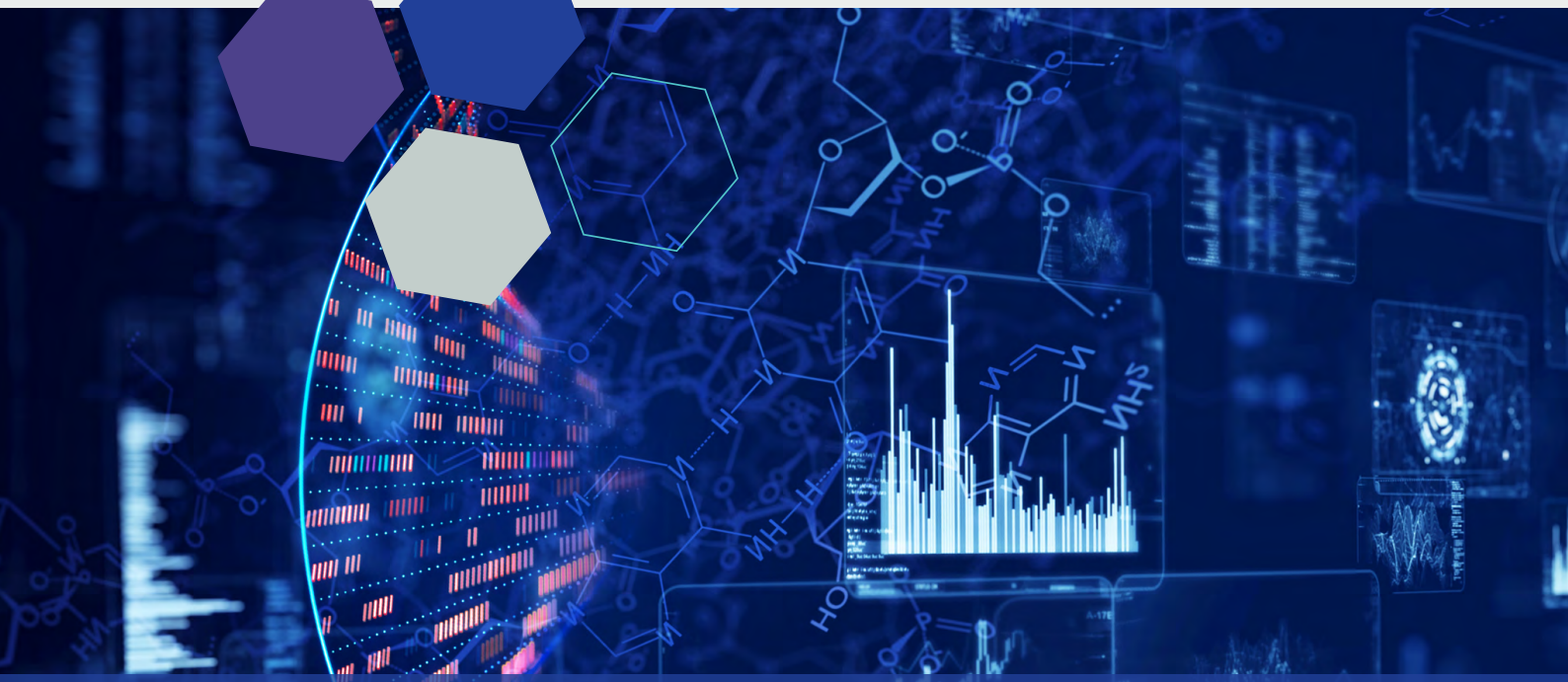


Fueling the APAC Medtech Innovation Engine: An Ecosystem Investment

APACMed & L.E.K. Consulting

September 2024

Contents

1. Foreword 3

2. Approach 4

3. Executive summary 5

4. APAC early-stage innovation is at risk 11

4.1. Funding under threat: declines in medtech investment 11

4.2. Direct cost challenge: rising costs and operational uncertainties 12

4.3. The ecosystem should step in to support innovation 14

5. Building a more supportive ecosystem 16

5.1. Regulatory authorities: acceleration through approval, market access and payment 17

5.2. Governments: funding and incentives fueling the medtech innovation engine 27

5.3. Universities and research institutions: nurturing the seeds of innovation 31

5.4. Large medtech firms: catalysts of innovation in a challenging market 34

5.5. Investors (family offices): fuel for the engine 40

5.6. Industry associations and accelerators: a unified voice for innovation 41

5.7. Startup companies: the basis of ecosystems 42

6. Recommendations for implementations 44

7. Acknowledgments 48

8. References 50

1. Foreword

Early-stage medtech innovation is a lifeblood of healthcare systems around the world. Many of today's leading medtech conglomerates began as small, visionary startups. These companies, once fledgling enterprises, have grown into industry titans, driving forward the frontiers of medical science and technology. However, the journey from a small business to a global giant is fraught with challenges , particularly within the healthcare sector which is characterized by a high-risk, high-reward profile.

The medtech industry stands at a pivotal juncture. The inherent risks associated with healthcare innovation — regulatory hurdles, elongated R&D timelines, fragmented commercial opportunities, a varied reimbursement environment and significant capital requirements — create formidable barriers to entry, and therefore to growth. Despite these challenges, the potential rewards for successful innovations are unparalleled, offering transformative benefits to patient care and public health.

However, the landscape for early-stage medtech companies in the Asia-Pacific (APAC) region has become increasingly challenging. Recent market developments have intensified the struggle for survival among these innovators. Investment in the medtech sector has seen a marked decline, a trend exacerbated by economic uncertainties and shifting investor priorities. Concurrently, the cost of operations has surged, driven by inflationary pressures, supply chain disruptions, R&D costs and the escalating expenses associated with regulatory and market access pathways.

This confluence of decreasing investment and rising costs threatens to stifle the very innovation that is essential for the evolution of medtech. Medtech startups, which are typically more agile and capable of pioneering disruptive technologies, find themselves in a precarious position. Without adequate funding, many promising ventures face the grim prospect of stagnation or failure, unable to bring their groundbreaking ideas to fruition.

To ensure the continued delivery of innovative and lifesaving treatments, the medtech industry in APAC in the public and private sectors alike must address the critical issue of insufficient capital flow into early-stage innovation. Ecosystem-level support is required to reinvigorate investment and support the growth of these nascent enterprises.

Dr. Chris L. Hardesty
Head of SME Portfolio,
APACMed

Stephen Sunderland
Head of APAC,
L.E.K. Consulting

2. Approach

In developing this special whitepaper, the L.E.K. Consulting team has drawn upon extensive experience in all corners of the medtech industry as well as a diversity of primary and secondary sources.

For a key source of current insight on the ecosystem, L.E.K. conducted 12 one-on-one discussions with key market participants, including policy advisors, large medtechs and medtech startup executives. These discussions aimed to, respectively, elucidate current and anticipated trends in the industry, understand medtech company initiatives and their impact on the innovation ecosystem, and determine actionable and impactful support for startups in advancing early-stage innovation.

Additionally, L.E.K. held two discussion sessions with the APACMed team and its steering committee to further enrich the existing research.

For secondary research, L.E.K. drew upon information from government statistical offices, third-party data providers and disclosures by industry analysts to obtain factual evidence about the current market landscape and dynamics.

3. Executive summary

APAC early-stage medtech innovation is at risk

The medtech investment landscape in the APAC region has experienced a notable downturn since its peak in 2021. Venture financing and M&A deals have decreased by 22% and 37%, respectively, over the past two years (through 2023). This decline is driven by global factors such as market volatility, rising interest rates and geopolitical instability, as well as specific regional challenges.

These challenges are compounded by escalating operating costs, including increased inflation pressure, supply chain disruptions, research costs and regulatory hurdles, which collectively strain the financial sustainability of startups.

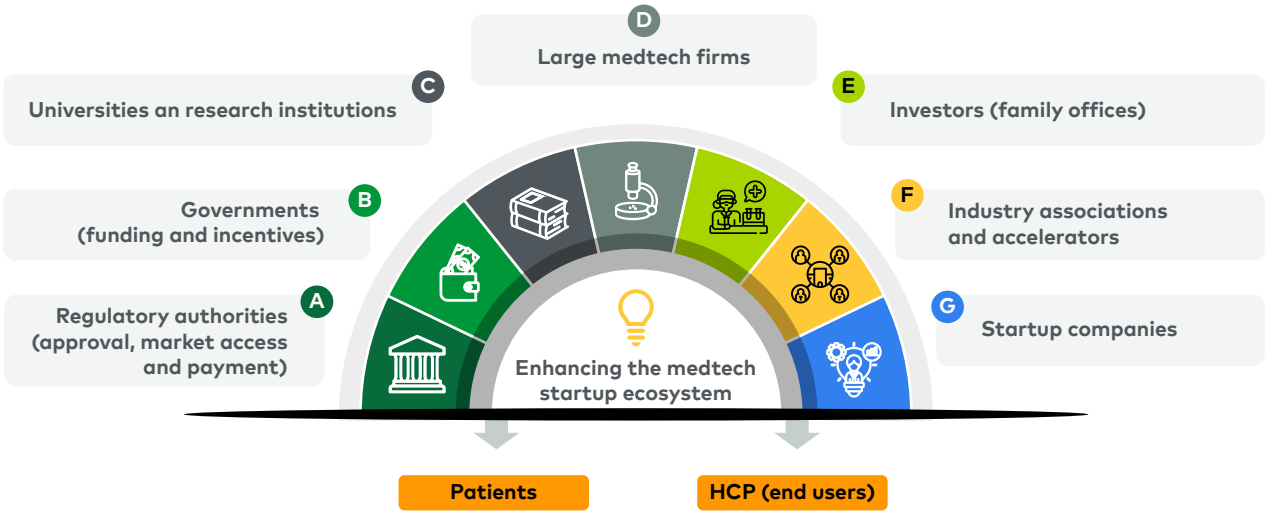
The participants in APAC's medtech innovation ecosystem are grappling with critical issues that require urgent attention. Despite these challenging conditions , the region's pivotal role in advancing medtech innovation for the world is recognized. Addressing inadequate capital allocation is crucial for sustaining innovation and delivering lifesaving interventions. This requires a collective effort from all stakeholders, across the public and private sectors, to foster a more favorable investment climate through enhanced collaboration and strategic initiatives.

Yet a significant gap remains in the ecosystem's ability to support innovation effectively. L.E.K.'s sentiment survey rates the maturity of the APAC medtech ecosystem at at 2 (out of 5), compared with 5 in the U.S., highlighting the need for further development to better nurture and sustain medtech advancements. This whitepaper delves into stakeholder perspectives and identifies key areas for improvement within the ecosystem.

Action from the whole ecosystem is needed to support successful medtech startups

Addressing the decline in innovation investment in APAC requires proactive measures among stakeholders, including regulatory authorities (approval, market access and payment), governments (direct funding and incentives), universities and research institutions, large medtech firms, investors (specifically family offices in this report), industry associations and accelerators, as well as startup companies themselves. By collectively addressing barriers and implementing strategic initiatives, these stakeholders can accelerate the quantity, quality and pace of medtech innovation in the region.

Figure 1:
Medtech ecosystem stakeholders required for innovation to scale



Source: L.E.K. research and analysis

In this report, we detail the challenges and potential areas of development faced by each stakeholder, drawing from our conversations with interviewees and L.E.K.'s proprietary sources. By incorporating insights from case studies that highlight best practices, we offer informed recommendations. The main body of the report provides an in-depth analysis, while this section summarizes the key challenges and suggestions.

A. Regulatory authorities

Challenges highlighted by innovation community	Potential areas of development
A1. More streamlined and flexible processes are needed to accelerate the real-world implementation of innovation, reduce development costs, and create more opportunities for groundbreaking advancements **A2.** Clearer guidance, more accessible communication mechanisms and approachable channels are essential to help startups more effectively navigate the complex regulatory landscape **A3.** Enhancing integrated and targeted support — particularly in a landscape where approval, market access and payment are managed by separate authorities — can significantly improve startups' ability to successfully commercialize their products	**Regulatory approval** • Develop accelerated approval pathways for breakthrough and high-need medical products • Improve communication through comprehensive materials and a robust process-tracking system, which will provide greater transparency and efficiency • Establish pre- and in-process communication mechanisms for innovative startups, and provide support and guidance to navigate regulatory landscapes • Initiate cross-recognition of clinical trial data and registration between APAC jurisdictions to enhance efficiency and reduce the burden on startups • Implement clear guidelines and align local regulations with international standards (e.g., U.S. FDA, EU CE) to streamline approval processes and reduce redundancy **Market access** • Allow fast-track access programs for hospital listings, including rapid evaluation and reimbursement support • Refine the listing criteria for public tenders, focusing on innovation and impact rather than just costs • Encourage early adoption by hospitals to foster easier validation of new technologies and real-world testing **Payment** • Align regulatory approval and payment/reimbursement mechanisms to ensure quick listing for reimbursement upon approval • Implement value-based pricing and outcome-based reimbursement models that incentivize innovation, rewarding new technologies that demonstrate high effectiveness and efficiency

B. Governments

Challenges highlighted by innovation community	Potential areas of development
Direct funding **B1.** Direct funding support is crucial for medtech companies to successfully scale up **B2.** Some rigidity in funding mechanisms, which at times could be the bootstrap of the development process **B3.** Lengthy application processes, preventing timely access to government funding **B4.** Additional requirements (e.g., local employment or manufacturing) along with investment, impeding startups' ability to innovate and grow **Indirect funding and nonfinancial incentives** **B5.** Limited relevance of indirect funding to startups, as the funding is often awarded after commercialization, rendering it less pertinent to early-stage innovations	• Provide holistic support for innovation to maximize the impact of direct funding; establish "medtech office" format agency to coordinate all government agencies that provide funding • Enhance indirect funding and nonfinancial incentives by tailoring mechanisms to the evolving needs of startups

C. Universities and research institutions

Challenges highlighted by innovation community	Potential areas of development
C1. Intellectual property (IP) ownership concern due to involvement of multiple stakeholders, which may cause disputes and hinder the progress of innovation **C2.** Concern about talent leakage from the university, which may result in reduced willingness to collaborate with startups **C3.** Resource constraints, in that universities may not be able to allocate resources to support extensive research projects, as they are struggling with limited funding and personnel **C4.** Lack of understanding about commercialization among university professors and researchers due to their devotion to research and academic pursuits, reducing the likelihood of product success	• Provide R&D support by establishing dedicated research centers and connecting startups with subject matter experts to enrich research quality and facilitate real-world testing • Foster talent development by offering mentoring workshops to better navigate the business environment and innovation landscape • Foster knowledge transfer by developing interdisciplinary programs to equip innovators with the diverse skills needed for medtech innovation • Foster partnerships between startups and relevant stakeholders by organizing conferences and networking events

