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MediGate: a MedTech product innovation development process from university research to successful commercialization within emerging markets

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Abstract

This study proposes a comprehensive MedTech product innovation development framework tailored for university research commercialization within emerging markets. The MediGate framework, built on the Augmented Stage-Gate model, addresses the unique challenges of MedTech innovation, including regulatory compliance, stakeholder engagement, and market dynamics. The framework integrates critical decision-making criteria for different types of inventions to drive academic research toward commercialization in clinical settings. Through detailed case studies, including innovations like albumin strip test, 3D-printed patient-specific implant, COVID-19 nasal spray, and AI platform for depression detection, and iterative refinement, the framework provides actionable guidelines for navigating the complexities of product development. These guidelines ensure alignment with clinical needs, regulatory requirements, and market strategies. The research highlights the importance of early-stage valuation, reimbursement strategies, legal and IP considerations, and manufacturing and quality management. By offering a structured pathway, this research contributes to the theoretical and practical understanding of MedTech commercialization, aiming to enhance innovation success and healthcare impact in emerging markets.

Keywords: Entrepreneurship, New product development, Innovation, MedTech, Digital health, Medical devices, Research commercialization, Technology transfer, Regulatory compliance, Intellectual property, Venture creation, Innovation-driven enterprise, Financial valuation, Clinical readiness level

Introduction

Medical technology (MedTech) refers to the product, service, software, or solution resulting from the technology developed and practiced within the healthcare delivery systems to improve the quality of life of patients and caregivers (Bandeiras, 2020; Bosque Ortiz & Hsiang, 2018; Wurcel et al., 2017). It comprises the services provided within healthcare facilities and the products utilized around the delivery of healthcare services. MedTech utilizes and addresses specific medical objectives supporting human health

and life (Karthika & Vijayakumar, 2022; "Springer Handbook of Medical Technology", 2011). Moreover, MedTech can be classified into different technological areas, such as medical devices, digital health, personalized treatment, etc. (Bandeiras, 2020).

MedTech has radically changed the way we manage, treat, and perceive diseases (Brodsky, 2010), plays a crucial role in advancing and transforming healthcare delivery systems, and contributes to its valuable impact in several ways; for example, improving patient outcomes, increasing access to healthcare, reducing healthcare costs, enhancing patient experience, advancing health diagnostic, and reducing risk exposure. Consequently, it leads to an improvement in the quality of life for people and society (David et al., 2019; Timmermans & Berg, 2003).

Many factors have driven the growth of global healthcare demand and pushed the industry to adopt innovation faster and better to improve patient life and reduce healthcare costs. The demand for automatic patient data collection and analysis led to the creation of integrated electronic health records (Lester & Hobbs, 2007). Meanwhile, megatrends, such as the rising prevalence of chronic diseases, the aging population, the COVID-19 pandemic, and the growing demand for minimally invasive procedures, are driving global healthcare demand to create healthcare innovations, such as personalized medicine, telehealth, and advanced materials.

Thus, launching MedTech is necessary to overcome healthcare challenges and drive economic growth. Yet, to develop successful product commercialization, applying a systematic product innovation development process can increase the chance of exploitation success and help management to understand user insights, challenge assumptions, redefine problems, make good decisions using critical thinking, and create innovative solutions to prototype and test with target users to exploit the market effectively. However, successful MedTech launching typically requires complex implementation due to the high complications of the industry and complex interactions among key stakeholders (Kimberly & Evanisko, 1981; Sobrio & Keller, 2007), such as complexity of medical treatment decisions, strict regulatory control, variations in clinical practice and healthcare delivery, different expectations from multiple stakeholders, etc. Another big challenge comes from how medical innovation is diffused into the complex healthcare system. According to the classical innovation diffusion theory proposed by Rogers (2003), diffusion is a process that explains why individuals, or other decision-making units, in a social system communicate or receive information about innovation through specific channels over time. Diffusion in healthcare pays more attention to the social system and how to communicate and absorb among different stakeholders, whether it be individuals, organizations, or cities, which sometimes require different approaches as innovations do not diffuse uniformly (Wisdom et al., 2014).

Therefore, to overcome such challenges, MedTech strongly requires strategic planning to drive adoption apart from individual levels as the decision-making within the industry depends on many factors such as patient, physician, hospital, National Health Security Office (NHSO), ecosystem, etc. (Dearing & Cox, 2018) as well as collaboration as early as possible among diverse teams, including design, healthcare, engineering, ergonomics, physiotherapy, occupational therapy, social research, and more (Moody, 2015), each with its own distinct needs and expertise (Heron & Tindale Obe, 2015). Another research also highlighted that the newer models of innovation policy are required to promote

interaction among stakeholders to overcome the valley of death from research to market (Hudson & Khazragui, 2013), which is similar to the concept of the triple helix model, which promotes the way of working that the government, private sector, and academia must collaborate to form a solid, innovation ecosystem to support manpower, finance, know-how, production facilities, regulation, and sandbox testing in order to expedite the speed of innovation development (Leydesdorff & Etzkowitz, 1998).

Hence, this research aims to achieve the following objectives: (1) to propose the MedTech product innovation development framework, named MediGate, with critical decision-making criteria for different types of inventions to drive academic research toward commercialization in clinical settings within emerging markets; (2) to increase the chance of research commercialization success, encouraging key users to participate in innovation development, and raising adoption and diffusion within the healthcare system; (3) to develop clinical readiness level assessment and valuational calculation methods for early-stage MedTech to achieve clearer communications among stakeholders and more transparent comparison among different investment and commercialization options. While the study addresses various types of MedTech, its scope does not delve into the pharmaceutical industry or extend to established markets.

Literature review

Healthcare innovation diffusion and adoption

Healthcare innovation involves the adoption of proven and effective practices that enhance patient safety and outcomes while improving organizational performance and enabling healthcare professionals to work more efficiently and cost-effectively (Thakur et al., 2012). For innovation to diffuse in the healthcare system, it needs more attention to the social system and how to communicate and absorb among their stakeholders, including individuals, organizations, or countries, which sometimes require a different approach as innovations do not diffuse uniformly (Wisdom et al., 2014). Despite people resisting change, it is important that MedTech startups focus more on individuals or micro-level perspectives that later contribute to any organizations change action (Milella et al., 2021). Additionally, increasing employees' attitudes toward technology acceptance can lead to a rise in the intention to use of technology inside the organization (Davis, 1989; Venkatesh & Davis, 1996; Venkatesh & Ramesh, 2006; Venkatesh et al., 2003). Individual success in embracing change can drive an organization towards the diffusion and adoption of innovation. This is particularly vital in the medical field, where competitiveness and sustainability are closely linked to innovation. Consequently, this shift can enhance the organization's learning competitiveness, raising its innovativeness and capacity to innovate (Ignacio et al., 2010; Rogers, 2003).

Co-creation innovation in healthcare

Co-creation innovation with users in healthcare settings can play significant roles in many ways to solve unmet needs and drive adoption. User innovation is defined as the struggle of users for a solution that does not exist in the market, and they are willing to pay for its development (von Hippel, 2005). Lead users, which are advanced users and a subset of user target groups who deal with individual problems very intensively (von Hippel, 1986), contribute a vital role in testing, validating, and gaining valuable

feedback on the early development of the product. According to healthcare setting, clinicians' innovations within the workplace can enhance both the frequency and depth of user innovation, facilitate the creation of high-value innovations, and yield high returns; however, there is a gap in expanding the actual benefits to specific users and especially clinicians, which are limited due to under-diffusion as user-innovators often show disinterest in conventional market-based diffusion strategies (Svensson & Hartmann, 2018). Thus, understanding different customers' jobs is also important as it can help the management to deeply understand customers' struggle for progress and then create the right solution and attendant set of experiences, including functional, emotional, and other perspectives, to ensure solving all customers' jobs well, every time (Christensen et al., 2016). Moreover, patient-led innovation, while embraced by patients, often challenges professionals and policymakers. To increase the success rate in launching innovation, it is recommended to incorporate as early as possible among diverse teams, including design, healthcare, engineering, social research, etc. (Moody, 2015), to work collaboratively using their own distinct needs and expertise (Heron & Tindale Obe, 2015). Therefore, the new development approach is required to promote divergent thinking by placing patients at the forefront of the innovation process during critical decision-making stages of the product development process. It also requires strong leadership to question conventional practices, a solid commitment to collaboration, a shared benefits among user participants, and an investment in cultivating a culture that prioritizes the patient perspective (McNichol, 2012).

Product innovation development process in MedTech

Literature in systematic product innovation development models, potentially applicable to the MedTech domain, has been reviewed to create an NPD model that aims to launch new MedTech products and services under a condition of extreme uncertainty (Ries, 2011) in academic research origin settings and emerging markets. For example, Shaw (1998) identified ten stages in the innovation cycle of the UK medical equipment industry, whose success required effective management enhanced by continuous networking and interaction among entrepreneurs and stakeholders, with overlapping stages and rich information sharing to integrate activities, leverage societal knowledge, and build credibility. Thakur et al. (2012) suggested the decision-making and implementation process of healthcare innovation to be adopted in the healthcare organization, which addresses key factors such as idea generation, decision-making, rollout, evaluation, and modification. Pietzsch et al. (2009) proposed the comprehensive modified stage-gate model (Cooper, 1990) that incorporated regulatory and several aspects that are suitable for medical devices. Additionally, Soenksen and Yazdi (2017) suggested the modified stage-gate process that incorporated an investment decision-making system that could be found useful for identifying and managing life science-related projects. Ocampo and Kaminski (2019) suggested product development models for medical devices in emerging markets led by small and medium-sized enterprises (SMEs). Furthermore, Mejtoft et al. (2022) proposed the design-driven MedTech innovation development process within the technological research center context in developed countries and clinical readiness levels (CRLs) for supporting the understanding of clinical application readiness.

While these models provide valuable insights into MedTech product development, they often lack adaptability to the specific challenges faced by university research initiatives in emerging markets. For instance, the regulatory frameworks and resource constraints in these markets differ significantly from those in developed countries (Gasmi & Recuero Virto, 2005; Panda & Dash, 2014; Ray & Ray, 2010). Moreover, existing models may not fully integrate clinical, regulatory, and business strategies, which are essential for successful commercialization (Namati, 2019; Panescu, 2009).

This study addresses the following gaps in the literature: (1) the practical application of the MedTech-focused NPD model that is suitable for university research initiatives within emerging markets; (2) the effective business strategies that align with specific clinical needs and legal requirements; (3) the suitable legal and regulatory readiness in MedTech for better communication; (4) the integration of clinical, regulatory, and tech transfer strategies that align with product development progress; (5) the economic value calculation of early technology; (6) the appropriate clinical adoption strategies, and (7) redefining failure from the NPD's Stage-gate Go/No-go to launch new imaged-ends that are more suitable for venture creation context. Additionally, there is an opportunity for various product development models for different types of commercial purposes, such as not-for-profit organizations, contract research, etc.

Our previous research proposed the Augmented Stage-Gate product development process for DeepTech innovation, which can give deep-tech startup entrepreneurs, researchers, and management a systematic guideline and recommended activities from ideation to scale-up stage while increasing business and technology readiness level (TRL) (Kruachottikul et al., 2023). Therefore, this research redesigned the previous Augmented Stage-Gate for DeepTech to be the practical implementation of a MedTech-focused NPD model, tailored for university research initiatives in emerging markets.

Methods

This research aims to construct a comprehensive framework for the MedTech development process, focusing on the research-to-commercialization journey within emerging markets. We adopt a process-oriented approach developed by Platts (1993) as the methodology. This methodology has gained popularity among technology and innovation management scholars for its effectiveness in developing novel approaches, frameworks, and business tools (Ilevbare et al., 2016; Park et al., 2020). For example, Baker and Bourne (2014) employed this methodology to refine stage-gate controls to improve NPD decisions. Vinayavekhin and Phaal (2019) leveraged it to propose a framework for synchronizing technology and innovation strategies across different business units and hierarchical levels within a firm. Weyrauch et al. (2021) utilized this methodology to develop the "Objective-Conflict-Resolution" approach for facilitating the development of radical and frugal innovations. Similar to the previous literature using this methodology, this research comprises three distinct phases: development, improvement, and validation. It is important to acknowledge that these phases are not entirely discrete and that there might be some overlap between them, involving multiple iterative cycles and continuous interactions with key stakeholders, such as patients, clinicians, mentors, and experts.

