WHITE PAPER

Value & Access in MedTech: Critical Competencies for an Effective V&A Organization

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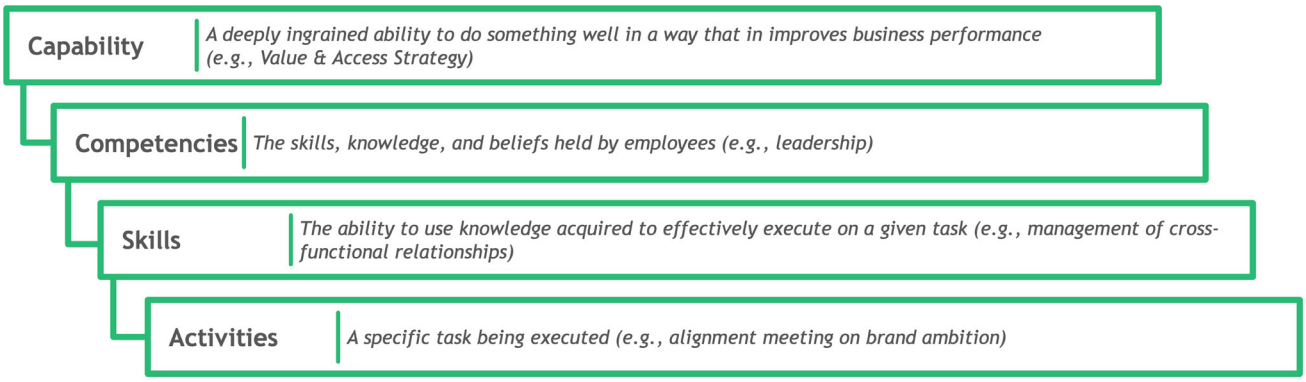
Abstract: Many factors influence what kind of work V&A professionals will be required to do on behalf of their medical device organizations. The maturity of the organization, breadth of product portfolio, and the level of product innovation all influence what competencies—in other words, groups of similar skills—a V&A professional requires to be effective. As a MedTech business leader, understanding these factors more deeply will enable you to identify competency gaps in your V&A capabilities, and better position your organization to capture differentiated value.

Recap of Publication #1: How We Define "Value & Access": V&A activities in MedTech focus on defining, demonstrating, and communicating the value of MedTech innovations and ensuring broad and equitable access for the patients who need it. Value primarily accrues to patients, but also families and caregivers, providers, payers, and the wider healthcare ecosystem. It includes health gains (improved mortality, morbidity, and quality of life), financial gains (reduction in the need to treat severe complications and sequelae of disease, avoidance of duplication and waste, and improved efficiency and productivity), and peace of mind (being assured that there are appropriate technologies to diagnose and treat people when they are affected by diseases, accidents, and/or emergencies including epidemics/pandemics). In our prior publication, we laid out a recommendation on how to operationalize V&A teams to create the most value for customers. In this paper we provide a framework for thinking about the capabilities, competencies, skills, and activities needed for an effective V&A team.



Challenge: MedTech companies require a different mix and constantly evolving set of V&A competencies depending on their maturity, the underlying product portfolio and a host of other factors—yet there is no consistent industry definition of what these competencies are or to what degree they are needed.

V&A professionals are key players in the demonstration and communication of the value of a technology as well as ensuring access for patients to the technology. To effectively deliver on their objectives, V&A professionals need a certain set of competencies and underlying skills, such as a deep understanding of health systems and their stakeholders, the ability to develop pricing models, and knowing what evidence external stakeholders require to make reimbursement or purchasing decisions. There is not, however, a clearly articulated way of thinking about this within MedTech (note that our colleagues in the pharma industry have been thinking about this for some time).