D. Large medtech firms

Challenges highlighted by innovation community	Potential areas of development
D1. Limited market size of startups, as the fragmentation of the APAC region (e.g., market access) inevitably causes startups to limit their geographical focus **D2.** Asset's emphasis on achieving commercial success (vs. addressing unmet needs), due to pressure to deliver quick returns and limited resources among startups **D3.** Overweighting toward "me-too" products instead of innovative products, as the core technology (having already been validated) reduces development risks and R&D costs **D4.** Lower return on investment compared with the U.S. due to the immaturity of capital markets, stringent price controls and a limited exit channel within the APAC region **D5.** Limited communication channels between startups' and multinational companies' (MNCs') HQs, resulting in misalignments regarding startup offerings and MNCs investors' pursuits	• Build a success story in APAC by highlighting achievements (e.g., successful product launches) in order to enhance credibility, attract interest from potential partners and serve as a powerful testament to the potential of medtech innovation in APAC • Steer startups through complicated international markets by providing guidance and support on regulatory requirements, IP concerns and market entry strategies • Establish efficient communications forums for startups to effectively exchange information and align expectations with those of relevant stakeholders

E. Investors (family offices)

Challenges highlighted by innovation community	Potential areas of development
E1. Generally weak familiarity with the leading edge of healthcare technology and care delivery **E2.** Limited expertise in healthcare and medtech, preventing funds from thoroughly assessing the potential of and making an informed judgment on investment in a product **E3.** Reduced appetite for high risk investments among APAC family offices due to increased geopolitical and economic uncertainty	• Adequately educate family offices on the importance of and opportunities within the medtech sector, to prompt the onboarding of personnel with in-depth medtech expertise • Establish introductory forums in APAC to provide startups an opportunity to communicate their vision and product value proposition to family offices

F. Industry associations and accelerators

Industry associations and accelerators must step up and champion the cause of early-stage innovation by amplifying the voices of startups. While individual startups may struggle to influence government policy due to their limited scale, a united front can create a resonant voice within the ecosystem. Industry associations can play a pivotal role in this by gathering input from startups and advocating on their behalf, transforming their collective concerns into policy initiatives.

In addition to serving as a unified voice, associations play a crucial role in fostering innovation by acting as a meeting ground for corporations and startups. Both groups often seek innovative solutions but may face challenges due to limited resources and matchmaking opportunities. By facilitating these connections, associations and accelerators help scale innovation efforts and create valuable synergies.

Accelerators, with their proximity to startups, could provide targeted support that can significantly enhance a startup's development journey. They offer resources, mentorship, and strategic guidance that prepare startups to be more attractive to investors. By accelerating growth and refining their business models, accelerators position startups for investment more effectively and expediently than they might achieve on their own. This support not only increases the likelihood of securing investment but also enhances the overall impact and success of the innovative solutions being developed.

G. Final thoughts for startup companies

Last but not least, startups hold the keys to the transformative engine our medtech ecosystem desperately needs. But with great potential comes great responsibility. The journey begins with a commitment to the "right" innovations — those that fill the gaps in healthcare that others have overlooked. This requires startups to robustly understand the clinico-economic challenges facing the other stakeholders in the ecosystem.

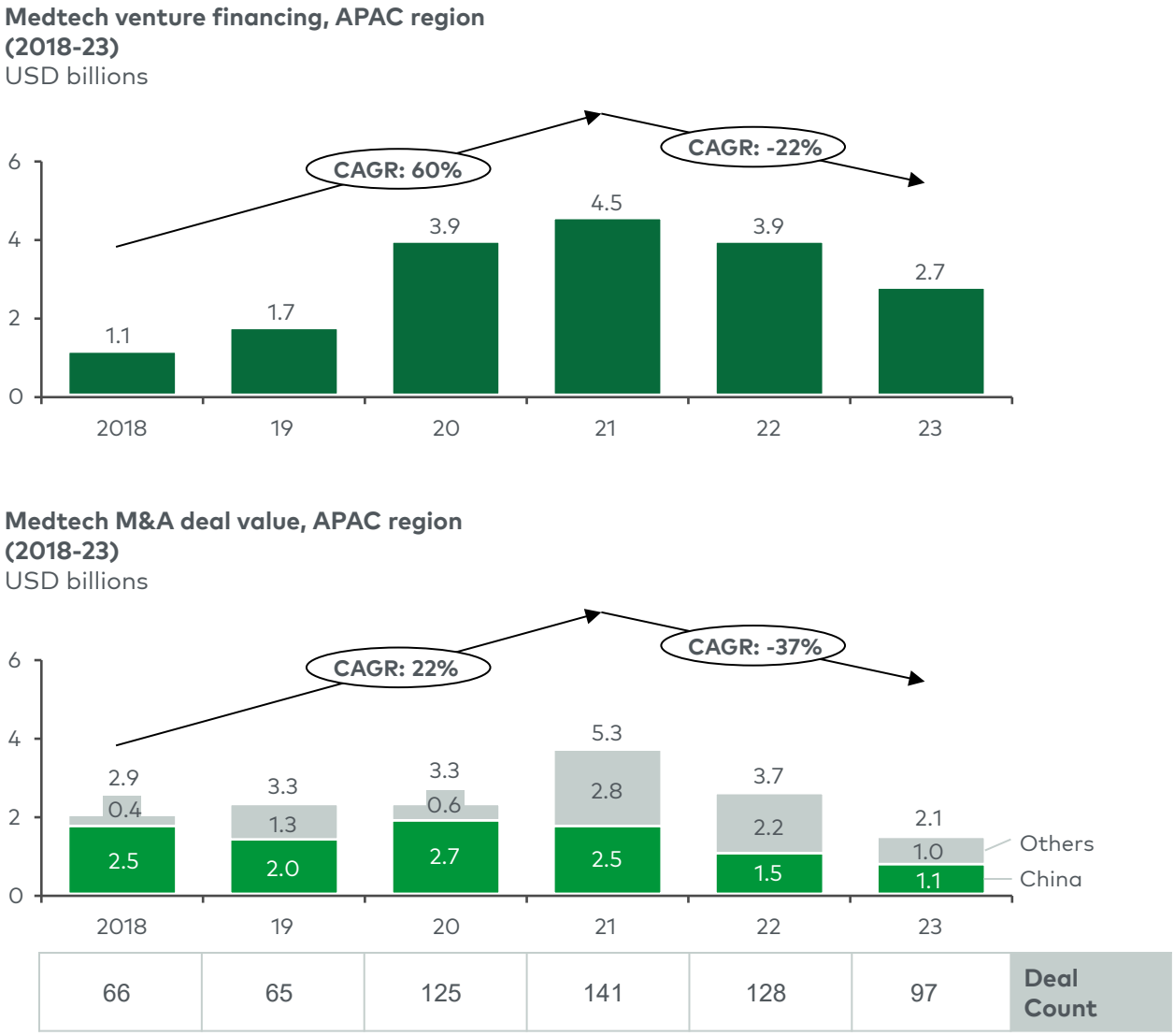
By crystallizing a clear innovation value proposition, startups can access funding and strategic partnerships that might otherwise remain hard to reach. A well-mapped innovation development pathway ensures that everyone — from the founders to the investors — marches in step, reducing the risk of costly delays and setbacks.
And let's not forget the power of communication. Keeping key stakeholders in the loop isn't just good business — it's essential for turning breakthrough ideas into tangible, world-changing realities.

4. APAC early-stage innovation is at risk

4.1. Funding under threat: declines in medtech investment

As most of us have perceived, the market has seen a consistent decline in medtech startup investments across the APAC region in recent years. Since a peak in 2021, both venture financing and M&A deals in medtech have experienced a significant drop, with reductions of 22% and 37%, respectively, over the past two years (see Figure 2).

Figure 2:
Medtech venture funding and M&A deal value in APAC



Note: APAC=Asia-Pacific; CAGR=compound annual growth rate
Source: GlobalData; L.E.K. research and analysis

Several factors have contributed to the decline in investment, encompassing both global influences and region-specific challenges within APAC.

Globally, market volatility and rising interest rates have led to diminished investor confidence, resulting in decreased funding for medtech innovation. Heightened geopolitical instability also creates uncertainty and risk in access to a global marketplace and supply chains, further challenging investment.

In addition, several region-specific challenges further intensify the decline in investment. Most notably, China, one of the foremost hubs for medtech innovation in APAC, experienced a stock market crash in recent years. Consequently, venture capital funding has tightened and investor confidence has been significantly shaken, leading to a reduction in funding.[1]

Moreover, indirect factors such as reimbursement and regulatory challenges also contribute to the decline in investment.[2] A complex and unpredictable reimbursement landscape creates uncertainty regarding the financial returns from new medtech products. Simultaneously, challenges in market access and stringent regulations often deter investments. These issues are particularly pronounced in emerging countries within the region, where the regulatory landscape is less transparent. Similarly, in emerging countries, the theme of market access increasingly revolves around cost control.[3] Consequently, innovation is not adequately rewarded within the payment system, making it challenging for startups to sustain themselves.

4.2. Direct cost challenge: rising costs and operational uncertainties

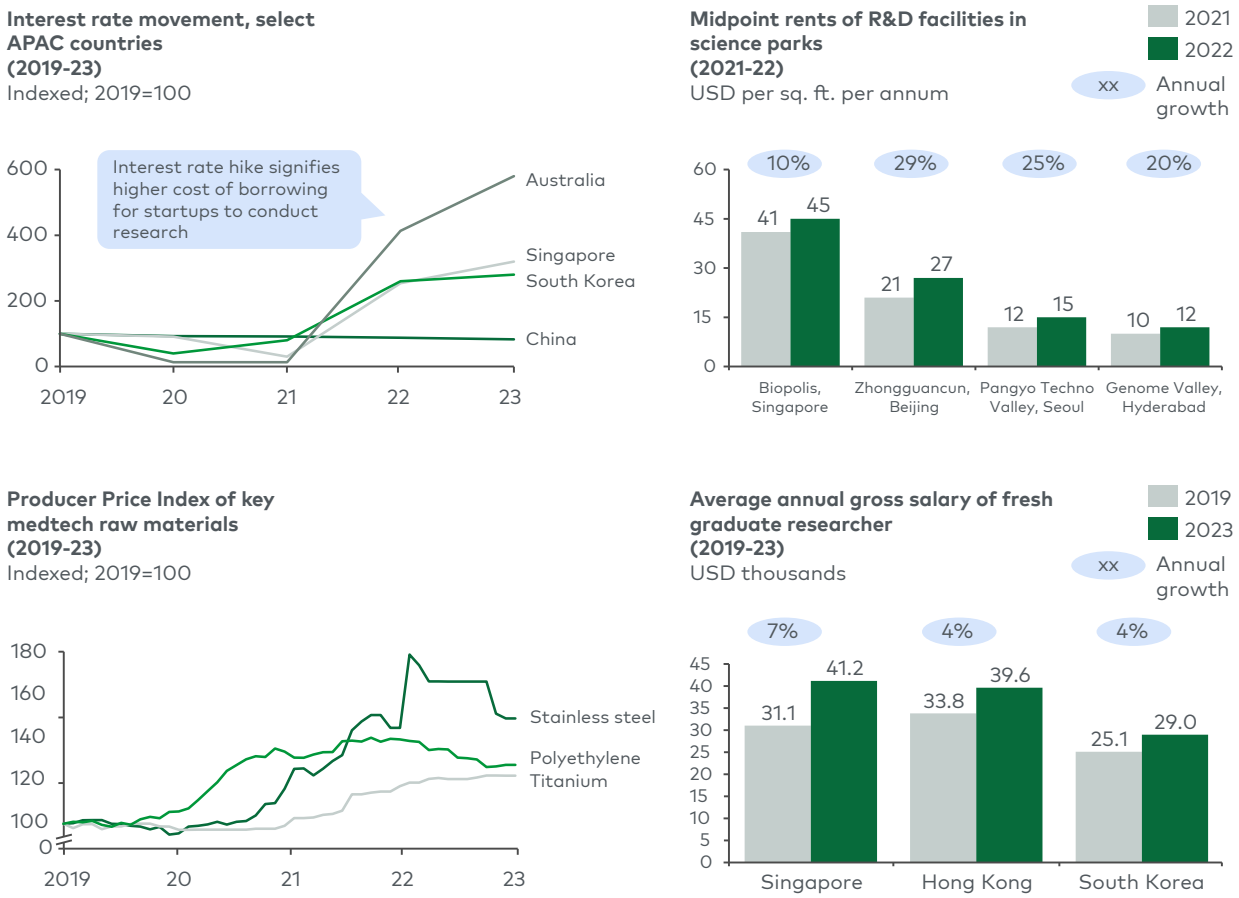
The challenges within the medtech innovation ecosystem cannot be attributed solely to the decline in investment; rising research expenses have significantly impacted the sustainability of startups as well. The costs of raw materials, manpower and lab rental have all increased substantially in recent years (see Figure 3).

Policymakers' efforts to contain post-pandemic inflation have led to a cyclical increase in global interest rates, making it increasingly difficult for startups to attract attention from investors given the high-risk-high-return nature of healthcare startups and the fact that capitalists can get higher returns from lower-risk assets. As one consequence of the high-interest-rate environment, we have observed a trend of rising R&D facility rental costs, with at least a 10% increase across all APAC countries, from Singapore to India. This directly adds to the financial burden on startups, particularly in their early stages.

Key medtech raw materials like polyethylene and titanium have also seen significant price hikes over the past two years, partly due to geopolitical crises such as the Ukraine war and the Red Sea crisis. These increases not only drive up direct costs but also result in longer lead times, creating additional challenges for startups that operate at a smaller scale.

The cost of manpower is also rising. The hiring cost for fresh graduate researchers is reported to have increased by up to 7% since 2019, and more so for higher-quality talent. This further exacerbates the financial pressures faced by early-stage medtech companies and impacts their attractiveness to investors.