Developing the framework

The first phase entails developing an initial framework grounded in the existing literature on MedTech product innovation in emerging markets. We conducted a comprehensive literature review to establish an initial framework based on current knowledge. Moreover, to incorporate real-world practice, we launched a questionnaire targeting participants of MedVentures, a prominent MedTech incubation program at Chulalongkorn University Technology Center (Chula UTC), which is Chulalongkorn University's research commercialization platform. We received responses from 27 out of 31 research projects/startups from the 2020 and 2021 cohorts. The questionnaire explored their perspectives on the entrepreneurial process and crucial aspects for successful MedTech startups. Subsequently, we conducted semi-structured interviews with ten research project/startup teams and eight representatives from university management, government grant agencies, and the Thai Food and Drug Administration (FDA) who participated in the program. These interviews aimed to capture insights on MedTech-specific entrepreneurial processes and critical functional aspects. The interview duration ranged from 45 to 90 min.

Analysis of the findings highlighted that a good understanding of MedTech-specific entrepreneurial processes and important functional aspects, including project management, sales and marketing, technology, legal and regulatory, reimbursement, manufacturing, clinical, financial, and minimum viable product (MVP) development, can help startups understand the complexity, role, and responsibility of each stakeholder in the healthcare system, network with key stakeholders in medical domain to eliminate roadblocks, improve the chance of successful exploitation, and increase the readiness level of technology, business, law, and regulation. Based on these findings, we constructed an initial draft NPD for MedTech based on the Augmented Stage-Gate framework (Kruachottikul et al., 2023), characterized by a simplified, iterative, and multi-stage linear structure.

Improving the framework

The second phase focused on refining the framework through in-depth case studies of actual firms. We deliberately selected four teams developing diverse MedTech products—the albumin strip test, 3D-printed patient-specific implant, a nasal spray that traps and inhibits the COVID-19 virus, and an artificial intelligence (AI) platform for depression detection—based on specific criteria to ensure a comprehensive representation of the MedTech innovation landscape. The criteria for selecting these case studies were:

1. Diversity of MedTech innovations: we aimed to cover a broad spectrum of medical technologies, including diagnostic devices, implantable medical devices, over-the-counter-medical devices, and digital health solutions. This diversity ensures the framework's applicability across various types of MedTech products.
2. Stages of development and commercialization: the selected projects are at different stages of the product development lifecycle and employ varied commercialization strategies, from licensing agreements to startup formations. This variation allows us to assess the framework's effectiveness at multiple development phases.

3. Origin in academic research within emerging markets: all innovations originated from university research initiatives in emerging markets, aligning with our focus on facilitating the commercialization of academic research in these contexts.

Selecting case studies that met these criteria ensured that the MediGate framework could be tested and refined across a spectrum of real-world scenarios, making it more robust and universally applicable. By closely examining the application of the framework across different stages of development and varied MedTech products via multi-day visits, conference calls, and phone calls with key stakeholders, tangible outcomes and insights that illuminate the effectiveness of the framework were gathered. This is to ensure that the real-world application of the framework contributes to the iterative enhancement of our framework, aligning it with not only theoretical expectations, but also the practical demands of the MedTech industry.

The draft NPD model served as a reference for these teams over a period of three to four months. We directly observed the teams as they progressed through each stage of the framework. Tangible outcomes such as sales figures, contract execution, regulatory approvals, and certifications were documented. Additionally, we gained access to relevant development process documents, including progress checklists and presentation slides, submitted by the teams. Information collected and analyzed for the case studies encompassed team composition, research and development (R&D) progress, regulatory processes, business plans, project planning and concepts, product design, milestones, risk assessments, technology verification and validation (building MVP), market validation, legal activities, intellectual property (IP) status, implementation and operations, sales and marketing activities, and financial activities. We supplemented observations with interviews involving stage-gate committees and two to three members from each team (principal investigator and one to two additional team members). These interviews explored the teams' journeys, their application of the framework, and the achieved results. We also discussed significant challenges encountered during implementation and the solutions developed by the teams. The interviews were recorded, transcribed, and used to create a final case summary reviewed and approved by the interviewees. In some instances, we revisited the interviewees for further information or follow-up interviews when implementation details and results became clearer.

The four case studies showcase how the draft NPD model was applied in various MedTech contexts. The first, the albumin strip test, is a rapid urine test developed at Chulalongkorn University, offering a portable and cost-effective solution for kidney disease screening, particularly useful in remote areas. This case highlights the challenges of manufacturing reliable test strips in Thailand and efforts to establish GMP-certified laboratories to ensure consistent production. The second case, 3D-printed patient-specific implant, involves personalized titanium bone implants created using 3D printing technology. Originating from a research-focused laboratory, the company customizes implants based on individual patient CT scans, navigating strategic planning, regulatory compliance, and technology transfer for successful market entry and clinical adoption. The COVID-19 nasal spray is the third case, an over-the-counter product developed to trap and inhibit the COVID-19 virus using human antibodies. It offers a non-prescription method for self-prevention during the pandemic and involved rapid

development and regulatory strategy with the Thai FDA. Lastly, the AI platform for depression detection is a digital health application from the Research Center of Excellence in AI for Mental Health (AIMET). It provides mental health screening and support using AI, integrated into public health systems, with a user-centric design and a focus on social impact, having already helped over 2,000 severe depressive cases and screened more than 200,000 individuals in 2023. Together, these cases illustrate the complexity of MedTech innovation, covering product development, regulatory navigation, market adoption, and the integration of technology into healthcare. The detailed explanations of each case study are presented in the Supplementary Materials.

The outcome of this phase is a comprehensive framework with detailed explanations for each stage, including recommended functional activities and decision-making processes at the stage-gate before transitioning to the next stage.

Validating the framework

The final phase is aimed to validate the framework's applicability for broader practical use. We recruited ten organizations and presented them with the refined framework developed in the previous phase to gather feedback (details on interviewees in Table 1). The objective was to obtain insights and integrate minor refinements into the framework. We engaged in detailed discussions with each interviewee regarding the

Table 1 MediGate validation interviewees' demographics

No	Interviewees	Positions	Roles	Products	Employees	Type of organization	Duration (min)
1	MedTech startup	CEO	Management and research	Class 4 Medical devices	> 100	Startup	80
2	MedTech research organization	Director	Research and QMS	Medical devices development, and validation service	> 10	Academic organization	70
3	MedTech startup	CEO	Management and research	Class 4 Medical Devices	> 10	Startup	71
4	MedTech government funding agency	Director	Investment	Funding	> 100	Government agency	73
5	MedTech startup	CEO	Management and research	Class 4 Medical Devices	> 10	Startup	63
6	Consultant firm	Director	Management and consulting	Business strategy	> 20	Consultancy	83
7	Business school	Deputy director	Management and research	Business education programs and research	> 100	Academic organization	86
8	Law firm	Partner and co-head	Legal advisory and management	IP law services	> 200	Law firm	86
9	Thai FDA	Director	Regulatory oversight and compliance	Medical device regulations	> 500	Government agency	51
10	Law firm	Associate	Legal advisory and management	Corporate law services	> 1000	Law firm	46

framework's activities and decision points to ensure a precise and comprehensive understanding of the presented framework. The absence of major modification suggestions and a significant decrease in proposed changes indicated a thematic saturation (Ilevbare et al., 2016), suggesting broad acceptance of the framework as an accurate reflection of the MedTech development process.

To further validate the framework, we conducted an experience survey using three criteria established by Platts (1993) for framework assessment: feasibility (understandability), usability (ease of use), and utility (practicality). The survey's design and format were based on the evaluation sheet developed by Vinayavekhin and Phaal (2020), modified to fit the framework's application and goals. We then sent it to participants to evaluate these criteria through five questions: overall comprehension, completeness, consistency, educational usefulness, and practical usefulness.

Results

Constructed product development framework: MediGate

This section will explain the proposed framework called "MediGate", a comprehensive NPD model constructed specifically for MedTech, focusing on translating from university research into commercialization in clinical settings within emerging markets. The MediGate framework is derived from the Augmented Stage-Gate DeepTech NPD framework from our prior research (Kruachottikul et al., 2023), incorporated with insights gathered from literature reviews, in-depth interviews, questionnaires, and case studies throughout the three phases of the process approach (Platts, 1993). The experience survey results showed positive reception across all criteria, with average overall comprehension rated at 3.80 (SD = 1.23), completeness at 4.40 (SD = 1.26), and consistency at 4.50 (SD = 0.71). Educational usefulness and practical usefulness were both rated highly at 4.40 (SD = 0.52) and 4.20 (SD = 0.92), respectively. These ratings validate the framework's feasibility, usability, and utility.

In addition, we also modified Mejtoft et al. (2022)'s CRL to reflect the complexities involved in product development, regulatory compliance, and market acceptance, as shown in Table 2. Clinical trial product validation is separated into 3 stages (CRL 5–7) to address a deeper focus at each stage, and post-market clinical validation and surveillance (CRL 9) is added to acknowledge the critical importance of continually assessing the product's performance, safety, and effectiveness beyond the initial approval stages. The CRL is incorporated into the assessment of the project's progress in addition to the TRL and investment readiness level (IRL) used in the DeepTech NPD Framework (Kruachottikul et al., 2023).

The MediGate framework, as shown in Fig. 1, is divided into six stages (Stages 0–5), as same as in the Augmented Stage-Gate framework (Kruachottikul et al., 2023). The high-level representation of MediGate's functional activities, deliverables, and decision criteria at gates are shown in Figs. 2 and 3, while the activities are explained in detail in Tables 3, 4, 5, 6, 7, 8. For each stage, the framework lists suggested activities for each functional group (management, business development, financial management and funding, revenue model and reimbursement, technology development, legal & tech transfer, regulatory, clinical, manufacturing & operations, and quality), expected deliverables, and required criteria to pass each gate. The following subsections explain the overview and selected essential components of each stage.

Table 2 Constructed readiness level assessment: modified CRL

Conceptualization		
CRL1	Secure clinical competence in the project to complement the technical competence in the development process	Determine how to achieve relevant clinical competence to facilitate clinical adoption of the technical product or method. Furthermore, identify an intended user (key opinion leader) in the environment who will be capable of pushing the idea forward. Assess the possibility of collaboration around validation of the clinical need and, further on, in the context of a pre-clinical and/or clinical study/trial
CRL2	Verify and define gap/need and risk analysis	Verify that the product meets a real need within health care. Alternatively, the solution needs to be a relevant improvement of the existing solution. Perform risk analysis to determine user-safety classifications
Concept validation		
CRL3	Perform tests in a lab environment	Test that a fully operational prototype provides the intended clinical functionality in a relevant laboratory environment, e.g., through a pre-clinical study
CRL4	Perform user studies in relevant clinical environments	Verify the need with the intended users and assess how the proposed solution is received by relevant clinical environments
Product development		
CRL5	Validate product in an animal study	Validate prototype functionality regarding stability/repeatability (if applicable) and diagnostic or treatment performance in a relevant animal study environment. The IRB should be granted by this step
CRL6	Validate product in a clinical trial (small group) to obtain an early result	Validate prototype functionality regarding stability/repeatability (if applicable) and diagnostic or treatment performance in a relevant clinical environment including safety for human use. Also evaluate the prototype user friendliness with end users Apply for ethical permission from the relevant authority Apply relevant standards for study design Carefully consider all data that need to be assessed to perform a health economic analysis
CRL7	Validate product in a clinical trial (large group and meet regulatory requirements)	Similar to CRL6 but aim for a high evidence level (e.g., by performing randomized, controlled multicenter studies, possibly using a double-blind approach with placebo control). Clinical trial results are used to support product registration
CRL8	Validate the product's usability	Further clinical trial is used to support marketing and customer adoption. Evaluate the product's user-friendliness and validate that the product meets the end users' needs and expectations
Post-market clinical validation and surveillance		
CRL9	Post-market clinical validation and surveillance	Continue to gather and assess clinical information regarding the performance and safety of the product to validate the existing clinical benefits claimed and reveal any potential unknown adverse effects, risks, or improper use outside its intended purpose

