WHITE PAPER

Value and Access in MedTech: What It Is and Why It Matters

December 2023
By Arthi Chandran, John Hernandez, Brock Schroeder, Frederic Rupprecht, Stefan Seliger, James Jenkins, Jens Grueger, Meghna Eichelberger, Michel Hochstrasser, Srikant Vaidyanathan, Allena Goren DePaoli, Kristen Cook, and Monica Schwarm

Abstract

Value & Access (V&A) activities can add significant value for medical technology companies, helping to accelerate market uptake and revenues while minimizing risk along each step of the product lifecycle. To boost value creation significantly, medtech companies should align Value & Access with strategic goals, involve them in product innovation decisions, and promote healthy collaboration with other functions. Understanding, leveraging, and communicating the importance of Value & Access capabilities will be critical for long-term differentiation.

Commissioned by the Value & Access in Medtech Roundtable, BCG surveyed 86 senior market access executives from medtech companies across North America, Europe, and Asia in late 2022. The aim was to collect industry-level data for assessing the role of V&A across the industry. The data was then presented at a roundtable discussion, where participants shared their thoughts & experiences on how companies can get more from this important function.

Broadly defined, V&A activities focus on communicating the value of medtech products and services and ensuring broad and equitable access for the patients who need them. While patients, families and caregivers are the primary beneficiaries of these efforts, the broader health care ecosystem benefits as well. The gains are substantial: better health outcomes through improved mortality, morbidity, and quality of life; lower costs through more efficient and effective therapies resulting in fewer severe complications and long-term consequences. Not to mention the peace of mind that comes from knowing that there are appropriate technologies for diagnosing and treating people affected by diseases, accidents, and emergencies – including epidemics and pandemics.

Yet the medtech industry has not yet fully recognized the importance of V&A. At a time when digital and AI are increasingly important, care is shifting to lower acuity settings, and evidentiary requirements, payment models and coverage frameworks are evolving, the role of V&A professionals is more important than ever.