Figure 3:
Rising medtech research costs



Note: APAC=Asia-Pacific
Source: Trading Economics; Federal Reserve Economic Data; CBRE; University Graduate Employment Survey; L.E.K. research and analysis

Beyond the direct cost increases, additional indirect barriers further compound the financial strain on startups. The high barriers to entry in each APAC market and the unjustifiable return on investment required to navigate regulatory and market access challenges, present significant hurdles.

Fragmented commercial opportunities in markets close to home, along with regulatory inconsistency and delay, are necessitating larger resources to navigate these challenges and adding complexity to operations. In terms of market access and processes, new product registration typically takes six months to a year in Indonesia, Malaysia and Thailand, with approval in Singapore potentially accelerating the process in Thailand. Conversely,

Vietnam's registration process can take three to four years. Additionally, countries like Indonesia, China and India have a policy preference for locally manufactured products, while other jurisdictions appear to be more open to imports. The public reimbursement environment also varies significantly across APAC countries. Indonesia, Thailand and Vietnam have over 90% of their populations covered by government reimbursement, whereas Malaysia lacks a formal public reimbursement system yet subsidizes public hospitals. These differences create invisible costs and significant barriers to the growth of startup companies, potentially limiting their scale and rewards.

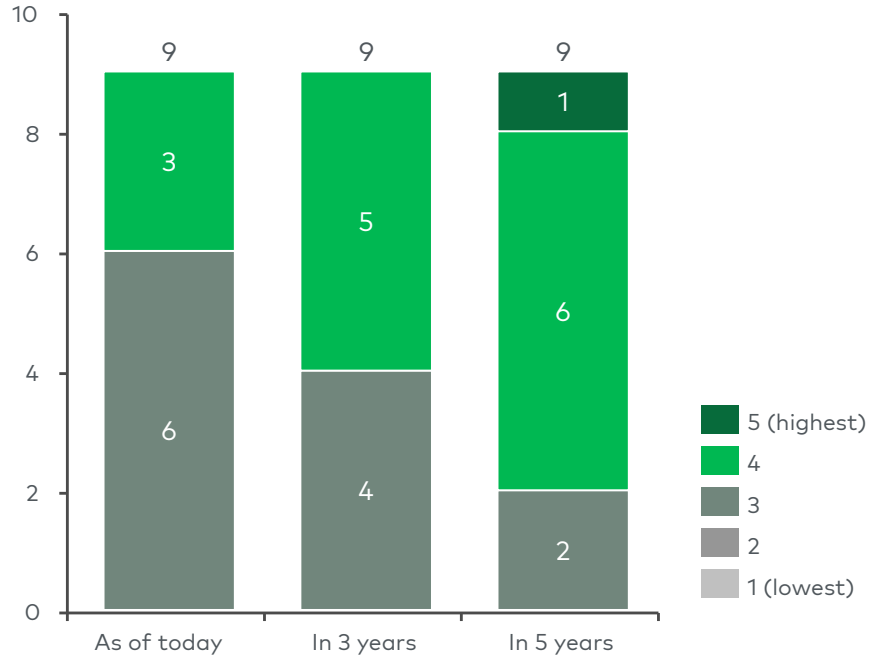
4.3. The ecosystem should step in to support innovation

As the innovation community raises its concerns, it is imperative for the medtech industry to strategize on how best to support the advancement of new technologies. These technologies are, after all, the lifeblood of healthcare innovation.

Despite the current suboptimal conditions for innovation development in APAC, the industry acknowledges the region's pivotal role over the next five years. According to L.E.K.'s sentiment survey, confidence in the medtech ecosystem in APAC averages 3.3 (out of 5). However, this confidence is expected to rise to 3.5 in three years and 3.9 in five years (see Figure 4).

Figure 4:
Confidence in the APAC medtech ecosystem

The confidence level of APAC medtech ecosystem (2024, 2027, 2029)
# of response, N=9; scale 1-5, 5 being the highest



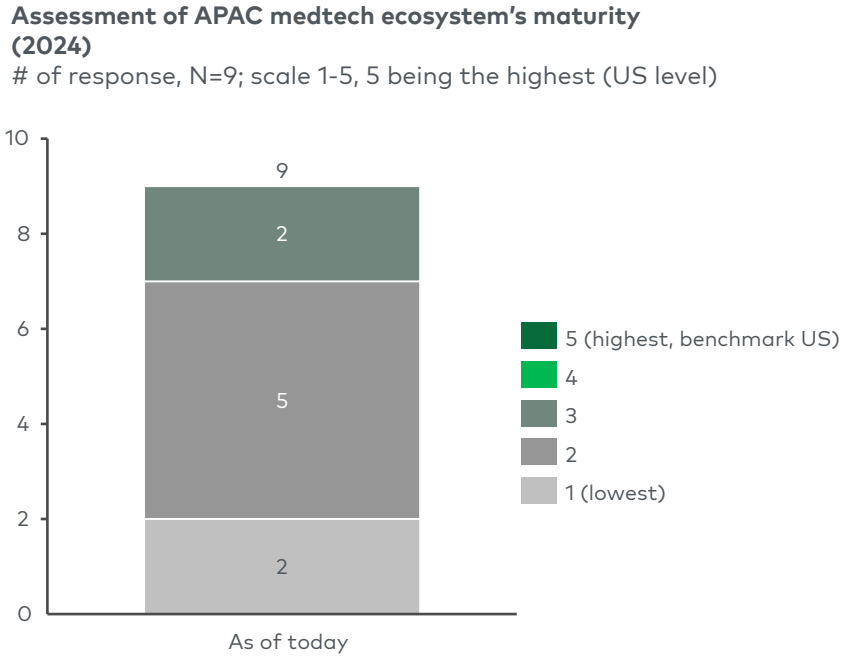
Note: APAC=Asia-Pacific
Source: L.E.K. survey and analysis

To sustain the delivery of innovative and lifesaving treatments, the medtech industry must urgently address the issue of inadequate capital allocation to promising APAC innovations. This challenge requires a collective effort from all ecosystem stakeholders to cultivate a more favorable investment climate. Through enhanced collaboration and strategic initiatives, the industry can secure the necessary funding for early-stage medtech companies, ensuring a continuous flow of groundbreaking technologies that will revolutionize patient care and improve public health outcomes across the region.

Yet a pressing question remains: Is the ecosystem prepared?

L.E.K.'s sentiment analysis reveals that the maturity rating of the APAC ecosystem stands at an average of 2, compared with 5 in the U.S. This disparity indicates that the APAC ecosystem is not yet fully equipped to curate innovation effectively (see Figure 5).

Figure 5:
APAC medtech ecosystem's maturity

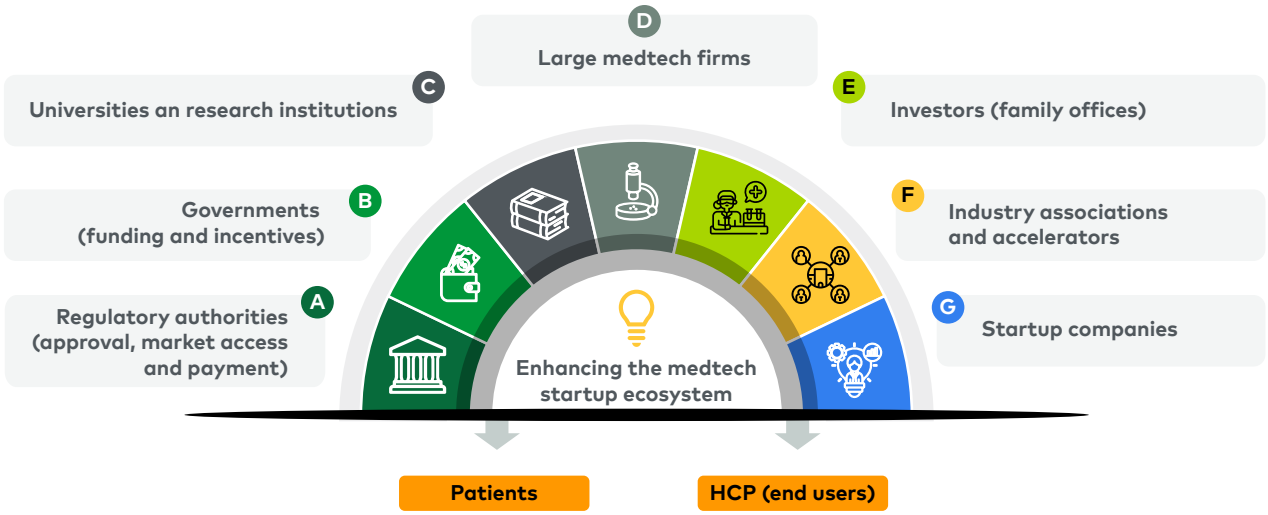


Note: APAC=Asia-Pacific
Source: L.E.K. survey and analysis

5. Building a more supportive ecosystem

Addressing the decline in innovation investment in APAC requires collective, proactive measures among stakeholders, including regulatory authorities (approval, market access and payment), governments (funding and incentives), universities and research institutions, large medtech firms, investors (specifically family offices in this report), industry associations and accelerators, and startup companies themselves (see Figure 6). By collectively addressing barriers and implementing strategic initiatives, these stakeholders can accelerate the quantity, quality and pace of medtech innovation in the region.

Figure 6:
Medtech ecosystem stakeholders required for innovation to scale



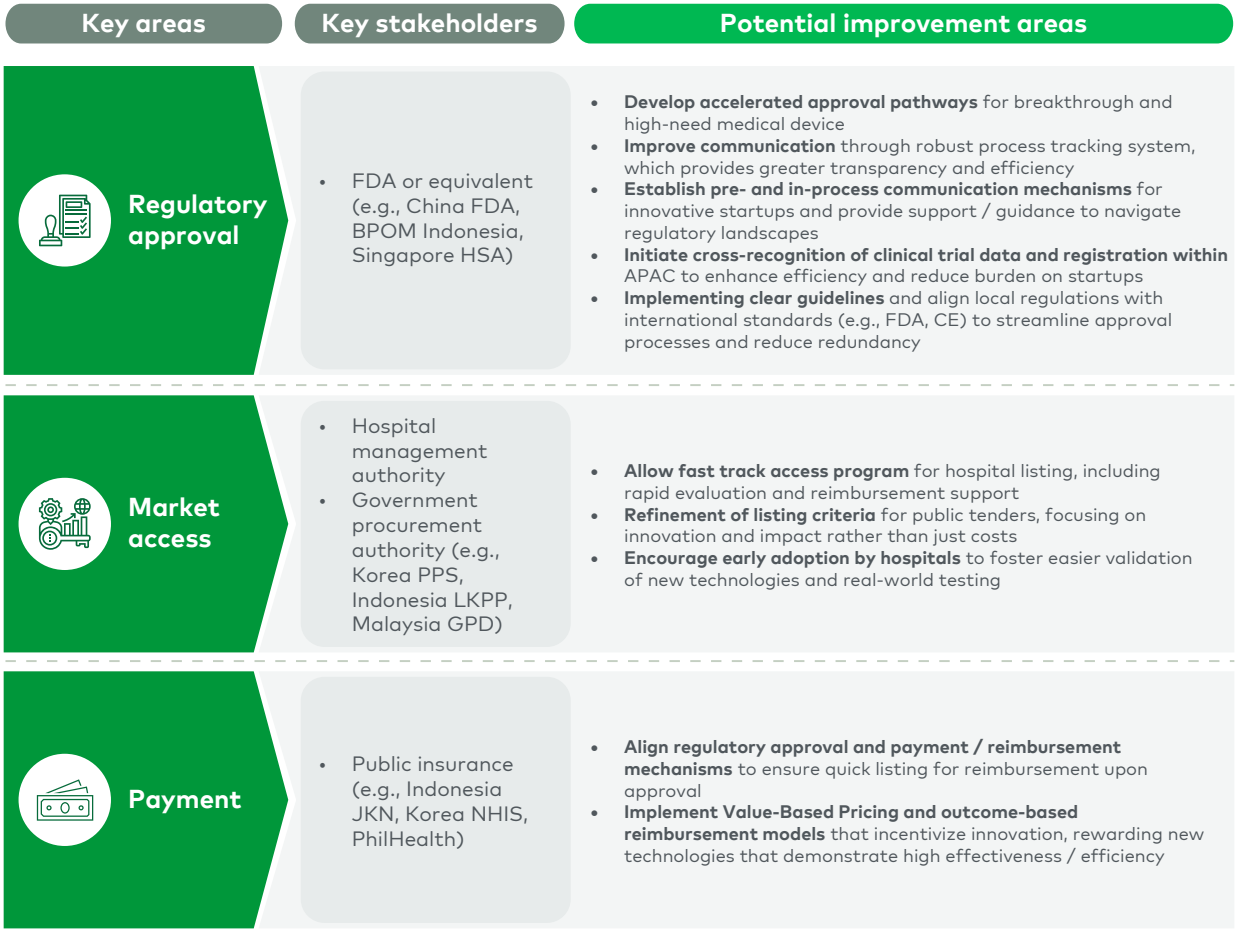
Source: L.E.K. research and analysis

In the following sections, our aim is to provide a comprehensive summary of the significant advancements and contributions made by various stakeholders in the APAC region over recent years. We delve into the myriad challenges encountered in fostering and supporting innovation within this dynamic landscape. Finally, we offer recommendations aimed at enhancing the ecosystem, ensuring it becomes an ever more fertile ground for groundbreaking innovations and sustained growth.

5.1. Regulatory authorities: acceleration through approval, market access and payment

Regulatory authorities play a pivotal role in accelerating the regulatory process and providing market access support, which are crucial to bolstering startups' innovation efforts. In this white paper, we focus on the key areas of approval, market access and payment. These three components are intrinsically linked, guiding a product from initial approval through adoption and utilization to its eventual compensation within the healthcare system. By examining these elements, we aim to shed light on the pathways and challenges that startups face in bringing innovative healthcare solutions to market (see Figure 7).