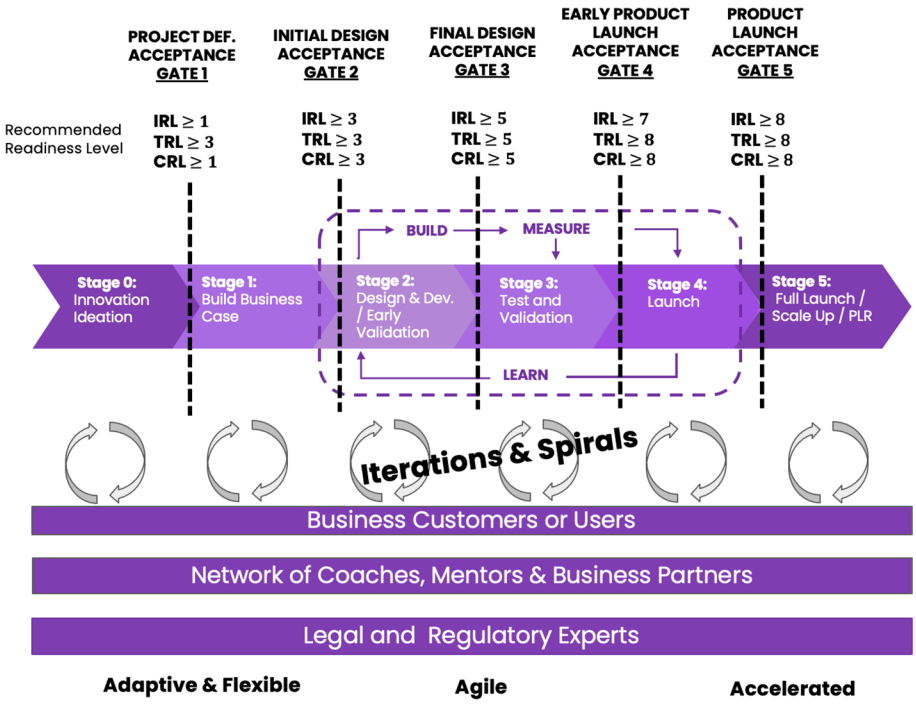

Fig. 1 MedTech augmented stage-gate model (MediGate framework)

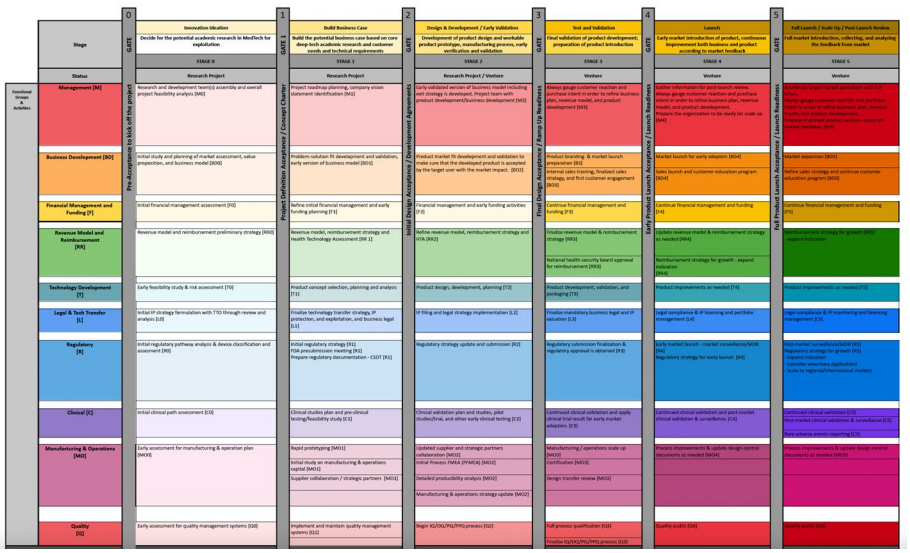

Fig. 2 MediGate: high-level representation of development stages and functional activities. The code in the bracket, e.g., [M0], [BD4], indicates the activities for each functional group and stage and points to its corresponding details in Tables 3, 4, 5, 6, 7, 8

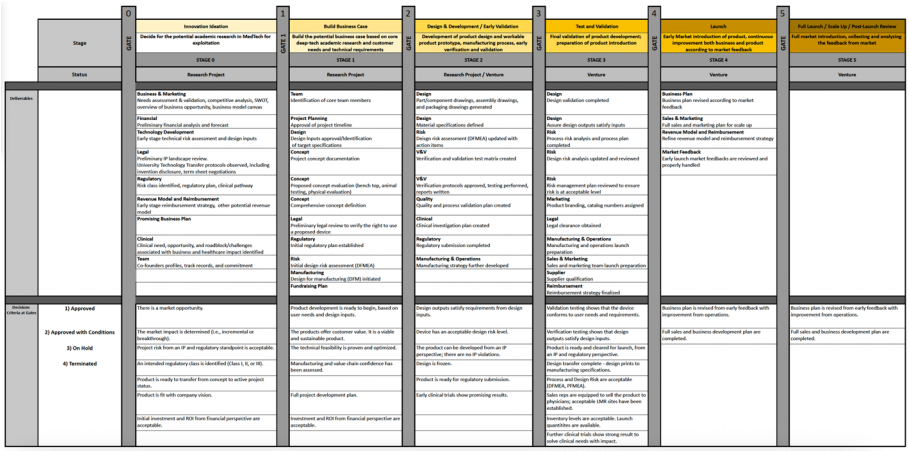

Fig. 3 MediGate: high-level representation of deliverables and decision criteria at gates

Stage 0: feasibility analysis and innovation ideation

Stage 0 is essential for deciding whether to start the stage-gate activities. Its primary goal is to find impactful clinical needs with high market potential by identifying opportunities in a clinical setting and then conducting a feasibility analysis (Barringer & Ireland, 2018). Opportunity identification can be done alone or along with (1) observing trends, particularly mega trends that cause far-reaching impacts in various aspects, such as economic forces, social trends, technological advances, political and regulatory changes, and health diseases, (2) solving the problem, (3) finding gaps in the marketplace. Then, feasibility analysis of the chosen opportunities is conducted; this typically involves vital aspects such as market potential, financial feasibility, legal and regulatory compliance, organizational readiness, and product/service development that usually leverage the core technology or experiences of the research team. Moreover, an early management team, oftentimes a group of researchers, usually carries out the initial feasibility assessment. Personal characteristics, including prior experience, cognitive factors, social network, creativity, and attitudes toward research commercialization, play a crucial role in research exploitation opportunities more than at the institutional level (Wu et al., 2015); therefore, it is important to assemble team members with suitable characteristics and attitudes toward entrepreneurship and research commercialization.

Once the team decides to move forward, MediGate is then applied as a guideline throughout the product development process. Even though the proposed model consists of in-depth detail in various aspects, adjustments to the stage-gate activities and decision criteria are possible to suit the characteristics and requirements of the project, as shown in Table 9. For example, a for-profit research project with a licensing option is not required to complete certain aspects that the licensee can handle, such as manufacturing and operations, quality, and regulatory. In the case of external partnership or outsourcing, some activities can be co-handled or assigned to an external party under the supervision of the research team.

While the full activities are listed out in Fig. 1, the following aspects are critical for Stage 0:

- Entrepreneurial characteristics, passion, and decision-making

Table 3 MediGate Stage 0 (innovation ideation) functional activities in detail

Code	Functional group	Activities
M0	Management	Key co-founding members are assembled with cleared roles and responsibilities to kick start the project
		Startup vision and mission is created
		Entrepreneurship knowledge is provided to enhance the knowledge and skill of the founding team
BD0	Business development	Innovation strategy is assessed in terms of newness, market impact, value to the user, potential for market adoption, etc
		Market assessment is evaluated for both internal (e.g., SWOT analysis) and external (e.g., PESTEL and Competitor Analysis)
		Feasibility analysis is conducted for product/service, industry/target market, organization, and financial aspect
		Key opinion leaders are invited to participate in idea validation
		Risk assessment is early evaluated
		Value proposition strategy is conducted, and the idea is validated with early target users to understand customers' motivation in terms of function, emotion, and social perspective
F0	Financial management and funding	Financial management is prepared including forecast, proforma financial statements, and ongoing analysis of financial results comparing with competitors/industry norms
RR0	Revenue model and reimbursement	Multiple revenue models are carefully assessed including a reimbursement path
T0	Technology development	Early technological development feasibility and risk assessment is performed
L0	Legal and tech transfer	Engagement has been made with the University Technology Transfer Office
		A preliminary study on IP background, including a survey of field/peripheral technology and potential risks and benefits, has been conducted
		The initial IP strategy, encompassing IP identification, the IP landscape has been formulated
		Academic IP guidelines, such as invention disclosure protocols and term sheets, are being studied
R0	Regulatory	Exploration of the regulatory and clinical pathways is underway
		The identification of the medical device type and risk class has been completed
		The device assessment has been predicated
C0	Clinical	Clinical path is assessed and evaluated
		Key clinical opinion leader is identified and validated with a defined clinical path
MO0	Manufacturing and operations	Early assessment for manufacturing and operation plan is prepared
Q0	Quality	Early assessment for quality management systems is performed

Early project teams in research-focused environments typically consist of members with strong technical backgrounds responsible for developing the technology. Despite lacking business co-founders, a technical-oriented leader can develop proficient managerial skills, driven by entrepreneurial motivation and passion (Clarysse & Moray, 2004). Thus, the entrepreneurial skills and growth mindset, including leadership, creativity, personal characteristics, and intelligence, should be well developed and embedded into the team along the venture creation process (Billingsley et al., 2023). As the team progresses, entrepreneurs should learn to adapt and evolve to meet the real demands. External advisors and mentors play a vital role in providing guidance

Table 4 MediGate Stage 1 (build business case) functional activities in detail

Code	Functional group	Activities
M1	Management	Project team members are recruited and developed to ensure enough human resources for further development
		Initial project planning using agile methodologies is proposed and implemented
		Advisory board is invited to give an advice and mentoring to the project team
		Network with key stakeholders to broaden the knowledge and connection and to increase project visibility
		Build a real business case and validate earlier business model to make sure that problem–solution fit with a possibility of market impact
BD1	Business development	More users and key opinion leaders including physician champions are invited to engage in the validation activities to refine the value proposition into a better version
		Prototype is developed using UX/UI principles in order to validate and obtain the user feedback
		Plan and decide an appropriate commercialization (e.g., spin-off, licensing, JV, etc.)
		Key stakeholders and medical association collaboration are identified and invited to collaborate in the project
		Roadblocks, healthcare/user journey, and market penetration are initially identified and planned
		Participate in an entrepreneurship, incubator, or accelerator program to gain knowledge, increase exposure, and build networking
F1	Financial management and funding	Revised financial management is developed and proposed
		Explore multiple fundraising options and planning for fundraising strategy
		Participate in early fundraising activities. Typical funding sources are non-dilutive funding (e.g., university grants, government grants, contract research funding) and pre-seed funding (e.g., bootstrapping, angels, friends and families, university holdings, incubators)
RR1	Revenue model and reimbursement	Revenue models and reimbursement plan are validated and refined with key stakeholders. Identify reimbursement claims codes, e.g., diagnosis codes (ICD-10), procedural codes (CPT), facility codes, etc
		Health technology assessment including cost-effectiveness, availability of clinical practice guidelines, health system readiness, budget impact on universal coverage scheme (UCS), and ethical and social issues is prepared
T1	Technology development	Early technical development concept is designed, evaluated and selected by R&D team and key opinion leaders
		Product prototype analysis is performed for both hardware and software in lab/real environment
		Initiate and maintain design history file (DHF) is prepared, evaluated, and selected by R&D team and key opinion leaders
		Initial design risk analysis (design failure mode and effect analysis; DFMEA) is prepared, evaluated, and selected by R&D team and key opinion leaders
		Human factors engineering (HFE) is prepared, evaluated, and selected by R&D team and key opinion leaders
L1	Legal and tech transfer	The company and employee business legal matters are being handled
		The technology transfer strategy has been finalized
		The groundwork for IP protection, including patent search, patentability analysis, and the early drafting of patents and/or trade secret policies, has been initiated
		The IP exploitation to a licensee has been executed

