Navigating Collaboration Between MedTech Startups and Incubators: Enhancing MedTech Entrepreneurship Ecosystem

Melika Feyzi

A Thesis

in

The Department

of

Concordia Institute for Information Systems Engineering

Presented in Partial Fulfillment of the Requirements

For the Degree of Master of Applied Science (Quality Systems Engineering) at

Concordia University

Montréal, Québec, Canada

April 2025

CONCORDIA UNIVERSITY
School of Graduate Studies

This is to certify that the thesis prepared

By: Melika Feyzi

Entitled: XXX

and submitted in partial fulfillment of the requirements for the degree of

Master of Applied Science (Quality Systems Engineering)

Complies with the university's regulations and meets accepted standards concerning originality and quality.

Signed by the final examining committee:

_____ Chair
Dr. Farnoosh Naderkhani

_____ Examiner
Dr. Farnoosh Naderkhani

_____ Examiner
Dr. Arman Sadreddin

_____ Supervisor
Dr. Andrea Schiffauerova

Approved by _____
Dr. C. Wang, Director
Concordia Institute for Information Systems Engineering

2025/00/00 _____

Dr. M. Debbabi, Dean
Gina Cody School of Engineering and Computer Science

Abstract

Navigating Collaboration Between MedTech Startups and Incubators: Enhancing MedTech Entrepreneurship Ecosystem

Melika Feyzi

This thesis investigates the challenges and opportunities within the MedTech entrepreneurship ecosystem, focusing on the collaborative dynamics between startups and incubators. The research identifies the specific needs of MedTech startups, including regulatory guidance, resource access, and specialized mentorship, which are often unmet in general incubation settings. Through a comprehensive literature review, thematic analysis of expert interviews, and validation via survey data, this study uncovers prevalent ecosystem challenges, such as resource fragmentation and regulatory complexity. A model is proposed to enhance collaboration and facilitate efficient resource-sharing across ecosystem actors. This approach provides a structured framework for incubators and startups to address funding, mentorship, and regulatory compliance gaps. Future research should explore real-world applications of this model to validate its effectiveness in diverse settings, ultimately advancing the MedTech ecosystem and improving support structures for startups.

Table of Contents

List of Tables

List of Figures

Motivation

My journey into innovation has been shaped by a strong foundation in mathematics, engineering, and management, which has taught me to think critically, systematically, and strategically. Throughout my academic and professional life, I've sought to merge these analytical skills with effective management practices, constantly improving quality—particularly in healthcare, where innovation directly impacts people's lives.

With a master's in management and another in Quality Systems Engineering, I've developed a unique combination of skills that are highly applicable to my research. My management degree equipped me with essential project management, leadership, and stakeholder collaboration skills, which are crucial for navigating the complexities of the healthcare innovation ecosystem. Meanwhile, my Quality Systems Engineering background honed my ability to analyze processes, identify inefficiencies, and implement continuous improvement strategies—skills directly relevant to understanding the challenges that MedTech startups face in collaborating with incubators, which is the focus of my thesis.

During my 18-month internship as an Innovator in Residence, I worked closely with a MedTech startup, a university incubator, a hospital incubator, and a medical principal investigator. This allowed me to observe firsthand the dynamics of collaboration in healthcare innovation. Through this experience, I became aware that MedTech startups face unique challenges—such as regulatory hurdles, market entry barriers, and limited funding—that require not only the support of incubators but the collaboration of the entire ecosystem.

Initially, my thesis explored how incubators could better support MedTech startups. However, incubators alone cannot address all the challenges startups face. The entire ecosystem—investors, academic institutions, regulatory bodies, and more—must work together to provide the necessary support for startups to thrive.

This led me to develop a model, applied through a digital platform, that facilitates collaboration and resource sharing between startups and incubators. As startups succeed, so do the incubators supporting them, fostering mutual growth and overcoming shared challenges. By acting as a hub for the ecosystem, this model ensures that startups receive the necessary support to drive innovation and, ultimately, improve healthcare outcomes.

However, startups often face significant obstacles, including regulatory hurdles, market entry barriers, and limited access to funding.

By focusing on how incubators and the broader ecosystem can better support MedTech startups, my research aims to create a more supportive environment for innovation. This work not only contributes to my academic growth but also seeks to make a meaningful impact on the healthcare sector by helping foster an ecosystem where innovation thrives, leading to better health outcomes for all.

Chapter 1. Introduction

The MedTech entrepreneurship ecosystem plays a vital role in advancing medical innovation and addressing complex healthcare needs. MedTech startups often rely on external support—such as funding, clinical access, regulatory expertise, and mentorship—to transform innovative ideas into validated, market-ready solutions. While incubators and support organizations are designed to offer such resources, many MedTech startups still face significant delays, inefficiencies, and misaligned expectations due to gaps in ecosystem collaboration.

The existing literature acknowledges the role of incubators in startup development, highlighting both their potential and limitations in sectors like MedTech. Several studies identify recurring issues such as inadequate infrastructure, poor networking, limited regulatory knowledge, and fragmented support models [79] [86]. However, most research addresses these issues in isolation—focusing either on individual incubator performance or startup barriers—without examining the ecosystem as an interconnected system. This siloed approach limits our understanding of how collaboration breakdowns emerge and persist across actors.

This study addresses that gap by investigating how collaboration between MedTech startups and incubators can be enhanced to better support startup development. Drawing from a literature review, seven semi-structured interviews with ecosystem stakeholders, and a validation survey of 26 experts, the study identifies root challenges and proposes an improved collaboration model tailored to the needs of the MedTech sector. The research emphasizes ecosystem-wide interactions rather than isolated actor performance, offering a practical model that accounts for shared responsibilities, specialized resource needs, and communication structures.

The findings reveal several systemic barriers to collaboration—including regulatory misalignment, lack of tailored mentorship, post-incubation support gaps, and inconsistent communication. The proposed model integrates insights from stakeholders and the literature to address these pain points, offering structured solutions and implementation strategies. By approaching collaboration as an ecosystemic issue rather than an individual actor limitation, the study extends current knowledge and contributes a MedTech-specific framework that can inform future incubator design, policy, and support models.

The remainder of this thesis is organized as follows:

Chapter 2 presents a literature review on MedTech incubators, collaboration models, and systemic challenges.

Chapter 3 outlines the research methodology, including interview and survey design. Chapter 4 presents the results of the thematic analysis and survey validation. Chapter 5 discusses the proposed collaboration model, implementation strategies, and limitations. Finally, Chapter 6 concludes with contributions, future research opportunities, and policy implications.

Scope and Context: This study is based on the MedTech entrepreneurship ecosystem in Canada, with specific observations relevant to Quebec's provincially managed healthcare system. While the findings and recommendations are informed by this context, they may be transferable to similar healthcare ecosystems with centralized incubator support and regulated medical device frameworks. Nonetheless, generalizability to global settings may be limited.

Chapter 2. Background

While innovation can take many forms, this thesis focuses on product innovation—specifically, the development of new medical technologies within startups aiming to improve health outcomes. Product innovation is mostly aligned with the startup-incubator relationship, particularly in regulated sectors like MedTech.

2.1. MedTech

MedTech is an abbreviation for medical technology. The Global Medical Device Nomenclature (GMDN) Agency defines MedTech as "a broad field of healthcare products and technologies that include instruments, devices, implants, software, materials, and other solutions used for the diagnosis, prevention, monitoring, treatment, or alleviation of disease and disability" (1). As depicted in Figure 1, MedTech is categorized into four categories as below:

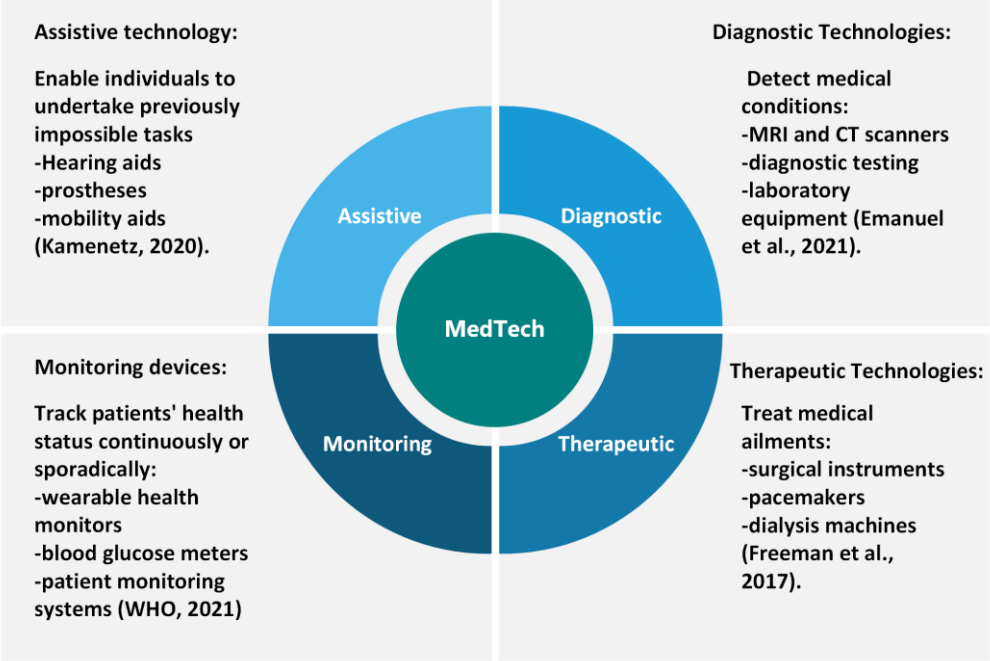


Figure 1 MedTech categories

MedTech is critical to modern healthcare, delivering tools and solutions that enable precise diagnosis, effective treatments, and better patient outcomes. These technologies help healthcare providers deliver high-quality care while also promoting patient participation and self-management (9).

2.2. Innovation in MedTech

MedTech innovation is developing and applying new medical technologies to improve patient care, health outcomes, and healthcare delivery. This includes improvements in medical devices, diagnostics, and digital health solutions (2). As presented in Figure 2 MedTech Innovation compromises:

Medical Devices: From simple instruments to complicated machinery, medical devices enhance precision, safety, and efficiency in medical procedures (2).

Diagnostics: Advancements in imaging, molecular, and point-of-care testing allow for faster and more accurate disease identification (10).

Digital Health Solutions: Telemedicine, mobile health apps, and wearable health monitors promote patient participation, remote monitoring, and data-driven decision-making (11).

Combination Products: Combine medications, devices, and/or biological products to offer comprehensive treatment solutions, such as drug-eluting stents and prefilled syringes containing therapeutic drugs (12).

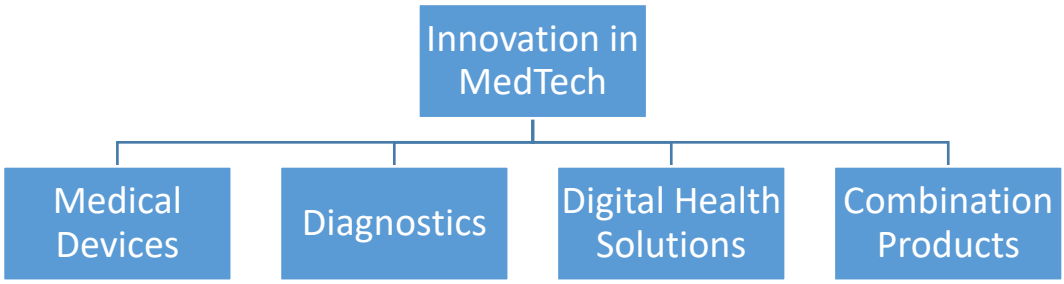


Figure 2 Innovation in MedTech

There are different drivers in MedTech innovation, including technological advances that are the result of innovation in material science, IT, and biotechnology (13). Also, Regulatory frameworks encourage innovation by providing guidelines for developing, testing, and approving medical technologies in terms of safety and efficacy (14). Unmet medical needs are a critical driver of innovation, especially in cost-effective treatments, chronic diseases, and aging populations (15). Besides, Investment from venture capital firms and government grants make the MedTech innovations possible. On the other hand, MedTech innovation encounters several challenges, including regulatory hurdles, market access issues, and the protection of intellectual property (16).

Some innovations are the trend in MedTech, such as Personalized Medicine, Artificial Intelligence (AI), Telehealth, and Sustainability. Individual patients' Personalized medicine devices and diagnostics are the result of Advances in genomics and biotechnology (16). Diagnostic tools, robotic surgery systems, and patient remote monitoring devices have been developed by integrating AI and machine learning technologies (11). Telehealth solutions have been adopted more during the COVID-19 pandemic era (17). Also, sustainable and environmentally friendly medical technologies are trends to improve the environmental impact of healthcare (18).

2.3. MedTech Innovation Through Entrepreneurship

MedTech innovation is critical to advancing healthcare, improving patient outcomes, and meeting unmet medical needs. MedTech entrepreneurship is critical in this process because it converts cutting-edge research into useful medical equipment and treatments. Entrepreneurs use their knowledge, skills, and networks to create innovative medical innovations that solve specific healthcare issues, resulting in substantial advances in medical care.

Empirical research demonstrates the impact of entrepreneurship on MedTech innovation. Kaplan et al. (2009) found that MedTech startups are more likely to deliver game-changing breakthroughs than established corporations because entrepreneurial enterprises are more nimble and ready to explore high-risk, high-reward projects (19). Furthermore, Stern (2014) emphasized the significance of academic entrepreneurship in the MedTech industry, concluding that universities and research institutions are critical sources of innovation (3). Academic entrepreneurs play an essential role in commercializing novel medical technology by establishing new enterprises and collaborating with industry stakeholders.

Medical technology innovation through entrepreneurship entails clinical problem identification, translational research, regulatory navigation, funding acquisition, and interdisciplinary collaboration. Scientific research provides strong evidence that entrepreneurs play a crucial role in advancing medical discoveries and improving healthcare outcomes. By promoting an entrepreneurial culture, the MedTech sector can realize its full potential for innovation, resulting in dramatic advances in medical care and patient outcomes.

2.4. MedTech Entrepreneurship Ecosystem

The most updated definition by the Global Entrepreneurship Monitor (GEM) describes an entrepreneurship ecosystem as "a complex and dynamic system of interconnected and interdependent actors and factors that collectively contribute to the creation, development, and sustainability of new ventures within a specific geographical area or industry" (20).

The MedTech entrepreneurship ecosystem is the network of actors, resources, and infrastructures supporting medical technology startups' creation, growth, and sustainability. This ecosystem includes startups, innovation hubs, incubators, accelerators, co-working spaces, clusters, angel investors, venture capitals (VCs), government bodies, regulatory authorities, and other support entities. Early conceptualizations of entrepreneurial ecosystems emphasized the interactions and interdependencies among these actors.

2.4.1. MedTech Entrepreneurship Ecosystem Actors

Startups

MedTech startups drive innovation by developing novel solutions to address unmet medical needs. They are characterized by agility, high innovation, and risk-taking (21).

Innovation Hubs

Innovation hubs are centers designed to foster innovation by providing resources, networks, and support to startups and entrepreneurs. These hubs often host co-working spaces and laboratories and provide access to mentors and industry experts (22). Innovation hubs are increasingly recognized as critical components of the MedTech ecosystem, offering collaborative environments that stimulate creativity and innovation (23).

Incubators

Incubators are organizations that support the early-stage development of startups by providing resources such as office space, mentorship, and access to funding. Incubators help startups survive the critical initial phase and accelerate their growth (24) (25).

Accelerators

Accelerators are time-limited programs offering intensive mentorship, education, and resources, culminating in a demo day (26). They align MedTech startups with market demands and foster cross-regional collaborations (27).

Angel Investors and Venture Capitals (VCs)

Angel investors provide early-stage funding with terms favorable to founders, helping startups secure initial resources while retaining control. VCs contribute financial capital and strategic guidance, enabling startups to scale. VCs prioritize high returns on investment (ROI) through exits like acquisitions or IPOs, often favoring market-driven innovations (28) (29).

Lead investors

Lead investors play a pivotal role in funding rounds by performing due diligence, negotiating deal terms, and attracting additional co-investors. They often secure a seat on the startup's board, providing strategic guidance and driving further investment, which is vital for a startup's growth and financial trajectory (30).