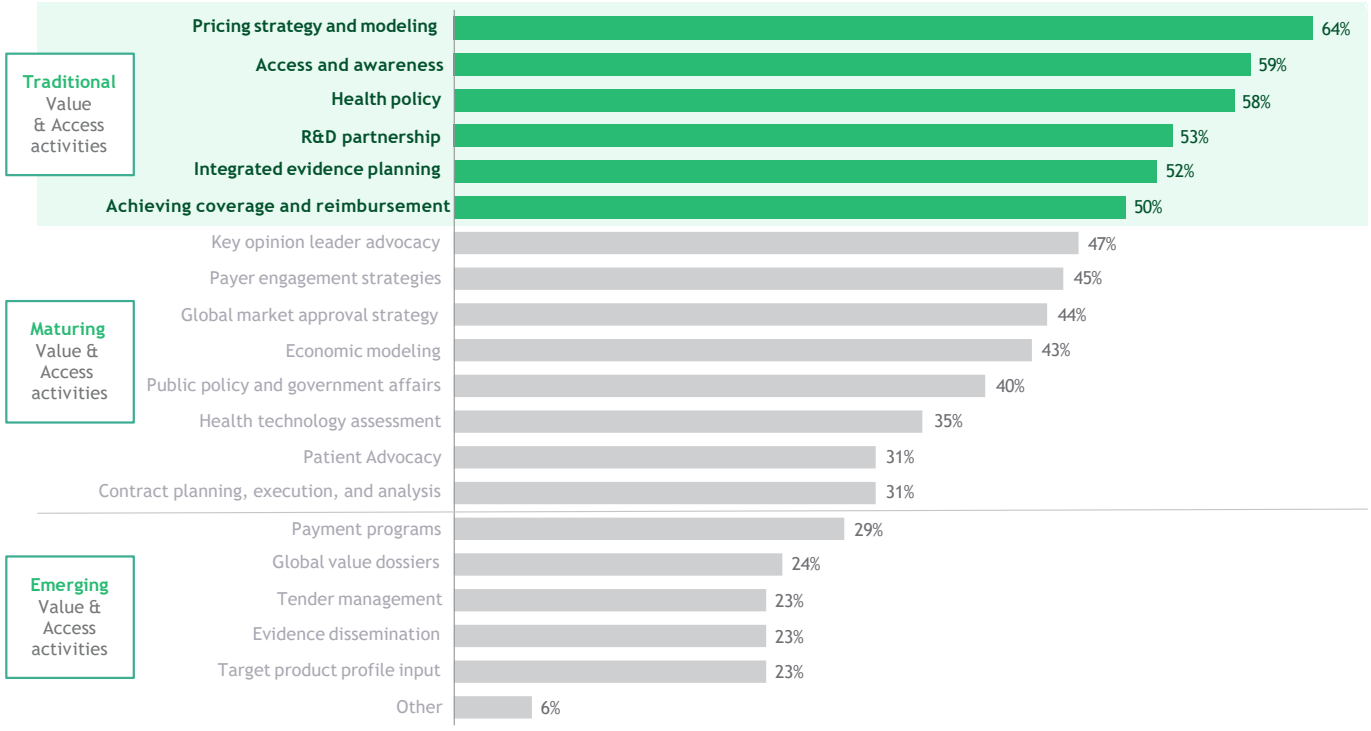
The Key V&A Challenges

V&A teams address many important issues, including health economics, evidence generation, reimbursement, health policy, health system strengthening, and health equity. These efforts are critical for novel products of high medical value, meaning offerings that leverage a new technology or provide a step-change in value over the current standard of care to patients, HCPs, and the health system.

The COVID-19 diagnostic tests offer a prime example. These products needed much more V&A effort than existing ones, requiring the approval of new reimbursement codes or for existing ones to be changed.

Despite the strategic importance of V&A, Medtech companies are inconsistent in how they organize and execute V&A activities. Activities pertaining to V&A tend to be spread across functions and geographies, often the result of how the company has evolved over time. While this has allowed for the specialization of skills, it has also limited general internal awareness and hampered V&A's strategic input—indeed, our survey found that the function is typically viewed as more technical than strategic. (See Exhibit 2).

Exhibit 1 - Activities Used to Define Value & Access



Q: In your experience as a professional in the MedTech industry, which of the following activities (i.e., the scope of work undertaken to get things done) do you typically find included under market access functions?

Source: BCG MedTech Market Access Landscape Survey, N=86.

Perhaps, then, it is not surprising that the survey also found that the job titles, scopes, and remits of V&A positions vary from company to company. (See Exhibit 2)

Exhibit 2 – Ten Medtech Companies, Ten Different V&A Job Titles

	Simplified Title	Geography	Experience (yrs)
1	Reimbursement	North America	>15
2	Public Affairs	Europe	>15
3	Access & Policy	Europe	>15
4	Health System Value Transformation	North America	5-9
5	Health Economics & Market Access	Global	>15
6	Global Regulations & Standards	North America	>15
7	Health Economics & Reimbursement	North America	>15
8	Health Economics and Outcomes Research	North America	>15
9	Quality	North America	>15
10	Business Excellence	Asia/Pacific	5-9

Source: Source: MedTech Market Access Landscape Survey, N=86

These inconsistencies can be attributed to the heterogenous nature of the medtech industry: companies develop a wide range of technologies, from large capital equipment to consumer-facing devices to implantable technologies to diagnostic tools, each of which targets a different audience, with different access needs.