Table 4 (continued)

Code	Functional group	Activities
R1	Regulatory	The initial regulatory strategy has been developed
		The FDA presubmission meeting has been arranged
		Regulatory documentation for the common submission dossier template (CSDT) is being prepared
C1	Clinical	Initial clinical studies are well planned including clinical safety and effectiveness, regulatory approval, financial value for reimbursement, and marketing end points
		Scientific Advisory Board (SAB) / Key Opinion Leader (KOL) is formed to give an advice to the R&D and management team in terms of clinical adoption and trial
		Clinical principle investigator (PI) is selected to lead the clinical trial
		In case of human subjects studies, an Internal Review Board (IRB) to protect the welfare, rights, and privacy of human subjects and a clinical investigation (CE Study) to assess safety and clinical performance are reviewed, prepared, and submitted
		Pre-clinical testing / feasibility study is conducted including user testing, bench testing, stimulated use testing, tissue testing, acute animal testing, human cadaver testing, and chronic animal testing
		Clinical plan and studies are approved by KOL and IRB board
MO1	Manufacturing and operations	Rapid prototyping, e.g., UX/UI, computer simulation, 3D printing, etc., is developed and used for initial market and technical validation
		Initial study on manufacturing and operations capital is conducted
		Key suppliers / strategic partners are identified and invited to collaborate in the project
Q1	Quality	Implement and maintain quality management systems

through its various stages of growth, avoiding the pitfall of being too stubborn to the original business idea and resisting necessary pivoting (Duening et al., 2012).

Furthermore, understanding self-motivation and entrepreneurial passion at different venture stages is crucial for driving the business effectively because this passion may diminish during the journey (Cardon et al., 2009).

Nevertheless, embracing effectual logic helps entrepreneurs solve problems in highly uncertain market environments using existing resources within their controls, such as knowledge, capital, and partnerships. This approach helps entrepreneurs manage affordable risk-taking and set achievable goals, which later can evolve through iterative learning (Wiltbank et al., 2006). Meanwhile, entrepreneurs assess resources and seek out value-adding partnerships or co-founders rather than waiting for these to be available to start. Consequently, effectual logic can augment the NPD process by redefining failure to learn and pivot to launch new goals using feedback instead of killing it from the Stage-gate Go/No-go concept (Duening et al., 2012). As entrepreneurs gain diverse work experience and develop a stronger sense of sensemaking, they become more open to identity-sharpening feedback. This approach allows them to carefully assess feedback in relation to their self-identity and determine whether re-engineering their core business idea is necessary (Grimes, 2018).

Overall, this foundation step is essential in enhancing the team's ability to professionally handle the complex challenges of translating academic research into a

Table 5 MediGate Stage 2 (design and development / early validation) functional activities in detail

Code	Functional group	Activities
M2	Management	Final version of business model including exit strategy is developed
		Continue product / market fit activities to make sure that the developed product is accepted by the target user with the market impact
BD2	Business development	Customer prototype is proposed and evaluated with the user
		Procurement plan is developed and validated
		Distribution channels are identified and validated
F2	Financial management and funding	Financial management of the earlier phase is reviewed. The revised financial statement is proposed and monitored
		Continue participating in fundraising activities. Typical funding sources are pre-seed funding and seed funding (e.g., angels, family offices, early-stage VCs)
RR2	Revenue model and reimbursement	Reimbursement strategy is validated with key stakeholders and update
		Revenue model is validated and updated
		Health Technology Assessment (HTA) Assessment by Health Intervention and Technology Assessment Program (HITAP) and International Health Policy Program (IHPP) including economic evaluation and budget impact is prepared
T2	Technology development	Product design development is prepared and approved by management
		Design verification and validation is prepared
		Maintain DHF and project timeline is prepared
		DFMEA is prepared
		Product design freeze is proposed and approved by management
		Design master record (DMR) and design history record (DHR) are developed and maintained
L2	Legal and tech transfer	Ongoing business legal matters are being managed
		The patent has been finalized and filed, and a trade secret scheme has been adopted
		The patentability analysis has been conducted
R2	Regulatory	The regulatory strategy has been updated
		The regulatory submission, including listing, partial CSDT, and full CSDT components, has been submitted
		The establishment registration for medical device manufacturing has been completed
C2	Clinical	Clinical validation plan and studies are reviewed and updated
		Investigational device exemption (IDE) is proposed and approved
		Clinical trial activities are initially conducted and managed via contract research organizations (CRO) or others
		Pilot studies for first-in-human testing (FIH) are planned and conducted
		Pivotal studies including safety & efficacy and clinical performance are conducted
		Biocompatibility testing is planned and ready to conduct the testing
		IRB is approved before launching clinical trial activities
MO2	Manufacturing and operations	Supplier and strategic partners collaboration are reviewed and updated
		Initial process failure mode and effects analysis (PFMEA) is prepared
		Detailed producibility analysis (e.g., planning, procurement, testing, training, etc.) is prepared
		Manufacturing and operations strategy is reviewed and updated

Table 5 (continued)

Code	Functional group	Activities
Q2	Quality	Initiate the process of installation qualification (IQ), operational qualification (OQ), performance qualification (PQ), and product performance qualification (PPQ)

Table 6 MediGate Stage 3 (test and validation) functional activities in detail

Code	Functional group	Activities
M3	Management	Always gauge customer reaction and purchase intent in order to refine business plan, revenue model, and product development
BD3	Business development	Product branding and marketing concepts are developed
		Initial market launch plan and sales forecast are developed
		Sales training plan is prepared and sales representatives attend surgical cases
		Initial procurement contract or purchase intent awarded (if possible)
		Distribution channels is finalized
F3	Financial management and funding	Continue participating in fundraising activities, particular with pre-series A, series A/B, e.g., startup accelerators, angels, VCs, CVCs
RR3	Revenue model and reimbursement	Reimbursement strategy is validated and finalized
		Revenue model is validated and finalized
		Engaging with National Health Security Organization (NHSO) Board to get approval for reimbursement
T3	Technology development	DHF is reviewed, updated, and finalized
		DFMEA is reviewed, updated, and finalized
		Assure that design outputs satisfy requirements from design inputs
		DMR and DHR are finalized
		Product labeling and packaging is designed and finalized
		Develop, test, and validate commercial product model according to the design freeze
L3	Legal and tech transfer	The finalization of business legal matters is in progress
		The IP strategy, encompassing protection and management, as well as regulatory strategies, including the university technology transfer process (if any), has been implemented., FTO
		The IP valuation assessment process has been initiated, utilizing income, cost-based, and market methods
R3	Regulatory	The final regulatory submission has been completed and submitted
		Obtain regulatory approval/clearance
C3	Clinical	Clinical validation is reviewed and continuously improved
		Early clinical result is obtained, reviewed, and used for market adoption strategy
MO3	Manufacturing and operations	Manufacturing and operation scale-up plan is prepared for post-launching
		Required manufacturing certification is secured
		Design transfer review is conducted to determine whether established processes yield finished devices that meet the project requirements
Q3	Quality	Full process qualification is reviewed and finalized
		Process of IQ/OQ/PQ/PPQ is finalized

Table 7 MediGate Stage 4 (launch) functional activities in detail

Code	Functional group	Activities
M4	Management	Methods used to gather information for post-launch review
		Always gauge customer reaction and purchase intent in order to refine business plan, revenue model, and product development
		Lesson learned and recommendations arising from the project
		Prepare the organization to be ready for scale–up, e.g., human resource, skill, knowledge, etc
BD4	Business development	Sales and marketing launch plan for early adopters and key influenced customers are implemented. Feedback from early launch is closely monitored and reviewed
		Newer business plan is refined according to the market feedback / opportunity
		Customer education program is offered to the key customers and physicians, e.g., sales reps attend surgical cases and physician training and continued sales efforts
		Sales reps try to secure procurement contract awarded and create sales activity with key influenced customers so that it can be used for the reference
		In case of complex medical device, technical team is required to educate customers and provide a training
		Maintenance and service team are setup and responsible for installation and after-sales service
F4	Financial management and funding	Continue participating in fundraising activities
		Typical funding sources such as VCs, CVCs. In addition, non-equity funding, e.g., loans can be explored as an alternative
RR4	Revenue model and reimbursement	Reimbursement is reviewed and updated as needed. Explore the reimbursement strategy for scale-up
		Revenue model is reviewed and updated as needed. Also, exploring other revenue model if necessary
T4	Technology development	Product improvement from the early market feedback
L4	Legal and tech transfer	Patent portfolio management
		Preliminary IP valuation can be employed, while additional data can be collected to generate a more accurate IP valuation in the future
		In-licensing and out-licensing strategies are being considered and evaluated
		The payment and management of royalties are being handled
R4	Regulatory	Market surveillance and compliance with the Medical Device Regulation (MDR) are ongoing as part of the early market launch strategy
		The regulatory strategy for the early launch has been devised and is in place
C4	Clinical	Clinical validation activities are reviewed and continued
		Rare adverse events are accumulated and reported
MO4	Manufacturing and operations	QC and process improvement process is continued. In addition, preparing for a productivity expansion in order to lower cost or increase volume
Q4	Quality	Quality audits are assigned for creating and running tests, identifying errors and providing feedback to ensure a final product meets a company's quality standards

real-world clinical application. This approach assists entrepreneurs in recognizing global opportunities, especially since local emerging markets often have limited scope.

- Preliminary analysis and planning for value proposition and business model

Table 8 MediGate Stage 5 (full launch / scale up / post-launch review) functional activities in detail

Code	Functional group	Activities
M5	Management	Accelerate target market penetration with full effort
		Always gauging customer reaction and purchase intent in order to refine business plan, revenue model, and product development
		Newer and better versions of commercial products are proposed according to the market feedback
BD5	Business development	Customer education program is continued and expanded to cover other customers according to the business plan
F5	Financial management and funding	Continue participating in fundraising activities. Typical funding sources such as VCs, CVCs. In addition, non-equity funding, e.g., loans can be explored for alternative
RR5	Revenue model and reimbursement	Reimbursement is reviewed and updated as needed
T5	Technology development	Product improvements as needed
L5	Legal and tech transfer	The ongoing monitoring of IP, including infringement and violations by the team or others, is being conducted
		The management of in-licensing and out-licensing activities is underway
		The payment and management of royalties are being handled effectively
R5	Regulatory	Post-market surveillance and compliance with the Medical Device Regulation (MDR) are ongoing to ensure product safety and effectiveness in the market
		The regulatory strategy for growth includes expanding indications, exploring veterinary applications, and scaling to regional and international markets
C5	Clinical	Post-market clinical validation and surveillance method is continued
MO5	Manufacturing and operations	Process improvements as needed
		Update design control documents as needed
Q5	Quality	Quality audits

Table 9 Stage-gate activities and decision-making adjustments according to the type of invention

Type of invention	Risk (return on investment/ ROI)	Recommended type of commercialization (entrepreneur characteristic)	Recommended NPD model (full, partial)	Decision criteria* (high, medium, low)
For-profit project	High risk (high ROI)	Startup (high) Licensing (low)	Full**	High
	High risk (low ROI)	Licensing	Partial	High
	Low risk (high ROI)	SME or privately owned company (high) Licensing (low)	Full	Medium
	Low risk (low ROI)	Licensing	Partial	Medium
Not-for-profit or social driven project	High risk (–)	Licensing	Partial	Low
	Low risk (–)	Social enterprise (high) Licensing (low)	Partial	Medium

*Note that the different scales of decision criteria can be defined as

High: scaling format with high threshold criteria

Medium: scaling format with lower threshold criteria (or can be skipped)

Low: yes/no format with lower threshold criteria (or can be skipped)

**In case the project requires equity financing, the criteria and activity should incorporate the investors' expectations

While a business model is designed to generate value for the company, the value proposition is crucial for creating value for customers from its products and services. Osterwalder et al. (2014) outlined a method for identifying value propositions through the relationship between two components: the value map and the customer profile. This involves analyzing a specific customer segment's needs, or "customer jobs", from functional, social, emotional/personal, and support perspectives (Christensen et al., 2016) along with the customer pains and gain. A successful fit happens when the value map aligns with the customer profile, leading to the creation of products or services that not only alleviate customer pains but also enhance their gains. In the early product development life cycle, the main focus is to find and validate the fit between the problem statement and the proposed solution. After the problem–solution fit is confirmed, later stage activities shift to developing a product and validating with the target users on a particular market, also called a product–market fit activity.