Government

Governments provide financial support, infrastructure, and policies that foster innovation and entrepreneurship (31). Government funding programs are critical in the MedTech ecosystem, particularly for early-stage research and development (R&D) and commercialization (32).

Regulatory Bodies

Regulatory bodies such as the U.S. Food and Drug Administration (FDA) and Health Canada establish and enforce standards and guidelines to ensure the safety, efficacy, and quality of medical technologies (33). They facilitate innovation while maintaining rigorous standards for patient safety and product efficacy (34).

Principle Investigators (PIs)

PIs oversee clinical trials, ensuring regulatory compliance and ethical standards. Their expertise bridges clinical insights with MedTech innovation (35).

Universities

Universities drive innovation by conducting R&D, hosting incubators, and fostering technology transfer. They provide skilled graduates and serve as a link between academia, industry, and healthcare (36).

Hospitals

Hospitals act as testbeds for innovation, offering environments for trials and feedback. They collaborate with startups to align technologies with clinical needs and regulatory standards (37).

Other Support Entities

Trade associations, research institutions, and service providers that offer specialized support to MedTech startups. Trade associations, research institutions, and service providers offer specialized support, advocacy, and networking, essential for a robust MedTech ecosystem (38).

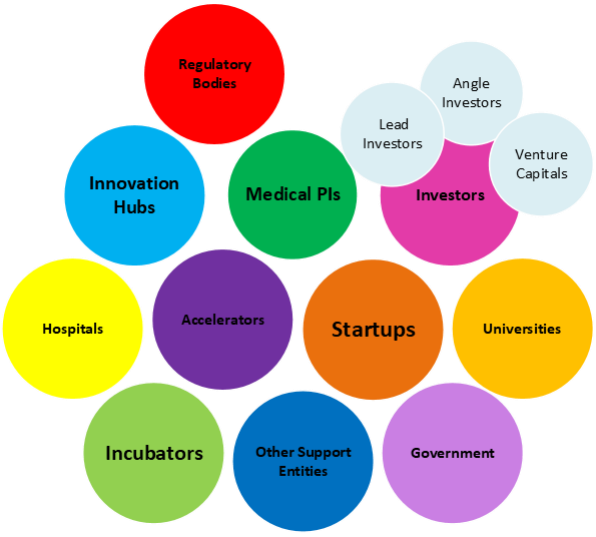


Figure 3 MedTech Entrepreneurship Ecosystem Actors

Chapter 3. Literature review

While several studies have explored the roles of incubators and innovation in general few have focused specifically on how MedTech startups interact with incubators in a highly regulated and resource-intensive environment [78] [135]. Existing models often lack practical strategies tailored to the needs of MedTech startups. This study adopts an inductive approach, allowing insights to emerge from qualitative data (interviews and survey responses) rather than testing a predefined framework. The goal is to contribute a bottom-up model grounded in the lived experiences of stakeholders within the MedTech ecosystem.

3.1. MedTech Product Life Cycle

The product life cycle (PLC) in the MedTech industry refers to the stages a medical technology product goes through from its inception to its withdrawal from the market. Theodore Levitt first introduced the concept in 1965 to describe the evolution of a product over time (43).

The MedTech product lifecycle is a structured process that guides the development and commercialization of medical technologies from concept to market. As demonstrated in Figure 4 Product lifecycle, the lifecycle typically consists of several key stages, each with specific activities and considerations:

Conceptualization: This initial phase involves identifying a clinical need, conceptualizing a solution, and conducting preliminary market analysis. It is crucial to assess the idea's feasibility from both a technical and commercial perspective. Activities include brainstorming sessions, risk assessment, and initial prototyping.

Concept Validation: In this phase, the concept is further developed and validated through various tests and market evaluations. This stage often includes developing early prototypes, conducting usability testing, and refining the product concept based on feedback from potential users and stakeholders.

Product Development: This stage involves detailed design and development of the MedTech product, including engineering design, software development, and preparing for regulatory submissions. Key activities include verification and validation testing to ensure the product meets all technical and regulatory requirements.

Product Launch: The product is launched into the market after regulatory approval. This phase includes finalizing manufacturing processes, marketing, and distribution plans, as well as initiating post-market surveillance to monitor the product's performance in real-world settings.

Post-Market Monitoring: This ongoing phase focuses on collecting data from the field, managing feedback, and making necessary updates or improvements to the product. It also involves regulatory compliance activities, such as reporting adverse events and updating risk management documentation (44).

These stages are iterative, with feedback loops that allow for continuous improvement of the product based on real-world data and regulatory updates.

Figure 4 Product lifecycle

3.2. MedTech Startups

3.2.1. Types of MedTech Startups

MedTech startups are newly established companies that develop innovative medical technologies to improve patient care and healthcare delivery. Startups can be classified based on their affiliations and focus areas. Based on their affiliation like startups in other industries can be classified as academic spin-offs, corporate ventures, independent startups, and government-supported enterprises (45).

Types of Startups based on their affiliations (Figure 5):

Academic Spin-offs: Startups originating from academic institutions, often leveraging university research and innovation (46).

Corporate Ventures: Startups created by established corporations to explore new technologies or markets (47).

Independent Startups: New ventures established by individual entrepreneurs or small teams, independent of larger organizations (48).

Government-Supported Enterprises: Startups that receive funding or support from government programs and initiatives to foster innovation (49).

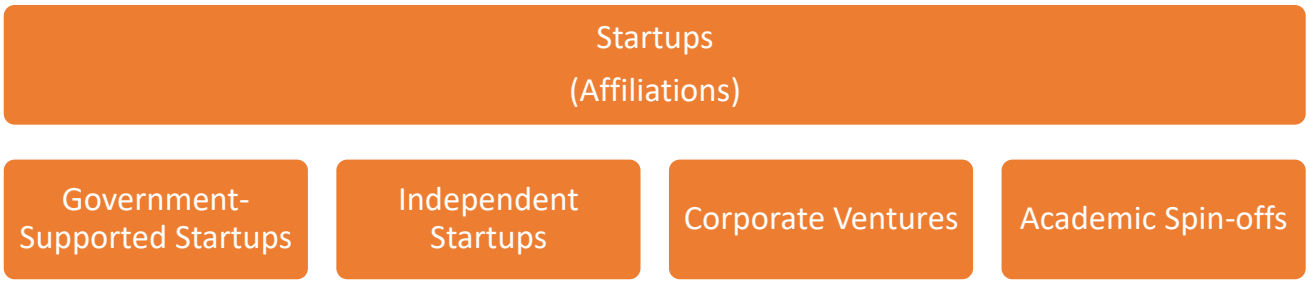


Figure 5 Types of Startups based on their affiliations

Types of Startups based on their focus area (Figure 6):

There are different classifications for MedTech startups based on their focus, the solutions they provide, and the type of technology they utilize. The most common types are diagnostics, therapeutics, wearable devices, Robotics and AI, and Health IT and Digital Health.

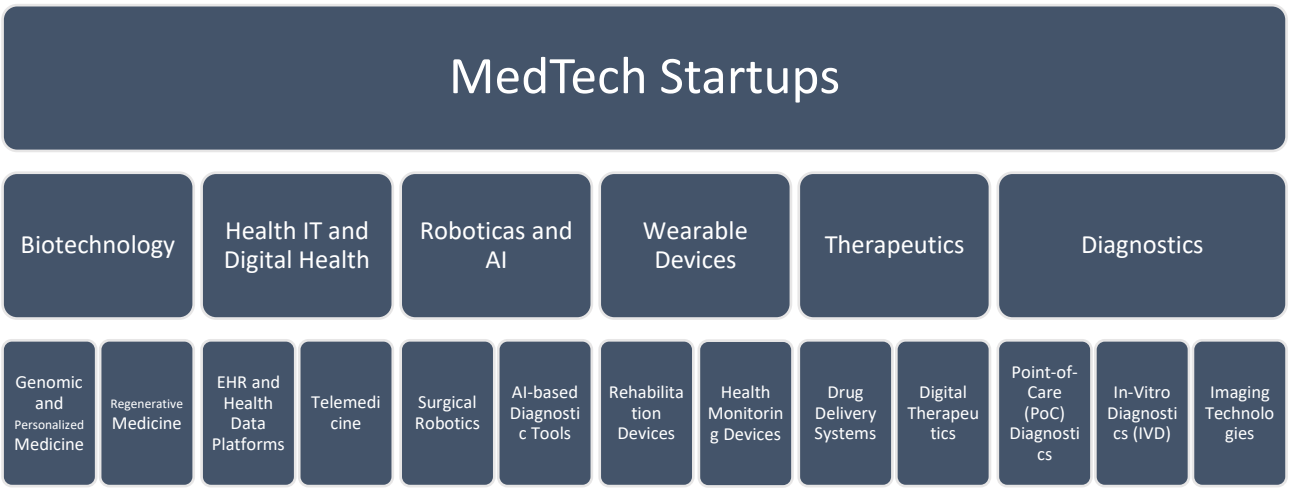


Figure 6 Types of Startups based on their focus area

Diagnostics:

Point-of-Care (PoC) Diagnostics: Startups focusing on rapid, on-site diagnostic tools used in clinics, hospitals, or even at home. These include startups developing portable devices or kits that provide quick and accurate diagnostics (50).

In-Vitro Diagnostics (IVD): These startups develop laboratory-based testing tools that analyze blood, tissue, or other samples to diagnose diseases.

Imaging Technologies: Startups focusing on innovative imaging solutions, including advanced MRI, CT scans, or ultrasound technologies.

Therapeutics:

Drug Delivery Systems: Startups in this category develop novel methods to deliver drugs more effectively, such as targeted delivery systems, implantable drug delivery devices, or nanoparticle-based therapies (51).

Digital Therapeutics: These startups create software-based interventions, often mobile or web applications, that provide evidence-based therapeutic interventions to patients.

Wearable Devices:

Health Monitoring Devices: Startups focus on wearable devices that monitor various health parameters like heart rate, blood pressure, glucose levels, and more.

Rehabilitation Devices: Startups developing wearable technologies to aid in the rehabilitation process, such as exoskeletons or smart prosthetics (52).

Robotics and AI:

Surgical Robotics: Startups that develop robotic systems to assist or automate surgical procedures, providing more precision and reducing recovery time (53).

AI-based Diagnostic Tools: Startups leveraging artificial intelligence and machine learning to analyze medical data and provide diagnostic recommendations.

Health IT and Digital Health:

Electronic Health Records (EHR) and Health Data Platforms: Startups that create platforms for managing patient records and health data, ensuring interoperability and security (54).

Telemedicine: Startups providing platforms for remote medical consultations, reducing the need for in-person visits and improving access to healthcare (55).

Biotechnology:

Genomic and Personalized Medicine: Startups that focus on genomic sequencing, personalized treatment plans based on genetic information, and gene editing technologies (56).

Regenerative Medicine: Startups working on technologies such as stem cell therapies, tissue engineering, and other regenerative approaches to treat diseases (57).

3.2.2. MedTech Startup Development Stages

The development stages of a MedTech startup begin with Ideation and Concept Development, where the initial concept is formulated, early market research is conducted, and basic prototypes are built. During this stage, funding primarily comes from founders, friends, family, and early angel investors. However, this phase is marked by high uncertainty and a limited financial runway (58).

Next is the Early Research and Development (R&D) phase, where startups focus on refining their prototypes, conducting feasibility studies, and validating their business model. Funding at this stage typically comes from angel investors, seed funds, and early-stage venture capital firms. The primary challenge here is demonstrating a clear market need and achieving initial traction (59).

The third stage, Product Development and Initial Regulatory Work involves scaling up product development, expanding the team, and achieving product-market fit. Venture capital firms, including those focusing on tech, are the prominent investors at this stage. Startups must make significant progress in development and gain early market acceptance to succeed (59).

As the startup moves into Preclinical and Clinical Trials and Manufacturing Preparation, the focus shifts to conducting comprehensive clinical trials, finalizing regulatory submissions, and preparing for large-scale manufacturing. Established venture capital firms are typically the key investors here. Startups face the challenge of meeting high investor expectations while preparing for commercialization (59).

Finally, the Market Entry and Commercialization stage focuses on scaling operations, entering new markets, and enhancing sales and marketing efforts. Funding is provided by late-stage venture capital firms, private equity, and strategic corporate investors. The main challenges at this stage include maintaining growth momentum and preparing for potential exit strategies, such as an IPO or acquisition (59).

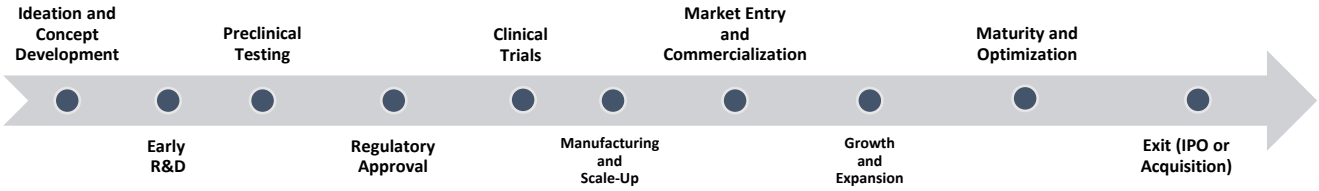


Figure 7 Development stages of a MedTech startup

3.2.3. MedTech Startup Investment Sources and Funding Rounds

There are diverse investment sources for MedTech startups, each catering to different stages of development and needs. Bootstrapping involves entrepreneurs using their own funds to start a company, offering speed and full ownership, but risks exhausting personal resources before profitability. Friends and family can provide flexible early funding, demonstrating the entrepreneur's commitment. Angel investors who specialize in early-stage ventures may offer both capital and domain expertise. VCs invest for financial returns, often offering strategic guidance and control, with a focus on sector and investment size. Corporate investors interested in both financial and strategic value may provide additional expertise. Grants offer non-dilutive funding[1] but come with stringent requirements and long application cycles, making them a competitive yet valuable resource (53).

Figure 8 MedTech Startup Investment Sources

Funding rounds refer to the stages of investment that startups go through to raise capital. These stages were first outlined in venture capital literature in the early 1980s (60).

The current understanding classifies funding rounds into several stages: pre-seed, seed, Series A, Series B, and subsequent rounds. Each round reflects the startup's growth and funding needs (61)

Pre-seed and seed funding are the earliest stages of investment in a startup, typically sought when the company is developing a prototype or proof of concept. These rounds provide the initial capital needed to form the core team, refine the product idea, and validate the market potential. Seed funding

[1] Non-dilutive funding refers to capital that businesses obtain without giving up equity or ownership stakes.(162)

often comes from angel investors, incubators, or early-stage venture capital firms and helps the startup move from concept to a functional product that can attract more prominent investors.

Following seed funding, Series A, B, and C rounds enable further growth and expansion. Series A marks a startup's transition from concept validation to product development and market entry, with investors looking for a viable product, a clear market opportunity, and a solid business plan. Series B focuses on scaling operations and expanding market presence, requiring startups to demonstrate market traction, revenue growth, and the ability to meet demand. Series C is for mature companies aiming for global expansion, mergers, and acquisitions, where investors look for profitability, steady revenue growth, and market leadership. Each round provides critical financial support while validating the startup's potential and viability at different growth stages.

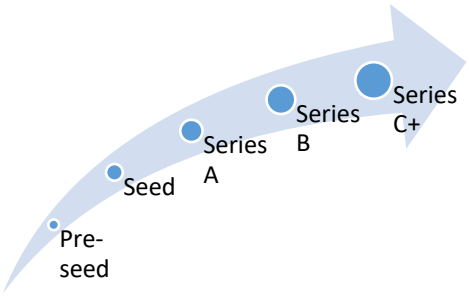


Figure 9 MedTech Startup Funding Rounds

3.2.4. MedTech Startups Key Performance Indicators (KPIs)

MedTech startups rely on various KPIs to measure their growth, progress, and market readiness. Critical metrics include product development milestones, where startups track their journey from ideation to prototype creation and clinical validation. These milestones are essential as they demonstrate the feasibility and functionality of the innovation. Regulatory approvals, such as FDA clearance or CE marking, are vital for ensuring the startup's product can legally enter and thrive in the healthcare market, signalling product viability (62)(63).

