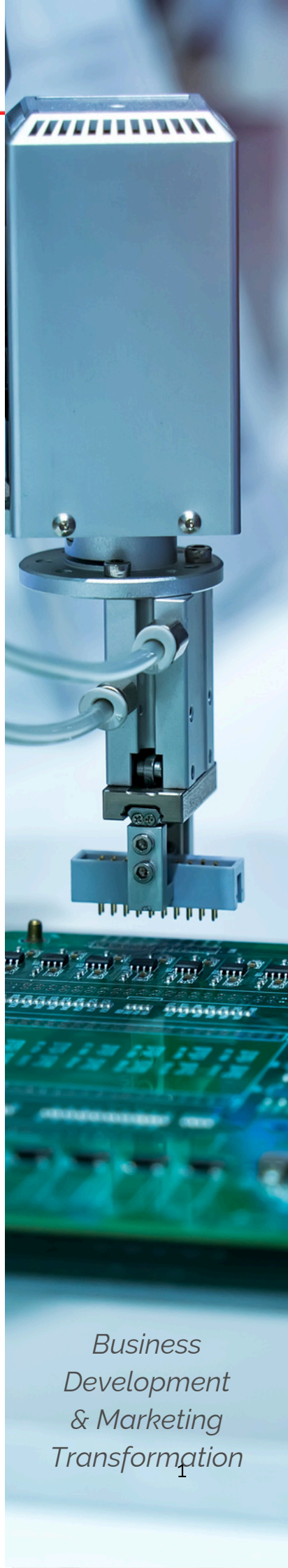
Building Market Credibility Pre-FDA: How 30+ KOL Interviews Shaped a Medical Robotics GTM Strategy

Leveraging Primary Research Across Integrators, Clinicians, Industry Leaders, and Others to De-Risk U.S. Entry



BDMT Global
TRANSFORM AND DRIVE DEMAND

Business Development & Marketing Transformation

Situation

Company X was a global innovator in medical robotics, built on over two decades of research, preparing to enter the U.S. market. The company had developed a novel platform designed for minimally invasive procedures and was seeking 510(k) FDA clearance, with U.S. commercialization on the horizon. While earning an award-winning status for its cutting-edge technology, the company lacked a comprehensive go-to-market (GTM) strategy and network within the complex U.S. healthcare ecosystem.

With a limited budget and no U.S. presence, the company faced a classic business dilemma: how to build market traction before having the clearance to sell.

Market Entry Barriers

The U.S. market for major medical devices offers the largest opportunity for global innovators, but it is also among the most complex to navigate. Device adoption is rarely driven by a single decision-maker; instead, it requires consensus across a diverse ecosystem of stakeholders, including clinicians, hospital administrators, value analysis teams, and billing managers.

New entrants must navigate this multi-layered decision-making process while building credibility from the ground up. Success demands not only clinical evidence but also a deep understanding of how these stakeholders interact and what motivates their choices.

Challenges

1. Lack of Brand Value and U.S. Ecosystem: With no U.S. presence, Company X had no established reputation or credibility with key opinion leaders (KOLs), hospital systems, or potential partners. The innovator was missing the local network needed for industry growth. Company X needed a stronger foothold in the U.S. medical innovation ecosystem to accelerate awareness and consideration.

2. Missing Market-Facing Assets: The company lacked essential materials to build trust, including summarized clinical and operational effectiveness evidence, patient and provider success stories, case studies, and KOL testimonials that could be leveraged for advocacy.

3. GTM Knowledge Gaps: The dedicated leadership team, while deeply committed to technical superiority and expertise in their home market, had limited experience with U.S. market commercialization, such as product marketing knowledge and strategic partnership development. They knew their technology, but not yet the intricate "who's who" and the "how" of the U.S. adoption pathway.

Company X initially planned to delay U.S. market engagement until after receiving FDA clearance, believing they had little to offer stakeholders without an approved product. BDMT Global advised otherwise: waiting would mean losing a critical 12-18 month window to build relationships, gather market fit feedback, and secure early adopters.

We recommended launching a pre-FDA stakeholder engagement campaign immediately, not to sell, but to listen, learn, and lay the groundwork for a faster commercial launch.

Deliverables

To address these challenges and prepare for a successful U.S. entry, BDMT Global delivered the following services:

1. Audited Gaps in Internal Capabilities: Assessed the company's internal strengths, team expertise, and existing resources to identify critical gaps and additional needs for U.S. market entry.

2. Mapped the U.S. Healthcare Ecosystem: Developed a comprehensive map of the regulatory requirements, reimbursement structures, and healthcare delivery settings in medical equipment purchasing.