Finding the right value proposition to MedTech to create a successful innovation requires incorporating other strategies apart from a viable business perspective, despite the fact that healthcare company valuation is highly influenced by the company's technology portfolio and management profile (Cosh et al., 2007). MedTech focuses strongly on identifying the quality of clinical needs and level of innovation, which addresses important factors such as how the technology can enhance an existing clinical solution or introduce a completely new one and to what extent it will disrupt established clinical practices. The early value proposition diagram modified from Davey et al. (2011) is shown in Fig. 4.

- Initial market and clinical assessment

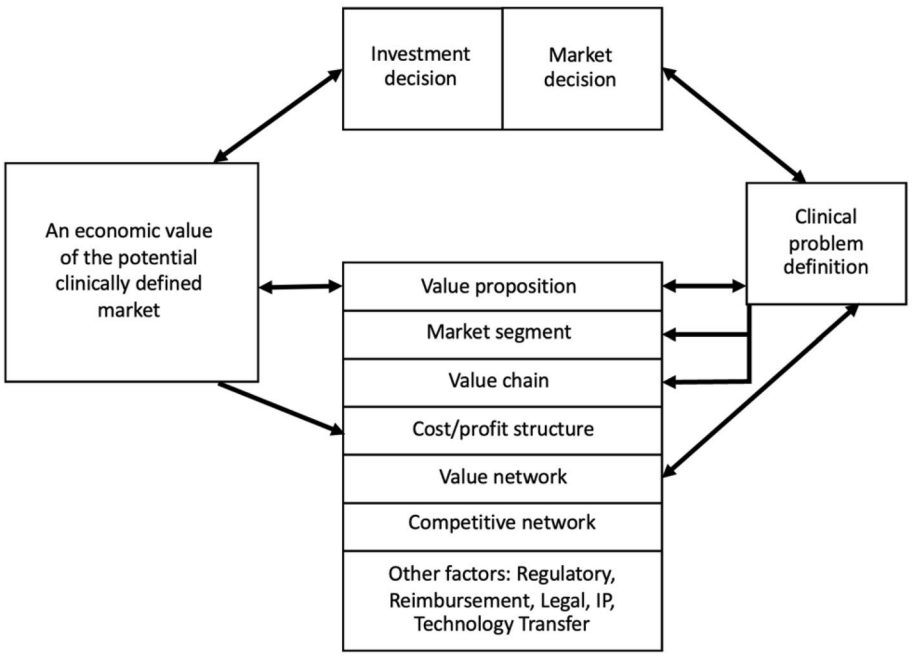

Fig. 4 Modified early value proposition of healthcare technologies with a business model framework (modified from Davey et al. (2011))

Both internal and external market analysis are required during this step to understand the high-level business environment and competitive landscape. It is vital for new business ventures to find the proper impactful clinical needs with high business potential, which are associated with the total addressable market and disease impact on the healthcare system. This step can start by searching for information on the internet, attending medical conferences, or directly observing and interviewing with key stakeholders such as physicians, patients, healthcare staff or management, etc. Entrepreneurs should aim for a global or at least regional market since the opportunity and market size are much higher while using the local emerging market as an initial launch and pivot to gain higher market share before expanding to other markets. In addition, sometimes it is helpful for startups to study alternatives in the market to understand opportunities and threats for both direct and indirect competitors.

Next, startups should be aware of challenges and risks in clinical needs, especially in emerging markets, which consequently create many roadblocks for medical innovation, such as lack of local expertise, low infrastructure, limited funding support, unsupported laws and regulations, etc. This aligns with the study by Pitts (2015) that highlighted the roadblocks in medical innovation beyond discovery and development including complex politics dynamics, perspectives on healthcare economics, friction among buyers, providers, manufacturers, and regulators, the battle for better patient education, and the need for a stronger, factual debate on the value of innovation. Therefore, even though there might be many feasible clinical needs at the start, innovators should be able to narrow them down by comparing the market potential, competitive landscape, risk, and clinical impact.

- Early regulatory planning

Early regulatory planning involves a preliminary study of the regulatory path, clinical trial, and risk according to the approval process in the target market. Innovation can be classified into two levels: incremental and breakthrough innovation (Johannessen et al., 2001). The level of innovation newness is associated with the regulatory planning strategy because, on the one hand, incremental innovation typically requires simpler regulatory planning as the product can be replaced or inserted into the existing medical procedure. On the other hand, breakthrough innovation not only requires more complicated regulatory planning and changes in the clinical procedure but also needs to be adopted by key opinion leaders in the clinical field. Moreover, it is beneficial for the team to understand exceptions in country-specific laws and regulations, such as the Thai FDA allowing personalized medicine to be exploited under the supervision of the registered medical organization (New Drug Act of B.E., 2546, 2003).

Therefore, the research team should be aware of regulatory challenges before launch because a project with high regulatory risk will require higher investment and a longer startup runway. Failing to plan exposes the project to unpredicted high risks and problems, which could result in a negative cash flow or company net loss if the finished product cannot be commercialized because of unapproved use or unpredicted additional required clinical studies.

- Preliminary reimbursement and payment strategy

This step involves understanding how reimbursement and payment paths work in the entrepreneurial journey. Understanding them early helps the team to develop a successful revenue model strategy within a known period before market entry. This is important for starting a new MedTech company in emerging markets because the team can plan to spend their resource more effectively as fundraising in the early stage is typically difficult.

- Legal and IP awareness

Due to the complexity and competition in the healthcare industry, startups are exposed to a high risk of legal and IP violations, which can cause financial and existential concerns. Therefore, startups should be aware of their legal and IP issues and take them seriously. First, the startups should identify the legal issues prevalent in the medical technology industry, such as contracts, employment, and product liabilities (Chakraborty et al., 2021). These issues should then be registered for future monitoring. At the same time, the startups should engage with the UTTO to take necessary actions, such as invention disclosure, material transfer, and co-research arrangement. The startups should also do a primary survey on the IP landscape of the field and peripheral technology. The startup can then sketch their initial IP strategy focusing on high-level direction, like whether they plan to rely on a patent or trade secret.

- Exit strategy for university research in MedTech

Startup exit, such as licensing, merger and acquisitions, initial public offering, and joint venture, is a significant event in a business venture. The exit strategies, which are driven by financial or non-financial basis, are associated with key factors such as motivation, decision-making process, opportunity, founding team, and number of employees (DeTienne et al., 2015). Understanding the exit strategies, including exit options that are related to the characteristics of university research and MedTech startups (e.g., high risk, level of innovation, technology life cycle, and investments), can help entrepreneurs plan and manage their resources efficiently and increase their chances of success.

- Initial assessment of manufacturing, operation, and quality management plan

Products used in medical and healthcare applications are required to be manufactured within the certified manufacturing standard depending on regulatory classes. Thus, understanding the requirements and constraints of prior market entry is important to avoid loss from duplicate work due to unmet manufacturing standards. Additionally, even though the certified manufacturing infrastructure is important, investing in all required certified manufacturing infrastructure might be too expensive for an early-stage startup. Thus, a startup should consider hiring external infrastructure services or collaborating with other stakeholders from either the private or government sectors. Legal considerations, such as a non-disclosure agreement to avoid leakage of confidential information or a formal contract agreement to prevent the misunderstanding of project objectives and responsibility, should be considered before commencing the actual activity. In addition, value chain analysis can be used to understand the collaboration between different parties from the end-to-end of the customer journey.

Furthermore, early assessment and planning of a quality management system (QMS) and risk management should be considered to guarantee that every product embodies a full commitment to safety, efficacy, and the well-being of every patient it serves. It is important to note that the QMS is an important process. It is not a static endeavor, but it is a continuous improvement, including regular audits, feedback loops, and the adoption of emerging technologies to keep the process agile and effective.

Stage 1: build business case

The main objective of this stage is to identify, build, and validate the potential impactful business case with target users by using a product prototype in a near clinical setting to confirm a problem–solution fit in both clinical and market aspects. Even though technology is important for building unique strength and IP, the primary driver for success in the early stage usually comes from understanding the product value proposition of the target group. Thus, the startup should balance resources between developing superior deep technology and validating the value proposition with target users. The key activities included in this stage are typically as follows:

- Design concepts and prototype analysis

The technology development team plays a pivotal role in generating comprehensive product concepts using both internal and market inputs. Successful product development often undergoes multiple iterations of frequent modifications and refinements, which requires close multidisciplinary collaboration among the startup's development team, management, physicians, or other stakeholders to ensure a problem–solution fit.

A rough and rapid prototype is designed and tested to confirm the design concepts as quickly as possible. For example, digital health product prototypes can be developed using no-code programming tools within a short period of time. Meanwhile, hardware-based MedTech product prototypes can be built with a three-dimensional solid model in computer simulation software before producing a physical prototype. This process, done iteratively, facilitates computational analyses, including other tests such as solid mechanics and fluid dynamics, to enable the investigation of design limitations and analysis of the theoretical behavior of the product (Morrison et al., 2017). The construction of physical prototypes, including mockups and 3D printing models, to be assess in benches, cadavers, and initial animal studies, serves to evaluate the device's physical performance.

Moreover, IP, legal, and liability risks are continually closely assessed throughout the process. In order to ensure a comprehensive overview of prototype development, R&D frequently organizes design reviews, inviting all cross-functional team members to participate. This approach facilitates holistic feedback, incorporating diverse perspectives into the device development process (Pietzsch et al., 2009).

- Project management plan

In this stage, an initial project management plan is developed among all key members. It is a comprehensive roadmap that guides the project toward its goals and generally covers many aspects including project objectives, scope, responsible person, schedule, costs, quality, resources, risks, communication, procurement, and change management. Its benefits are to provide an end-to-end framework for project

managers to effectively execute, monitor, control, and communicate with the stakeholders. Furthermore, stakeholder analysis can be conducted to identify individuals or organizations with an interest in participating in the project. The next steps include prioritizing these stakeholders based on influence and interest, analyzing their needs and impact, and developing strategies for engagement and management. Project management plans and stakeholder analysis can improve communication, mitigate risks, and enhance project success through a systematic framework and effective stakeholder engagement.

- Early financial strategy

Regardless of the intrinsic value of its product or service, a startup's long-term success depends on the financial sustainability of financial resources, which can be derived from either external capital injections, e.g., investor funding and loans, or internal revenue generation. Consequently, establishing and employing appropriate financial control mechanisms is essential for ensuring the long-term success of early-stage businesses (Barringer & Ireland, 2018).

Another important aspect of MedTech is fundraising. As a MedTech startup usually requires longer development time due to the high complexity of business and regulations, a MedTech entrepreneur should develop a fundraising strategy and engage in funding activity as early as possible to secure enough capital for the new venture. Maximizing the chance for success requires several key considerations, such as validating the idea, building a strong team, choosing the funding source, crafting a data-driven pitch deck that tells a compelling story, and networking.