Another key metric is customer acquisition and retention, which reflects market adoption and user satisfaction, playing a crucial role in establishing a solid market presence. Startups also track revenue growth, highlighting financial health and sustainability, while market penetration evaluates how widely the product is adopted across different regions or sectors. The success of clinical trials is an essential KPI for MedTech startups, as it directly influences investor confidence and scalability potential (64)(65).

Regarding funding, non-dilutive funding options such as grants and awards provide crucial capital without diluting the founders' equity, bridging the gap between early research and larger venture capital investments. Studies, like those from Deloitte and PLOS ONE, have highlighted the significance of such funding, especially for early-stage startups (63)(62)(64). Furthermore, startups with experienced founders, particularly those who are not first-time entrepreneurs, are more likely to succeed due to their industry insights and networks. Having medical expertise on the founding team is another critical factor, as it ensures alignment with clinical needs and helps navigate regulatory complexities (62)(65).

Finally, research shows that startups led by founders from top global universities benefit from access to cutting-edge research and professional networks, which often leads to a higher likelihood of securing funding and achieving long-term success (65). These KPIs, combined with the right funding strategies and team composition, are essential for MedTech startups to thrive in a competitive market.

3.2.5. Challenges Facing MedTech Startups

MedTech startups face numerous challenges that often lead to high failure rates. One of the primary issues is the complex regulatory environment, especially when navigating the FDA or other regulatory bodies. The approval process for medical devices, particularly for PMA (Premarket Approval) devices in the U.S., is costly and time-consuming, with the majority of funds going towards regulatory-related activities. For example, it costs over $30 million to bring a 510(k)[2] product to market, and the time required for regulatory approvals can significantly delay commercialization, sometimes stretching up to a decade (66).

However, in Canada, the equivalent process for high-risk medical devices is overseen by Health Canada through the Medical Device Licensing (MDL) system. While the U.S. FDA uses the PMA for Class III devices, Canada classifies devices into four risk categories (I-IV), with Class IV being the highest. For Class III and IV devices, Canadian regulations require a comprehensive review involving clinical trial data, manufacturing processes, and safety information (Health Canada).

Another challenge for MedTech startups is market access planning. Many startups fail to plan for market entry early, which hinders their performance post-approval. Establishing a market access roadmap early in the development phase is crucial to ensure successful commercialization. Without

[2] A 510(k) is a premarket submission made to the U.S. Food and Drug Administration (FDA) to demonstrate that a medical device intended for marketing is as safe and effective.(163)

this planning, startups struggle to introduce their innovations effectively, limiting adoption and sales growth (67).

One of the most significant hurdles is market adoption barriers, where convincing hospitals, insurance companies, healthcare providers, and patients to adopt new technologies is extremely challenging. Hospitals and insurers are often reluctant to adopt unproven innovations without clear evidence of cost-effectiveness or clinical superiority, while healthcare providers may be resistant to change (68). This creates additional roadblocks for MedTech startups, even after regulatory approval.

Additionally, many MedTech founders come from technical or clinical backgrounds, which, while beneficial for product development, often leads to a lack of commercial acumen. Startups may struggle to navigate marketing, sales, and scaling operations once their product is developed. This shift from development to commercialization is critical, and founders must have the necessary skills or team members to manage this transition (69).

Lastly, the high financial demands associated with developing medical technologies, combined with insufficient early-stage funding, contribute to failure. Many startups exhaust their resources during the development phase and struggle to secure additional funding for scaling and market entry (70). These factors highlight why around 75% of MedTech startups fail, with most not returning cash to investors and many facing insurmountable hurdles during commercialization (67).

3.2.6. Why Do Startups in MedTech Need Incubators?

MedTech startups, especially those founded by recent university graduates, often face unique challenges due to their lack of experience in healthcare, business, and regulatory frameworks. These founders frequently struggle with critical aspects such as regulatory strategy, reimbursement models, marketing, intellectual property (IP), go-to-market strategies, and distribution channels. Without a deep understanding of these areas, navigating the complex MedTech ecosystem becomes particularly difficult. Consequently, incubators play a vital role in bridging these knowledge gaps, providing guidance, mentorship, and essential resources. Incubators help startups understand regulatory pathways, secure funding, and develop strong business models and commercialization plans, all of which are crucial for success in the highly regulated and competitive MedTech industry (71).

Moreover, incubators offer additional support by providing physical infrastructure, technical expertise, and access to networks that can help MedTech startups accelerate their growth. They play a crucial role in improving the survival rates of early-stage firms, as well as promoting job creation and

innovation within the industry. By fostering collaboration, incubators enable startups to overcome the challenges of regulatory approval, funding, and market entry (72) (71).

The survival rates for startups are significantly higher within incubators due to the combination of networking opportunities and specialized support services that cater to the MedTech sector. For instance, a study showed that firms within incubators experience higher growth, with many achieving faster market entry and greater stability compared to those outside such programs. Incubators also play a crucial role in job creation, innovation promotion, and technology transfer, which are pivotal in the MedTech field (73).

3.3. MedTech Incubators

3.3.1. Types and Affiliations of Incubators

In the MedTech and HealthTech sectors, incubators are vital for early-stage startups, offering crucial resources like mentorship, networking, and access to funding. Incubators help startups navigate the highly regulated healthcare and medical technology landscape. There are various types of incubators, including university-affiliated incubators, government-backed incubators, corporate incubators, and independent private incubators.

University-affiliated incubators are connected to academic institutions, providing startups with access to research facilities, labs, and academic expertise. They often focus on fostering innovation through academic research and helping to translate that research into commercial products (74). Hospital-affiliated incubators are also prominent in MedTech, offering startups access to clinical settings to validate their technologies in real-world medical environments. This access is essential for regulatory processes, such as obtaining FDA or CE certifications, and for product development through clinical trials. These incubators allow startups to engage with healthcare professionals, ensuring that products are aligned with clinical needs and practices (75).

Government-backed incubators are funded by local or national governments with the goal of stimulating economic growth and job creation. In the MedTech sector, they often offer specialized support in regulatory processes, helping startups navigate complex regulatory requirements (73). Corporate incubators are created by large companies to support startups that align with their strategic goals. These incubators provide not only funding but also extensive industry networks and access to potential customers, making them an attractive option for startups seeking to scale rapidly (75). Independent private incubators, while not tied to specific universities or corporations, offer general

business development resources but may lack the specialized industry connections of other incubator types (74).

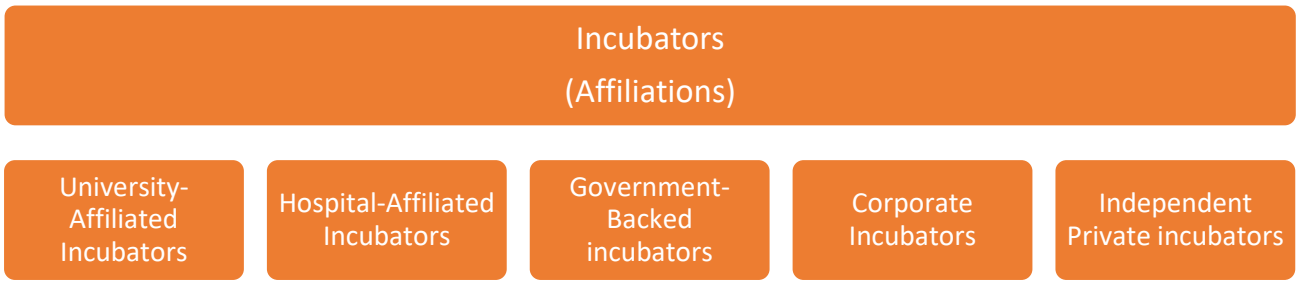


Figure 10Affiliations of Incubators

Incubators can also vary in their focus. Specialized incubators, common in the MedTech sector, cater to specific industries like healthcare or medical technology, offering targeted support that aligns with the unique challenges and regulatory requirements of the sector, such as FDA or CE certifications. These incubators provide access to industry-specific mentors, regulatory experts, and specialized labs, making them particularly valuable for MedTech startups (74)(75). On the other hand, incubators with mixed industry streams support startups from various sectors. While these incubators provide general services such as networking and business model development, they may lack the specialized resources that MedTech startups require (73).

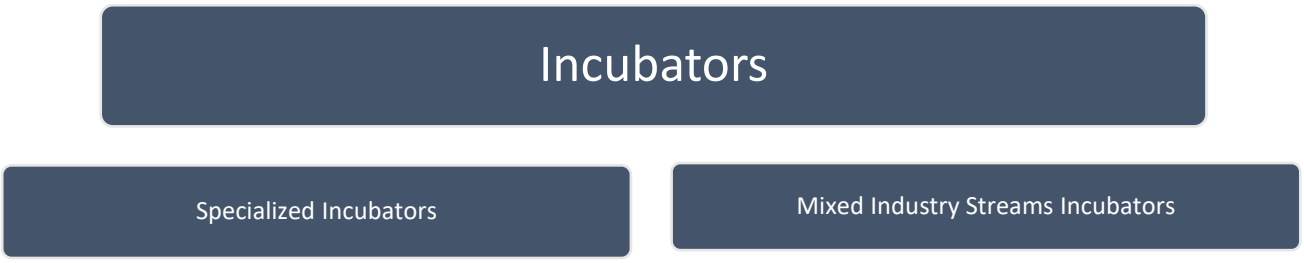


Figure 11 Types of Incubators

Overall, university and hospital affiliations in incubators create a supportive ecosystem that fosters innovation, helping MedTech startups overcome the industry's high barriers to entry, such as regulatory challenges, product validation, and clinical adoption (74) (75).

3.3.2. Selection Process, Program, Exit

MedTech incubators typically follow a structured process for selecting startups, providing support through various programs, and defining clear exit strategies to ensure sustainability and growth (76). The selection process includes screening the startups' applications based on innovation potential, market viability, and team capabilities. The selection process follows by interviewing the selected startups to check their fit with the incubator's goals and resources (24). The program structure includes mentorship, resource access, and networking opportunities. Startup graduation by achieving predefined milestones or after a set period, startup acquisition by larger companies, and startup IPO by going public through an Initial Public Offering (IPO) (77) can be exit strategies for incubators.

3.3.3. MedTech Incubator Key Performance Indicators (KPIs)

MedTech incubators rely on several KPIs and factors to measure their success and the impact they have on supporting startups. Key performance indicators in MedTech incubators often include startup survival rates, time to market, funding success, and clinical validation milestones. These KPIs help determine the effectiveness of incubators in guiding startups through the complexities of product development, regulatory approval, and commercialization (72) (75).

Additionally, factors such as customized services, including regulatory support and access to clinical networks, play a significant role in improving incubation outcomes. Given the sector's stringent regulatory requirements, the ability to provide tailored guidance in areas such as intellectual property (IP) strategy, clinical trial design, and reimbursement pathways is critical to MedTech startups. Incubators that offer these customized services typically demonstrate higher incubation performance (72).

Moreover, the innovation ecosystem surrounding the incubator is another critical factor. This includes the availability of collaboration opportunities with academic institutions, hospitals, and industry stakeholders, which helps facilitate knowledge sharing and access to resources like specialized labs and clinical trial environments (78). The incubator's capacity to integrate these innovation elements with its incubation services significantly enhances the performance and success rate of startups (72).

3.3.4. Challenges Facing MedTech Incubators

MedTech incubators face several unique challenges that can hinder their effectiveness in supporting startups. One major challenge is navigating the complex regulatory landscape. Incubators that lack

in-depth expertise in regulatory compliance can inadvertently lead startups astray, resulting in costly delays or issues with approvals from bodies like the FDA or for CE marking in Europe. This can significantly slow down a startup's progress (79).

Another challenge is the lack of solid networking and collaboration. Successful MedTech startups often rely on strong partnerships with academia, hospitals, and industry professionals. Incubators that fail to establish these connections may limit the growth potential of the startups they support. Furthermore, the absence of collaboration among the startups within the incubator can hinder knowledge sharing and synergy (79).

Infrastructure inadequacies also present a problem. MedTech startups often require access to state-of-the-art laboratories, cleanrooms, and specialized medical testing facilities. Incubators that do not provide access to such infrastructure can hold back startups' progress, especially those working on complex medical devices or biotechnologies (79).

Additionally, mentorship deficiencies can impede the success of startups. Mentorship from experienced professionals is critical for guiding startups through product development, market entry, and regulatory compliance. Incubators that lack a robust mentorship program or fail to connect startups with industry experts risk leaving founders without the support they need (79).

Lastly, unrealistic expectations can also cause issues, where incubators may pressure startups to achieve rapid success without considering the long lead times often required in MedTech development. This can result in disillusionment and conflicts, ultimately impacting both the incubator and the startup negatively (79).

3.4. MedTech Startup-Incubator Collaboration

3.4.1. Evolution of Collaboration Models

Collaboration models between MedTech startups and incubators have evolved significantly to ensure that startups receive the right combination of resources, mentorship, and network opportunities tailored to their needs. Initially, incubators focused on providing basic services such as office space and administrative support. However, modern collaboration models are more comprehensive, offering structured support like access to funding, mentorship, strategic partnerships, and specialized facilities. The collaboration model is shaped by both what services are provided and how they are tailored to meet the specific needs of startups at various stages of development. This approach ensures that

startups in industries like MedTech, which require specialized regulatory and clinical support, receive more relevant and timely resources, enhancing their chances of success (80).

Modern incubators now emphasize flexibility in their collaboration models, offering both traditional and advanced forms of support depending on the developmental stage of the startup. This shift enables startups to navigate complex areas such as clinical trials, regulatory approval, and market access more effectively, with the incubator acting as a pivotal partner in their journey from ideation to commercialization (81) (82).

3.4.2. Challenges in MedTech Startup-Incubator Collaboration

As collaboration models evolved, it became clear that MedTech startups face unique challenges when interacting with incubators. These challenges, widely recognized in the literature, often hinder the success of partnerships that aim to drive innovation. One significant challenge is aligning goals and expectations between the two entities. Incubators are often designed to foster a broad range of startups, but the highly regulated and specialized nature of MedTech requires more tailored support. Startups may expect rapid progress or resources that incubators are not equipped to provide, leading to misaligned objectives (83). This goal misalignment can be further complicated when incubators have broader institutional or strategic goals that may not fully align with the specific needs of MedTech startups (24).

Resource Adequacy in MedTech Collaboration

Alongside misaligned goals, resource adequacy is another significant challenge in MedTech startup-incubator collaboration. MedTech startups typically require highly specialized resources, including access to laboratories, clinical trial support, and regulatory expertise. Unfortunately, many general-purpose incubators may not be equipped to provide such specialized infrastructure, which can slow down the development process for MedTech innovations. A study highlighted that while incubators provide mentorship and business development resources, many fall short in providing the specialized infrastructure required by medical device and digital health startups, placing strain on both the startup and the incubator's capabilities (84).

Effective Communication in Collaboration

Effective communication presents another key challenge in the startup-incubator relationship. Consistent, clear, and timely communication is vital for addressing the dynamic needs of MedTech startups as they navigate their complex journey, including regulatory hurdles. Miscommunication or lack of transparency can result in missed mentorship opportunities and delays in resolving critical issues, further complicating the startup's progression through regulatory approvals (85). Clear communication also helps manage expectations and fosters a collaborative environment where issues can be addressed promptly.

Regulatory Environment Challenges

One of the most significant challenges faced by MedTech startups is navigating the stringent regulatory frameworks required for medical device approvals, such as FDA regulations in the U.S. and CE certification in Europe. Many incubators may lack the specialized regulatory expertise to provide adequate guidance throughout this complex process. Studies emphasize that incubators can mitigate this gap by offering targeted workshops and forging partnerships with regulatory agencies, ensuring continuous updates and practical compliance support for startups (86).

In conclusion, incubators remain integral to the success of MedTech startups, offering critical resources, mentorship, and support. However, addressing persistent challenges—such as misaligned expectations, resource limitations, communication gaps, and regulatory hurdles—is essential for improving startup-incubator collaboration. Future models should prioritize tailored, sector-specific support and partnerships to enhance the growth and commercialization of MedTech innovations (83)(24).