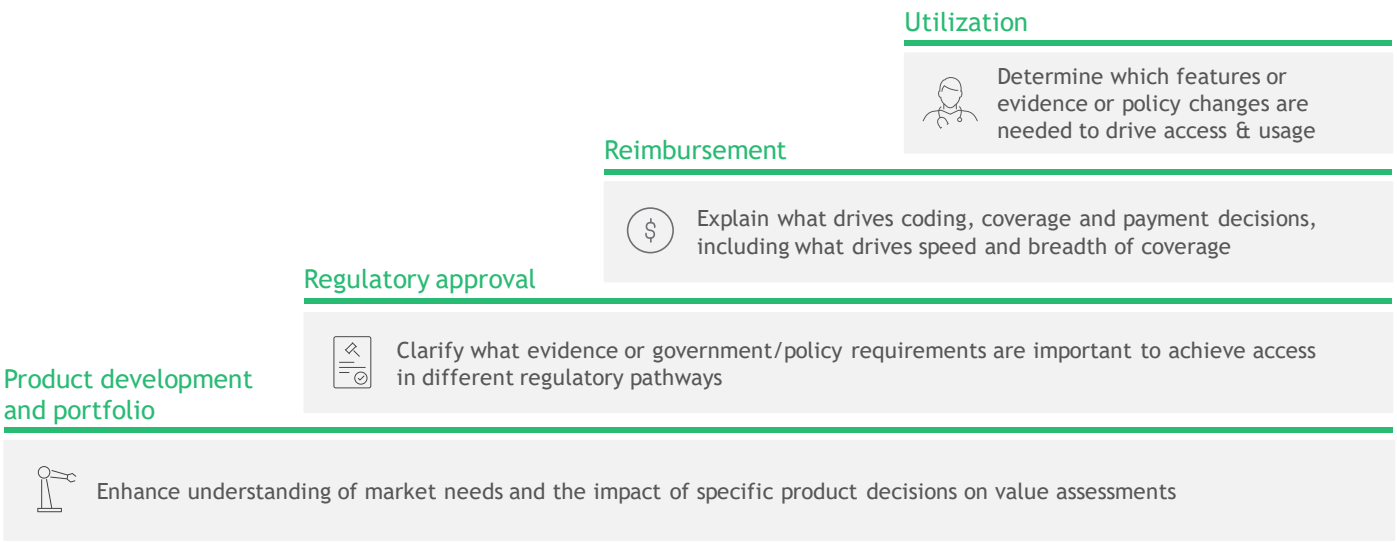
Another challenge is that V&A considerations enter the product lifecycle too late, if at all, which can impede launch success and market adoption. Too often, medical devices are developed, business cases are created, and evidence strategies are designed with limited input from V&A professionals.

These issues have the potential to cause multiple problems—confusion as to roles and responsibilities, unrealistic expectations, limited integration into mid- and long-term business planning, and more. Coming to terms with V&A, therefore, is essential for strengthening its mandate and evolving it into a proactive capability.

V&A's Role in Overcoming the Four Hurdles to Maximum adoption

The roundtable participants had a lot to say about the survey findings, and how V&A can realize its full potential. The discussion focused largely on the four major hurdles to adoption and V&A's role in overcoming each. (See Exhibit 3.)

Exhibit 3 – Value and Access Involvement is Critical for Overcoming the Four Hurdles to Maximum Adoption



Source: Source: BCG analysis.

Product Development and Portfolio

The innovation needs to result in additional medical value in the form of a better diagnostic or therapeutic, improved patient outcomes, reduced health care resource utilization, and so on. V&A's role is to enhance the company's understanding of market needs and how specific product decisions may impact access and value assessments.

M&A decisions

When evaluating a technology's potential for growth, acquiring companies must contend with the risk that revenue assumptions of the target company are overly optimistic. This holds especially true for novel technologies: reimbursement pathways may not be fully established or scalable because relationships with local payers do not always translate to regional, national or government coverage. Involving V&A teams early on can be a big help. In a recent multi-billion-dollar acquisition of a cardiac device maker, the acquiring company's

V&A team pressure-tested pricing assumptions, suggested alternative launch timelines, and ultimately improved the robustness of the deal model.

Market expansion

Product teams make many decisions during development that will be shaped by the market dynamics and patient populations in which the devices will be used. While these product teams can investigate what individual markets need, V&A teams are well equipped with epidemiological, population, claims, and reimbursement data to supplement the product team's knowledge of the market, ensure products & GTM strategies are appropriately designed for the population that they serve. For example, in categories like interventional oncology, expansion into other indications requires potential design modifications and significant analysis of current reimbursement codes and coverage to understand the holistic value assessment for a new standard of care.