In addition to fundraising, understanding the valuation process is crucial for MedTech startups, as it helps both investors and founders navigate the challenges of early-stage investments. The process of valuing a start-up is crucial for both investors and founders (Cumming & Dai, 2011; Engel & Keilbach, 2007; Gompers et al., 2010; Hochberg et al., 2010; Hsu, 2004). It is a big challenge in the early stage due to the absence of historical data and the uncertainties surrounding various factors that may impact its growth and development (Peemöller et al., 2001). Davey et al. (2011) proposed a qualitative model with various factors that can effectively assess the initial valuation proposition for MedTech companies. Yet, quantitative approaches are often favored, especially by investors, for clearer and more transparent comparisons among different investment options. Two methods are commonly used to calculate the valuation: the VC method and the Discounted Cash Flow (DCF) method (Block, 2007; Chaplinsky & Reed, 2021; Moro-Visconti, 2021). Details of these methods are elaborated in the Supplementary Materials.

Festel et al. (2013) modified the DCF method by adjusting the beta coefficient based on the risks for early-stage high-tech startups. This work proposed an adjustment to Festel et al. (2013)'s guidelines to suit early-stage MedTech startups, as shown in Table 10. We propose using the beta coefficients by multiplying them with the values obtained from the post-money valuation obtained via any of the methods outlined above. This approach integrates the adjusted beta coefficient with the post-money valuation obtained from the VC method and the DCF method, providing a more tailored and accurate valuation for early-stage MedTech startups.

- Initial regulatory planning and strategy

Table 10 Modified assessment scheme to adjust the basic beta coefficient for early-stage MedTech startups (modified from Festel et al. (2013))

Category	Subcategory	Adjustment of the beta coefficient				
		+1	+0.5	0	−0.5	−1
Technology	Maturity of technology	Technology still in initial experimental stage	Technology successful on a laboratory scale	Technology successful in pilot plant	Technology successful in demo plant	Technology successful in technical application
	Advantages compared to competitive technologies	No advantages identified	Advantages not clearly identifiable	Costs or quality advantages identifiable	Costs and quality advantages identifiable	Significant costs and quality advantages identifiable
	Reputation of scientist	No reputation	Poor reputation	Moderate reputation	Good reputation	Very good reputation
	Technology transfer	No engagement with the Technology Transfer Office	Engagement with the Technology Transfer Office started	Technology transfer strategy justifiable	Technology transfer strategy finalized	Technology transfer completed
Products	Product benefits	Product benefits not identifiable	Product benefits not clearly identifiable	Product benefits clearly identifiable	Product benefits confirmed by first clients	Product benefits confirmed by numerous clients
	Unique selling proposition	Unique selling proposition not identifiable	Unique selling proposition not clearly identifiable	Unique selling proposition clearly identifiable	Unique selling proposition confirmed by first clients	Unique selling proposition confirmed by numerous clients
	Scalability	Very low scalability	Low scalability	Moderate scalability	High scalability	Very high scalability
	Competition	Currently strong competition	Potentially strong competition	Moderate competition	Low competition	Long-term low competition
Implementation	Business plan	Business plan unjustifiable	Business plan with open questions	Business plan plausible	Business plan occasionally proven	Business plan frequently proven
	Technical development plan	Technical development plan unjustifiable	Technical development plan difficult to justify	Technical development plan justifiable	Technical development plan likely to be feasible	Technical development plan very likely to be feasible
	Marketing plan	Marketing plan unjustifiable	Marketing plan difficult to justify	Marketing plan justifiable	Marketing plan likely to be feasible	Marketing plan very likely to be feasible
	Business development plan	Business development plan unjustifiable	Business development plan difficult to justify	Business development plan justifiable	Business development plan likely to be feasible	Business development plan very likely to be feasible

Table 10 (continued)

Category	Subcategory	Adjustment of the beta coefficient				
		+1	+0.5	0	−0.5	−1
Organization	Competences of the management team	Management team with major flaws	Management team with some flaws	Management team is complete	Management team is complete and competent	Management team is complete and very competent
	Headquarters location	Headquarters location problematic	Headquarters location can be improved	Headquarters location is fine	Headquarters location has advantages	Headquarters location has many advantages
	Competences of advisory board	Very low level of competences of advisory board/ consultants	Low level of competences of advisory board/ consultants	Moderate level of competences of advisory board/ consultants	High level of competences of advisory board/ consultants	Very high level of competences of advisory board/ consultants
	Process efficiency	Process inefficient	Process not very efficient	Process efficient	Process very efficient	Process exceptionally efficient
Finances	Sales plan	Sales plan unjustifiable	Sales plan difficult to justify	Sales plan justifiable	Sales plan conservative	Sales plan very conservative
	Costs plan	Costs plan unjustifiable	Costs plan difficult to justify	Costs plan justifiable	Costs plan conservative	Costs plan very conservative
	Profitability	Fundamentally low profitability	Risk of low profitability	Average profitability	Currently high profitability	Fundamentally high profitability
	Liquidity plan	Financial resources for next year are not secured	Financial resources for next year are secured	Financial resources for next 2 years are secured	Financial resources for next 3 years are secured	Financial resources for next 4 years are secured
Compliance	IP protection	No IP application	First IP application filed	Basic IP close to being granted	Basic IP granted	Extensive portfolio of granted IPs
	Regulatory	No regulatory strategy	Regulatory strategy is explored	Initial regulatory strategy is developed	Regulatory submission is submitted	Regulatory approval is obtained
	Reimbursement strategy	No reimbursement strategy	Reimbursement strategy is assessed	Reimbursement strategy is validated with key stakeholders	Reimbursement strategy is validated and refined	Reimbursement strategy is finalized
	Clinical study	No clinical studies are planned	Clinical studies are planned	Clinical studies are being conducted	Clinical studies are validated	Clinical studies are validated and continued

Regulations in MedTech are crucial for safeguarding patients and guaranteeing the effectiveness and safety of the product. Driven by new technologies, demand, and innovation to improve healthcare, these advancements could cause significant risks to patients if there is no proper regulation. The goal of this process is to study and understand the required regulations for MedTech in the target market, such as the European CE mark, US FDA, etc.

Regulatory activities include submitting design and test data for review and regulatory approval. The FDA submission is a major milestone in the MedTech product development process. Preparing for a submission requires a strong collaboration among several cross-functional areas, such as clinical, R&D, quality, and regulatory. Moreover, it is recommended that startups should consult and work closely with the local regulatory body, which is responsible for regulating the product to fully understand the work process and to significantly reduce the time and cost caused by duplicate work. The regulatory team generally includes two functions: regulatory affairs, which handles submissions and market clearance, and regulatory compliance, which administers the quality system. If a product requires clinical trials for regulatory submission, the regulatory team submits an investigational device exemption (IDE) to allow the product to be used in a clinical study. The regulatory team will also oversee the clinical trials, analyze results, and submit data required for regulatory submission. Clinical trials are of utmost importance for a successful commercialization of medical devices and thus need to be carefully planned and conducted. Therefore, understanding the regulatory pathway according to each product innovation development stage, from idea to market launch, is vital for MedTech startups to accelerate time to market and reduce cost and duplicate work. Table 11 shows the regulatory pathway activities and certificates in Thailand (FDA).

- Legal and IP foundation for commercialization

The research team should be familiar with and engage with the UTTO regarding business development and policies and regulations required for the translation of university research toward commercialization, such as the Bayh–Dole Act, University IP licensing/tech transfer. At this stage, the groundwork for IP protection, such as confidentiality policy, patent search, and patentability analysis, should also be initiated. Then, the startups can start drafting IP acquisition and utilization strategies suitable for their business and revenue model. At the same time, if applicable, the startups will need to handle legal matters regarding incorporation of the company and employment.

- Initial study on manufacturing and operation plan

At this stage, a design for manufacturing (DFM) and design for operation capability should be initiated in parallel with technical and business development to support the product development process to prepare for full-scale production. It includes the process of identifying and addressing any issue that might happen to avoid project delay and loss. For example, a medical device product might have to address how fixture and tooling might be developed, while a digital health product might have to address software infrastructure architecture and integration, etc.

Table 11 The regulatory pathway activities and certificates in Thailand (FDA)

Product Development stage	Regulatory pathway	Regulatory activities and certificates
Stage 0: Innovation ideation and Stage 1: Build business case	Concept, definition, and feasibility study	Regulatory review, including product definition, risk classification, etc
Stage 2: Design and development/ early validation and Stage 3: Test and validation	Design and development	Design process, from design input (e.g., market requirement) to design output (e.g., specification and prototype)
	Design verification	Inspection (e.g., dimension, visual inspection), testing (e.g., pre-clinical testing and animal testing), analysis (e.g., software validation, sterilization validation) Note: The regulator requires approving prior for testing, analysis, and inspection. The standard certificate, such as ISO certificate, will be issued after verification approval
	Design validation	Clinical evaluation from clinical data, clinical investigation, and clinical performance Note: it is required to get approval from the ethical committee and regulator prior to this step
	Design transfer	Design transfer (e.g., production specification and trial run & process validation) to design production, according to QMS standard, such as ISO13485 for Medical Device
Stage 4: Launch	Registration approval	Establish a registration with the regulator and prepare technical documents for submission
Stage 5: Post launch review	Post-market surveillance and compliance	Post-market surveillance and compliance to ensure product safety and effectiveness

Usually, an incremental product innovation can focus on manufacturing work at this early development stage, while a breakthrough product innovation might need more time on R&D and prototyping, which can suggest design adjustments to suit commercial level manufacturing in the later stage. Furthermore, key suppliers and strategy partners are identified and invited to collaborate on the project. Additionally, to improve product–market fit and faster time to market, rapid prototypes, such as computer simulation, lab prototype, 3D printed material, etc., are developed and used for initial market and technical validation to get real-world feedback from users and stakeholders.

- Quality

In this stage, initial quality assurance assessments for components manufactured internally and purchased from an external supplier are considered. It includes risk management, which identifies and mitigates potential hazards throughout the development cycle, design control, which ensures designs meet all functional and safety requirements, document control, which maintains records of every step and decision, non-conformance management, which addresses any deviations from established standards with corrective and preventive actions, and certificate of analysis (COA), which gives assurances for the analyzed goods in term of feature and specification.

Stage 2: design and development/early validation

This stage aims to achieve the product–market fit using a workable product prototype that is tested and accepted by the target users in the near clinical or final environment, meanwhile refining a plan and strategy for business strategy, clinical, regulatory, and manufacturing. Several key activities include developing a product design, validating a workable product prototype with key stakeholders to obtain early feedback, developing detailed design plans for manufacturing and operation, and preparing the verification and validation (V&V) testing.

Regarding the business model, value proposition validation activities are continued to complete all aspects of the nine-block business model canvas (Osterwalder et al., 2005) strategies, namely, value proposition, customer relationship, channels, customer segments, key partners, key activities, key resources, revenue streams, and cost structure. Additionally, other business strategy tools, such as value chain analysis (Porter, 2001) and balanced scorecard (Kaplan & Norton, 1992), can be applied according to the characteristics of the startup business to make the business operation more efficient before the market launch. Moreover, in the case of contract manufacturing, it is advisable to initiate collaboration with suppliers and strategic partners to ensure that production capabilities and quality align with the design and expectations. Then, the business model is refined to be closer to the final commercial version.

- Manufacturing and operation plan

This process is to prepare for translating design to production, which emphasizes risk management. Additionally, collaborating and managing expectations among suppliers and strategic partners are recommended to ensure that their capabilities and commitments remain aligned.

Next, the Design Failure Mode and Effects Analysis (DFMEA) is conducted to achieve the latest design while initiating the Process Failure Mode and Effects Analysis (PFMEA) to identify potential vulnerabilities and establish mitigation strategies from design to safe and effective manufacturing. A detailed producibility analysis, such as planning, procurement, testing, and training, examines deeper by analyzing every step's feasibility, from resource allocation and procurement to precise testing and training. Then, the manufacturing and operations strategy is reviewed, updated, and finalized by incorporating insights from the market.

After this stage, process excellence and productivity tools, such as lean manufacturing, Six Sigma (Schroeder et al., 2008) for hardware products, and agile methodologies for software products, can be introduced into the operation process to increase efficiency, quality, and collaboration and further highlight the commitment to quality and continuous improvement. Then, by integrating risk management, design control, and process validation, the MedTech product development team can prioritize quality throughout the product lifecycle for a successful market launch.