3.4.3. Role of Partnerships with Universities, Government, and Industry

Effective collaboration among MedTech startups, universities, government agencies, and industry partners is crucial for successful commercialization. These stakeholders provide essential resources, such as funding, research facilities, regulatory guidance, and mentorship. Universities contribute significantly to the early stages of product development through their innovation and research capabilities. Governments often play a pivotal role by offering financial support and policy frameworks. In turn, industry partnerships facilitate access to market channels, helping startups with product

development and market entry. Such collaborations are instrumental in navigating regulatory landscapes and achieving clinical validation (87,88).

3.4.4. Incubator-Startup Collaboration Success Factors

MedTech startups need access to specialized facilities, mentorship, and regulatory expertise for success. Organizations like Greenlight Guru emphasize the importance of medical device incubators and accelerators such as JLABS by Johnson & Johnson, which provide comprehensive support, including access to state-of-the-art facilities (89). These services enable startups to scale effectively and overcome technical challenges. Additionally, incubators such as StartX Med at Stanford University offer equity-free support, fostering unbiased mentorship and allowing startups to refine their business models (90).

3.4.5. Global Collaboration Models in MedTech

The literature also touches on the broader healthcare sector and how healthcare incubators leverage regional strengths while fostering global collaborations. A study on top healthcare incubators in the U.S. underscores the importance of access to specialized research facilities and global networks, which are instrumental in product development and market entry. For example, programs like AstraZeneca BioHub and CCIT facilitate access to cutting-edge research and provide the necessary infrastructure for healthcare innovation (91). This regional and global support allows startups to navigate the complex MedTech landscape more effectively.

Furthermore, studies such as TBI MSMF highlight the role of strategic partnerships with medical associations in supporting MedTech startups. These partnerships provide clinical networks, market feedback, and regulatory guidance, all of which are crucial for aligning innovations with healthcare needs and regulatory standards. Early and continuous engagement with such associations is essential for MedTech startups to navigate the complexities of the healthcare industry and achieve long-term success (92).

3.4.6. Addressing Regulatory, Financial, and Market Access Barriers

The growing complexity of the MedTech sector has also brought attention to the need for specialized support from incubators, particularly in addressing regulatory and financial challenges. Wilson et al. identified gaps in support, noting that MedTech startups often face difficulties navigating regulatory

pathways and securing funding. Their research suggests that incubators should provide tailored workshops on regulatory compliance and establish partnerships with regulatory bodies to ensure continuous updates and guidance. Such targeted interventions are crucial for helping startups overcome regulatory and financial barriers and bring innovations to market (86).

MarkiTech's report further explored the role of health tech incubators in overcoming challenges specific to MedTech startups. Their findings emphasize the need for access to capital, regulatory guidance, and strategic partnerships with healthcare institutions. The tailored support programs offered by incubators, which adapt to the evolving healthcare regulations and startup needs, are highlighted as essential for fostering growth and innovation in the MedTech space (88).

3.4.7. Mentorship and Networking for MedTech Startups

Mentorship and networking opportunities are often highlighted as essential to MedTech startup success. MedTech Innovator's annual Showcase and Accelerator program underscores the importance of mentorship and networking for startups navigating the complex MedTech landscape. This program's success demonstrates how structured mentorship can significantly enhance commercialization success for MedTech innovations. By connecting startups with industry veterans, healthcare professionals, and investors, such programs ensure that emerging companies receive the guidance and resources necessary for growth and scalability (93).

Additionally, Greenlight Guru compiled a list of medical device incubators and accelerators, such as JLABS by Johnson & Johnson and StartX Med. These organizations offer comprehensive support, including access to state-of-the-art facilities and specialized regulatory guidance, helping startups overcome technical challenges and scale their innovations more effectively (89).

PitchDrive also emphasizes the importance of structured mentorship programs and skill development workshops, particularly those offered by incubators like StartX Med at Stanford University. These programs leverage extensive networks and resources without taking equity from startups, ensuring focused and unbiased support that enables startups to refine their business models and scale their operations (90).

3.4.8. The Role of Specialized Facilities in Supporting MedTech Startups

Access to specialized facilities and cross-disciplinary teams is vital for the success of MedTech startups. Programs like JLABS and StartX Med provide not only mentorship and funding but also

access to state-of-the-art facilities that enable startups to tackle technical challenges effectively. These programs offer laboratory spaces, advanced research equipment, and testing environments essential for product development in the MedTech field (89).

Kolabtree highlights how these organizations, particularly in the U.S., serve as regional hubs that allow MedTech startups to access not only research facilities but also global networks of partners, including academic institutions and healthcare providers. This network is instrumental in ensuring that startups have the resources they need for product development and clinical validation (91).

3.4.9. Global Collaborations and Partnerships in MedTech

Healthcare incubators are increasingly leveraging both regional strengths and global collaborations to foster innovation. A study on top healthcare incubators in the U.S. underscores the importance of specialized research facilities and global networks. For instance, programs like AstraZeneca BioHub and CCIT enable startups to access cutting-edge research infrastructure while collaborating globally. These regional and global partnerships help startups navigate the complexities of product development, clinical validation, and market entry, ensuring they can scale effectively and reach broader markets (91).

3.4.10. Partnerships with Medical Associations for Clinical Feedback

Studies such as TBI MSMF emphasize the strategic value of partnerships with medical associations in supporting MedTech startups. These partnerships provide critical clinical feedback, regulatory guidance, and access to clinical networks, all of which are essential for aligning new innovations with healthcare needs. Early and continuous collaboration with medical associations helps startups ensure that their products meet regulatory standards and are clinically viable, which is crucial for long-term success in the healthcare industry (92).

The literature review highlights the evolving nature of MedTech startup-incubator collaborations and their critical role in supporting innovation. Incubators provide essential resources such as mentorship, regulatory guidance, funding, and networking opportunities, all of which help startups overcome significant barriers. However, these partnerships are not without challenges—especially regarding resource adequacy, communication, and regulatory navigation. Addressing these gaps, along with fostering global collaborations and partnerships with key stakeholders like universities and medical

associations, will enhance the support system for MedTech startups and ultimately lead to more successful commercialization efforts.

3.5. Objectives

The following objectives have been established to guide this research. By systematically exploring the intersection between MedTech startups and incubators, the study aims to contribute new insights and practical solutions to enhance collaboration. These objectives reflect the research focus on identifying, analyzing, and addressing the key challenges faced by MedTech startups within incubation environments. Through validation and ecosystem actors' engagement, this study seeks to offer actionable strategies for improving outcomes in the MedTech entrepreneurship ecosystem.

1. Explore the challenges faced by MedTech startups in their development and collaboration with incubators through a comprehensive literature review and targeted interviews.

2. Identify existing solutions in the literature that address these challenges.

3. Develop and propose new solutions to enhance collaboration and address the challenges.

4. Validate the effectiveness of the proposed solutions through surveys, ecosystem actors' feedback, and data-driven analysis.

Chapter 4. Methodology and Results

This thesis employs an applied research approach to address practical challenges encountered by MedTech startups, incubators, and their collaborations. "This research follows a qualitative methodology, incorporating thematic analysis from interviews to propose an improved MedTech ecosystem model.

Initially, a qualitative phase is conducted, which includes a literature review and in-depth interviews to explore and describe the challenges faced by MedTech startups and incubators in collaboration. This exploratory and descriptive phase provides in-depth insights (94,95). Following this, a survey was used for validation, where percentages from multiple-choice questions provided descriptive quantitative insights. The survey was administered to validate the proposed collaboration model—specifically the relevance and perceived effectiveness of its components and solutions. While the platform is a proposed future implementation of this model, the validation effort in this study focuses on the conceptual framework and its practical alignment with stakeholder needs.

Some challenges in collaboration within the MedTech ecosystem were identified through the literature review and some challenges were found through the interviews.

4.1. Interview Design

In-person and virtual interviews were conducted with experts in the MedTech ecosystem to uncover real-world challenges. Interviewees were selected to ensure a diverse range of perspectives, enriching the research findings. Given the nature of the topic, semi-structured interviews were chosen, as this format balances guided questions with the flexibility for interviewees to share insights beyond the initial queries. This conversational approach is particularly beneficial for qualitative research, allowing for unexpected insights to emerge.

Table 1 The specifications of the interviews demonstrates the specifications of the interviews, including dates, duration, and type of interviews. The names of the interviewees and their affiliations are omitted for confidentiality purposes.

Table 1 The specifications of the interviews

Job Title	Date of Interview	Type of Interview	Duration
Clinical Trial Manager	Nov. 23, 2023	In-person	15 mins
Fractional CTO and COO, Senior Professional in Supply Chain, Operations, and Quality, Technology Consultant, Technical Advisor, and Business Coach, driving innovation and advancement in HardTech and MedTech sectors	Dec. 22, 2023	Zoom	2 hours
Medical Principal Investigator, Assistant Professor of Medicine, Division of Geriatric Medicine	Jan. 10, 2023	Zoom	40 mins
Manager of the Third IeR Program - Living Lab & Innovation director	Jan. 11, 2023	Zoom	1 hour
Leader of Healthcare Stream at university incubator	Jan. 24, 2023	Zoom	25 mins
Executive Director of Strategy, Development, Sustainability	Jan. 30, 2023	Zoom	40 mins
Director of Major Societal Challenges of FRQ	Jan. 23, 2023	Zoom	1 hour

The interview questions were open-ended to encourage detailed responses and exploring experiences, opinions, and practices. The questions are included in

Appendices

Appendix A: Interview Questions.

Ethical Considerations and Consent

The interviews conducted for this research focused on professional insights within the MedTech entrepreneurship ecosystem and did not involve sensitive personal data. Participants were informed that the interviews were part of my thesis research, and their voluntary participation served as informal consent.

Participants requested confidentiality regarding any critical remarks about other stakeholders, and I respected this throughout the research. All efforts were made to maintain the privacy and integrity of the data, with no identifiable information or criticisms included in the final analysis. The interviews were recorded (with permission) and transcribed, and detailed notes were taken in preparation for thematic analysis.

This research employed inductive thematic analysis for its flexibility and depth, enabling a rich representation of the data. This method is ideal for exploring the dynamic relationships between startups and incubators in the MedTech sector. Its inductive nature allows themes to emerge naturally from the data, ensuring that the analysis is grounded in the actual experiences and perspectives of the stakeholders involved. This flexibility is crucial for capturing the complexity inherent in the MedTech startup-incubator collaboration.

4.2. Interview Analysis: Thematic Analysis

Thematic analysis is a qualitative research approach utilized to identify, analyze, and report patterns or themes within a data set. While it primarily organizes and provides a detailed description of the data, it often extends beyond mere description to interpret multiple dimensions of the research subject. This method systematically identifies, analyzes, categorizes, describes, and reports themes within the data(96). Thematic analysis typically follows a series of distinct phases, as presented in Figure 12.

Phase 1: Familiarization with the Data

it is essential for researchers to thoroughly engage with the data to grasp its full scope and complexity. This immersion requires researchers to read the data multiple times in a purposeful manner, actively searching for meanings and patterns. They recommend that researchers review the entire data set at

least once before starting the coding phase, as this initial exposure can help form ideas and reveal emerging patterns in the data(96).

Phase 2: Generating Initial Codes

The second phase begins after researchers have carefully analyzed the data and understood its content, allowing them to create preliminary insights about its relevance (96). In qualitative research, coding acts as a reflective exercise and a method for actively engaging with and interpreting the data(97). This approach enables researchers to isolate and focus on particular data features. Researchers can enhance their comprehension of the findings by evolving from raw data to well-articulated concepts regarding the key themes (98). During the coding phase, significant portions of the text are identified, and labels are assigned to categorize these sections in relation to relevant themes or issues. This method assists in highlighting essential elements within the data that could aid in formulating themes across the overall data set (99).

Phase 3: Searching for Themes

The third phase initiates after all data have been initially coded and compiled, resulting in a comprehensive list of distinct codes identified throughout the data set. During this phase, researchers organize and combine relevant coded data excerpts into overarching themes(96).

Themes can be generated either inductively from raw data or deductively from existing theories and prior research. An inductive approach produces themes that are closely related to the data itself and may not directly align with the specific questions asked of interviewees. This method focuses on coding without fitting the data into a predetermined framework, making it a data-driven process. Conversely, deductive analysis is shaped by the researcher’s theoretical interests, which may lead to more detailed examinations of specific data aspects but can compromise the richness of the overall data description (96).

In this research, an inductive approach was employed to identify themes. The researcher derived codes directly from the data, listening to recorded interviews, transcribing them, and highlighting significant and recurring points raised by the participants. This organic code development process was informed by the data itself; for example, the repeated emphasis on mentorship quality as a critical need led to its identification as a code. Inductive thematic analysis offers flexibility, allowing for the emergence of unexpected themes. Through repeated review and summarization of the transcripts,

the researcher allowed the data to guide the formation of codes and themes, resulting in an exploratory and open-ended analytical process.

In this research, efforts were made to avoid being overly influenced by the research questions, as recommended by King, ensuring that themes which may not seem directly relevant were not overlooked, since they could still yield valuable insights (99).

Phase 4: Reviewing Themes

The fourth phase commences once a collection of themes has been established and requires further refinement. In this stage, researchers examine the coded data extracts for each theme to assess whether they create a coherent pattern. The validity of each theme is evaluated to ensure it accurately represents the meanings present in the overall data set.

If researchers discover a critical issue in the text that is not addressed by an existing code, they may introduce a new code. Conversely, if a code is deemed unnecessary or significantly overlaps with others, it may be removed (99). It is important to note that the need for recoding from the data set is normal, as coding is a dynamic and evolving process. By the conclusion of this phase, researchers gain a clearer understanding of the various themes, their interconnections, and the overarching narrative that emerges from the data (96).

Phase 5: Defining and Naming Themes

In the fifth phase, researchers focus on understanding what each theme reflects in the data and why those aspects are significant. At this point, they consider how each theme contributes to the overall narrative derived from the complete data set in relation to the research questions. By the end of this phase, it is crucial for researchers to clearly articulate what the themes encompass and what they do not represent. If researchers can effectively and succinctly define the scope and content of each theme, they can proceed to the next phase; otherwise, additional refinement may be necessary (96).

Phase 6: Producing the Report

The final phase commences once the researcher has fully developed the themes and is prepared to conduct the final analysis and compose the report. The report of a thematic analysis should deliver a concise, coherent, and logical account of the data, ensuring it remains engaging and avoids unnecessary repetition (96).

Researchers should strive to substantiate their choice of themes by referencing relevant literature. By integrating the literature with the findings, the narrative crafted gains credibility (100). Furthermore, the literature can be utilized not only to validate the research findings but also to challenge and expand upon existing literature (101).

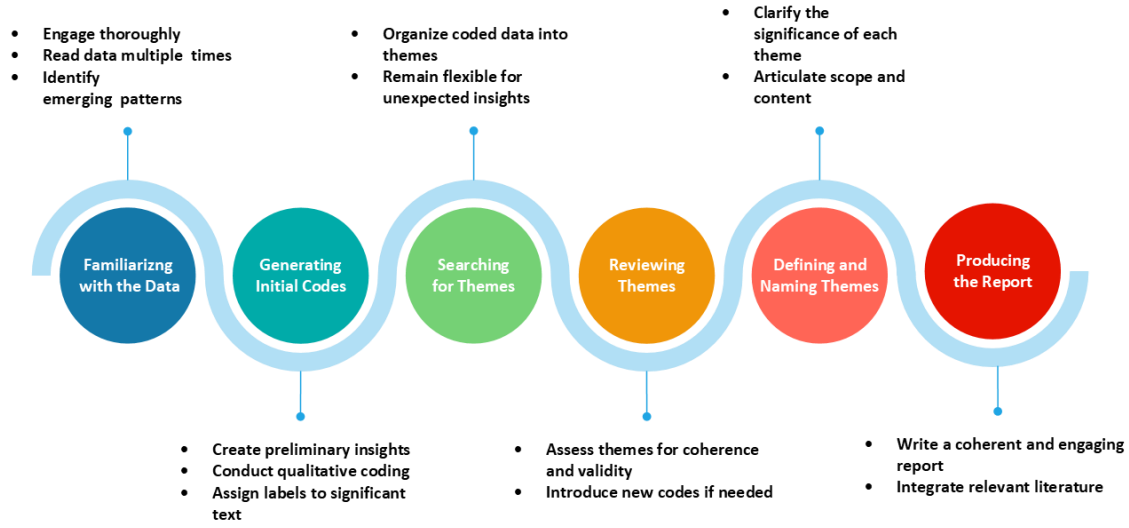


Figure 12 Phases of Thematic Analysis (9)

4.3. Results of Thematic Analysis of Interviews

The analysis of the interviews, conducted with experts in the MedTech ecosystem, revealed key insights into the collaboration challenges between startups and incubators. The interviews were analyzed using an inductive thematic approach, which allowed themes to emerge directly from the data. This approach was well-suited to the exploratory nature of this research, ensuring that the findings are deeply rooted in the lived experiences and perspectives of the participants.