This is not surprising given that every MedTech company is so different and can cover a much broader set of product types—from implantable devices to capital equipment to digital solutions—which make their prerequisite competencies for success harder to define. The optimal build of a V&A capability will depend on multiple contextual factors, such as breadth of portfolio, product maturity, and geographical reach. As an example, a company bringing to market a deep brain stimulation device will have different requirements for V&A competencies than a diagnostics company developing their next assay and set of underlying reagents. Similarly, a MedTech company with a multinational presence will need a different skillset than a company with an exclusively domestic presence (for example, having commercial presence in China and the US would require expertise in both knowledge of the National Medical Product Administration in China and commercial payer negotiations in the US). Without the right competencies within a company, there is a risk that strategic opportunities are missed and operational missteps lead to costly mistakes that could lock a player out of a market or severely delay commercialization and adoption. A definition of V&A competencies will need to encompass these differences while still being specific enough to enable action. As such, an appropriate V&A competencies framework is needed to help leaders decide where to invest and at what level of depth to ensure that their teams and leaders are set up for success.

We propose addressing this challenge with an approach that leverages the following two frameworks:

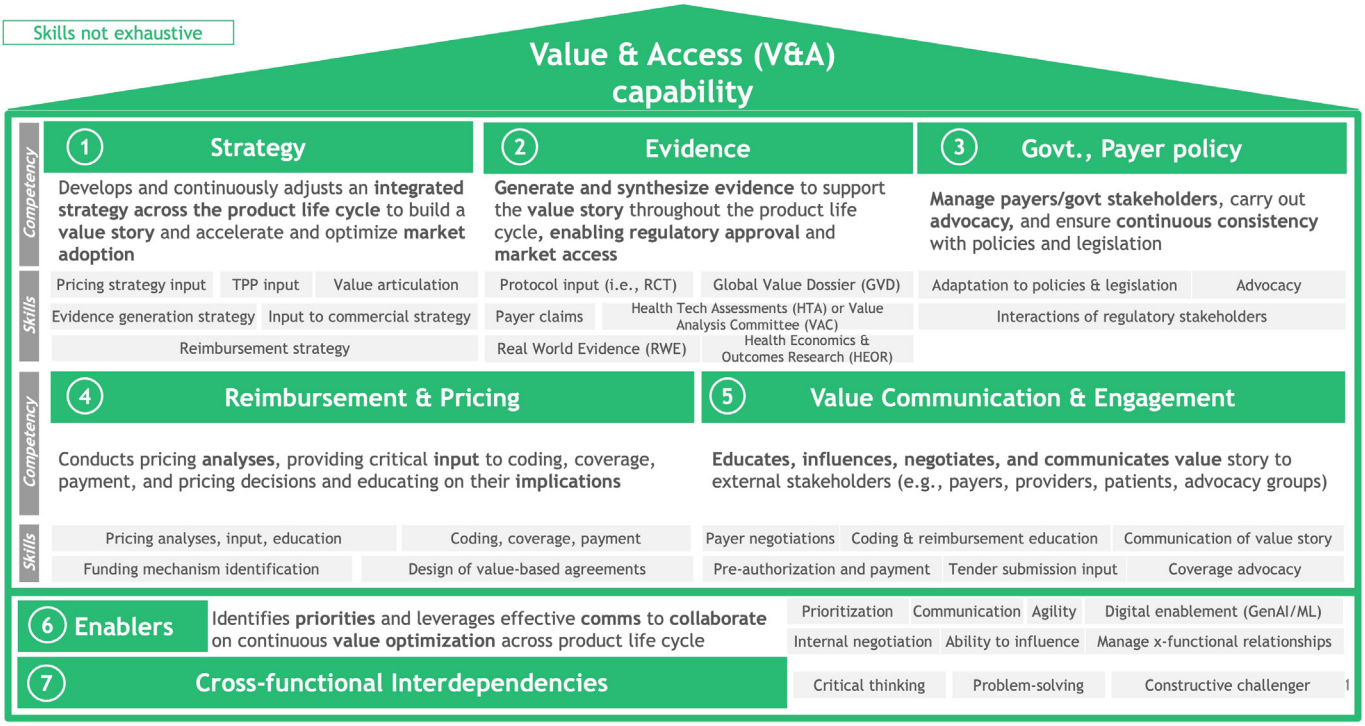
- **Framework 1:** a comprehensive view of core V&A competencies, which can serve as a reference for business leaders.
- **Framework 2:** set of "V&A company archetypes" that will help leaders understand the mix and depth of V&A competencies required for success depending on their specific context.