Figure 7:
The role of regulatory authorities



Note: FDA=U.S. Food and Drug Administration; BPOM=Badan Pengawas Obat dan Makanan (Indonesian National Agency of Drug and Food Control); HSA=Health Sciences Authority in Singapore; APAC=Asia-Pacific; PPS=Public Procurement Service in Korea; LKPP=Lembaga Kebijakan Pengadaan Barang/Jasa Pemerintah (Indonesian National Public Procurement Agency); GPD=Government Procurement Department in Malaysia; JKN=Jaminan Kesehatan Nasional (Indonesian National Health Insurance); NHIS=National Health Insurance Service in Korea
Source: L.E.K. research and analysis

The key performance indicators across all regions for regulatory authorities are largely similar: ensuring that safe and effective products are approved, listed and appropriately reimbursed. However, it typically takes at least three to five years for an innovative product to gain approval and be utilized within a healthcare system, even for just one jurisdiction. And timing is critical for innovations. Startups are eager to achieve positive cash flow from their product launches as soon as possible and as widely as possible to ensure their survival and continued growth.

Thus, the ecosystem needs to strike a delicate balance: ensuring that qualified products receive timely rewards while maintaining rigorous standards. Accelerating the regulatory pathway without compromising safety and efficacy is essential to fostering a supportive environment for innovation.

5.1.1. Regulatory challenges in fostering an ecosystem

Despite these progressive initiatives, startups still encounter challenges in navigating the diverse regulatory landscape across the countries in the region. Some of the most common hurdles include prolonged approval processes, lack of internationally recognized standards, unclear communication and insufficient targeted support mechanisms.

Prolonged and inflexible processes

Navigating the labyrinthine regulatory approval processes in the APAC region is both intricate and resource-consuming, demanding extensive data collection and stringent compliance with diverse agency requirements. For high-risk products, such as innovative implants, the approval administrative journey alone typically takes up to two years.[4,5,6] Only a select few regions have introduced acceleration programs aimed at expediting these timelines, leaving many startups grappling with opaque documentation requirements and convoluted approval pathways.

The challenges do not end with regulatory approval. Once a product is green-lighted, it often takes an additional one to two years to secure hospital listings and insurance reimbursement, further protracting the timeline. This prolonged process not only delays real-world implementation and inflates development costs but also stifles the opportunity for groundbreaking innovations to make a meaningful impact in healthcare settings.

Unclear guidance, inaccessible communication mechanisms and unapproachable channels

A recurring theme in our discussions with startups is the significant challenge posed by the lack of clear guidance, or even access to it. This absence of direction exacerbates the already formidable hurdles faced by emerging companies striving to bring their innovations to market.

The APAC region presents its own unique set of challenges, characterized by a mosaic of countries each with its own regulatory body and at varying stages of regulatory and market access development. Startups often need to consider global standards such as the U.S. Food and Drug Administration (FDA) or European Conformity (CE) certification for broader market recognition, adding another layer of complexity.

Innovation frequently introduces new categories of medical devices that can be difficult for some regions to evaluate effectively. This encompasses artificial intelligence (AI)-integrated innovation that has seen significant growth in the past few years at a speed that outpaces regulatory development. In many countries, regulatory requirements remain unclear and opaque, creating a significant understanding gap between regulatory authorities and startups. This lack of transparency hinders startups from efficiently navigating the regulatory landscape and addressing the necessary requirements for approval.

Unlike larger companies that can dedicate market access or regulatory affairs teams to navigate these complexities, startups must rely on their own limited capabilities. The lack of access to effective communication channels with regulatory authorities further compounds the problem.

Lack of integrated and targeted support

Approval, market access and payment are typically managed by three distinct authorities, necessitating an integrated regulatory support system across these areas. Without such cohesion, the support provided to startups is effectively diminished. Startups are seeking accelerated approval, faster market listing and reimbursement rates that value the innovation delivered. While there have been some improvements across the region, instances of an integrated system that links these elements are rare. For instance, accelerated approval processes are seldom connected to expedited hospital listings and enhanced reimbursement.

The Chinese government's Green Channel policy, designed to accelerate the approval process for medical devices (and described further below), serves as a case in point. Although it is intended to streamline regulatory approval, the lack of corresponding support in the market access and payment sectors — often accompanied by increased price pressures — diminishes its overall attractiveness to startups.

Other challenges

While these challenges cited by startups (as listed above) are the most prevalent and significant in the APAC region, they are by no means the only hurdles. The areas mentioned have garnered the most attention due to their widespread impact and the incremental improvements seen thus far.

Startups also face increasing pricing pressures, heightened clinical trial requirements and a lack of cohesive industry association connections across the region. These additional challenges complicate market access and stretch limited resources, making the environment particularly daunting for emerging companies.

5.1.2. Case studies

Case study 1 — China's Green Channel

One notable initiative is China's Green Channel, which aims to streamline regulatory approval processes for medical devices. This program provides a fast-track pathway for devices that offer significant advancements or address unmet medical needs within the country. To an extent, the Green Channel has significantly contributed to the surge of innovation in China's medical technology sector.

Under the Green Channel framework, eligible medical devices benefit from faster review times, simplified application procedures and direct communication channels with regulatory officials.[7] These streamlined processes enable innovators to navigate the approval process more efficiently, fostering a conducive environment for medical device development and market entry (see Figure 8).

Figure 8:
Features and impact of China's Green Channel

Key features

Fast-track review

- Review time through the green channel is reduced to an overall period of 60 working days, compared to 90-120 days through the standard path

Streamline procedures

- The program includes **simplified application procedures and direct communication channels** with regulatory officials, helping innovators navigate the approval process more efficiently

Eligibility criteria

- Be Class II / Class III medical devices or IVDs with significant clinical value
- Own valid invention patents
- Have China PTO coverage
- Complete the preliminary study on prototype with traceable data
- Have an authorized in-country legal entity

Impact of the China Green Channel

Accelerated innovation

- With the reduced time to market, the Green Channel promoted rapid deployment of innovative medical technologies, which enhances patient care and address critical health issues more efficiently

Competitive advantage

- Products that go through the innovative Green Pathway can gain a significant competitive edge for sales and marketing and future market competition. Products will also gain more market exposure.

Enhanced public health

- The program supports public health initiatives by ensuring that innovative and potentially life-saving medical devices are made available to patients in a timely manner

Note: FDA=U.S. Food and Drug Administration; BPOM=Badan Pengawas Obat dan Makanan (Indonesian National Agency of Drug and Food Control); HSA=Health Sciences Authority in Singapore; APAC=Asia-Pacific; PPS=Public Procurement Service in Korea; LKPP=Lembaga Kebijakan Pengadaan Barang/Jasa Pemerintah (Indonesian National Public Procurement Agency); GPD=Government Procurement Department in Malaysia; JKN=Jaminan Kesehatan Nasional (Indonesian National Health Insurance); NHIS=National Health Insurance Service in Korea
Source: L.E.K. research and analysis

Case study 2 – ASEAN Medical Device Directive

Beyond China, efforts to harmonize regulatory standards in the region are progressing, exemplified by the ASEAN Medical Device Directive (AMDD). This initiative seeks to establish uniform regulatory requirements among the 10 ASEAN member states, thereby facilitating regional market access.[8]

The harmonization of the regulatory framework for medical devices, as delineated in the AMDD, encompasses various critical aspects. These include, but are not limited to, the definition and classification of medical devices, premarketing requirements, the format for approval dossiers (i.e., a common submission dossier template), labeling requirements and the postmarketing alert system.[9]

While member states are progressing at different paces in aligning their regulations with the AMDD, as of March 2022, Singapore, Malaysia, Indonesia and Thailand had successfully completed this transition. The remaining member states are making significant strides toward full alignment.[10,11]

To keep up with recent advancements and trends in the medical device space, the ASEAN Medical Device Committee updates the AMDD on a yearly basis.

Case study 3 – In mature systems, different authorities are linking up to support innovation

Leading countries in the medtech innovation ecosystem have established mechanisms to support innovation through a targeted and integrated system encompassing approval, market access and payment.

A critical first step is the clear definition of "innovation" in each market, which serves as a gateway to various forms of support. Leading countries in the medtech field have recognized the importance of this and provided a precise definition of innovation in medical devices (see Figure 9). Clinical value often stands as the cornerstone of this definition, enabling products that meet these criteria to benefit from streamlined market access processes, such as faster approval timelines and prioritized reimbursement listings.

Figure 9:
Innovation definition and assessment from example countries

Country		US	UK	DE	JP	AU
Key definition		Provide **more effective treatment** or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions*	NICE-approved, **proven, cost-effective**, market-ready innovations	Innovative medical devices with proven **medical and economic need**	Medical devices with **new function** classification	Brand-new technologies Or products with **superior clinical performance**
Assessment and Approval		**CMS** defines innovation and provides supportive programs in market access; **FDA's** breakthrough devices is well recognized	**NHS** releases list of innovative technologies covered by funding program each year	**G-BA** develops a comprehensive innovative medical device evaluation process (NUB assessment)	**MHLW** has separate reimbursement classification for medical devices to reflect better pricing for innovative products	**PLAC** proposes requirement for increased benefit application of innovative medical devices
Benefits		✓ Faster market access to public insurance and higher DRG payment standard	✓ Faster market access with dedicated sourcing of funding for timely updated 'innovative' technologies	✓ Temporary payment before DRG inclusion with higher payment standard	✓ Pricing premium for 'innovative' devices through individual evaluation process	✓ Pricing premium for 'innovative' devices with increased benefit through self-application mechanism
Key learnings	Definition	• Clear definition • Emphasize clinical outcome • Recognition across FDA and payors	• A publicly available and annually renewed list of eligible innovative technology	• Assign clear status for innovative devices eligible for funding	• Set tiered definition of 'innovative' devices and differentiate each by reimbursement	• Clear criteria for incremental innovation certification with emphasis on clinical outcome
	Assessment	• Thorough examination by the FDA review team based on clear standards	• An independent organization (NICE) to provide HTA assessment including clinical and cost-effectiveness assessment	• NUB assessment process that includes medical and economic need assessment	• Clinical experts involved	• Clinical advisory groups involved in review of increased benefit application

Note: NICE=UK National Institute for Health and Care Excellence; CMS=US Centers for Medicare & Medicaid Services; FDA=U.S. Food and Drug Administration; NHS=National Health Service; G-BA=Federal Joint Committee in Germany; NUB= Neue Untersuchungs- und Behandlungsmethoden (New Examination and Treatment Methods) in Germany; MHLW=Ministry of Health, Labour and Welfare in Japan; PLAC=Prostheses List Advisory Committee in Australia; DRG=Diagnosis Related Group; HTA=Health Technology Assessment
Source: FDA; NHS; G-BA; MHLW; PLAC; L.E.K. discussion, research and analysis

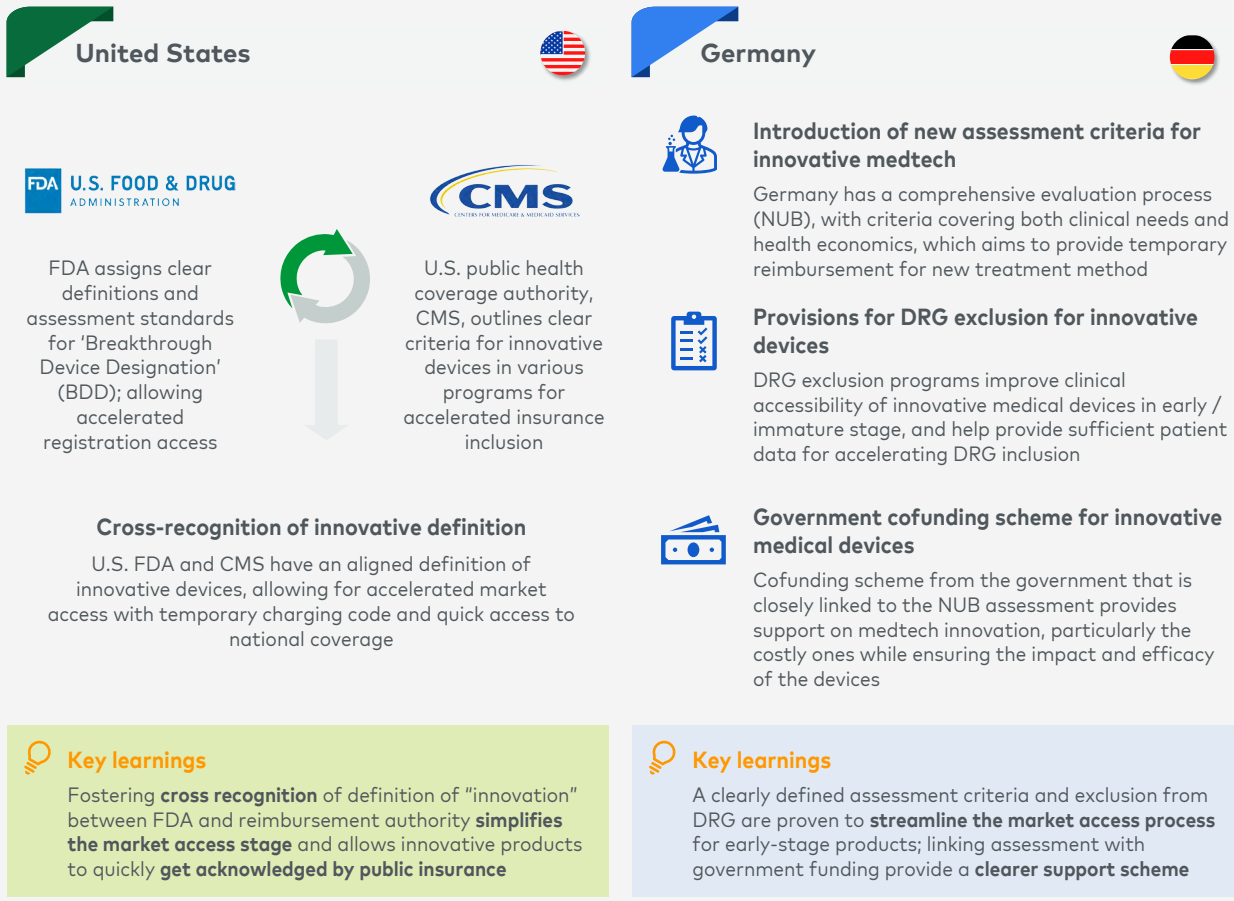
Given the challenges discussed above, it is crucial to explore solutions and learn from approaches adopted in other regions to address the regulatory challenges effectively. The U.S. and Germany are examples of how streamlining market access and having a clear definition of "innovation" could benefit the innovative landscape in a country (see Figure 10).