The use of semi-structured interviews enabled interviewees to share a wide range of insights, providing a rich data set for thematic analysis. Thematic analysis was chosen as it allows for systematic identification and interpretation of patterns in qualitative data, contributing to a nuanced understanding of the MedTech entrepreneurship ecosystem. The key themes identified through this analysis provide insights into areas such as resource allocation, mentorship, ecosystem integration, and startup challenges.

The process began with generating initial codes from the transcribed interviews, followed by grouping these codes into broader themes. As patterns emerged, they were refined into consolidated themes, which are presented in the table 2.

Table 2 Interviews thematic analysis results

Codes	Consolidated Themes	Grouped Themes
Stage-appropriate resource allocation	Customized Resource Matching for Startups	Customized Resource Allocation and Support
Tailored support packages		
Integrated service approach		
Tailored resource allocation	Fair Allocation of Resources	
Prevention of resource waste		
Encouraging self-sufficiency	Self-Sufficiency and Autonomy in Startups	Startup Independence and Growth
Balancing autonomy and support		
Reduction of dependency		
Real graduation criteria	Effective Graduation and Post-Incubation Support	
Post-incubation support		
Avoiding premature graduation		
Customized programs based on startup maturity	Tailored Incubation Programs	
Matching mentors with startup needs		Monitoring, Feedback, and Mentorship
Regular monitoring and feedback	Monitoring and Feedback Loops	
Gap analysis and targeted mentorship		
Chemistry and empathy		
Strict entry criteria	Strict Entry and Monitoring Criteria for Programs	Entry and Graduation Criteria
Outcome-based KPIs	Realistic Expectations and Outcome-Based KPIs	
Learning from failures		
Support for mental health	Mental Health and Burnout Prevention	Mental Health and Team Dynamics
Peer support systems		
Team strength and product fit	Startup Team Dynamics and Challenges	
Human relations and speed		
Pre-incubation challenges		
Neutrality of incubators	Unbiased Incubator Support	

Managing expectations		Incubator and Market Dynamics
Importance of trust	Trust and Validation Issues	
Need for validation		
Resource constraints	Incubator Challenges and Constraints	
No investment or service fee model		
Cross-incubator collaboration	Collaboration and Ecosystem Integration	Ecosystem Integration and Collaboration
Living lab approach		
Fragmented support structure	Fragmented Ecosystem and Inefficient Funding	
Need for a comprehensive structure		
Government's role in ecosystem alignment		
Unified mission constraints	Government Policies and Funding Agency Missions	Government and Investor Influence
Need for clear differentiation		
Entrepreneurs' responsibility to research		
Investor biases	Investor and FDA Challenges	
US market dominance		
Networking and pitching		
Academicians' time limitations	Time Constraints for Entrepreneurs	Time Management and Market Risks
Slow pace of incubators		
Need for targeted support		
Speed vs. thoroughness	Low Pace of Incubators and Market Risks	
Risk of being scooped		
Overvalidation by incubators		
Specialized incubators	Specialized and Complementary Incubation	Selection and Fit with Incubators
Complementary incubation programs		
Fit program	Importance of Selecting the Right Incubator	
Success stories from proper matching		
Incubator diversity		

Lack of entrepreneurial mindset in advisors	Need for Experienced Advisors	Advisory and Expertise Needs
Involvement of seasoned entrepreneurs		
Early consideration of supply chain	Importance of the Supply Chain in Startups	Sector-Specific and Technical Support
Supply chain as a partner		
Role of the incubator in supply chain education		
Thorough project evaluation	Investigating Project Needs Early/ Incubators as Intermediaries	
Understanding technical constraints		
Pre-clinical stage support		
Distance from healthcare	Challenges of Non-Healthcare Entrepreneurs in Healthcare	Sector-Specific and Technical Support
Role of the incubator in bridging the gap		
Importance of local presence	Need for Local Technical Representatives	
Challenges with remote support		

The thematic analysis offers a comprehensive understanding of the incubator-startup ecosystem by identifying and analyzing key themes reflecting the complexities and challenges within this environment. This approach ensures that the findings are deeply rooted in the data, providing valuable insights for enhancing the effectiveness of incubators and the success of startups. The process involved systematic coding, theme development, and thorough review to ensure the robustness and relevance of the analysis.

To ensure transparency in the thematic analysis, a sample of the coding process is described here. For instance, one participant stated, *"We didn't get enough regulatory guidance from the incubator, and that delayed us by months."* This quote was initially coded as **a lack of regulatory support**, which contributed to the broader theme of **regulatory challenges**. Another interviewee noted, *"Startups often struggle to find mentors with real MedTech experience. Most mentors were too generic."* This statement was coded as **inadequate sector-specific mentorship**, which helped form the theme **mentorship and expertise gaps**. A third participant commented, *"We needed clinical feedback early, but couldn't connect with hospitals through the incubator,"* which was interpreted as **lack of clinical access** and was grouped under the theme **collaboration and ecosystem barriers**. These examples

illustrate how raw qualitative data was systematically analyzed, coded, and categorized into themes to reflect recurring issues identified across interviews.

4.4. Addressing Challenges in the MedTech Ecosystem

After identifying challenges through the literature review and interviews, each challenge is systematically broken down into sub-gaps to ensure a comprehensive understanding and effective resolution. This breakdown allows for a focused analysis of specific issues within each challenge, ensuring no critical element is overlooked.

For each identified sub-gap, tailored solutions are developed, accompanied by detailed descriptions and scientific justifications. These solutions address the specific sub-gaps and include explanations that outline the reasoning behind them. Scientific literature is cited to provide evidence supporting the proposed solutions, ensuring that they are both relevant and effective.

To ensure the practical application of each solution, an implementation strategy is presented. These strategies offer concrete methods for applying the solutions in real-world scenarios, ensuring that they are actionable and achievable.

Finally, a graphical model is created to visually represent the sub-gaps, corresponding solutions, and their respective implementation strategies. This model helps clarify the structure and relationships between the challenges and solutions, making the overall process more transparent and comprehensible.

Considering the challenges, sub-gaps, and potential solutions, it was determined that involving key actors in the ecosystem is essential for supporting a more dynamic and efficient environment. To address the numerous sub-gaps, a comprehensive model has been proposed to enhance collaboration and resource sharing within the MedTech ecosystem. The road map is presented in Figure 13 Road map of addressing challenges in the MedTech ecosystem.

Surveys were conducted to collect feedback from ecosystem participants on the effectiveness of the proposed model. The gathered data is analyzed to draw comprehensive conclusions about the collaboration dynamics among the actors within the framework of the model.

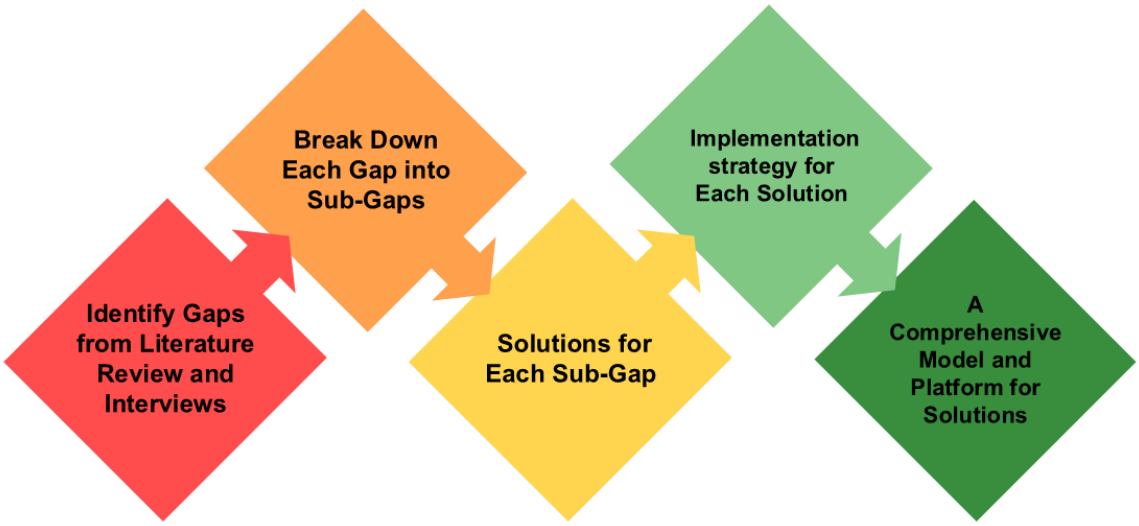


Figure 13 Road map of addressing challenges in the MedTech ecosystem

4.5. Challenges and Solutions

Based on the challenges identified through the literature review and interviews, this section delves into the specific issues that startups face in the MedTech ecosystem. Each challenge has been meticulously broken down into sub-gaps to ensure no critical aspect is overlooked. Tailored solutions have been crafted for each sub-gap, backed by scientific literature to guarantee their relevance and effectiveness. These solutions are accompanied by detailed implementation strategies presented in Appendix B, to ensure their practical application within real-world scenarios. Additionally, a graphical model has been developed to visualize the relationship between these challenges, contributing challenges, and solutions. This comprehensive approach not only addresses the immediate gaps within the ecosystem but also aims to foster greater collaboration and resource sharing among key actors. As the research progresses, a model is proposed to facilitate the implementation of these solutions, reinforcing the dynamic and efficient operation of the MedTech ecosystem. This section will present the key challenges faced by MedTech startups and their corresponding solutions, illustrating how they can be applied within the framework of the proposed model.

4.5.1. Fragmented Ecosystem

The MedTech ecosystem faces fragmentation due to disparate actors such as regulatory bodies, healthcare providers, and investors. Cohesive support is essential for integrated collaboration.

Contributing challenge 1: Disparate Regulatory Bodies

Navigating complex, region-specific regulatory frameworks, such as FDA and EMA requirements, is time-intensive and hinders startups' progress.

Solution 1.1: Centralized Regulatory Support: Establish incubator-based teams or partnerships with regulatory experts to guide startups in navigating multiple regulatory bodies. Services include consultation, document preparation, and regulatory updates (102).

Solution 1.2: Regulatory Harmonization Efforts: Promote global regulatory harmonization through international collaboration among key stakeholders. Regular summits and coordinated efforts can help streamline regulations, reduce redundancy, and accelerate approvals(103)

Contributing challenge 2: Lack of Coordination Among Healthcare Providers

Insufficient coordination among healthcare providers complicates startups' solution implementation.

Solution 2.1: Integrated Healthcare Network Partnerships: Develop shared digital platforms for startups and providers to co-develop pilot programs and track progress in real time.

Solution 2.2: Collaborative Healthcare Workshops: Organize interactive workshops that engage stakeholders in simulated scenarios, allowing them to explore different perspectives, understand workflow challenges, and enhance collaboration. These workshops can facilitate knowledge-sharing, problem-solving, and alignment of best practices across diverse groups, ultimately strengthening coordination within the ecosystem(104).

Contributing challenge 3: Investor and Funding Fragmentation

A fragmented investor landscape limits consistent funding for startups.

Solution 3.1: Unified Investment Platforms: Develop online platforms managed by incubators to facilitate connections between startups and potential investors, including venture capitalists, angel investors, and government funding bodies. These platforms should provide structured access to investment opportunities, featuring tools such as pitch deck repositories, funding history tracking, and direct communication channels. By streamlining interactions and increasing visibility, such platforms can enhance funding accessibility and foster strategic partnerships for emerging startups(105).

Solution 3.2: Incentivizing Collaborative Investments: Design blockchain-based platforms to facilitate secure and transparent co-funding, enabling multiple stakeholders to pool resources while minimizing financial risks. By leveraging smart contracts and decentralized ledgers, these platforms can ensure accountability, traceability, and trust in funding agreements, making investment processes more efficient and reducing potential disputes(106).

Contributing challenge 4: Inter-Organizational Communication

Poor communication hinders collaboration and innovation across the ecosystem.

Solution 4.1: Digital Collaboration Platforms: Develop real-time digital platforms integrated with AI-driven analytics to enhance decision-making and collaboration among stakeholders. These platforms can provide data-driven insights, trend analysis, and predictive modeling, enabling users to make informed, strategic decisions while fostering more efficient and transparent interactions within the ecosystem(107).

Solution 4.2: Regular Multi-Stakeholder Meetings: Establish a system of recurring meetings with rotating leadership, ensuring continuous alignment, diverse perspectives, and inclusive decision-making. By periodically shifting leadership roles, these meetings can encourage shared responsibility, foster innovation, and promote equitable participation among all stakeholders(108).

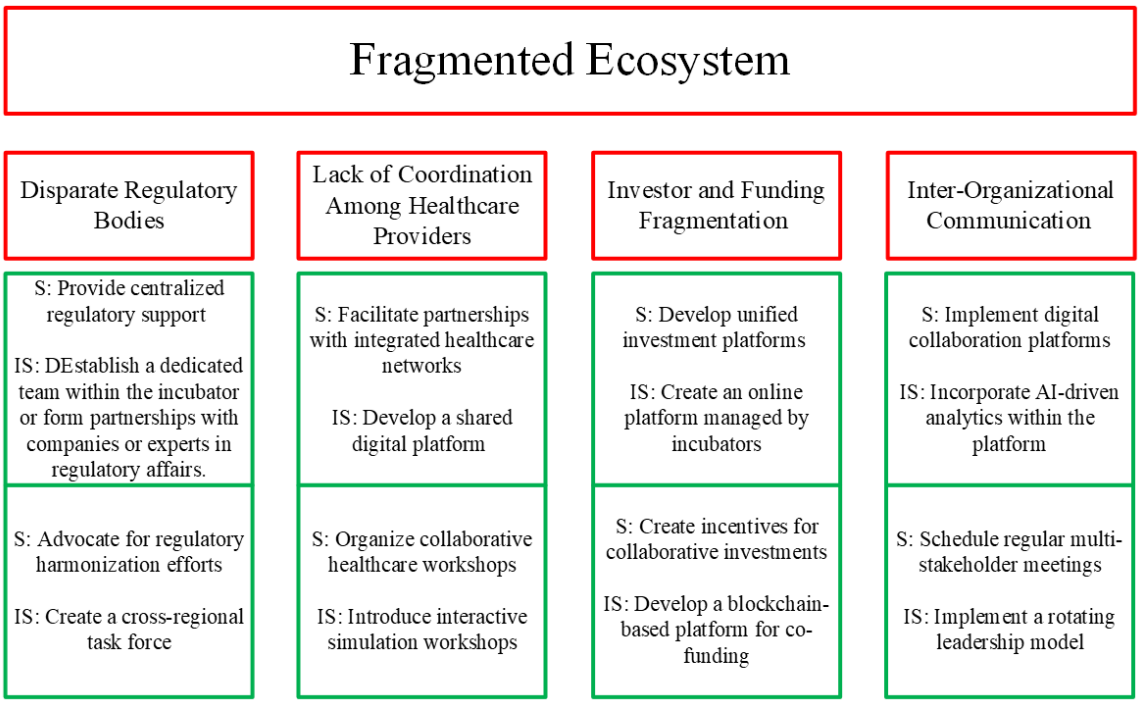


Figure 14 Fragmented ecosystem challenge, contributing challenges, and solutions (S: solution, IS: implementation strategy)

4.5.2. Global Market Access

Expanding into international markets poses challenges related to regulatory requirements, cultural differences, logistical complexities, and tailored market entry strategies. Startups often lack sufficient incubator support to navigate these obstacles effectively.