Once these two frameworks are well understood, a MedTech leader should be able to design their own tailored set of V&A competencies, identify potential gaps, and then develop the training mechanisms or partnership options to close those gaps.

Framework 1: A V&A Competency Framework can help to define the competencies and skills that V&A teams must possess.

The work of V&A is highly cross-functional and spans the complete product life cycle. It requires a broad set of core competencies to be successful, encompassing skills, knowledge, and beliefs held by employees. We have defined **five competencies and a set of supporting enablers and interdependencies, which make up the building blocks of a V&A capability.** Each is made up of multiple underlying skills, defined as the ability to use knowledge acquired to effectively execute on a task (see Framework 1).

Framework 1 | V&A Competency Framework



1. **Strategy:** At its very core, V&A is strategic work. V&A professionals help ensure that the products being prioritized and developed create value for patients, as many of them as possible can access this value, and the company achieves a fair return on its investment so that it can continue to innovate.

2. **Evidence:** To support the value proposition, there is a need for thoughtful evidence generation. This serves to enable fast and sustained access by demonstrating the value at launch (usually through clinical studies) and throughout the life cycle as more experience in the actual use of the product is collected (typically through real-world evidence) and the value proposition is further solidified, including for new modifications of the product and additional competitors in the marketplace. V&A has a role to play in the direct generation of health economic evidence as well as indirectly informing other functions, such as medical and clinical affairs, through integrated evidence planning.

3. **Policy:** Policy is critical to facilitate an environment in which the value of the technology is recognized and the appropriate financial incentives and reimbursement mechanisms have been established. Policy initiatives are typically focused on an above-product level and require a long-term perspective and engagement with a broad set of stakeholders, including payers, governments, regulators, and even patients.

4. **Reimbursement & Pricing:** While pricing strategy rarely falls solely within its purview, V&A provides critical input. The range of underlying skills includes conducting qualitative and quantitative pricing research, such as value-based pricing and price sensitivity of demand, providing input to ensure that pricing is consistent with the value proposition and evidence base, and identifying opportunities to improve the pricing structure to enable broader access and increased revenues. This input is also incorporated into the broader coding, coverage, and payment considerations for gaining reimbursement that delivers on the revenue potential.

5. **Value Communication & Engagement:** V&A holds the reins on the evidence-based value story and plays a crucial role in the preparation of a company's field force. Beyond internal stakeholders, Value Communication & Engagement help educate, influence, negotiate, and communicate the value story to external stakeholders such as payers, providers, and patients.

These five competencies do not exist in a vacuum. To truly be successful, we need to recognize the importance of supporting enablers and cross-functional interdependencies. You need the right leaders in place to coordinate a united effort toward company objectives, establish agile ways of working that enable cross-functional alignment, and build a collaborative culture.

Framework 2: Identifying your company "archetype" will help MedTech business leaders understand the level of V&A expertise they need across their core competencies for their given context