United States: The FDA has implemented the Breakthrough Device designation in the registration phase, specifically for devices that meet the "More Effective" criteria, thereby fulfilling the "Substantial Clinical Improvement" requirement in Centers for Medicare & Medicaid Services (CMS) programs. CMS, responsible for reimbursement and payment within the public system, has outlined clear criteria for innovative devices across various supportive programs. These programs facilitate accelerated payer inclusion and recognize the FDA-designated breakthrough device status.[12]

This cross-recognition of innovation definitions has significantly benefited innovative devices, enabling faster market revenue ramp-up and expedited market access. The alignment between FDA and CMS allows for accelerated market entry with temporary charging codes and quicker access to national coverage.

Germany: Regulatory authorities issued new evaluation criteria that cover both clinical needs and health economics of innovative medtech, with the goal of providing temporary reimbursement for new treatment. Clearer definition of assessment criteria offers a more streamlined market access process. Moreover, innovative devices are allowed to be excluded from Diagnosis Related Group categorization, providing clinical accessibility for these devices even though they are still in an early or immature stage.[13]

Figure 10:
Case study from the U.S. and Germany on regulatory improvements



Note: FDA=Food and Drug Administration; CMS=Centers for Medicare & Medicaid Services; NUB= Neue Untersuchungs- und Behandlungsmethoden (New Examination and Treatment Methods); DRG=Diagnosis Related Group
Source: U.S. FDA; CMS; G-BA; L.E.K. research and analysis

5.1.3. Key improvement areas

Regulatory authority can be further divided into three main areas: regulatory approval, market access and payment. While closely linked, these areas involve different stakeholders and, therefore, nuances in how each party can contribute to advancing the startup environment.

Regulatory approval

Regulatory authorities are responsible for evaluating and granting approval for the commercialization of medical devices. These agencies assess the safety, efficacy and quality of medical devices through a rigorous review process, which is typically conducted by the equivalent of the U.S. FDA in each country.

To address the challenges posed by the time-consuming approval process, regulatory authorities should implement accelerated approval pathways for devices that represent clinical breakthroughs or meet urgent medical needs. Actions to consider could include:

- **Accelerated approval pathways for innovation:** Establish accelerated approval pathways for breakthrough and high-clinical-need medical devices to expedite market entry and patient access.
- **Enhanced awareness:** Improve education channels through the development of comprehensive materials and a robust process tracking system to ensure transparency and efficiency.
- **Communication mechanisms for startups:** Establish pre- and in-process communication mechanisms specifically for innovative startups, providing them the support and guidance they need to navigate regulatory landscapes. Especially for some first-in-class devices, preprocess communication with the authority is essential in order to build a more efficient cycle.
- **APAC cross-recognition:** Initiate the cross-recognition of clinical trial data and registration within the region to enhance efficiency and reduce the burden on startups.
- **Global connections:** Implement clear guidelines and align local regulations with international standards (such as FDA and CE) to streamline approval processes and reduce redundancy.

Market access

Hospital management authorities and government procurement authorities are key stakeholders in granting market access for medical devices. These agencies are responsible for listing devices in hospitals and conducting public tenders, ensuring that the devices are available for patients in need.

To address the challenges in market access, actions to consider could include:

- **Fast-track access programs:** Implement fast-track access programs for hospital listings, including rapid evaluation and reimbursement support, to accelerate the adoption of innovative medical devices.
- **Refined listing criteria:** Refine the listing criteria for public tenders to prioritize innovation and clinical impact over cost alone, ensuring that groundbreaking technologies receive the recognition and support they deserve.
- **Encouragement of early adoption:** Foster early adoption by hospitals to facilitate easier validation and real-world testing of new technologies, thereby accelerating their integration into healthcare systems.

Payment

The last stage of obtaining market access is to gain reimbursement listing in public insurance schemes. And it is one of the most important steps, as the listing determines what the company will be paid. Actions to consider could include:

- **Aligned approval and payment:** Synchronize regulatory approval processes with reimbursement mechanisms to ensure that products are quickly listed for reimbursement once approved, streamlining the pathway from approval to market access.
- **Value-based pricing:** Implement value-based pricing and outcome-based reimbursement models that incentivize innovation, rewarding new technologies that demonstrate high effectiveness and efficiency. To ensure that innovation is compensated distinctly from commodity products and that investment in innovation is appropriately rewarded, it is crucial to sustain a viable return on innovation.

5.2. Governments: funding and incentives fueling the medtech innovation engine

Government funding and incentives, while often not the primary source of growth financing for startups due to their project-based nature, lengthy processes or modest amounts, can nonetheless serve as valuable complements to private-sector funding. Such support also offers credibility and government endorsement, which can be instrumental in building a startup's image.

In the current climate, where external funding from investors is slowing down, such government funding and incentives are crucial in propelling the medtech innovation ecosystem forward and stimulating research, development and commercialization of medical technologies. Government support can manifest in various forms, including:

- **Direct funding/investment:** Support for the development of startups through direct investments or grants, or even partial ownership
- **Indirect funding:** Includes grants, tax incentives and subsidies that can alleviate financial pressures and encourage continued innovation
- **Nonfinancial incentives:** Talent development programs and infrastructure support schemes that help build a robust ecosystem for innovation

Several governments in APAC have launched noteworthy initiatives to support the ecosystem. For instance, both Singapore and South Korea have dedicated startup grants with a specific focus on healthcare innovation. These countries also provide various incentives to support the operations of these innovative companies, fostering an environment where medtech startups can thrive (see Figure 11).

Figure 11:
Government funding and incentives in Singapore and South Korea

	Types of incentives	Singapore	South Korea
Direct funding	Startup grants	✓ Enterprise SG, SG Innovate	✓ Startup Korea, Biotech Startup Fund
Indirect funding	Research grants	✓ NRF, A*Star, RIE	✓ NRF, MSIT grant, KDDF
	Operational funding support	✓ CDG	N/A
	Government affiliated investment	✓ IDF	✓ MSIT investment in medtech and biopharma
	R&D tax incentives	✓ RISC	✓ Tax incentives and R&D preferred tax credit rates
	Training grants	✓ PIC, Enterprise Development Grants	N/A
Non-financial incentives	Talent development	✓ BMS-Workforce skills qualification	✓ KIAT, JHU Cooperation Center
	Talent specific visas	✓ EntrePass	✓ E-7 special ability visa
	Industry partnership program	✓ Incubator and accelerator programs	✓ Incubator and accelerator programs
	Infrastructure support schemes	✓ JTC-Biomedical Hub	✓ Building of national biofoundry
	Others	N/A	✓ Strengthening of IP law

Note: IP=intellectual property; RIE=Research Innovation & Enterprise Grants; NRF=National Research Foundation; CDG=Capability Development Grant; BMS-IDF=Biomedical Sciences Industry Development Fund; RISC=Research Incentive Scheme for Companies; PIC=Productivity and Innovation Credit Scheme; JTC=Jurong Town Council; NRF=National Research Foundation of Korea; MSIT=Ministry of Science and IT of South Korea; KDDF=Korea Drug Development Fund; KIAT=Korea Institute for Advancement of Technology; JHU=Johns Hopkins University
Source: Government databases; organization websites; L.E.K. research and analysis

The effectiveness of these governments' support extends beyond just the comprehensiveness of the assistance; the substantial amount of financial backing provided is equally crucial. For example, the Singapore government demonstrates a strong commitment to fostering innovation within the medtech ecosystem by offering financial support for startup and research programs, with grants ranging from USD 180,000 to USD 370,000 per program.

Given the size of the companies operating in Singapore, this level of financial backing represents a powerful signal that the government is actively fostering a supportive and thriving ecosystem. Such substantial funding helps lower the barriers for startups and research entities, enabling them to advance their innovations and scale their operations effectively.

More important, much of this funding is nondilutive, meaning that startups do not need to give up equity to receive these incentives. This feature is particularly valuable to emerging companies, as it allows them to retain control over their ventures while benefiting from government support.

5.2.1. Medtech startups' challenges in accessing government incentives

However, startups still face several challenges when accessing such government funding and incentives.

Direct funding

Limited scale of direct funding support: Different governments will typically have different budget focus areas, depending on the development level of the country and national priorities. Even then, government funding for innovative products, particularly in the medtech industry, is still lacking in many countries in the region, which hampers startups' ability to scale, especially since external funding sources are declining.

Limited flexibility in funding mechanisms: Predominantly, government funding is project based, with milestones established prior to agreement finalization. However, startups often face numerous uncertainties and emergencies, necessitating adjustments to these milestones. In some cases, overly rigid milestones can be the bootstrap of development progress.

Lengthy application processes: Funding and incentives from government often involve lengthy applications and multilevel approvals from various authorities, making it long and tedious for startups to access the support. Moreover, incentives from government are not always clearly outlined, with many requiring case-by-case assessments, which makes the process opaque and unpredictable for the startups.

Additional requirements from government: Government funding often carries additional requirements beyond financial returns, such as stringent IP stipulations and tax considerations. These mandates can impede startups' ability to innovate and scale, potentially dissuading them from pursuing government funding altogether.

Indirect funding and nonfinancial incentives

Limited relevance of indirect funding to startup companies: Indirect funding typically arrives as a reward after commercialization, rendering it less pertinent to early-stage innovations. For instance, tax incentive schemes, though prevalent in many countries, may not benefit non-revenue-generating startups that lack chargeable income. Common mechanisms that use eligible expenses to offset chargeable income are less impactful and less appealing compared with refundable tax offset systems, such as those in Australia (see Figure 12).

Figure 12:
R&D tax incentive comparisons between Singapore and Australia

		Singapore	Australia
Overview of R&D tax incentives	**Tax incentive schemes**	• Under the EIS R&D tax incentive scheme, Singapore provides a 100% tax deduction for in-house R&D conducted wholly in Singapore: ▪ Additional 300% tax deduction on the first USD 298K on staff costs (excluding directors' fees) and consumables ▪ Additional 150% tax deduction on the balance of qualifying R&D expenditure over USD 298K	• Refundable tax offset at corporate tax rate of the entity (25%-30%) plus an 18.5% premium for entities with an aggregated turnover of less than USD 13.5M • Nonrefundable tax offset at corporate tax rate plus an incremental premium of 8.5%-16.5% (based on the company's R&D intensity) for entities with an aggregated turnover of USD 13.5M or more
	Cap for eligible R&D expenditure	• No cap on amount of eligible R&D expenditure	• The cap for eligible R&D expenditure is USD 99.5M per year, with no cap on the amount of refundable R&D tax offset
Cash refund option		• Convert up to USD 74.5K of the total qualifying expenditure into cash at a conversion rate of 20%	• Convert entire tax offset, i.e., 25%-30%, plus the premium as cash
R&D expenditure coverage	**Clinical trial costs**	✗	✗
	Staff costs	✓	✓
	Consumables	✓	✓
IP registration, licensing and acquisition		• Reduced corporate tax rate of 5% or 10% on qualifying IP • Tax deduction of 400% on the first USD 298K expenditure	✗
Eligibility requirements		• Only those activities performed in Singapore are eligible for the enhanced deduction ▪ However, qualifying R&D expenditures associated with overseas activities are eligible for a 100% base R&D deduction • For outsourced R&D payments, 60% of the costs are deemed as qualifying expenditure unless otherwise justified	• All activities performed outside Australia are also eligible for the enhanced deduction • Annual R&D expenditure must exceed USD 13.5K • Phase IV trials only eligible if they are being carried out as experiments for the purpose of resolving further medical research
			More attractive mechanisms in Australia

Note: EIS=Enterprise Innovation Scheme
Source: IRAS; EY R&D global tax guide; L.E.K. research and analysis

5.2.2. Key improvement areas

The way forward in addressing the improvements needed in government funding and grants is a complex topic, as it varies significantly across different regions and grant types. Below are some key areas for improvement, with more detailed suggestions requiring targeted analysis.

Holistic support for innovation: To maximize the impact of direct funding, governments should adopt a proactive stance in supporting the startups they invest in. Beyond financial returns, governments can leverage their authoritative position to offer additional support, such as assistance with clinical trials and preferential market access.

Mechanism and process optimization: Governments should enhance indirect funding and nonfinancial incentives by tailoring their mechanisms to better meet the evolving needs of startups. This includes balancing governmental key performance indicators (e.g., employment, tax revenue, efficient funding use) with the actual needs of startups, such as timely support and flexible terms.

5.3. Universities and research institutions: nurturing the seeds of innovation

Universities and research institutions can also support the innovation ecosystem through their contribution in research capability and as a knowledge source. These institutions also serve as incubators for talent and innovators. Many innovative products were developed at universities and research institutions, often in collaboration with medtech providers and other industry stakeholders. Though many campuses have started to provide dedicated support for innovations, some barriers still persist in supporting medtech innovation.

5.3.1. Barriers to supporting medtech innovation

Concerns about IP ownership: Collaborating with universities in innovation endeavors often sparks concerns regarding the ownership of IP. Given the diverse contributions from multiple parties involved in the development process, disputes over IP ownership can emerge, potentially hindering the advancement and commercialization of new technologies.

Concerns about talent leakage: When universities engage in collaborations with startups, they often face concerns about talent poaching, fearing that such partnerships could deplete their intellectual capital and hinder their own research endeavors.

Resource constraints: Universities often have limited funding, infrastructure and personnel that they can allocate to support extensive research projects. Moreover, universities might not have a lot of flexibility in deploying their resources, as the funding decisions often involve multiple stakeholders.

Lack of understanding about commercialization: The expertise of university professors and researchers is focused on research and academic pursuits, and thus they often lack the business skills required for successful product commercialization.

5.3.2. Case studies of university-backed medtech innovation fostering

Several university-backed schemes in the U.S. offer exemplary programs to foster innovation. For example, the University of California, San Francisco (UCSF) Clinical & Translational Science Institute offers support throughout the development and commercialization journey of innovative medtech devices to facilitate the transition from research to market.[14] This includes technology validation, clinical trial operational support, provision of regulatory guidance and, through UCSF Innovation Ventures, advisory for commercialization strategies. Eko Devices, a medtech company developing devices to detect cardiovascular and pulmonary disease, is an example of the many startups that have undergone clinical validation at UCSF.