- Verification and validation

V&V testing is performed to ensure that the design and manufacturing meet the required product's safety, quality, and effectiveness. The design verification process, which consists of testing and inspection activities, is to confirm that the design of the

product meets quality, efficacy, and safety needs. Key example tests are performance and safety, biocompatibility, devices containing biological material, software V&V, sterilization validation, stability and shelf-life, packaging validation, and transportation test. Meanwhile, the design validation testing assesses final product prototypes before the design freeze and ensures that the new product meets user needs and requirements in terms of quality, efficacy, and safety. It typically involves simulated use tests, which may require the use of anatomy models or cadavers, and requires studies of user interfaces and human factors.

As regulatory compliance is very important in MedTech, a startup should study and understand the required standards for the target market, such as the International Electrotechnical Commission (IEC), the Clinical and Laboratory Standards Institute (CLSI), the International Organization for Standardization (ISO), etc. By understanding this thoroughly, a V&V test matrix is planned and mapped across the product development life cycle using multiple inputs from diverse functional teams in the organization, such as technical development, test and quality, and business development with real market and clinical feedback. These tests are important for design adjustments and fundamentals formulation before moving to the third stage—the final test and validation. Additionally, documenting every V&V study and its methodology is necessary for regulatory compliance to prove the product's reproducibility in terms of quality and performance.

Furthermore, in the case of manufacturing medical devices, certificate of manufacturing, or GMP, is also required by the FDA quality system regulation to ensure its quality management in various aspects, including design and development, manufacturing, and distribution. In the case of technology transfer and licensing, the licensee manufacturer must comply with the GMP standard too. Furthermore, the GMP activities include Installation Qualification (IQ) to confirm that the equipment is installed according to precise specifications, Operational Qualification (OQ) to analyze the equipment's operational performance under expected conditions, Performance Qualification (PQ) to analyze the product beyond normal use to guarantee consistent and reliable performance even under extreme circumstances, and Product Performance Qualification (PPQ) to make sure that the finished product meets all predetermined performance and safety criteria.

- Product design, development, and planning

As translating a MedTech product idea into reality demands detailed planning and execution, the journey typically begins with product design, carefully defined and examined by management. Next, accurate testing highlights both design verification, internal functionality, validation, real-world efficacy, performance guarantee, and user satisfaction. Every decision and change along the way is carefully documented in the Design History File (DHF), ensuring traceability and compliance. A robust project timeline keeps development on track while proactively identifying and mitigating potential issues through Failure Mode and Effects Analysis (FMEA). Once the design reaches its ideal form, a design freeze is proposed and approved, halting further alterations unless carefully re-validated. Finally, the Device Master Record (DMR) develops the approved manufacturing instructions, and the Device History Record (DHR) preserves the product evolution, serving as a valuable tool for future iterations and

regulatory oversight. This process of development ensures that a MedTech innovation emerges safe, effective, and ready to improve lives.

- Reimbursement

Ministry of Public Health, through its Health Intervention and Technology Assessment Program (HITAP), in collaboration with the International Health Policy Program (IHPP), conducts a comprehensive Health Technology Assessment (HTA) for a specific healthcare intervention or technology. This HTA goes beyond assessing clinical effectiveness and reaches broader implications, including social, ethical, and most importantly, economic aspects. The focus on economic evaluation and budget impact ensures a thorough understanding of the potential costs associated with adopting the technology, both directly, such as purchasing costs, training, etc., and indirectly, such as resource allocation, system changes, etc. This information will be crucial for policymakers in determining whether and how to integrate this technology into the healthcare system, ensuring responsible resource allocation and sustainable healthcare improvement.

- Legal and IP

At this stage, the startups continue to manage legal issues that arise. Particularly, as the startups finalize their product development, patentability analysis and patent drafting should be finalized. Then, if possible, a patent application should be filed at appropriate venues. Alternatively, if the startups decide to utilize trade secrets, they should have a concrete confidentiality policy ready to be implemented. The legal and IP readiness at this stage will make sure that the startup can test and validate its technology with peace of mind during the following stage.

- Regulatory

As the FDA submission is the major checkpoint in the regulatory pathway, this requires a strong collaborative effort among diverse parties throughout the product development journey. The regulatory affairs team is responsible for preparing regulatory submissions and navigating its path to market clearance, while the regulatory compliance team ensures the quality system meets the regulatory requirements. Together, they guarantee that the product not only meets domestic regulations, but also complies with international standards for future market expansion. The result from the clinical study demonstrates clinical performance to ensure alignment with regulatory requirements.

- Clinical

The success of any MedTech relies on a careful and well-managed clinical trial program, the result of which can be used to support both regulatory and marketing. This process begins with the ongoing review and refinement of the clinical validation plan and studies to ensure that it aligns with the data and regulatory requirements. Next, an IDE is thoroughly proposed and submitted for approval by the FDA, granting permission to initiate clinical trials. Moreover, pilot studies for first-in-human testing are carefully planned and conducted to ensure best practices and ethical standards. These

initial trials with a small group of participants gather initial safety and feasibility data, preparing for larger pivotal studies. These pivotal studies are important to assess the product's safety and efficacy of the product and its clinical performance in real-world settings. Furthermore, thorough biocompatibility testing is planned and executed alongside clinical trials to evaluate the product's compatibility with human tissue and the potential for harmful reactions. Finally, securing Institutional Review Board (IRB) approval is an essential before launching any clinical trial activities, ensuring ethical considerations and participant safety are prioritized throughout the research process.

Stage 3: final test and validation (pre-regulatory approval)

This stage continues to refine the business plan and revenue model by incorporating customer reaction and purchase intent to finalize the business strategy. Meanwhile, the research team completes regulatory submissions and secures legal and IP protection and management to prepare a MedTech startup for an early market introduction. In the case of a research project that uses a university IP, the project team should decide on suitable exploitation methods and complete the tech transfer process. Additionally, the team should continue participating in fundraising activities, attending incubator programs, and exploring partnerships.

- Clinical trial and adoption

Clinical trial activities in this stage are meant to prepare the data for successful regulatory submissions. Usually, after the results from pilot studies are validated and confirmed successfully with the regulatory requirements and key opinion leaders, further clinical studies engaging more clinical trials or human studies are conducted as required by regulators to confirm the clinical efficacy and safety and complete the regulatory submissions. The clinical trial results and key findings are usually published in medical conferences or journals, which can be used by the marketing team for strategic business development and marketing communication to ensure successful market acceptance and launch.

- Final reimbursement strategy

Securing reimbursement is crucial for both market adoption and revenue generation in the medical field. Ideally, it should be addressed early in the development process. However, navigating reimbursement intricacies can be complex. A MedTech startup needs to assess carefully whether a reimbursement model is essential; otherwise developing alternative revenue strategies is required. For products aiming for future reimbursement but not currently listed, seeking guidance from NHSO or policymakers early on can accelerate the process. By proactively addressing reimbursement and revenue models, MedTech startups can ensure their market penetration and financial success.

- Legal and IP

At this stage, startups should be familiar with legal issues related to their business and industry and should finalize a plan to take care of the issues. With data from the test and validation process, the startups can start evaluating the value of their IPs and technology and creating a strategy to maximize the value of such IPs and technology.

- Regulatory submissions and approval

The regulatory approval and clearance are required to be secured in this stage. These involve the strict development and implementation of a working quality system, detailed technical data, clinical trial results, and risk assessments required for compliance with the particular products, such as 510(k)s for low-risk medical devices, premarket approval (PMA) for high-risk medical devices, or device software functions and mobile medical apps (MMAs). Regulatory bodies like the FDA usually review and approve only if they are convinced of the device's risk–benefit.

- Final plan for manufacturing and operation and quality management to support early commercial activities

As product–market fit happens, product design and specification shall be finalized and frozen to further develop the manufacturing and operation blueprint and standard operating procedure (SOP), including required human resources or tools, to be ready for commercial launch. Furthermore, in the case of products consisting of hardware components, the blueprint should comply with Geometric Dimensioning and Tolerancing (GD&T) standards to communicate engineering drawings and computer-generated 3D models among designers and production members. Moreover, the rest of the components in product design, such as specification, product design, software graphical user interface (GUI), and packaging design, are reviewed and finalized within this stage. The final V&V and risk management are further reviewed and updated to confirm the required product's safety, quality, and effectiveness according to the regulatory requirements. Also, the process excellence and productivity are reviewed and updated to increase its operation efficacy. Additionally, even though documents are finalized within this stage, it is recommended that the team should review and revise those documents throughout the product lifecycle after launch.

- Preparation for sales and market introduction

Sales, marketing, and business development activities for an initial market introduction, e.g., sales materials, website, exhibition, sales visits, etc., are done within this stage. The sales channel strategy, either business-to-business (B2B) or business-to-consumer (B2C), is developed. In the case of B2B, such as hospitals or drugstores, understanding the vendor requirements is important as it may vary from customer to customer, like vendor registration process, decision-making process, trial units, and payment term. Furthermore, a working SOP shall be developed and prepared for the later stage of sales expansion. To prevent unauthorized or unintended use of the product, startups should consult with a legal expert to develop terms and conditions, such as sales agreements or product usage guidelines. Also, in case user information is collected for product improvement, it is recommended to finalize the Personal Data Protection Act (PDPA) at this stage. The main aim is to secure early customers, especially key target customers, for the first sale and subsequent repeat orders. Clinical results, which are published through medical journals or conferences, are normally used to endorse sales and marketing activities for better chance of medical adoption and professional brand image reputation. Educational marketing activities, such as training, workshops, demonstration programs, and consultations for internal salesforce or early key account customers,

are usually introduced in this stage. The benefit is to create brand awareness since the knowledge of the brand and its role, both rational and emotional, are more important to customers' attitudes and purchase intent for high-involvement products, which are purchased by customers only after careful decision-making, than low-involvement ones (Akbari, 2015; Radder & Huang, 2008). Furthermore, as a startup usually comprises few members, all internal cross-function teams are recommended to support each other in terms of sales and technical support or inventory preparation to ensure successful initial market adoption and fulfill sales forecasts.

Stage 4: launch (regulatory approval)

Launching a product after receiving regulatory approval is a critical stage in its life cycle. For high-involvement products marketed through professional medical channels, startups often focus on key early adopters who receive pre-launch training or demonstrations of new products. A targeted customer education program is provided to key customers and physicians, involving sales representatives attending surgical cases and conducting physician training, alongside ongoing sales efforts. Sales representatives also focus on securing procurement contracts and fostering sales activity with key influential customers to establish reference cases. In the case of complex products like medical devices, a technical support team is essential to educate both internal sales forces and customers. Moreover, a dedicated maintenance and service team is established, responsible for installation and after-sales service, ensuring complete customer satisfaction and product reliability. Additionally, for products sold over-the-counter or via online channels, startups can collaborate with clinicians to recommend the products, which can later create consumer awareness and increase user adoption. User feedback from the market, especially around customer satisfaction, purchase intent, and actual use, is closely monitored and carefully analyzed in order to refine the business and revenue model.

Once the product or service is launched, the startup can continue evaluating or revaluating its IP valuation from after-launch data. At the same time, the startup should see and manage IPs as a portfolio. The management may include in- and out-licensing and royalty payments.

Clinical trials are sometimes continued with selected physicians or clinics. This is done to gain support for marketing, secure reimbursement, and expand regulatory clearance into other territories or for additional indications as required by regulators. Furthermore, a startup is still required to conduct market surveillance and compliance with the regulation in order to provide statistical data of clinical evidence that can demonstrate the product's effectiveness and safety, meeting application requirements as claimed.

Moreover, preparations for scaling up involve enhancing the organization's human resources, skills, and knowledge base. The sales and marketing launch plan, specifically designed for early adopters and key influential customers, is implemented, and feedback from this early stage is closely monitored and reviewed for insights. Based on market feedback and opportunities, the business plan, revenue model, and product development strategies are continuously refined. Additionally, lessons learned and recommendations from the project should be carefully documented and reviewed by the responsible team and management.