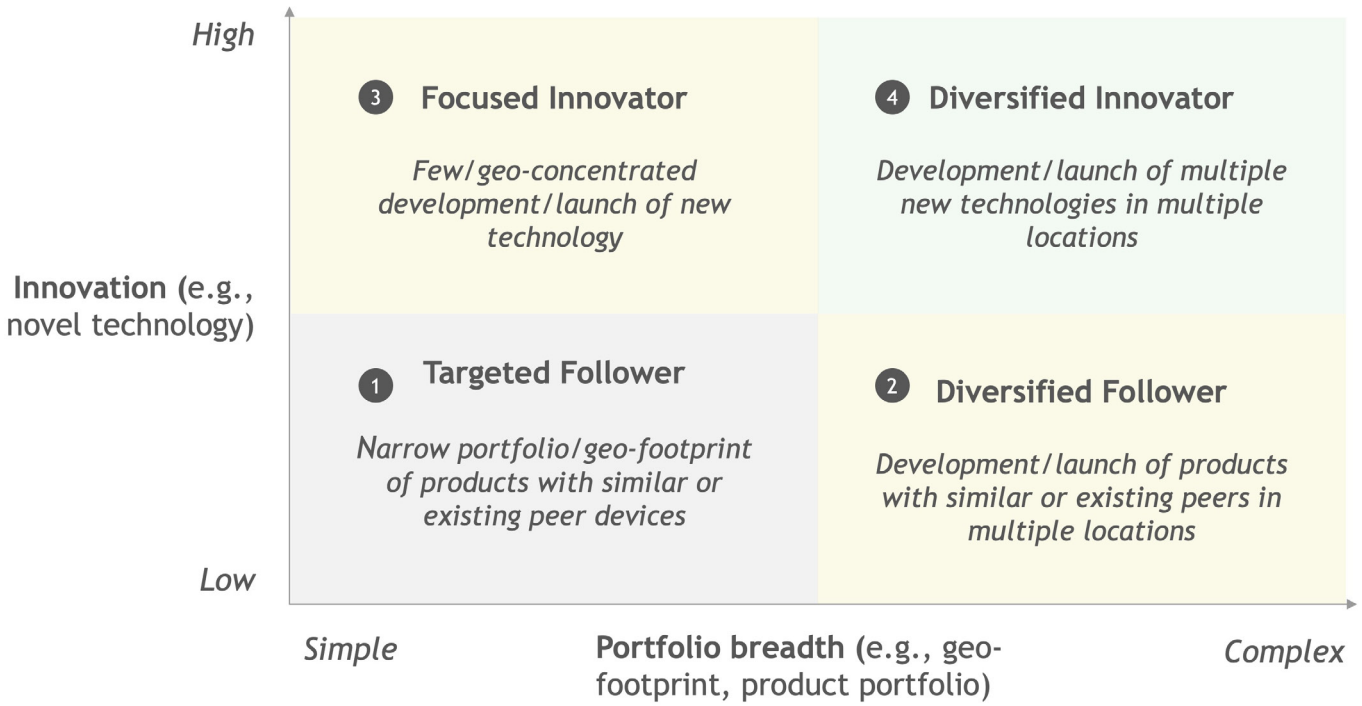
All five competencies and underlying enablers are needed; however, the level of depth will typically not look the same across MedTech companies, given their unique context and ambitions. Several contextual "lenses" can be applied, as outlined in Framework 2, and we suggest that the two most impactful for defining the needs of V&A competencies within a company are the following:

1. **Innovation:** The degree of innovation within the portfolio—truly high-value novel technology vs. more incremental technology with multiple prior versions or "predicate" devices.

2. **Portfolio complexity:** Breadth of a company's portfolio, such as multiple therapeutic areas and multiple types of products, and geographical footprint.

We believe that these two dimensions can help MedTech leadership understand the types of V&A capabilities they need and why. **Based on our experience, most device companies can be segmented across these dimensions into one of four distinct archetypes** (see Framework 2).

Framework 2 | V&A company "archetypes"



1. **Targeted Follower:** This archetype has a narrow portfolio of products in a market with multiple competing or prior devices, or predicates, in a concentrated geography. Consequently, both up- and downstream processes are battle tested and can be leveraged as a base for V&A work, such as familiarity with evidence required for approval, ongoing relationships with relevant decision-makers such as regulators and payers, and familiarity with different reimbursement mechanisms. Given the presence of similar prior devices, a company should focus on Pricing and Field & External Engagement to enable differentiation downstream with end users, providing convenience and ease of use for patients and health care providers. Evidence, similar to Strategy and Policy, can be shaped according to prior products, and therefore requires a lower level of expertise and investment from a V&A perspective.