Stanford University's Biodesign Program provides a combination of coursework, hands-on projects and mentorship from industry experts to accelerate the development of innovative medtech products. These include fellowship programs that offer rigorous support in identifying innovation opportunities and their translation into products, and also hands-on training and mentorship programs (such as the Invention Accelerator Program) to give guidance from early preclinical/clinical testing all the way to business model development. Biodesign moreover offers numerous grants (e.g., Spectrum Medtech Grants for up to USD 50,000 for one year) to further support the realization of innovative products. Successful medtech startups such as Auris Health, iRhythm Technologies and Earlens have emerged from this program.[15]

Within the APAC region, Kyoto University Innovation Capital (Kyoto-iCAP) is a venture capital firm with 100% investment from Kyoto University that supports the development and commercialization of innovative seeds in numerous sectors, including medtech. Specifically, through the two schemes offered (ECC-iCAP and EIR-iCAP), select researchers can obtain hands-on support from experienced entrepreneurs leading mentorship and training programs to accelerate and ensure a successful product development and commercialization pathway.[16] Kola-Gen Pharma, developing devices for ophthalmic disorders, and Cleanhearing, developing a tinnitus treatment system via electromagnetic and acoustic stimulation of the cerebral cortex, are examples of the many startups that have emerged from Kyoto-iCAP.

5.3.3. Key improvement areas

In the rapidly evolving landscape of medtech innovation, universities play a pivotal role in enhancing the ecosystem. By providing support in research and development, fostering talent, facilitating knowledge transfer, and building strategic partnerships, universities serve to significantly contribute to the growth and success of medtech startups. These institutions offer a wealth of resources and expertise that can help startups navigate the complex journey from concept to commercialization (see Figure 13).

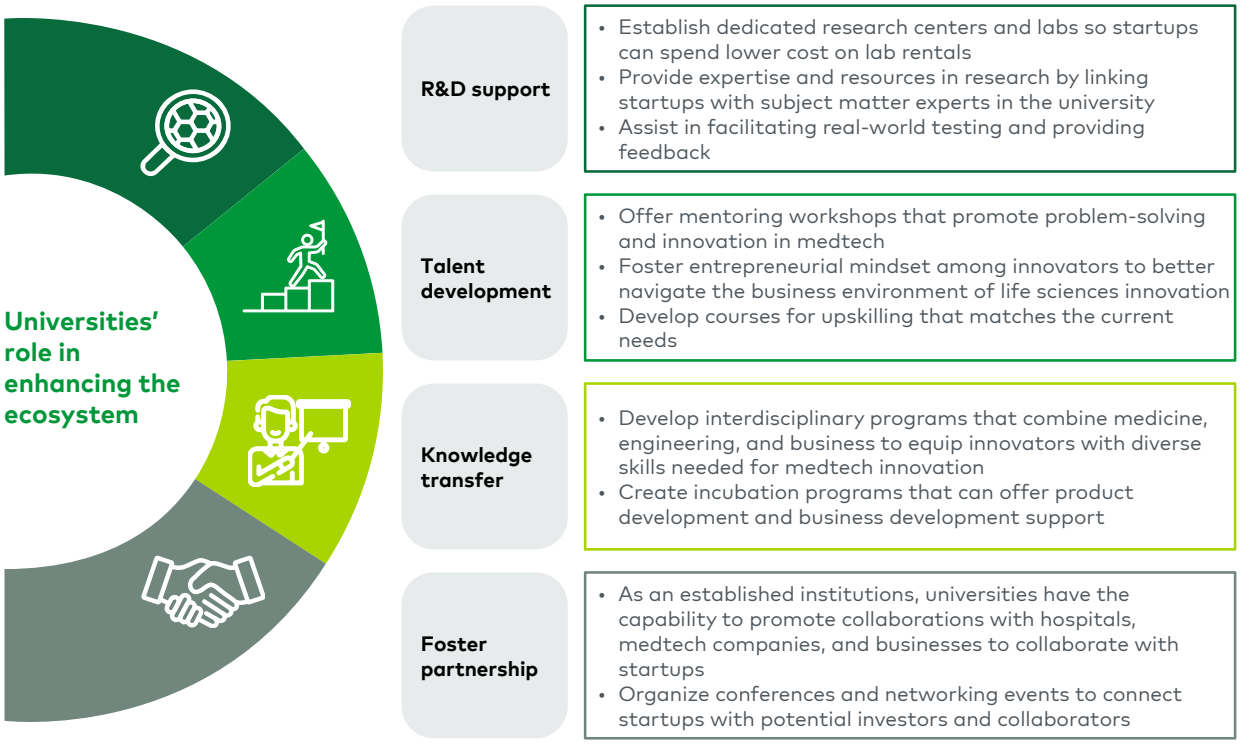
R&D support: Universities can enhance the medtech innovation ecosystem by establishing dedicated research centers and labs. Universities can also connect startups with subject matter experts to enrich research quality and facilitate real-world testing, offering access to clinical facilities and valuable feedback for refinement. These initiatives enable startups to allocate resources more efficiently, access specialized knowledge and validate their technologies in practical settings.

Talent development: Mentoring workshops focused on problem-solving and fostering an entrepreneurial mindset among innovators are beneficial for startups in navigating the business environment. Moreover, universities can develop upskilling courses targeted to innovators that address the evolving needs in the industry.

Knowledge transfer: Since universities have access to faculties and capabilities from various areas, developing interdisciplinary programs that combine medicine, engineering and business will be highly beneficial in equipping innovators with the diverse skills needed for medtech innovation. Many universities also have incubation programs that offer product and business development support for startups.

Fostering of partnerships: As reputable and established institutions, universities have the capacity to initiate collaborations between startups and hospitals, medtech companies and other industry stakeholders. This could be done through organizing conferences and networking events that connect startups with potential investors and collaborators.

Figure 13:
Universities' role in enhancing the ecosystem



Source: L.E.K. research and analysis

5.4. Large medtech firms: catalysts of innovation in a challenging market

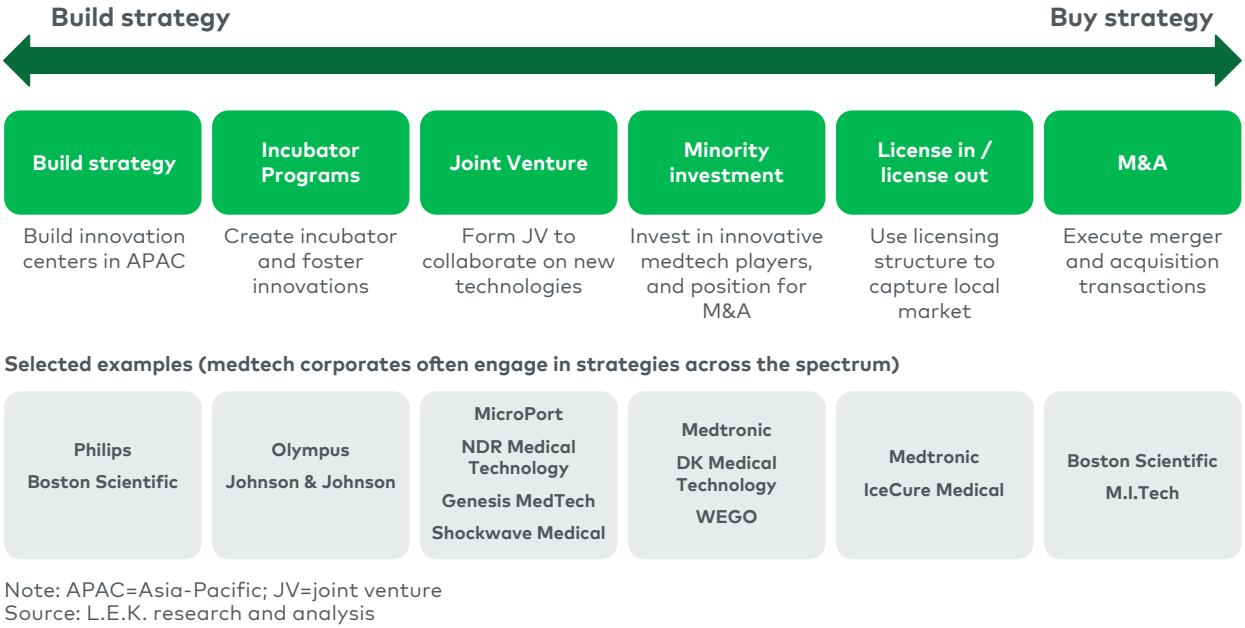
5.4.1. Large medtech firms' role in enabling innovation ecosystems

In the dynamic landscape of the medtech industry, large medtech companies serve as pivotal stakeholders, driving the innovation ecosystem forward. Amid a notably subdued private market and an equally quiet initial public offering (IPO) market, these industry giants have emerged as the predominant exit channels for numerous startups. Concurrently, large medtech companies are ardently striving to enrich their product pipelines with cutting-edge innovations, recognizing the unparalleled potential of large medtechs' commercialization capabilities.

To harness the full spectrum of innovation, large medtech companies deploy a variety of strategies within the buy-and-build paradigm (see Figure 14). These include developing greenfield strategies, such as establishing innovation centers, as well as forming joint ventures and engaging in M&A.

Several notable examples highlight the involvement of large medtech companies in the region's innovation ecosystems, showcasing their commitment to fostering technological advancements and supporting burgeoning startups for innovation, to best reap the full potential of the commercialization arms.

Figure 14:
Participation of large medtech firms in innovation in APAC



Note: APAC=Asia-Pacific; JV=joint venture
Source: L.E.K. research and analysis

We've observed a recent trend of large medtech firms exploring different types of investment in the APAC region. Here are a few examples of their involvement in the medtech innovation ecosystem.

"Buy" strategy

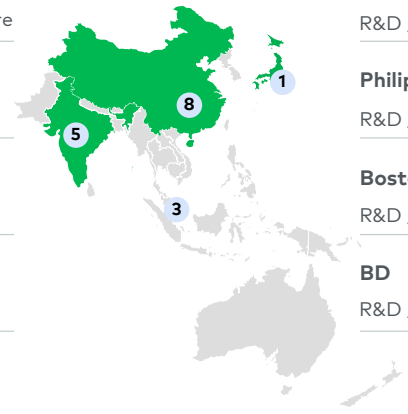
- **Strategic investment in innovation enterprises:** Examples include Medtronic China's launch in May 2023 of a Phase II fund intended for innovative medtech diagnostics/ therapeutics for cardiovascular and neurological diseases
- **Acquisition of innovation enterprises:** Examples include 1) Boston Scientific's USD 230 million majority-stake acquisition in June 2022 of M.I.Tech, a Korean startup focused on endoscopic and urologic procedures, and 2) Boston Scientific's USD 523 million majority-stake acquisition in December 2022 of Acotec Scientific, a Beijing-based startup focused on cardiovascular treatment devices
- **Cooperation with innovation enterprises:** Examples include Stryker's collaboration in November 2022 (undisclosed deal value) with Novelbeam Technology, a Chinese startup developing optical instruments, for the accelerated joint development of an endoscopic camera system (expected development timeline reduction of 30 months)

"Build" strategy

However, as mentioned above, buying has slowed in recent years with fewer M&A deals and investment in the region. Even so, large medtech companies can support the ecosystem by building innovators and incubator programs. Top global medtech companies have established their R&D capabilities in APAC, mostly in China, Singapore and India (see Figure 15).

Figure 15:
Top 10 medtech multinational companies* and their R&D/innovation centers in APAC

Medtronic	R&D / innovation centers: China, Singapore	**Stryker**	R&D / innovation centers: India, China
Abbott	R&D / innovation centers: China, Singapore	**Cardinal Health**	R&D / innovation centers: India
Johnson & Johnson	R&D / innovation centers: China	**Philips**	R&D / innovation centers: India, China
Siemens Healthineers	R&D / innovation centers: China	**Boston Scientific**	R&D / innovation centers: China, India, Japan
GE Healthcare	R&D / innovation centers: India	**BD**	R&D / innovation centers: China, Singapore



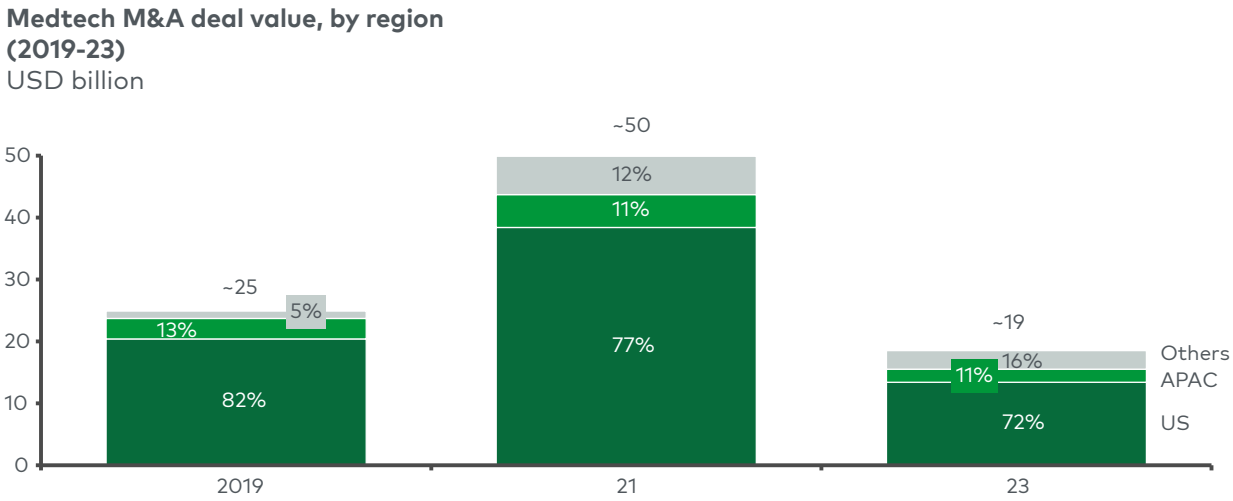
x Number of innovation / R&D centers in top 10 medtech

*Based on FY2022 revenue
Note: APAC=Asia-Pacific
Source: Company websites; company annual reports; L.E.K. research and analysis

5.4.2. Barriers hindering large medtech company investments in APAC

Despite the burgeoning innovation development trends in the region, investment in medtech remains notably lower compared with that in the United States and Europe. Data reveals that mergers and acquisitions in the APAC region have consistently accounted for only 10%-15% of the global deal value over the past three years (see Figure 16). This significant disparity prompts critical examination: Why does the region lag in medical technology investment, and what can be done to address this imbalance?