Stage 5: scale up/post-launch review

After the initial launch of the product is successful, a startup aims to accelerate market penetration with full effort. This is achieved through implementing sales and business development, continuous monitoring of customer reactions, and gauging purchase intent. These insights directly inform the refinement of the business plan, revenue model, and product development, leading to the proposal of newer and improved versions of commercial products based on market feedback. In business development, the focus is on continuing and expanding customer education programs. These programs are designed to cover a broader customer base as outlined in the business plan, ensuring customers are well-informed and can fully appreciate the value of the products and services offered. Moreover, the revenue model and reimbursement strategies are regularly reviewed and updated to stay aligned with the market dynamics. Also, as the business grows, the startups should continue to monitor legal and IP issues, especially IP infringements. They will also have to continue managing in- and out-licensing and royalty payments for the whole life cycle of the IPs.

Moreover, the technology development team works on product improvements and manufacturing methods using real market feedback to stay competitive and meet customer needs. Startups should try to develop a strategy to collect feedback so that when complaints are reported, actions can be analyzed, and solutions can be tailored to the issue, such as label change for unindicated failures, customer-specific modification for unique clinical needs, or even comprehensive redesign if significant flaws emerge or the regulator mandates a recall.

In clinical operations, post-market clinical validation and surveillance methods are consistently applied to confirm efficacy and safety. The regulatory strategy is elaborated due to business development that aims for growth through expanded indications, exploring alternative applications, creating portfolio solutions, and scaling operations to regional and international markets.

Next, manufacturing and operations generally focus on process improvements and updating design control documents as necessary, which is due to any new design transfer and further modifications, to enhance efficiency and product quality.

Lastly, all functional activities are usually interlinked and support each other; therefore, management and key functional teams should discuss and support each other to drive toward the goal of delivering superior solutions while ensuring compliance, quality, sustainability, and profitability in a dynamic market environment.

Discussion

This study has advanced our understanding of the MedTech product innovation development process from academic research within emerging markets by providing a refined framework tailored to the unique challenges and opportunities these contexts present. The iterative development, improvement, and validation of the MediGate framework underscore its potential to significantly influence the MedTech landscape, echoing the findings of Platts (1993) on the effectiveness of process-oriented approaches in fostering innovation.

Our findings resonate with existing research, such as that by Chaturvedi and Srinivas (2021) and Menshenin et al. (2023), highlighting the critical role of a structured

development process in enhancing the success rates of MedTech innovations. The case studies and expert interviews conducted as part of this research not only validate the framework, but also offer insights into its practical application across various stages of product development, which is crucial for meeting both clinical and commercial milestones.

The MediGate framework is grounded in theoretical foundations, contributing to three key literatures. The first is the literature on the stage-gate model. As a simple yet powerful framework, the stage-gate model has been researched and further developed to fit various specific contexts. On the one hand, existing studies such as Pietzsch et al. (2009) and Thakur et al. (2012) provide insights into the healthcare industry; however, their limitations lie in the context of developed countries. On the other hand, there is an increasing trend to research the stage-gate model in the underrepresented context of emerging markets, but the model is generic and not specific to the healthcare industry (Kruachottikul et al., 2023). Thus, the introduction of the MediGate framework bridges the knowledge gap between these two research streams by integrating healthcare-specific insights into the existing Augmented Stage-Gate framework for deep-tech innovation in emerging markets (Kruachottikul et al., 2023). While the number of stages remains similar at six, including 1) innovation ideation, 2) build business case, 3) development, 4) test and validation, 5) launch, and 6) scale-up, guidelines specific to MedTech have been added: regulatory, clinical, manufacturing and operations, and quality management. The MediGate framework also emphasizes a process-oriented, iterative approach to product development that is sensitive to the regulatory, cultural, and economic landscapes of these markets.

The second is the literature on innovation diffusion. This study reinforces the notion from innovation diffusion theory that successful technology transfer and commercialization require adaptations to local contexts, aligning with Rogers (2003)'s principles on the importance of socio-cultural factors in the diffusion process. Especially in the healthcare industry, clinicians' innovations often face diffusion challenges as user-innovators frequently show disinterest in conventional market-based diffusion strategies (Svensson & Hartmann, 2018). Besides, patient-led innovation, while embraced by patients, often challenges healthcare professionals and policymakers. In response, the MediGate framework was designed to prioritize patients in the innovation process during each critical decision-making stage, while providing relevant stakeholders with detailed activities to collaborate towards successful innovation diffusion.

The third is the literature on product readiness assessment. As suggested by Soenksen and Yazdi (2017), the stage-gate process can be modified to incorporate an investment decision-making system for identifying, managing, and modifying healthcare-related projects. The assessments of technology readiness level (TRL) (Mankins, 2009) and investment readiness level (IRL) (Blank, 2014) have already been integrated into the stage-gate framework proposed by previous research (Kruachottikul et al., 2023). In the MediGate framework, we propose the Clinical Readiness Level (CRL) as another assessment tool for evaluating and communicating with stakeholders, as well as incorporating startup valuation methods to benefit fundraising strategy and communication with investors. Building on the previous literature by Mejtoft et al. (2022), we modified the CRL to reflect the complexities involved in product development, regulatory

compliance, and market acceptance (Table 2). This is reflected in the more detailed separation of Clinical trial product validation into three stages of CRL 5 to 7 and the addition of CRL9, defined as post-market clinical validation and surveillance.

However, this study is not without limitations. First, the sample size, although diverse, is relatively small and limited to a specific geographic region, which may affect the generalizability of the findings. Future studies could benefit from a broader geographic scope and a larger number of participants to enhance the robustness and applicability of the proposed framework. Second, the presentations and training materials in MedVentures were conducted both in English and Thai; however, many of the local startups preferred to use Thai, so the Thai-speaking mentors and judges who have strong knowledge and experience in the medical device innovation and investment space were extremely limited. Future recommendations would be to fully conduct the event in English so potential internationally qualified experts can participate. Additionally, the demographic scope of the startup cases is limited. Future research could focus on engaging overseas startups that aim to commercialize in emerging markets and local startups looking to expand into other countries. Lastly, while the MediGate framework was designed to cover MedTech innovation development as comprehensively as possible, tailoring the framework to fit the specific needs and capacities of individual organizations or sectors within MedTech may be necessary.

A critical observation during this study was the caution against a "tech push" approach, where technology development precedes understanding of market and clinical demand. This misalignment can lead to innovations that, despite their technological sophistication, fail to meet actual market needs or integrate smoothly into existing healthcare systems. The MediGate framework emphasized the importance of this issue by including market and clinical assessment and product–market fit in the early stages of development. By addressing the specific needs and challenges of academic origin and emerging markets, the MediGate framework promises not only to enhance the success rates of MedTech innovations, but also to facilitate their integration into the healthcare systems of emerging economies.

MedTech innovation plays a crucial role in enhancing healthcare outcomes and driving economic growth. Through the development of products and solutions that address pressing clinical needs, the MediGate framework supports the advancement of healthcare quality and accessibility, which also contributes to Sustainable Development Goal (SDG) 3. Additionally, the commercialization of MedTech products promotes industrial growth, job creation, and technological advancement, leading to broader economic and social benefits (SDG 9). This aligns with the notion of sustainable development, as it ensures long-term economic, social, and environmental benefits by promoting an interdisciplinary approach that integrates knowledge, technology, and industry practices to address complex healthcare challenges (Manioudis & Meramveliotakis, 2022; Meramveliotakis & Manioudis, 2021; Tung & Kaur, 2020).

Conclusion

The process of developing MedTech product innovation from research, particularly within emerging markets, presents unique challenges and opportunities that necessitate a tailored approach. This research has significantly contributed to the theoretical and

practical understanding of this process through the development and refinement of the MediGate framework.

Theoretical implications

Theoretically, this study extends the existing Augmented Stage-Gate framework for DeepTech innovation (Kruachottikul et al., 2023) by integrating insights specific to MedTech and emerging markets, which the latter has often been underrepresented in academic research. While the stages remain similar (six stages: Innovation Ideation, Build Business Case, Development, Test and Validation, Launch, and Scale-up), guidelines in aspects specific to MedTech have been added: regulatory, clinical, manufacturing and operations, and quality management. This research underscores the importance of a process-oriented, iterative approach to product development that is sensitive to the regulatory, cultural, and economic landscapes of these markets. The study also reinforces the notion from innovation diffusion theory that successful technology transfer and commercialization require adaptations to local contexts, aligning with Rogers (2003)'s principles on the importance of socio-cultural factors in the diffusion process. Besides, this research proposed the CRL as another assessment tool for evaluating and communicating with stakeholders, as well as startup valuation methods for the benefits of fundraising strategy and communicating with investors.

Managerial implications

From a managerial perspective, the MediGate framework offers a structured pathway that managers and practitioners can follow to enhance the likelihood of successful MedTech innovation development and commercialization in emerging markets. It provides clear, actionable stages and decision gates that can help MedTech ventures navigate the complex interplay of product development, regulatory compliance, clinical pathways, and market strategies. Additionally, the framework emphasizes the importance of stakeholder engagement, critical thinking, and the alignment of technology development with clinical needs and market demands, which are crucial for achieving market penetration and adoption.

Ideas for future research

Future research could focus on several areas to expand upon the findings of this study. For example, applying the MediGate framework in different geographic and economic contexts would help in testing its universality and adaptability. This could involve comparative studies between emerging and developed markets to identify commonalities and distinctions in framework application. Furthermore, quantitative validation of the framework's impact on MedTech startup performance metrics such as time to market, market share, and return on investment would provide a more objective measure of its efficacy. One could also explore how the MediGate framework can be expanded to incorporate sustainability principles more deeply, ensuring that MedTech innovations not only address immediate clinical needs, but also contribute to long-term economic, social, and environmental well-being. Another promising area is the development of a legal readiness level (LRL) metric, similar to the clinical and technological readiness levels used in the framework. An LRL would systematically assess the legal and regulatory

preparedness of a MedTech innovation, providing a structured evaluation of potential legal risks and compliance requirements throughout the development process.

By addressing these theoretical, managerial, and future research implications, this study not only contributes to the academic literature, but also provides practical guidelines that can assist practitioners in navigating the intricate MedTech innovation landscape within emerging markets.

Abbreviations

AI	Artificial intelligence
B2B	Business-to-business
B2C	Business-to-consumer
CLSI	Clinical and Laboratory Standards Institute
COA	Certificate of analysis
CRL	Clinical readiness level
DCF	Discounted cash flow
DFM	Design for manufacturing
DFMEA	Design failure mode and effects analysis
DHF	Design history file
DHR	Device history record
DMR	Device master record
EBITDA	Earnings before interest, taxes, depreciation, and amortization
FDA	Food and Drug Administration
FMEA	Failure mode and effects analysis
GD&T	Geometric dimensioning and tolerancing
GMP	Good manufacturing practice
GUI	Graphical user interface
HITAP	Health Intervention and Technology Assessment Program
HTA	Health technology assessment
IDE	Investigational device exemption
IEC	International Electrotechnical Commission
IHPP	International Health Policy Program
IP	Intellectual property
IQ	Installation qualification
IRB	Institutional Review Board
IRL	Investment readiness level
ISO	International Organization for Standardization
LRL	Legal readiness level
MMA	Mobile Medical App
MVP	Minimum viable product
NHSO	National Health Security Office
NPD	New product development
NPV	Net present value
OQ	Operational qualification
PDPA	Personal Data Protection Act
PFMEA	Process failure mode and effects analysis
PMA	Premarket approval
PPQ	Product performance qualification
PQ	Performance qualification
P/E	Price-earnings
QDD	Qualified diagnostic development
QMS	Quality management system
R&D	Research and development
SME	Small and medium-sized enterprise
SOP	Standard operating procedure
TRL	Technology readiness level
TV	Terminal value
UI	User interface
UTC	University Technology Center
UTTO	University Technology Transfer Office
UX	User experience
VC	Venture capital
V&V	Verification and validation

Supplementary Information

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Supplementary Material 1

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Author contributions
PK and PT contributed to the conceptualization, funding acquisition, project administration, resources management, supervision of the study, writing the original draft, and reviewing and editing the manuscript. PD, SH, NN, OJ, and SV conducted the qualitative and quantitative research and analysis, developed the methodology, and wrote the results section.

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Declarations

Competing interests
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