3. Market Segment: Mapped the adoption drivers and barriers across clinical stakeholders, institutional decision-makers, and patients to tailor messaging and engagement strategies.

4. Assessed Competitive Dynamics: Analyzed current players, emerging technologies, and unmet needs in minimally invasive procedures to identify market opportunities and differentiation points.

5. Developed a Data-Driven GTM Strategy: Created a specific, actionable plan that includes recommendations for selecting partnerships and engaging early adopters across targeted geographic areas. The ultimate short-term goal was to build trust through clinical data, co-branding partnerships, and strategic alliances.

6. Executed Initial Stakeholder Engagements: Proactively began building relationships across the complex healthcare ecosystem to validate assumptions and gather real-world feedback well in advance of FDA clearance. The goal was not just to gather data, but to initiate the relationship-building process that would accelerate adoption once cleared.

Results & Outcomes

Through a structured primary research campaign, BDMT delivered in-depth interviews and GTM adjustment recommendations coming from more than 30 stakeholders across the U.S. healthcare ecosystem.

These were not passive information-gathering sessions; they were the first step in building a relationship pipeline. Conversations included clinicians, hospital administrators, industry influencers (including an executive who previously helped adopt a competing robotic platform), billing and coding experts, and potential service partners.

1. A Validated Market Map
BDMT's secondary and primary research provided a clear understanding of the reimbursement and decision-making processes for equipment procurement within both private practices and large hospital/health systems. This included insights into who holds budget authority, how value analysis committees function, and what clinical and economic evidence is required at each stage.

2. A Prioritized Engagement Roadmap
Leveraging BDMT's expertise in market entry sequencing, the team developed a detailed, phased GTM roadmap that lined up ecosystem targets in the optimal order. The roadmap answered a critical question: who should Company X talk to first, second, and third to build momentum efficiently with a limited budget? Company X now had a clear plan for which stakeholders to engage, what messages would resonate, and how to build credibility over time.

3. Actionable Partnership Opportunities
Utilizing interviews and BDMT's extensive network, we identified specific partnership pathways, including potential collaborations with resellers and service providers, and co-branding opportunities that would accelerate trust-building in the short term. These conversations began during the pre-FDA phase, meaning partnerships were already warming up before the product was approved.

4. Early Ecosystem Traction
The initial stakeholder engagements yielded real-world feedback that refined the company's value proposition and validated key assumptions, providing confidence and clarity as the team moved toward FDA clearance.

For example, a billion-dollar leader in the same space as Company X acknowledged that their innovation would be a game changer, meeting with them privately while also publicly sharing their impressions. Company X now has a group of U.S.-based stakeholders who are familiar with their technology and invested in their success, a critical asset that cannot be bought and can only be built over time.

By engaging 30+ stakeholders early, Company X achieved three goals simultaneously: they gathered critical market feedback, built authentic relationships, and established themselves as attentive partners rather than just another vendor waiting for FDA clearance. Once cleared, their GTM engine will not start from zero; it will resume conversations already in motion.

About BDMT Global

Founded in 2014, Business Development & Marketing Transformation (BDMT) Global is led by a group of award-winning commercialization experts with deep insights and know-how for market entry and expansion. BDMT combines outsourced business development (BD) and marketing expertise (MT) to help companies entering new markets, offering strategic go-to-market plans, business development, and full marketing execution services. The firm collaborates with innovators across industries, including manufacturing, technology, and life sciences, building trust-based relationships to connect innovative companies with the right stakeholders to achieve a faster impact.

Led by accredited investor and Managing Partner Suzy Im, BDMT drives growth through 100% customized programs, in addition to core services, such as 'MASS' (Market Approval Starter-Scaler) solutions for innovators seeking more rapid U.S. market entry and expansion, with seven key benefits, including funding.

The team aims to bring "tomorrow's innovation today" by bridging the gap and fast-tracking collaboration opportunities. To achieve this, the team leverages its strong network of industry leaders, including investors, C-suite executives, and influencers across the B2B and B2C sectors. BDMT's DAC (Digitization, Automation, and Cross-Industry Collaboration) movement was launched in 2023, with Mayo Clinic as the inaugural sponsor, and is a gateway to fostering collaboration between global innovators and U.S. stakeholders to solve critical market challenges.

Under DAC, BDMT enables one-stop destinations for partnership opportunities. In 2025, BDMT partnered with MEDevice Boston to launch the BDMT Global + MEDevice Boston Innovator Summit and Top Innovators Series, further expanding the DAC movement.

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