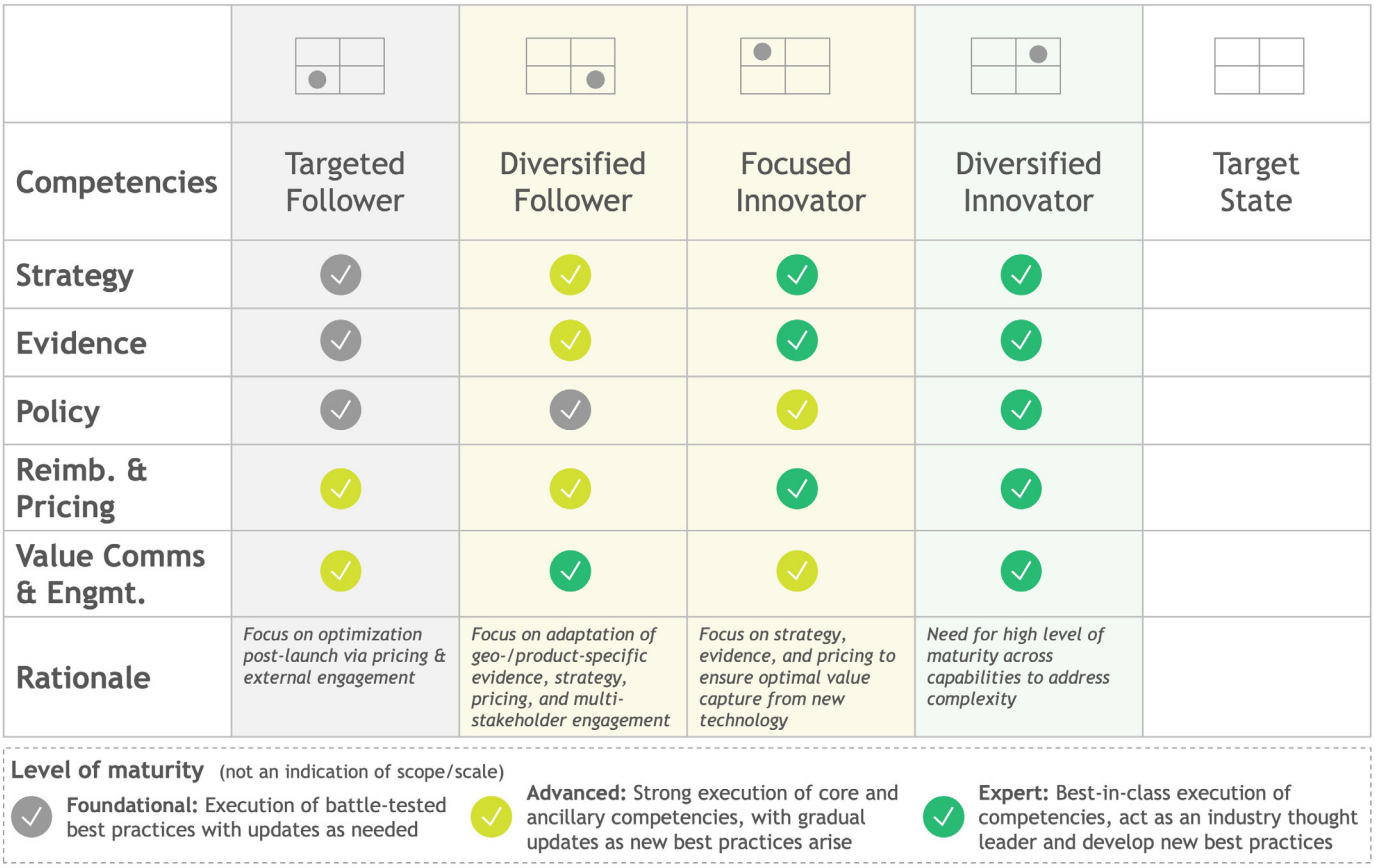
2. **Diversified Follower:** This archetype has a broad portfolio, such as different trading areas, and/or geographic reach of products in trading areas with multiple prior devices. Given the increased level of complexity, a company needs to be able to build product-specific and/or geographically specific strategies, evidence, policy approaches, etc. It requires a higher level of expertise across V&A competencies, especially in Field & External Engagement, to address the differentiated set of relevant stakeholders. That said, the technology is not novel in nature, hence there is past precedent set in the market (for example, in relation to evidence generation), which can be leveraged to steer V&A work.