Contributing challenge 1: Navigating Varying International Regulatory Requirements

Startups face difficulties complying with diverse regulatory frameworks in different countries.

Solution 1.1: International Regulatory Guidance: Comprehensive guidance on CE marking, FDA approval, and other region-specific regulations can streamline market entry. Hines and Guy emphasize the importance of regulatory support for medical products in the EU (109). The recommended Implementation Strategy 1.1.1 is to develop a global regulatory team (see Appendix B).

Solution 1.2: Partnerships with Global Regulatory Experts: Collaborations with regulatory specialists provide startups with accurate and up-to-date compliance information. Kramer, Xu, and Kesselheim underscore the need to address differences in regulatory frameworks across

regions(110). The recommended Implementation Strategy 1.2.1 is to create a network of regulatory consultants (see Appendix B).

Contributing challenge 2: Addressing Cultural Differences

Cultural nuances influence market strategies, customer engagement, and operational success.

Solution 2.1: Cultural Training Programs: Training programs help startups understand cultural expectations, improving customer relationships and marketing strategies. Trompenaars and Hampden-Turner highlight the value of cultural awareness in global business(111). The recommended Implementation strategy 2.1.1 is to develop interactive cultural workshops (see Appendix B).

Solution 2.2: Local Market Expertise: Forming partnerships with regional experts enables a deeper understanding of consumer behavior, regulatory landscapes, and market dynamics, which can enhance strategic decision-making. Kotler and Keller emphasize the critical role of local knowledge in developing effective market entry strategies, tailoring solutions to regional needs, and ensuring successful commercialization(112). The recommended Implementation strategy 2.2.1 is to create a local expert advisory panel (see Appendix B).

Contributing challenge 3: Managing Logistical Complexities

International expansion involves intricate logistics related to supply chain management and distribution.

Solution 3.1: Logistics and Supply Chain Support: Effective logistics management plays a crucial role in ensuring timely delivery, regulatory compliance, and operational efficiency in global markets. Christopher highlights the significance of robust supply chain strategies in minimizing disruptions, optimizing resource allocation, and maintaining high standards across international operations(113). The recommended Implementation strategy 3.1.1 is to establish a global logistics hub (see Appendix B).

Solution 3.2: International Distribution Partnerships: Partnering with established distributors facilitates efficient market entry and product distribution, while ensuring adherence to local regulatory requirements. Chopra and Meindl emphasize that leveraging existing distribution networks can help companies navigate regulatory complexities, reduce logistical challenges, and accelerate market

penetration (114). The recommended Implementation strategy 3.2.1 is to create a partnership network of distributors (see Appendix B).

Contributing challenge 4: Developing Market Entry Strategies

Startups need tailored market entry strategies to penetrate international markets successfully.

Solution 4.1: Customized Market Entry Plans: Customized market entry strategies, incorporating competitive analysis and strategic positioning, enhance the likelihood of successful market penetration. Root underscores the importance of region-specific approaches, emphasizing that adapting strategies to local market conditions, consumer preferences, and competitive landscapes is essential for effective global expansion(115). The recommended Implementation strategy 4.1.1 is to develop a regional market analysis toolkit (see Appendix B).

Solution 4.2: Mentorship from International Business Experts: Facilitating connections between startups and experienced mentors strengthens their ability to overcome challenges and navigate complexities in global markets. Hisrich emphasizes the crucial role of mentorship in international business success, noting that guidance from industry experts helps startups refine strategies, mitigate risks, and accelerate growth(116). The recommended Implementation strategy 4.2.1 is to establish a global mentorship program (see Appendix B).

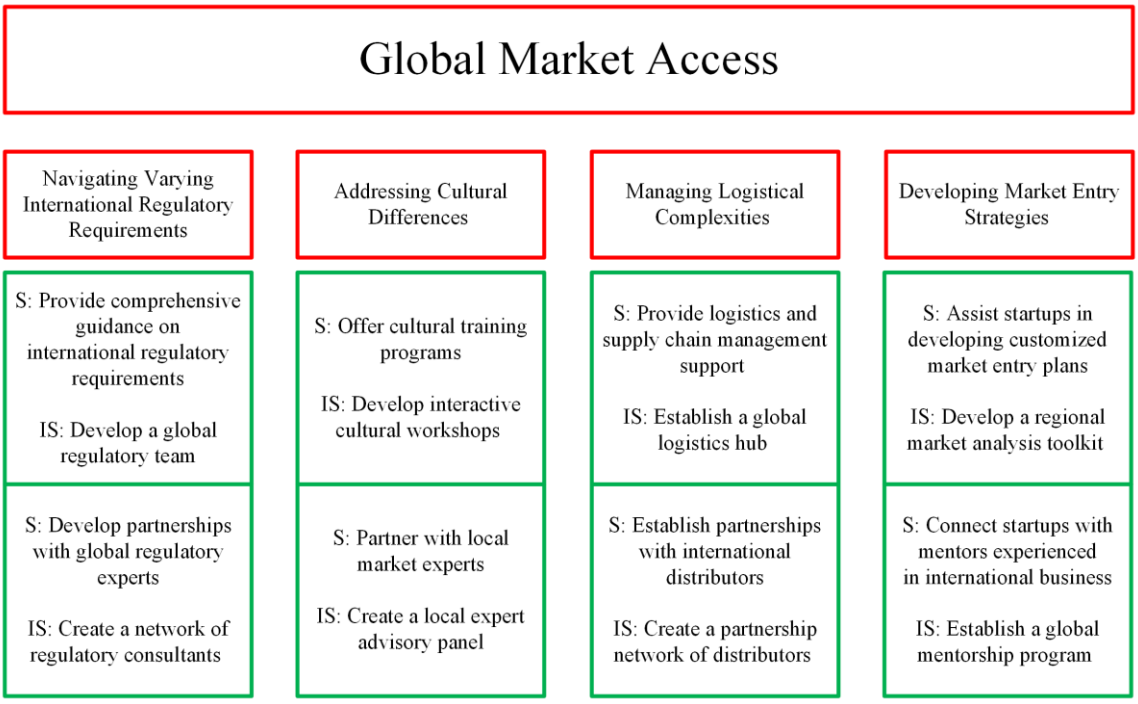


Figure 15 Global market access challenge, contributing challenges, and solutions

4.5.3. Reimbursement and Health Economics

Successfully navigating reimbursement processes and understanding health economics are crucial for MedTech startups to secure insurance coverage and demonstrate cost-effectiveness to healthcare payers. However, incubators often lack the expertise to provide sufficient guidance in these areas.

Contributing challenge 1: Navigating the Reimbursement Landscape

Understanding the intricacies of reimbursement processes, including coding, coverage, and payment mechanisms, is critical for market success.

Solution 1.1: Reimbursement Strategy Support: Offering expert guidance on financial strategies and reimbursement processes helps startups secure necessary funding and improve market accessibility for their products. Sorenson et al. emphasize that effective reimbursement frameworks play a critical role in shaping healthcare expenditure, influencing product adoption by providers and accessibility for patients (117). The recommended Implementation strategy 1.1.1 is to develop an in-house reimbursement team (see Appendix B).

Solution 1.2: Engagement with Payers: Engaging healthcare payers early in the product development process allows startups to align their innovations with reimbursement requirements, improving the likelihood of approval and adoption. Scientists highlight the importance of understanding payer perspectives, as early alignment with their criteria can streamline the reimbursement process and enhance market access(118). The recommended Implementation strategy 1.2.1 is to create a payer advisory panel (see Appendix B).

Contributing challenge 2: Demonstrating Cost-Effectiveness

Startups need to demonstrate the cost-effectiveness of their products to healthcare payers to secure reimbursement.

Solution 2.1: Health Economics and Outcomes Research (HEOR): Conducting HEOR studies provides evidence on the cost-effectiveness, clinical benefits, and overall impact of new technologies, strengthening their case for reimbursement and market adoption. Scientists emphasize the role of economic evaluations in healthcare decision-making, as demonstrating value for payers, providers, and policymakers is essential for successful commercialization (118). The recommended Implementation strategy 2.1.1 is to Establish an HEOR center of excellence (see Appendix B).

Solution 2.2: Real-World Evidence (RWE) Generation: Generating Real-World Evidence supplements clinical trial data by demonstrating product effectiveness, safety, and impact in real-world settings. Makady et al. emphasize the importance of RWE in health technology assessments, as it provides valuable insights into long-term outcomes, patient adherence, and real-world applicability, supporting regulatory approvals and reimbursement decisions(119). The recommended Implementation strategy 2.2.1 is to develop a real-world evidence platform (see Appendix B).

Contributing challenge 3: Lack of Expertise in Health Economics

Incubators often lack in-house health economics expertise to support startups.

Solution 3.1: Partnering with Health Economics Experts: Partnering with external experts provides specialized knowledge and strategic insights, ensuring the development of cost-effective solutions that align with market and regulatory expectations. It is important leveraging expert input in economic evaluations, as it enhances decision-making and strengthens the case for reimbursement and adoption. The recommended Implementation strategy 3.1.1 is to create a health economics advisory board (see Appendix B).

Solution 3.2: Health Economics Training for Incubator Staff: Providing incubator staff with health economics training strengthens their ability to guide startups in developing cost-effective solutions and navigating reimbursement pathways. A strong understanding of health economics enables incubators to offer more targeted support, improving startups' market readiness and long-term success. The recommended Implementation strategy 3.2.1 is to develop a health economics training program (see Appendix B).

Contributing challenge 4: Educating Startups on Reimbursement and Health Economics

Many startups lack knowledge of reimbursement processes and health economics.

Solution 4.1: Educational Workshops and Training Programs: Providing targeted education helps startups develop the skills and knowledge needed to navigate reimbursement challenges and demonstrate cost-effectiveness to payers and regulators. Effective economic evaluation methods that can be integrated into such programs, ensuring startups are well-prepared to present compelling value propositions for their innovations. The recommended Implementation strategy 4.1.1 is to develop interactive training modules (see Appendix B).

Solution 4.2: Mentorship Programs with Reimbursement Experts: Connecting startups with experienced mentors provides tailored advice, improving their strategies for securing reimbursement. Mentorship’s importance in navigating complex health systems is essential The recommended Implementation strategy 4.2.1 is to create a mentorship matchmaking platform (see Appendix B).

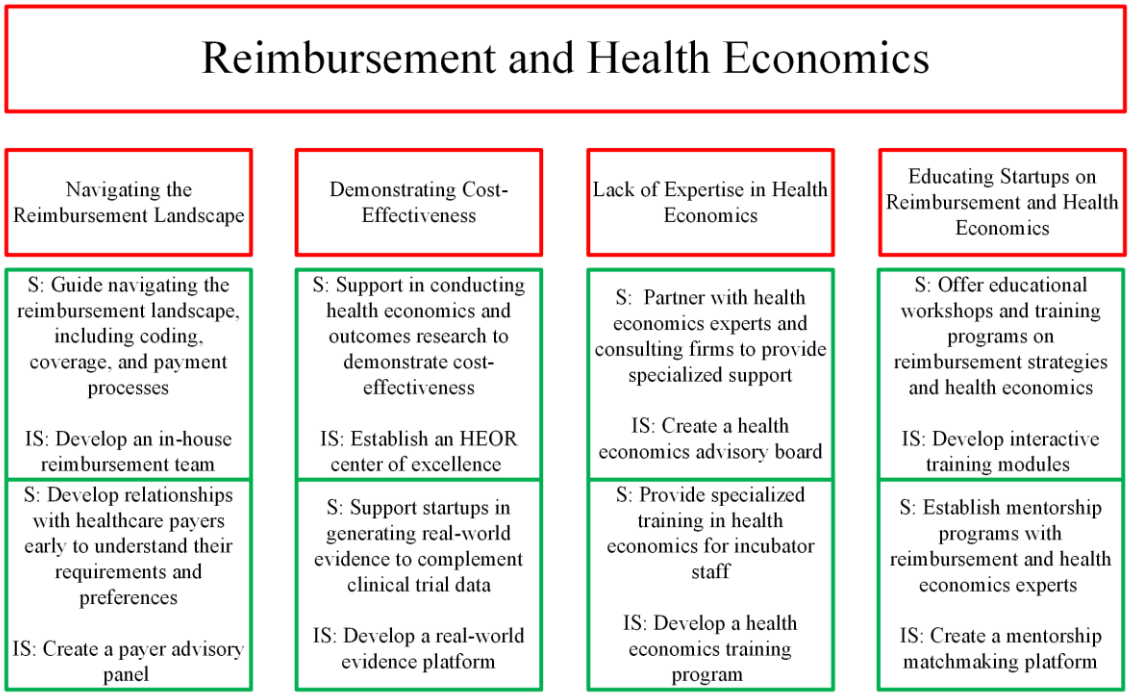


Figure 16 Reimbursement and health economics challenge, contributing challenges, and solutions

4.5.4. Regulatory Environment

MedTech startups face significant challenges navigating complex regulatory pathways to gain approval for their devices. Regulatory processes are lengthy, costly, and resource-intensive, often requiring specialized expertise that incubators lack. These barriers can delay or prevent startups from bringing their products to market.

Contributing Challenge 1: Navigating Stringent Regulatory Environments

Startups must comply with rigorous frameworks set by bodies like the FDA and Health Canada.

Solution 1.1: Streamlining Approval Processes**:** Regulatory bodies could simplify approval processes and provide more explicit guidance for startups. Digital transformation initiatives can unlock value by streamlining regulatory pathways, allowing for faster and more efficient market entry. The recommended Implementation strategy 1.1.1 is to develop a fast-track approval system (see Appendix B).

Contributing Challenge 2: Lack of Regulatory Expertise in Incubators

Incubators often lack in-depth expertise to guide startups through regulatory processes.

Solution 2.1: Partnering with Regulatory Consulting Firms**:** Partnering with consulting firms offers startups specialized guidance on compliance strategies, ensuring they meet regulatory requirements and streamline market entry. Such collaborations, as expert support can help startups navigate complex regulatory landscapes, mitigate risks, and enhance their commercialization prospects. The recommended Implementation strategy 2.1.1 is to develop formal partnerships with regulatory experts (see Appendix B).

Solution 2.2: Establish In-House Regulatory Advisory Boards**:** Establishing advisory boards within incubators provides startups with tailored, continuous guidance, helping them navigate challenges from early development to regulatory approval. These boards, composed of industry experts, regulatory specialists, and market strategists, bridge knowledge gaps and enhance startups' ability to align their innovations with industry standards and commercialization pathways. The recommended Implementation strategy 2.2.1 is to form in-house regulatory advisory boards (see Appendix B).

Contributing Challenge 3: High Costs of Regulatory Compliance

The financial burden of compliance often slows startups' progress.

Solution 3.1: Government Incentive Funds**:** Programs such as Quebec's Elevate IP Program can provide financial support for regulatory expenses, allowing startups to allocate more resources toward product development and innovation. By offsetting compliance costs, these initiatives help reduce financial barriers, accelerate market entry, and enhance the commercialization potential of new technologies. The recommended Implementation strategy 3.1.1 is to establish a grant program for regulatory compliance (see Appendix B).

Contributing Challenge 4: Slow and Inefficient Regulatory Processes

Regulatory bodies often delay approvals, hindering startups' timelines.

Solution 4.1: Enhance Communication with Regulatory Bodies**:** Real-time communication platforms facilitate faster issue resolution, minimizing delays in regulatory and market access processes. Initiatives such as the FDA's Interactive Review Program demonstrate the benefits of proactive engagement between stakeholders, enabling more efficient decision-making and streamlined approval pathways. The recommended Implementation strategy 4.1.1 is to implement a real-time communication platform (see Appendix B).

Contributing Challenge 5: Lack of Intensive Regulatory Training

Startups often lack comprehensive training on navigating regulatory landscapes.

Solution 5.1: Intensive Regulatory Workshops**:** Hosting workshops on classification, compliance, and submission processes can equip startups with essential regulatory knowledge, helping them navigate approval pathways more effectively. These workshops provide structured insights into regulatory frameworks, documentation requirements, and best practices, ensuring startups are well-prepared for market entry. The recommended Implementation strategy 5.1.1 is to develop a comprehensive training curriculum (see Appendix B).