Regulatory Approval

The innovation needs to meet safety and quality standards and show reproducible benefits. A key role of V&A teams, therefore, is to help regulatory submissions communicate the additional medical value their devices bring to the market and clarify what evidence may be needed for different regulatory pathways. Many markets and health systems require health-technology assessments to determine the incremental clinical and economic value an innovation offers versus existing standard of care alternatives before allowing the innovation to be considered. Failure to do so can result in regulatory delay, rejection, or removal of devices from the market.

Cost-benefit evidence

In the case of cardiac or diabetes monitoring devices, UK NICE has required significant evidence to justify the cost-benefit of a monitoring device, ensuring a satisfactory diagnostic yield while also balancing the clinical benefit to the patient population. This has accelerated approval of certain devices that had an adequate level of evidence to justify the value story around cost, benefit, and medical risk. When evidence is not sufficient, some manufacturers are not put on the 'recommended' list, which can significantly delay their opportunity in market.

Reimbursement (Coding, Coverage and Payment)

The innovation needs to be covered and paid at an acceptable level, whether directly through a provider or indirectly through a payer. V&A's role is to explain what drives payers' decisions around whether they will cover a new technology as well as how quickly and broadly they will cover it.

Long-term value

Many payers make cost-benefit analyses based on evidence focused on near-term cost drivers without considering the long-term benefit of a more expensive solution. V&A teams can provide the needed information to ensure that payers understand the added long-term benefit for a solution when it has short-term financial tradeoffs.

For example, whole exome sequencing (WES) and whole genome sequencing (WGS) have a significantly facilitated the early diagnosis of rare genetic diseases in children over the past decade because they are more comprehensive than traditional single gene and small gene-panel tests. But WES and WGS are also more expensive and so it has taken years for these technologies to achieve more widespread coverage with payers. Conducting robust clinical utility and cost effectiveness studies, V&A demonstrated not only that early diagnosis provided decided clinical advantages, but that the more-comprehensive WES and WGS tests offset costs in other areas. Specifically, the tests reduced the total number of diagnostic tests, imaging tests, specialist visits, and length of hospitalization. V&A approaches like these have helped build a more comprehensive view of long-term health system value to support the access & adoption of WES and WGS globally.

Reimbursement tiering

When new products with similar use cases enter the market, payers often are reluctant to support the newer technology. V&A teams are vital because they know what types of evidence the payer requires to agree to reimbursement. Their proactive communication of this information to leadership helps to ensure that innovative products are not hindered by copious step-edits.

Take, for example, more recently marketed inhaled insulin devices. Most U.S. payers have been slow to provide coverage even though manufacturers have improved the design to provide more patient convenience – newer versions are smaller and far more discreet than past generations. However, two years after hitting the market, only one product was assigned to tier 3 or 4 (non-preferred brands), and many required prior authorizations, which created significant barriers to uptake. Most likely payers did not understand the added value of the new delivery system (convenience & more adherence) vs. more traditional subcutaneous insulin delivery because V&A teams were not involved to develop a robust value story.

Utilization (HCP and patient acceptance)

HCPs and individuals (patients or caregivers) need to know how to use the product or service and understand the benefit it provides. V&A, therefore, must know which features, evidence, or policy changes will be needed to drive access & usage. In conjunction with commercial teams, they ensure that the product's value is appropriately communicated to doctors and patients.

Value communication

Without such communication, utilization is likely to be hindered, as it was with an in-vitro diagnostic for preeclampsia. Although the test was able to rule out preeclampsia and prevent unnecessary hospitalization, many European health care systems did not adopt the test for years. Most likely this delay was partly due to the failure to adequately communicate the value of the test to the government and the industry bodies that write the guidance and standards that govern how providers practice medicine. However, when the value story is clear, manufacturers can work with the national payer to develop a national program to accelerate adoption of these types of technologies.

Maximizing the Promise of V&A

To unlock the full potential of V&A, companies need to recognize the strategic importance of this function and deploy it accordingly. Three practices are essential:

Align V&A Goals to the Business Strategy

When setting strategic goals and priorities at the enterprise level, companies should clearly link and translate these into V&A goals. That way, V&A will be able to better execute critical activities while building its capabilities for the long term.