3. **Focused Innovator:** This archetype has a geographically concentrated, narrow portfolio of innovative technology. Given the novel nature of the product, V&A professionals will have limited precedent to draw on. Hence, a company needs a high level of Strategy, Evidence, and Pricing competencies, as the strategy, integrated evidence plan, and pricing model will have to be built largely "from scratch." The stakes are high, as failure to secure access and/or adoption can allow time for potential new entrants to capture share, which, given the narrow portfolio, would be detrimental to a company's success. A somewhat lower level of investment is needed in Policy and Field & External Engagement, given the narrow focus of the portfolio.

4. **Diversified Innovator:** This archetype has a broad portfolio of innovative technologies with broad geographical reach. MedTech companies that align to this archetype are front runners in the industry and in need of a high degree of maturity across competencies. For example, new strategies, evidence plans, and relationships with stakeholders need to be built for a novel technology, with limited (if any) precedent to base it on, and adapted to local context for a large, complex portfolio. Inability to perform on any of these competencies would compromise the value capture of the technologies.

To help conceptualize and calibrate the level of maturity needed for each competency across company archetypes, we define the need as Foundational, Advanced, or Expert level (see Exhibit 1). Consider the following example: A company launching a technology with multiple predicate devices domestically (Specialized Follower), certainly needs a Policy competency. But a Foundational level likely suffices, given the familiarity with the technology and market. If the launch takes place in new markets (Diversified Follower), a more Advanced level could be required, as they would need to understand and engage with multiple, ever-changing policy systems and stakeholders. Lastly, had the technology also been novel (Diversified Innovator), V&A would need Policy at an Expert level to build an understanding of the technology-specific policies and regulation, plan for advocacy, and stakeholder relationships in multiple markets.

Exhibit 1 | Competency Across Company Archetypes



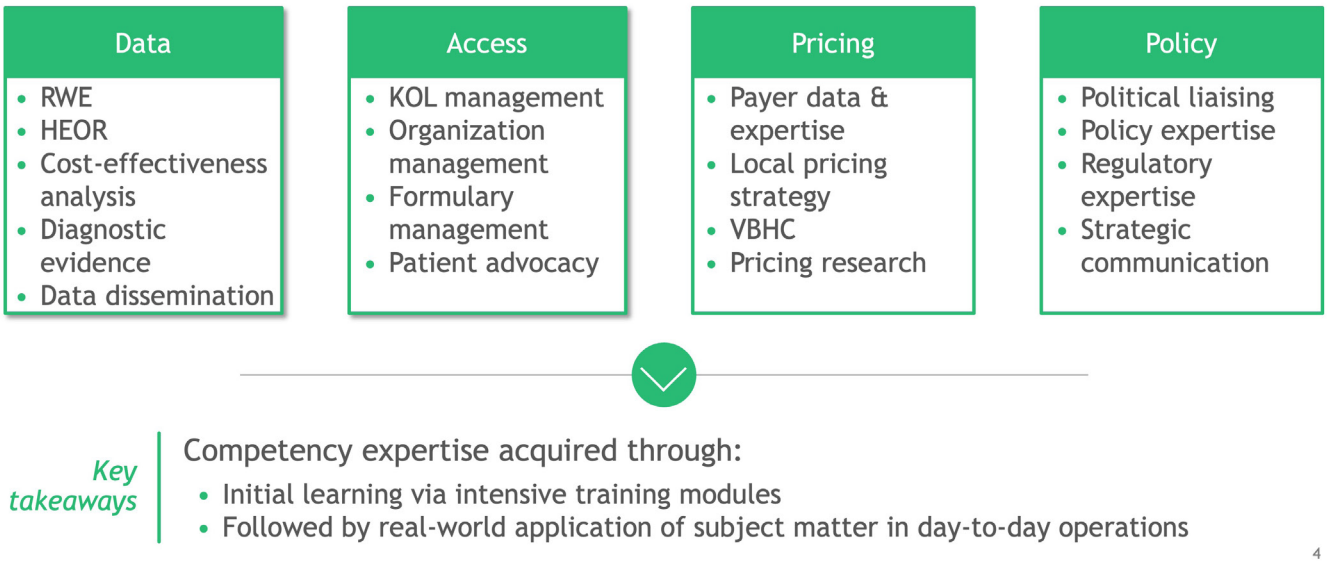
Think about your organization's V&A competency needs and use the target state column to jot down your assessment.