Contributing Challenge 6: Lack of Comprehensive Regulatory Strategy

Startups struggle with fragmented approaches to regulatory compliance.

Solution 6.1: Develop Customized Regulatory Roadmaps**:** Tailored roadmaps outlining milestones and documentation requirements can streamline approval processes. Regulatory simulation programs provide risk-free practice for startups navigating compliance pathways. The recommended Implementation strategy 6.1.1 is to develop and implement customized regulatory roadmaps (see Appendix B).

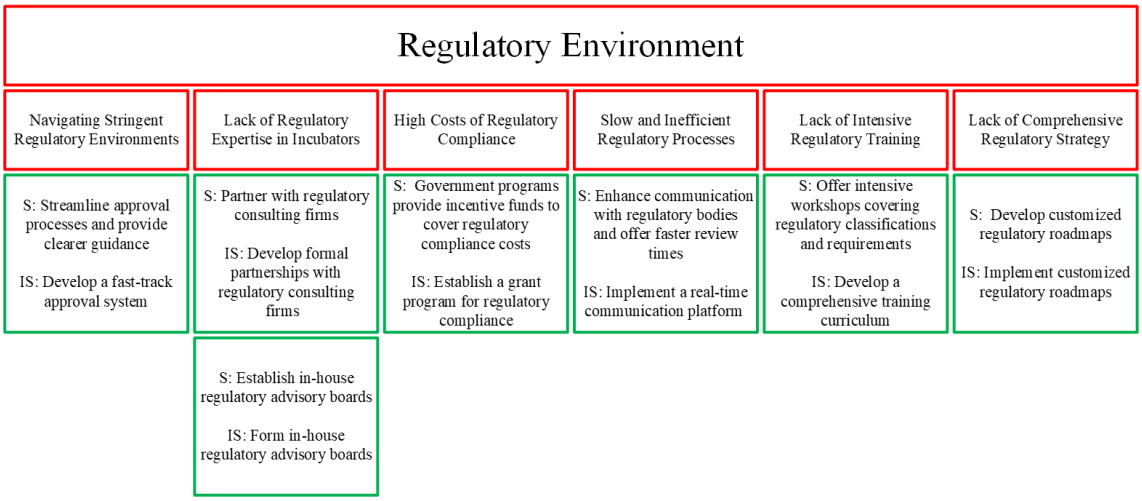


Figure 17 Regulatory environment challenge, contributing challenges, and solutions

4.5.5. Access to Capital

Securing adequate funding is a significant challenge for MedTech startups due to the high costs of research, development, and regulatory compliance. While incubators provide some financial support, their resources are often insufficient to meet the extensive funding needs of startups.

Contributing challenge 1: High-Risk Perception of Hardware Startups

VCs are often hesitant to invest in MedTech startups due to the risks associated with hardware development and regulatory requirements.

Solution 1.1: Government Bonuses for VCs: Offering financial incentives, such as tax reductions or matching funds, can reduce perceived risks and encourage VCs to invest in high-risk startups. Gompers and Lerner (106)emphasize the role of venture capital in fostering innovation and highlights the value of financial support for healthcare transformation (106). The recommended Implementation strategy 1.1.1 is to develop a government incentive program (see Appendix B).

Contributing challenge 2: Conservative Nature of Canadian VCs

Canadian VCs are generally more risk-averse than their US counterparts, which limits funding opportunities for startups.

Solution 2.1: Platform for R&D Funding: A centralized platform that aggregates non-dilutive funding opportunities, such as grants, loans, and subsidies, can help startups access critical capital without sacrificing equity. By reducing reliance on traditional venture capital, such a platform enables startups to secure funding aligned with their growth stage and innovation needs, enhancing financial sustainability and market entry potential. The recommended Implementation strategy 2.1.1 is to develop a centralized funding database (see Appendix B).

Solution 2.2: Public-Private Partnerships: Governments can collaborate with private companies to create innovation hubs offering funding, mentorship, and regulatory guidance. These hubs pool resources to support startups comprehensively, addressing gaps in VC funding. Hockerts (2006) discusses the role of such partnerships in fostering entrepreneurial opportunities. The recommended implementation strategy 2.2.1 is to establish innovation hubs (see Appendix B).

Contributing challenge 3: Reluctance of VCs to Lead Investments

VCs often prefer to invest in startups with a lead investor, making it difficult for early-stage startups to secure initial funding.

Solution 3.1: Incubator Financial Support: Incubators can integrate financial experts into their support programs to assist startups in identifying, applying for, and securing grants and loans. This guidance enables startups to achieve critical milestones, improving their financial stability and making them more attractive to lead investors for future funding rounds. The recommended Implementation strategy 3.1.1 is to hire financial advisors in incubators (see Appendix B).

Contributing challenge 4: High Costs of Regulatory Approvals

The financial burden of meeting regulatory requirements presents a significant barrier to startups.

Solution 4.1: Improved Health Canada Processes: Streamlining regulatory approvals through faster review times, clearer guidelines, and better communication channels can reduce costs and time-to-market for startups. Sorenson, Drummond, and Bhuiyan Khan emphasize the importance of efficient regulatory processes in controlling healthcare expenditures(120). The recommended Implementation strategy 4.1.1 is to develop an express review pathway (see Appendix B).

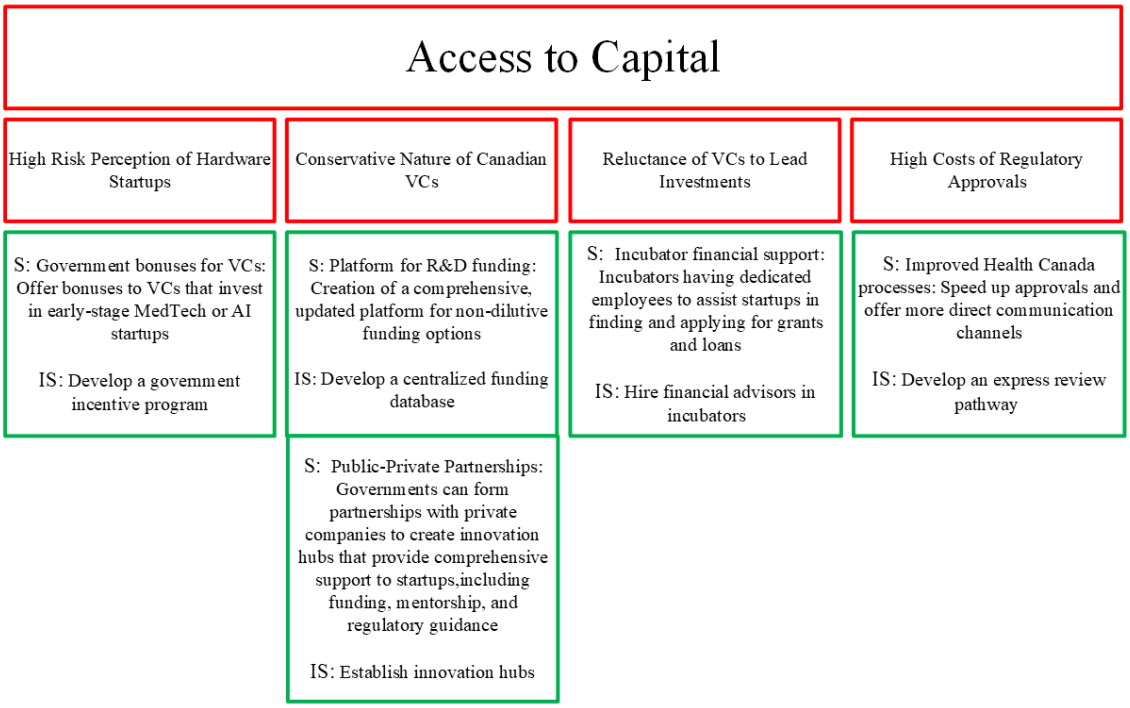


Figure 18 Access to capital challenges, contributing challenges, and solutions

4.5.6. Market Adoption

Achieving market adoption requires convincing healthcare providers to switch from established solutions.

Contributing challenge 1: Convincing Healthcare Providers to Switch from Established Solutions

Healthcare providers are often hesitant to adopt new technologies due to familiarity with existing solutions and concerns about reliability.

Solution 1.1: Establish Partnerships with Healthcare Providers: Collaborating with healthcare providers through pilot programs can demonstrate the benefits of new technologies in real-world settings. Partnerships with hospital innovation hubs and university incubators can connect startups with healthcare stakeholders, facilitating adoption. The recommended implementation strategy 1.1.1 is to develop pilot programs (see Appendix B).

Solution 1.2: Implementing Shadowing Programs: Shadowing healthcare professionals allows startups to understand clinical workflows and unmet needs, leading to user-centric solutions.

Shadowing is an experiential learning tool. The recommended Implementation strategy 1.2.1 is to create a shadowing program framework (see Appendix B).

Solution 1.3: Building Trust and Demonstrating Value: Trust can be fostered through patient testimonials, endorsements from key opinion leaders, and offering free training or support to early adopters. Kim and Lee underline the impact of testimonials in influencing adoption (121). The recommended Implementation strategy 1.3.1 is to create a testimonial and case study repository (see Appendix B).

Solution 1.4: Creating Incentive Programs for Early Adopters: Incentives, such as discounts and exclusive features, can encourage healthcare providers to try new technologies. Rogers notes the importance of incentives in the diffusion of innovations(122). The recommended Implementation strategy 1.4.1 is to develop an early adopter incentive plan (see Appendix B).

Contributing challenge 2: Lack of Support for Market Entry Strategies

Incubators might not offer adequate support for developing effective market entry strategies or for navigating the reimbursement landscape.

Solution 2.1: Promoting Adoption through Professional Associations: Professional associations can integrate new technologies into Continuing Medical Education (CME) programs, increasing awareness among healthcare providers. Scientists emphasize CME's role in improving adoption(123). The recommended Implementation strategy 2.1.1 is to integrate CME modules (see Appendix B).

Solution 2.2: Providing Market Research and Strategy Development Services: Startups can benefit from tailored market research and strategy development services to understand the competitive landscape and identify entry points. The recommended Implementation strategy 2.2.1 is to establish market research units (see Appendix B).

Solution 2.3: Providing Reimbursement Strategy Support: Addressing reimbursement challenges through expert guidance on coding, coverage, and payment processes is crucial for market access. The recommended Implementation strategy 2.3.1 is to develop reimbursement workshops (see Appendix B).

Solution 2.4: Access to Market Research Databases and Software: Affordable access to high-quality market research tools can provide startups with insights into customer behavior, industry

trends, and competition, enabling data-driven strategies. The recommended Implementation strategy 2.4.1 is to develop market research access program (see Appendix B).

Contributing challenge 3: Navigating Regulatory, Cybersecurity, and Data Privacy Requirements

Startups face challenges in meeting complex regulatory, cybersecurity, and data privacy requirements.

Solution 3.1: Awareness and Compliance with Cybersecurity and Data Privacy: Providing education on cybersecurity and data privacy requirements helps startups ensure regulatory compliance and robust patient data protection. Proactively addressing cybersecurity risks, as strong security measures not only safeguard sensitive information but also enhance trust and credibility in the healthcare industry. The recommended Implementation strategy 3.1.1 is to develop cybersecurity and privacy training programs (see Appendix B).

Solution 3.2: Providing Ethical Hacking Services: Implementing ethical hacking practices allows startups to identify security vulnerabilities, strengthen their cybersecurity frameworks, and ensure compliance with industry standards. By proactively testing their systems, startups can mitigate potential risks, protect sensitive data, and enhance the overall resilience of their technology. The recommended Implementation strategy 3.2.1 is to establish an ethical hacking lab (see Appendix B).

Solution 3.3: Offering Regulatory Guidance: Providing detailed regulatory guidance on FDA and Health Canada requirements enables startups to navigate approval processes more efficiently, reducing delays and compliance risks. Califf and Sugarman highlight the importance of clear regulatory guidance, as it helps innovators align their development processes with regulatory expectations, ultimately accelerating market entry(124). The recommended Implementation strategy 3.3.1 is to develop a regulatory compliance handbook (see Appendix B).

Solution 3.4: Government Incentives: Incentives for incubators to offer regulatory and cybersecurity support can help startups manage compliance challenges while reducing financial burdens. Gompers and Lerner discuss the role of government incentives in fostering startup growth(125). The recommended Implementation strategy 3.4.1 is to develop a government incentive program (see Appendix B).

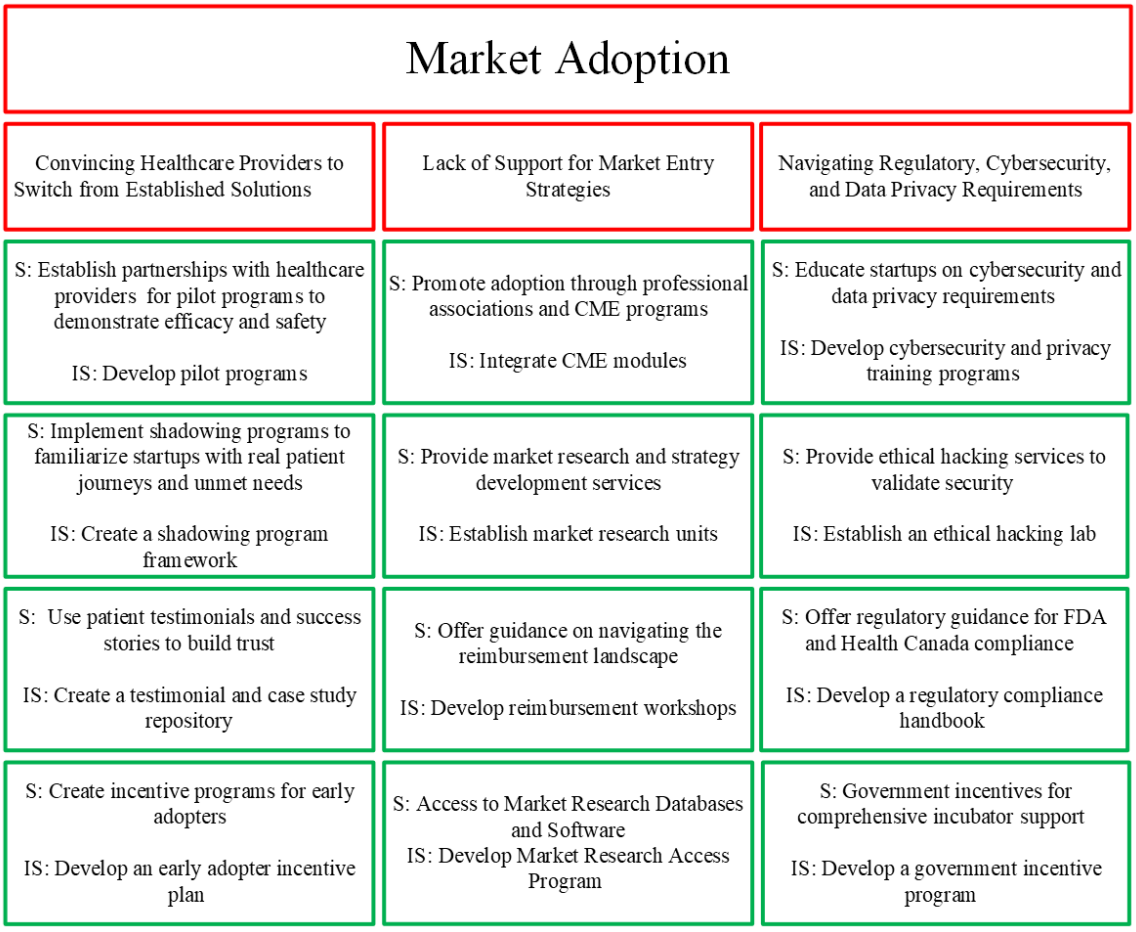


Figure 19 Market adoption challenge, contributing challenges, and solutions

4.5.7. Technical Integration with Healthcare Systems

Integrating new technologies into existing healthcare systems is a critical yet challenging task for MedTech startups. Compatibility issues, data integration challenges, and the need for interoperability create significant barriers to seamless integration. Addressing these challenges is vital for deploying innovations effectively in healthcare settings.