Involve V&A at Every Stage of the Product Lifecycle

The involvement of V&A teams is relevant at every stage of the product lifecycle of high-value products, from portfolio prioritization to utilization, to ensure that stakeholders—especially Health Authorities (HA), reimbursement organizations, and payers—adequately appreciate the value the new product confers. The earlier V&A teams are brought in, the more effective they will be, enabling teams to design, build, seek approval for, and launch products with a deeper knowledge of how the market perceives value. When entering new markets with existing competitive devices, V&A teams can help leadership understand what will be perceived as differentiated and what will not. And V&A teams should be brought in during evidence planning and study design to help ensure the right evidence is being captured.

Encourage Greater Collaboration Between V&A and Other Functions

Organizations need to communicate the achievements of V&A teams to other internal stakeholders on a consistent basis. An internal communications plan that includes progress updates and success stories will make V&A's strategic importance role clear and support collaboration between functions (including R&D, marketing, regulatory, medical, and clinical). And because other functions are often the final decision-makers, V&A professionals themselves need to be excellent communicators and cross-functional collaborators.

***

While these recommendations are a start, V&A faces other major challenges, including the task of acquiring the skills and capabilities that V&A teams should have. In our next publication, we will propose a framework that can help.

The opinions expressed in this paper are solely those of the co-authors, and do not represent the positions of their organizations.

The BCG MedTech V&A Roundtable – Purpose

The BCG MedTech V&A Roundtable brings together V&A executives to discuss global industry level challenges, form insightful perspectives, and shape internal and external narratives. The forum's aim is to ensure greater access to innovative medical device technologies and diagnostics. Roundtable members collectively select topics that are relevant but not central to other forums, and that can have near- or long-term relevance for the industry. Members collaborate on specific topic in working groups to develop thought pieces, frameworks, and policy-related publications, which are reviewed and approved by the Roundtable. BCG hosts the roundtable, facilitates the working groups, and co-authors the publications.

About the Authors

Arthi Chandran
Divisional VP, Health Economics
& Reimbursement

Meghna Eichelberger
Partner and Associate Director
Boston Consulting Group
Eichelberger.Meghna@bcg.com

John Hernandez
Head of Clinical Research, HEOR
Google Health

Michel Hochstrasser
Managing Director & Partner
Boston Consulting Group
Hochstrasser.Michel@bcg.com

Brock Schroeder
VP Market Access
Illumina

Srikant Vaidyanathan
Managing Director & Senior Partner
Boston Consulting Group
Srikant.Vaidyanathan@bcg.com

Frederic Rupprecht
WW VP, Health Economics & Market Access
J&J MedTech

Allena Goren DePaoli
Project Leader
Boston Consulting Group
DePaoli.Allena@bcg.com

Stefan Seliger
Global Head Access & Policy
Roche Diagnostics

Kristen Cook
Managing Director & Partner
Boston Consulting Group
Cook.Kristen@bcg.com

James Jenkins
Partner
Boston Consulting Group
Jenkins.James@bcg.com

Monica Schwarm
Managing Director & Partner
Boston Consulting Group
Schwarm.Monica@bcg.com

Jens Grueger
Partner and Director
Boston Consulting Group
Grueger.Jens@bcg.com

For Further Contact

If you would like to discuss this report, please contact the authors.

Boston Consulting Group partners with leaders in business and society to tackle their most important challenges and capture their greatest opportunities. BCG was the pioneer in business strategy when it was founded in 1963. Today, we work closely with clients to embrace a transformational approach aimed at benefiting all stakeholders—empowering organizations to grow, build sustainable competitive advantage, and drive positive societal impact.

Our diverse, global teams bring deep industry and functional expertise and a range of perspectives that question the status quo and spark change. BCG delivers solutions through leading-edge management consulting, technology and design, and corporate and digital ventures. We work in a uniquely collaborative model across the firm and throughout all levels of the client organization, fueled by the goal of helping our clients thrive and enabling them to make the world a better place.