Figure 16:
Medtech M&A deal value, by region



Note: APAC=Asia-Pacific
Source: GlobalData; L.E.K. research and analysis

Based on discussions with medtech leaders in the region, we have identified several challenges and barriers to investment (see Figure 17). Here are some key insights:

Limited market size due to narrow geographical focus

Many medtech products developed in the APAC region are primarily designed with a focus on the home market, often overlooking the broader regional and international markets. Given the fragmented nature of the APAC region, it is typically challenging for startups to target multiple countries simultaneously. As a result, many startups choose to concentrate on their home markets, where the founders have a greater familiarity and established networks.

Startups in the APAC region face additional hurdles when attempting to enter global markets. These challenges include navigating a complex array of regulatory environments, addressing IP concerns and making the substantial investments needed to meet international standards. The regulatory and compliance requirements can vary significantly from one country to another, creating a formidable barrier for companies looking to expand beyond their local markets.

Consequently, APAC startups, unless they have demonstrated significant success and capability in the U.S. or EU markets, are often not the top priority for mergers and acquisitions when large medtech companies consider strategic investments. The difficulties associated with international expansion and the relatively narrow focus on regional markets can make APAC startups less attractive as acquisition targets compared with those with established footprints in more mature markets.

Emphasis on achieving commercial success vs. addressing unmet needs

The pressure to deliver quick returns on investment, coupled with limited resources for high-risk ventures, often drives medtech acquirers to prioritize products with established market demand. This emphasis on achieving commercial success and rapid profitability frequently overshadows the pursuit of innovative solutions that could address critical gaps in healthcare.

Heavier focus on "me-too" products over innovation

In the APAC medtech sector, there is a significant focus on me-too products rather than on groundbreaking innovations. Such products, which are essentially variations of existing technologies, are often preferred due to their lower development risks and reduced research and development costs, given that the core technology has already been validated. These products generally compete on price, offering more cost-effective solutions for healthcare providers and patients.

The price-centric nature of me-too products makes them particularly attractive to large medtech companies investing in the APAC region. By focusing on products that can achieve immediate market acceptance and cost-efficiency, companies can mitigate the financial risks associated with higher-risk innovations. This approach, while providing quick market entry and financial returns, often diverts attention away from pioneering, high-risk innovations that could potentially address more significant gaps in healthcare but require longer development timelines and greater investment.

Lower return on investment

Historically, the return on investment for medtech deals in the APAC region has been lower compared with that of other regions. The median revenue multiple for medtech transactions in APAC is approximately 5.0x, whereas in the United States it was around 8.3x for the period from 2019 to 2023. This disparity can be attributed to several factors, including the immaturity of capital markets, stringent price controls on healthcare expenditure and, crucially, a tightening exit channel within the APAC region.

In addition, the exit options for medtech investments have traditionally been through IPOs or strategic investments. However, recent market conditions, such as the crackdown on Chapter 18A companies on the Hong Kong Exchange, have made the IPO route increasingly challenging. Furthermore, strategic investments have historically not been a major channel for exits, contributing to a more constrained investment environment. These developments

cast a shadow over the prospects for medtech innovation in APAC, as they limit the avenues available for realizing returns on investments and raise concerns about the overall investment climate in the region.

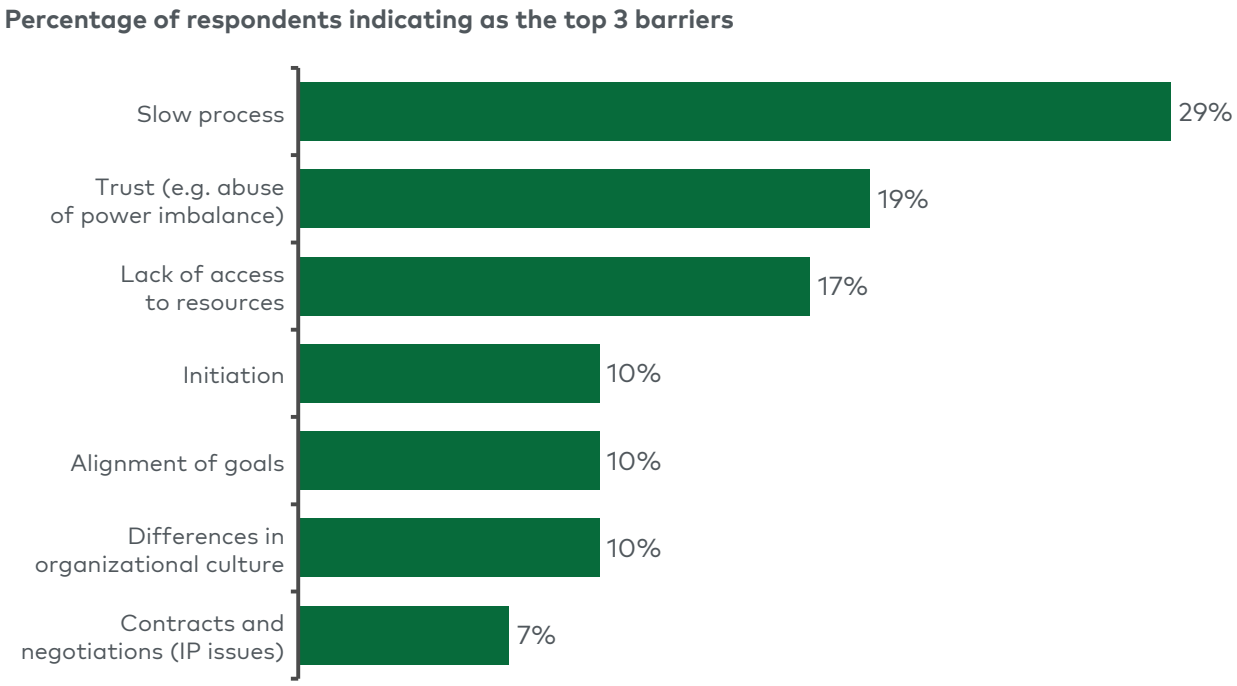
Limited communications between startups and large medtech companies in APAC

Beyond the fundamental market dynamics and product-related factors, a more subtle but significant challenge is the communication channel between startups and medtech companies. This challenge manifests in two primary areas: ensuring conversations are held with the appropriate stakeholders, and achieving efficiency in these discussions to align with both parties' needs.

Innovators frequently encounter difficulties related to pace, trust and commitment of resources when collaborating with larger corporations. These issues often arise from a lack of understanding of each other's needs during discussions. Innovators may perceive that their concerns are not adequately addressed, leading to inefficiencies and frustration.

Effective deal-making in APAC medtech requires engaging the right decision-makers, as key decisions often rest with global headquarters. Building strong relationships and aligning with HQ priorities are crucial steps. Additionally, the negotiation process can be slowed by back-and-forth discussions between regional and global HQs, highlighting the need for more efficient communication.

Figure 17:
Startups' views on barriers to partnership with corporations



Note: IP=intellectual property
Source: L.E.K. Consulting and Galen Growth Digital Health Index Survey; L.E.K. research and analysis

5.4.3. Key improvement areas

Building a success story in APAC

For the ecosystem to support and build a compelling success story in the APAC medtech sector, it is essential to focus on creating and demonstrating tangible value. This involves showcasing successful case studies and innovations that have made a significant impact within the region. Highlighting achievements such as successful product launches, effective market penetration strategies, and positive outcomes for healthcare providers and patients can enhance credibility and attract interest from potential partners and investors. Establishing a track record of success helps build trust and serves as a powerful testament to the effectiveness and potential of medtech innovations in APAC.

Leading medtechs in the APAC region play a crucial role here. They can accelerate start-ups' market access by leveraging their industry expertise and extensive networks. Additionally, they serve as strategic connectors between regional successes and global headquarters, effectively transforming local achievements into compelling global narratives that underscore APAC's innovation potential.

Steering startups through complicated international markets

Startups aiming to expand beyond their local APAC markets must effectively navigate the complexities of international markets. This involves understanding and addressing diverse regulatory requirements, IP concerns and market entry strategies tailored to each region. Providing startups with guidance and support on these aspects can facilitate smoother market entry and reduce barriers to global expansion. Leveraging local expertise and forming strategic partnerships with regional stakeholders can also help startups overcome challenges and successfully penetrate new international markets.

Establishing efficient communication forums in APAC

Developing efficient communication channels is crucial for fostering collaboration between startups and medtech companies. Establishing dedicated forums and platforms for dialogue can enhance the exchange of information and align expectations. These forums should facilitate direct interactions with key decision-makers and stakeholders, ensuring that conversations are productive and address both parties' needs. By creating structured and transparent communication pathways, both startups and medtech companies can better understand each other's goals, build trust and develop mutually beneficial partnerships.

5.5. Investors (family offices): fuel for the engine

As of 2023, roughly 19% of the 20,000 family offices globally are located in APAC,[17] and their growth in number is expected to generally outpace that of the rest of the world, largely due to the expected increase in ultra-high-net-worth individuals (those exceeding USD 30 million in net worth) in China (88,000 in 2022 to 132,000 in 2027) and India (12,000 in 2022 to 19,000 in 2027).[18]

Overall investment flowing to the APAC region is also expected to increase in the next five years.[19] Currently, only roughly 17% of family offices have their largest regional allocations in APAC, but 35% have suggested they will increase their investments in APAC due to its growth potential and sectorial opportunities, particularly in technology (e.g., AI, healthtech).

Given the recent decline in medtech startup investment from traditional investors (i.e., private equity and venture capitalists), the growth of and interest from family offices presents an opportunity for medtech startups. However, given the limited involvement of family offices within the healthcare and medtech sector and the associated high risk, there are certain barriers that must be overcome.

5.5.1. Challenges faced

Limited awareness of the forefront of healthcare

Family offices are typically known to operate in traditional investments, including publicly traded stocks, bonds and real estate. While these may include healthcare companies, it is likely their awareness of novel medtech startups is limited such that the emergence of a promising startup will go unnoticed.[20]

Limited expertise in healthcare and medtech

The medtech sector is considered a highly convoluted field, with its stringent regulatory requirements and constantly evolving treatment landscape. Especially when it comes to evaluating which medtech startup to invest in, there is a need to thoroughly understand the product's clinical value proposition, how it is differentiated from its competitors and how it addresses unmet needs, which poses a high barrier of entry for family offices with limited experience.

Reduced appetite for high-risk investments among APAC family offices

Historically, Asia's family offices had a bigger risk appetite due to a low-interest-rate environment and high expectations of China's post-COVID-19 recovery. However, reduced performances from notable Asian stocks (including a reduction of around 15% in Hong Kong's Hang Seng index in 2023 and around 13% in China's CSI 300 Index), due to increased geopolitical risks and economic uncertainty, have left investor risk appetite somewhat stagnant.[21] In contrast, the strong performances recorded by the S&P 500 and the STOXX 600 in the U.S. and the EU, respectively, have boosted the risk appetite of family offices in these respective regions. As such, there may be greater hesitation, at least in the short term, to invest in medtech startups, especially in the Asia/APAC region.

5.5.2. Improvement areas

Adequate education and onboarding of experts

Globally, family offices are increasingly seeking to hire personnel with specialized knowledge in specific sectors to make more informed investment decisions. Due to the family office area being less mature in APAC, the demand for heightened professionalism in APAC is more prominent compared with the rest of the world (32% vs. 25%, respectively, responded to increasing such hires).[22] Through appropriate education on the importance of and opportunities within the healthcare sector, and within medtech in particular, family offices in APAC may be more keen to prioritize hiring personnel with in-depth medtech expertise, fostering an environment that is more conducive to investing in medtech startups.

Establishing introductory forums in APAC

The medtech startup space is predominantly financed by traditional investors, resulting in forums targeting and being tailored to their interests, and limiting the opportunities for family offices to take part. Creating a platform for medtech startups to interact with and communicate their vision and their product's value proposition to family offices will increase not only awareness but also the chances of investments from family offices.

5.6. Industry associations and accelerators: a unified voice for innovation

Individual startups, due to their size and limited resources, often struggle to have their concerns recognized by policymakers and industry leaders. This lack of influence can leave many startups feeling unheard, as they typically lack the dedicated government affairs or external relations staff necessary to effectively communicate their needs to the appropriate authorities.

To create a more supportive environment for these emerging companies, industry associations and accelerators must take on the role of powerful advocates. It is imperative that these organizations not only amplify the voices of startups but also champion their causes on a larger scale, ensuring their concerns are given the attention they deserve.

When startup companies unite under the banner of an industry association, their collective voice can carry significant weight. Industry associations are uniquely positioned to gather insights directly from startups, gaining a deep understanding of their specific challenges and needs. By acting as a cohesive and representative voice, these associations can advocate for the systemic changes necessary to foster a more favorable ecosystem for innovation.

Accelerators, meanwhile, are deeply embedded in the startup journey, working closely with companies during their most formative stages. This proximity grants them an unparalleled understanding of the obstacles that startups face, from regulatory barriers to challenges in market access. As both observers and active participants in the innovation ecosystem, accelerators are positioned to identify industrywide challenges and offer strategic, actionable solutions. Their role goes beyond providing mentorship and funding; they are also well suited to advocate for broader changes that will benefit the entire startup ecosystem.

In conclusion, the path to a robust startup ecosystem lies in the collective efforts of industry associations and accelerators. These organizations must evolve from supportive partners into vocal leaders, ensuring that the needs of startups are not only heard but also acted on and driving the changes necessary for sustained innovation and growth.

5.7. Startup companies: the basis of ecosystems

Last but not least, medtech startups themselves are pivotal in enhancing the APAC innovation ecosystem. By actively engaging and collaborating within the ecosystem, these startups not only advance their own innovations but also contribute to the overall growth and development of the sector. Their proactive involvement helps build a stronger, more dynamic medtech landscape in APAC.

It is no exaggeration to say that startups are typically at the forefront of innovation, especially with their ability to take greater risks than established companies in the field. However, several factors are key for a startup company to be successful, as we heard directly from ecosystem stakeholders during our research.

Pursuing the "right" innovation that addresses unmet needs

Startups often fall short in thoroughly understanding the nuanced unmet needs of the healthcare market, which inevitably leads to underwhelming products. To mitigate this, it is crucial to conduct thorough market research and engage with relevant stakeholders (e.g., senior clinical advisors or large medtech companies) to understand the market's unmet needs and where innovation is heading.

Defining a clear product value proposition

Ambiguity in product value proposition often leads to challenges in securing funding/ partnerships and hinders product adoption after launch. As such, it is pivotal for startups to clearly define and articulate the clinical value of their product and how the product is distinguished from its competitors.