Once you understand the depth of V&A competencies that your organization requires for its given context, how can you ensure that these competencies are built and maintained over time? Roundtable members have seen several successful approaches across the industry, including options to build, buy, and partner for those competencies.

In one example (Exhibit 2), an access e-curriculum was defined across four key "modules," such as Policy, with underlying chapters to build expertise in more specific skills, including strategic communication. V&A leaders can then assign specific modules or chapters to their team members, depending on their given roles and responsibilities. Another approach is to define a set of "foundational" capabilities that all V&A professionals need to have, such as communication and strategic thinking) and then a set of more "technical" skills, such as economics and data analytics, for colleagues to build over time.

Partnerships with existing academic institutions can also be leveraged in building access competencies. A group of global pharma companies have partnered with the London School of Economics to create the Market Access Academy, a be-spoke program of lectures, workshops, and guest speakers on V&A topics. There are scant examples of similar academic partnerships on access within MedTech today—but similar ones could be created to the same effect.

Exhibit 2 | Curriculum of market access competencies across four categories



Recommendations: How to utilize these frameworks to define your Value & Access teams

How you decide on the level of depth across V&A competencies has a direct impact on your ability to gain access in your intended markets and achieve broad adoption among indicated populations. To ensure MedTech companies are equipped to capture the full value potential of their technology, we believe the following three steps must be taken:

1. **Understand your current state and target ambition:** Start with identifying where your company falls in the V&A Company "Archetype" Matrix based on the innovativeness of your pipeline and complexity of your portfolio (incl. portfolio breadth and geographical reach).

2. **Assess the competencies of your existing organization to understand gaps and areas of opportunities for investment:** For example, as you seek to expand your geographical presence, are you able to train the field force in the new markets, and do you have the needed understanding of and relationships with local stakeholders?

3. **Develop a point of view on the level of competencies required at a role level and the gap to target state:** For example, where do you need to acquire new talent or upskill your current talent? How do you assess the scale needed for success?

The purpose of these recommendations is to encourage and provide a framework for the critical assessment of the level of V&A competencies needed. It is by no means to be considered the be-all end-all for a MedTech company in building an effective V&A capability. Leaders in MedTech also need to consider how to organize these competencies internally and at what structural level, such as global centers of excellence vs. in-market local roles, to best support the product portfolio and other functional teams. In a future publication, we will explore organizational design implications to ensure maximal V&A impact.

The BCG MedTech Value & Access Roundtable—Our Purpose: The BCG MedTech Value & Access Roundtable is a forum that brings together Value & Access (V&A) thought leaders to discuss global industry-level challenges, form insightful perspectives, and shape internal and external narratives. Our aim is to ensure greater access to innovative medical device technologies and diagnostics. Roundtable members collectively select topics that, while relevant, are not central to other forums—and can have near and/or long-term relevance within the industry. Members work in smaller working groups on specific topics to develop thought pieces, relevant frameworks, and/or policy-related publications, which are collectively ratified by the Roundtable. The Boston Consulting Group (BCG) hosts the Roundtable, facilitates both the Roundtables and the working groups and co-authors publications.

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