Having a clear product development pathway

Many startups encounter challenges due to the lack of strategic planning and defined milestones, which results in delays and inefficiencies. To mitigate this, newer startups should follow examples of historically successful, more experienced startups to implement structured roadmaps that outline key objectives and timelines.

Initiating active communication

Regardless of how innovative the product may be, the lack of effective communication from startups with key stakeholders will undermine the product's potential. Communication with ecosystem stakeholders is crucial throughout the entire journey, from research and design to testing and commercialization. Startups should not passively wait for these stakeholders to engage; instead, they must proactively establish and maintain these communication channels.

6. Recommendations for implementations

A. Regulatory authorities

Challenges highlighted by innovation community	Potential areas of development
A4. More streamlined and flexible processes are needed to accelerate the real-world implementation of innovation, reduce development costs, and create more opportunities for groundbreaking advancements **A5.** Clearer guidance, more accessible communication mechanisms and approachable channels are essential to help startups more effectively navigate the complex regulatory landscape **A6.** Enhancing integrated and targeted support — particularly in a landscape where approval, market access and payment are managed by separate authorities — can significantly improve startups' ability to successfully commercialize their products	**Regulatory approval** • Develop accelerated approval pathways for breakthrough and high-need medical products • Improve communication through comprehensive materials and a robust process-tracking system, which will provide greater transparency and efficiency • Establish pre- and in-process communication mechanisms for innovative startups, and provide support and guidance to navigate regulatory landscapes • Initiate cross-recognition of clinical trial data and registration between APAC jurisdictions to enhance efficiency and reduce the burden on startups • Implement clear guidelines and align local regulations with international standards (e.g., U.S. FDA, EU CE) to streamline approval processes and reduce redundancy **Market access** • Allow fast-track access programs for hospital listings, including rapid evaluation and reimbursement support • Refine the listing criteria for public tenders, focusing on innovation and impact rather than just costs • Encourage early adoption by hospitals to foster easier validation of new technologies and real-world testing **Payment** • Align regulatory approval and payment/reimbursement mechanisms to ensure quick listing for reimbursement upon approval • Implement value-based pricing and outcome-based reimbursement models that incentivize innovation, rewarding new technologies that demonstrate high effectiveness and efficiency

B. Governments

Challenges highlighted by innovation community	Potential areas of development
Direct funding **B1.** Direct funding support is crucial for medtech companies to successfully scale up **B2.** Some rigidity in funding mechanisms, which at times could be the bootstrap of the development process **B3.** Lengthy application processes, preventing timely access to government funding **B4.** Additional requirements (e.g., local employment or manufacturing) along with investment, impeding startups' ability to innovate and grow **Indirect funding and nonfinancial incentives** **B5.** Limited relevance of indirect funding to startups, as the funding is often awarded after commercialization, rendering it less pertinent to early-stage innovations	• Provide holistic support for innovation to maximize the impact of direct funding; establish "medtech office" format agency to coordinate all government agencies that provide funding • Enhance indirect funding and nonfinancial incentives by tailoring mechanisms to the evolving needs of startups

C. Universities and research institutions

Challenges highlighted by innovation community	Potential areas of development
C1. Intellectual property (IP) ownership concern due to involvement of multiple stakeholders, which may cause disputes and hinder the progress of innovation **C2.** Concern about talent leakage from the university, which may result in reduced willingness to collaborate with startups **C3.** Resource constraints, in that universities may not be able to allocate resources to support extensive research projects, as they are struggling with limited funding and personnel **C4.** Lack of understanding about commercialization among university professors and researchers due to their devotion to research and academic pursuits, reducing the likelihood of product success	• Provide R&D support by establishing dedicated research centers and connecting startups with subject matter experts to enrich research quality and facilitate real-world testing • Foster talent development by offering mentoring workshops to better navigate the business environment and innovation landscape • Foster knowledge transfer by developing interdisciplinary programs to equip innovators with the diverse skills needed for medtech innovation • Foster partnerships between startups and relevant stakeholders by organizing conferences and networking events

D. Large medtech firms

Challenges highlighted by innovation community	Potential areas of development
D1. Limited market size of startups, as the fragmentation of the APAC region (e.g., market access) inevitably causes startups to limit their geographical focus **D2.** Asset's emphasis on achieving commercial success (vs. addressing unmet needs), due to pressure to deliver quick returns and limited resources among startups **D3.** Overweighting toward "me-too" products instead of innovative products, as the core technology (having already been validated) reduces development risks and R&D costs **D4.** Lower return on investment compared with the U.S. due to the immaturity of capital markets, stringent price controls and a limited exit channel within the APAC region **D5.** Limited communication channels between startups' and multinational companies' (MNCs') HQs, resulting in misalignments regarding startup offerings and MNCs investors' pursuits	• Build a success story in APAC by highlighting achievements (e.g., successful product launches) in order to enhance credibility, attract interest from potential partners and serve as a powerful testament to the potential of medtech innovation in APAC • Steer startups through complicated international markets by providing guidance and support on regulatory requirements, IP concerns and market entry strategies • Establish efficient communications forums for startups to effectively exchange information and align expectations with those of relevant stakeholders

E. Investors (family offices)

Challenges highlighted by innovation community	Potential areas of development
E1. Generally weak familiarity with the leading edge of healthcare technology and care delivery **E2.** Limited expertise in healthcare and medtech, preventing funds from thoroughly assessing the potential of and making an informed judgment on investment in a product **E3.** Reduced appetite for high risk investments among APAC family offices due to increased geopolitical and economic uncertainty	• Adequately educate family offices on the importance of and opportunities within the medtech sector, to prompt the onboarding of personnel with in-depth medtech expertise • Establish introductory forums in APAC to provide startups an opportunity to communicate their vision and product value proposition to family offices

F. Industry associations and accelerators

Industry associations and accelerators must step up and champion the cause of early-stage innovation by amplifying the voices of startups. While individual startups may struggle to influence government policy due to their limited scale, a united front can create a resonant voice within the ecosystem. Industry associations can play a pivotal role in this by gathering input from startups and advocating on their behalf, transforming their collective concerns into policy initiatives.

In addition to serving as a unified voice, associations play a crucial role in fostering innovation by acting as a meeting ground for corporations and startups. Both groups often seek innovative solutions but may face challenges due to limited resources and matchmaking opportunities. By facilitating these connections, associations and accelerators help scale innovation efforts and create valuable synergies.

Accelerators, with their proximity to startups, could provide targeted support that can significantly enhance a startup's development journey. They offer resources, mentorship, and strategic guidance that prepare startups to be more attractive to investors. By accelerating growth and refining their business models, accelerators position startups for investment more effectively and expediently than they might achieve on their own. This support not only increases the likelihood of securing investment but also enhances the overall impact and success of the innovative solutions being developed.

G. Final thoughts for startup companies

Last but not least, startups hold the keys to the transformative engine our medtech ecosystem desperately needs. But with great potential comes great responsibility. The journey begins with a commitment to the "right" innovations — those that fill the gaps in healthcare that others have overlooked. This requires startups to robustly understand the clinico-economic challenges facing the other stakeholders in the ecosystem.

By crystallizing a clear innovation value proposition, startups can access funding and strategic partnerships that might otherwise remain hard to reach. A well-mapped innovation development pathway ensures that everyone — from the founders to the investors — marches in step, reducing the risk of costly delays and setbacks.
And let's not forget the power of communication. Keeping key stakeholders in the loop isn't just good business — it's essential for turning breakthrough ideas into tangible, world-changing realities.

7. Acknowledgments

The authors express their sincere appreciation to all the individuals who generously took their time to participate in discussions. Their insights and expertise have been invaluable to the development of this whitepaper.

We also wish to thank APACMed for providing a platform that facilitated these important discussions. Their support and collaboration have been instrumental in bringing this project to fruition.

Name (alphabetical order)	Title	Company
Dr. Amit Garg (MD)	Regional Director of Medical Affairs and Digital Health	Terumo
Ashley Wittorf	APAC Head of Business Development	Johnson & Johnson Medtech
Creston Wong	Manager, APAC New Business Development & Strategy	Boston Scientific
Fatima Khan	Vice President, APAC Business Development and Strategy	Boston Scientific
Joaquin Lasso	Senior Vice President and General Manager Sports Medicine International	Smith+Nephew
Justin Leong	Chief Product Officer	ResMed
Kris Liang	APAC Director of Business Development & Integration	Stryker
Marc Radatt	Regional Chief Executive Officer	Olympus
Dr. Shailendra Bajpai, MD	Medical & Public Affairs Director - Asia	embecta
Yeonjung (YJ) Park	Senior Associate, Philips Ventures	Philips
James Sung	Chief Executive Officer	MatrixLabs
Dr. Lynne Lim	Founder and Chief Executive Officer	NousQ
Sampson Lau	President	PrimaNova

Below are the authors of the report.

Name	Title	Company
Dr. Chris L. Hardesty	Head of SME Portfolio	APACMed
Jaime Chua	SME Portfolio Analyst	APACMed
Stephen Sunderland	Head of APAC	L.E.K. Consulting
Feras Mahdi	Partner, APAC & MEA	L.E.K. Consulting
Wonder Wang	Manager	L.E.K. Consulting
Vincent Septian	Associate	L.E.K. Consulting
Dai Nakamura	Associate	L.E.K. Consulting

8. References

[1] MedTech World, "Investment in MedTech: A new hope.
" https://med-tech.world/news/investment-in-medtech-a-new-hope/

[2] Medium.com, "The Hard Thing about Medtech Startups & Why they're Worth it Anyway.
" https://medium.com/@fouadalnoor1/the-hard-thing-about-medtech-startups-why-theyre-worth-it-de41d4198084

[3] Medical Buyer, "Investment in MedTech startups takes a hit.
" https://www.medicalbuyer.co.in/investment-in-medtech-startups-takes-a-hit/

[4] Ministry of Health, Labour and Welfare of Japan, "新規医薬品等の保険収載の考え方について.
" https://www.mhlw.go.jp/content/12601000/000364051.pdf

[5] Sunflare, "承認申請における審査期間（医療機器・体外診断用医薬品）.
" https://md.sunflare.com/news/regulation/15264/

[6] QServe, "Things You Should Know About Medical Device Registration in Australia and New Zealand
" https://www.qservegroup.com/eu/en/i1488/things-you-should-know-about-medical-device-registration-in-australia-and-new-zealand#:~:text=If%20there%20is%20no%20overseas,completeness%20of%20the%20provided%20documentation

[7] Global Regulatory Partners, "China's Green Channel — Priority Review Approval for Medical Devices.
" https://globalregulatorypartners.com/wp-content/uploads/CHINAs-GREEN-CHANNEL-PRIORITY-REVIEW-APPROVAL-FOR-MEDICAL-DEVICES-Final.pdf

[8] ASEAN, "Asian Medical Device Directive.
" https://asean.org/wp-content/uploads/2016/06/22.-September-2015-ASEAN-Medical-Device-Directive.pdf

[9] Jetro Japan, "ASEAN 医療機器指令の概要と各国の.
" https://www.jetro.go.jp/ext_images/_Reports/02/2022/ab7026b72051af9f/AMDD_Report_20220331_vF3.pdf

[10] Global Compliance News, "ASEAN Medical Device Directive Implementation Updates.
" https://www.globalcompliancenews.com/2019/09/06/asean-medical-device-directive-implementation-updates-20190819/

[11] Qualtech, "Malaysia: Harmonised Classification of Medical Device in ASEAN —January/February 2024.
" https://www.qualtechs.com/en-gb/amdd-classification-guidance-2nd-edition

[12] U.S. Food and Drug Administration, "Breakthrough Devices Program.
" https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

[13] Reimbursement Institute, "NUB inquiry procedure.
" https://reimbursement.institute/en/nub-application/

[14] UCSF Clinical & Translational Science Institute, "Accelerating Research to Improve Health.
" https://ctsi.ucsf.edu/: https://ctsi.ucsf.edu/

[15] Stanford Byers Center for Biodesign, "Our Programs.
" https://biodesign.stanford.edu/programs.html

[16] Kyoto University Innovation Capital, "Kyoto University Innovation Capital.
" https://www.kyoto-unicap.co.jp/en/

[17] KPMG International, "The 2023 Global Family Office Compensation Benchmark Report.
" https://assets.kpmg.com/content/dam/kpmg/nl/pdf/2023/sectoren/global-family-office-compensation-benchmark-2023.pdf

[18] Empaxis, "The Rise of Asian Family Offices and the Growing Demand for Talent.
" https://www.empaxis.com/blog/asian-family-offices#:~:text=Asia%20Family%20Office%20and%20Wealth%20Stats&text=%E2%80%8D58%25%20of%20family%20offices,%25%20saw%20a%2010%25%20increase.&text=Asia%20has%20over%20950%20billionaires%2C%20more%20than%20any%20othe

[19] UBS, "UBS Global Family Office Report 2024: APAC set to be the top investment destination for family offices globally.
" https://www.ubs.com/global/ja/media/display-page-ndp/en-20240522-global-family-office-report-2024-apac.html

[20] Simple, "Family office investments: Recurring and new asset classes.
" https://andsimple.co/insights/family-office-investment/

[21] CNBC, "Asia's family offices have been betting big on risk — but that could be changing.
" https://www.cnbc.com/2023/12/18/asian-family-offices-bet-big-on-risk-but-that-could-be-changing.html

[22] Campden Wealth, "The Asia-Pacific Family Office Report 2022."

About APACMed

Founded in 2014 and headquartered in Singapore, APACMed represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics; industry associations ;and other key stakeholders associated with the medical technology industry in Asia-Pacific.

Providing a unified voice for the medical devices and in vitro diagnostics industry in Asia-Pacific, APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of medical technology and promote regulatory harmonization. We strive to promote digital health innovation and impact policy that advances healthcare access for patients by engaging with medical device associations and companies in Asia-Pacific.

About L.E.K. Consulting

We're L.E.K. Consulting, a global strategy consultancy working with business leaders to seize competitive advantage and amplify growth. Our insights are catalysts that reshape the trajectory of our clients' businesses, uncovering opportunities and empowering them to master their moments of truth. Since 1983, our worldwide practice — spanning the Americas, Asia Pacific and Europe — has guided leaders across all industries from global corporations to emerging entrepreneurial businesses and private equity investors. Looking for more? Visit **www.lek.com.**