Contributing challenge 1: Compatibility Issues with Existing Systems

New technologies often face compatibility issues that hinder integration with existing healthcare IT infrastructure.

Solution 1.1: Collaborate with Health IT Companies: Partnering with health IT companies ensures that new technologies are compatible with current systems. These companies provide expertise and

resources to address compatibility challenges. The recommended Implementation strategy 1.1.1 is to establish integration partnerships (see Appendix B).

Solution 1.2: Conduct Compatibility Testing Early in Development: Early compatibility testing during product development helps identify and resolve integration issues before deployment, reducing the risk of failures. The recommended Implementation strategy 1.2.1 is to develop a compatibility testing framework (see Appendix B).

Contributing challenge 2: Data Integration Challenges

Seamless data integration is complicated by differences in data formats, protocols, and standards across healthcare systems.

Solution 2.1: Develop Data Integration Middleware: Middleware serves as an intermediary layer, facilitating seamless integration by translating data formats and protocols, ensuring compatibility between new technologies and existing systems. Scientists highlight middleware's critical role in streamlining healthcare data exchange, enhancing interoperability, and improving overall system efficiency(126). The recommended Implementation strategy 2.1.1 is to create middleware development kits (see Appendix B).

Solution 2.2: Collaborate with Health Information Exchanges (HIEs): Partnering with Health Information Exchanges (HIEs) facilitates standardized and secure data exchange, enhancing interoperability between healthcare systems. Vest and Gamm highlight the critical role of HIEs in improving data integration, ensuring seamless communication among providers, and supporting more efficient and coordinated patient care(127). The recommended Implementation strategy 2.2.1 is to develop HIE partnership programs (see Appendix B).

Contributing challenge 3: Need to apply Standards earlier

The lack of standardized protocols and data formats hampers interoperability between new and existing technologies.

Solution 3.1: Promote Interoperability Standards: Collaborating with standards organizations such as HL7 and ISO ensures that new technologies adhere to industry protocols, enhancing interoperability and seamless integration within healthcare systems. HL7 and ISO provide essential frameworks that establish consistent data exchange, security, and compliance practices, supporting

the adoption of innovative solutions in a standardized and scalable manner(128). The recommended Implementation strategy 3.1.1 is to participate in standards development committees (see Appendix B).

Solution 3.2: Participate in Interoperability Consortia: Active participation in interoperability consortia allows startups to stay updated on evolving standards, contribute to their development, and align their technologies with industry expectations. Moyer highlights the importance of consortia in advancing interoperability(129). The recommended Implementation strategy 3.2.1 is to create an interoperability task force (see Appendix B).

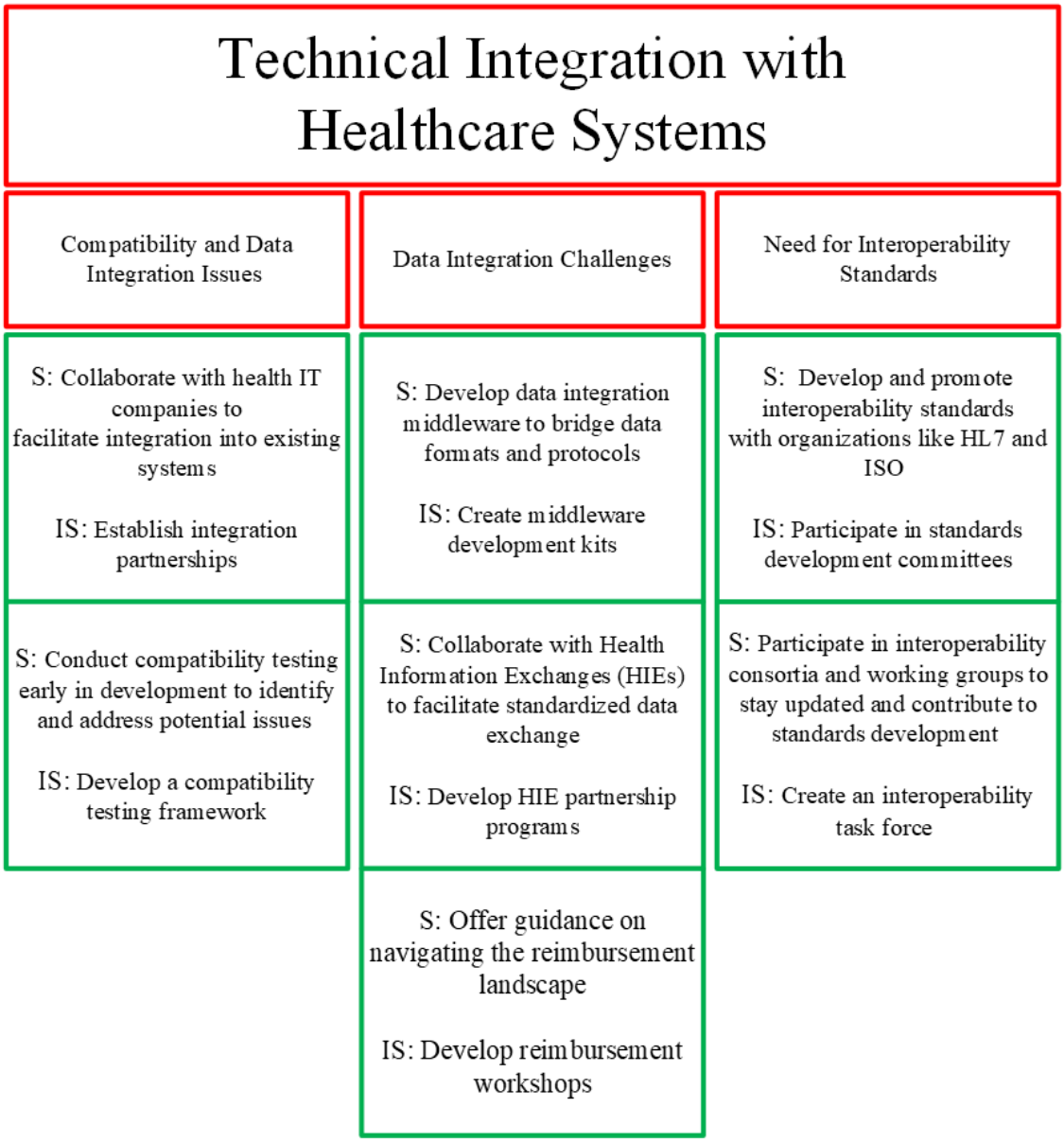


Figure 20 Technical integration with healthcare systems challenge, contributing challenges, and solutions

4.5.8. Stakeholder Engagement

Effective stakeholder engagement is critical for MedTech startups, as it provides clinical expertise, real-world insights, and collaborative opportunities necessary for successful product development and market integration. However, incubators often fall short in facilitating meaningful interactions with healthcare professionals, patients, and other key stakeholders.

Contributing challenge 1: Limited Access to Clinical Expertise

Startups often lack access to the clinical expertise necessary for product validation and integration.

Solution 1.1: Implement Matching Programs with medical Principal Investigators (PIs): Programs connecting startups with medical PIs from hospital innovation hubs ensure access to clinical expertise, facilitating the integration of medical innovations into clinical practice. The recommended Implementation strategy 1.1.1 is to develop PI matching portals (see Appendix B).

Solution 1.2: Develop Partnerships with Clinical Research Organizations (CROs): Partnerships with Clinical Research Organizations (CROs) provide startups with specialized knowledge and resources for clinical trials and regulatory submissions, increasing product success rates (130). The recommended Implementation strategy 1.2.1 is to create CRO partnership programs (see Appendix B).

Contributing challenge 2: Inadequate Engagement with Diverse Healthcare Stakeholders

Limited interactions with IT, cybersecurity teams, and other stakeholders hinder startups from addressing critical requirements.

Solution 2.1: Extend Matching Programs to Include IT and Cybersecurity Teams: Expanding matching programs to include IT and cybersecurity teams enables startups to effectively navigate procedural and security requirements, ensuring compliance with industry standards and data protection regulations. Integrating cybersecurity expertise early in development helps startups mitigate risks and build robust, secure systems. The recommended Implementation strategy 2.1.1 is to develop multidisciplinary matching portals (see Appendix B).

Solution 2.2: Facilitate Multidisciplinary Workshops and Seminars: Workshops that include diverse healthcare stakeholders promote knowledge sharing, collaboration, and holistic understanding of the healthcare ecosystem. The recommended Implementation strategy 2.2.1 is to establish regular interdisciplinary seminars (see Appendix B).

Contributing challenge 3: Lack of Real-World Experience and Insights

Startups need firsthand insights from healthcare providers and patients to design user-centered solutions

Solution 3.1: Establish Nurse Shadowing Programs: Shadowing programs allow startups to observe clinical workflows and patient journeys, uncovering unmet needs and improving product alignment with practical realities. The recommended Implementation strategy 3.1.1 is to develop a structured shadowing program (see Appendix B).

Solution 3.2: Implement Patient Feedback Mechanisms: Implementing structured patient feedback mechanisms, such as surveys and focus groups, allows startups to gather valuable user insights, ensuring that medical devices address real-world needs. This approach enhances usability, patient satisfaction, and overall healthcare outcomes, facilitating the development of more patient-centered innovations. The recommended Implementation strategy 3.2.1 is to create feedback integration systems (see Appendix B).

Contributing challenge 4: Limited Integration of Clinical Research and Hospital Practices

Integrating insights from clinical research into hospital practices is often inadequate, slowing innovation translation.

Solution 4.1: Facilitate Collaboration with Hospital Research Centers: Collaboration between research centers and hospitals bridges the gap between cutting-edge research and clinical practice, enabling startups to develop evidence-based solutions that align with real-world healthcare needs. This partnership fosters innovation, accelerates clinical validation, and enhances patient care by integrating the latest scientific advancements into practical medical applications. The recommended Implementation strategy 4.1.1 is to develop collaborative research programs (see Appendix B).

Solution 4.2: Develop Integrated Research-Practice Networks: Networks that connect researchers and clinicians facilitate the rapid translation of innovations into clinical practice, ensuring that new medical advancements are effectively implemented and continuously refined. Fagnan et al. emphasize that such collaborations enhance knowledge sharing, accelerate adoption, and drive ongoing improvements in patient care(131). The recommended Implementation strategy 4.2.1 is to create integrated network platforms (see Appendix B).

Solution 4.3: Military Connection: Partnering with the military sector gives startups access to rigorous reliability and safety standards, helping them develop more robust and resilient technologies. These collaborations enable startups to leverage military-grade testing protocols, enhance product durability, and meet high-security requirements, ultimately improving their competitiveness in both

defense and civilian healthcare markets. The recommended Implementation strategy 4.3.1 is to establish military collaboration units (see Appendix B).

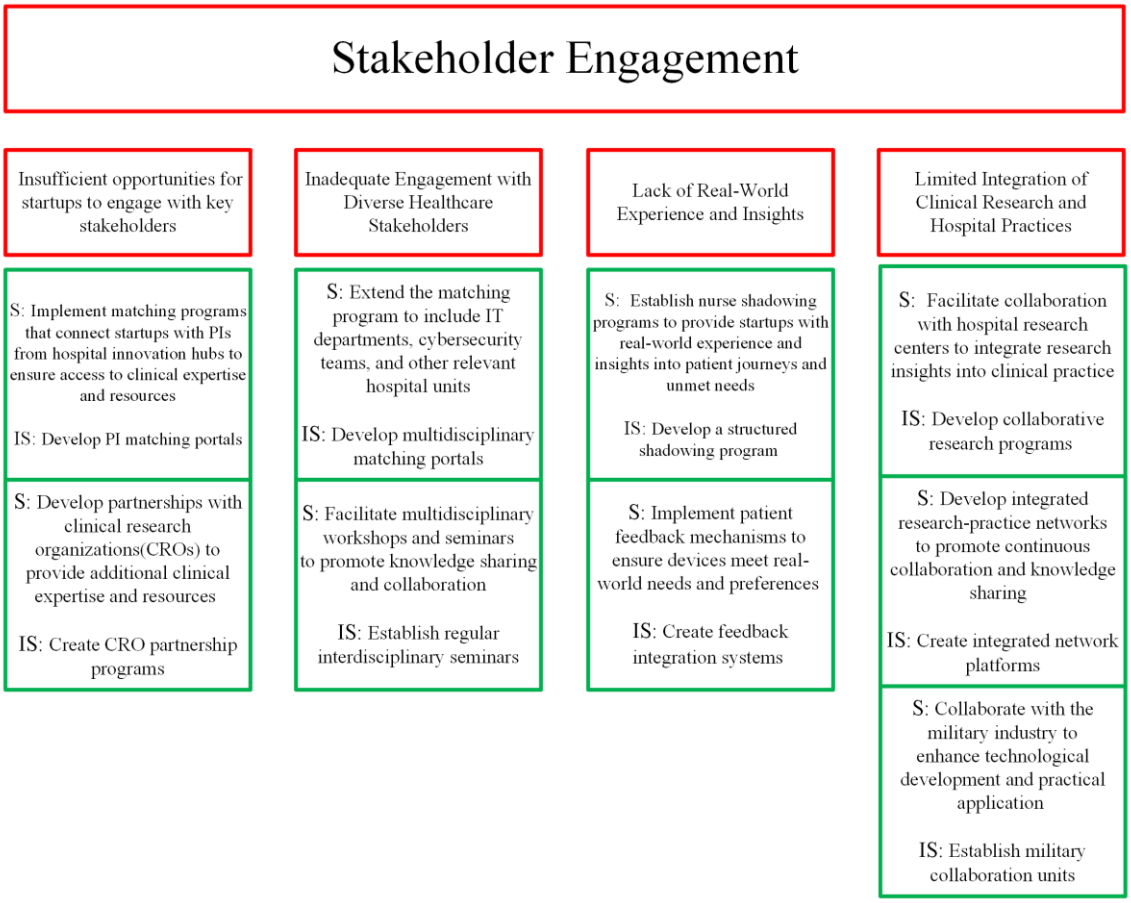


Figure 21 Stakeholder engagement challenge, contributing challenges, and solutions

4.5.9. Cybersecurity and Data Privacy Concerns

Ensuring cybersecurity and data privacy is essential for MedTech startups, as connected devices handle sensitive patient information and face potential vulnerabilities. However, startups often lack sufficient expertise, resources, and guidance in cybersecurity, leaving them at risk of breaches and compliance failures.

Contributing challenge 1: Insufficient Expertise in Cybersecurity

Startups often lack the technical knowledge to secure their devices effectively.

Solution 1.1: Partner with Cybersecurity Firms: Collaborating with cybersecurity firms enables startups to implement tailored security solutions, advanced protection measures, and ongoing threat monitoring, reducing vulnerabilities and ensuring compliance with industry standards. Deloitte highlights the importance of proactive cybersecurity strategies, which strengthen data protection, mitigate risks, and enhance overall system resilience (132). The recommended Implementation strategy 1.1.1 is to develop long-term partnerships with cybersecurity firms (see Appendix B).

Solution 1.2: Provide Cybersecurity Training Programs: Offering training programs ensures that startup teams stay informed about the latest threats and best practices, equipping them to implement robust security measures. The recommended Implementation strategy 1.2.1 is to develop comprehensive cybersecurity curricula (see Appendix B).

Contributing challenge 2: Lack of Comprehensive Security Guidelines and Best Practices

Startups struggle without clear, consistent guidelines for securing medical devices.

Solution 2.1: Develop Industry Consortia Guidelines: Industry consortia play a crucial role in developing and disseminating standardized best practices, providing startups with clear guidelines for implementing effective security measures. HIMSS emphasizes that such collaborations help align security protocols across the industry, enhance compliance, and reduce cybersecurity risks in healthcare technologies(133). The recommended Implementation strategy 2.1.1 is to establish a working group for guideline development (see Appendix B).

Solution 2.2: Create a Cybersecurity Best Practices Repository: A centralized repository containing resources, case studies, and practical tools can help startups adopt and implement robust cybersecurity protocols effectively. Accessible cybersecurity frameworks enables startups to enhance data protection, comply with regulations, and mitigate security risks in an evolving digital landscape. The recommended Implementation strategy 2.2.1 is to develop a user-friendly repository platform (see Appendix B).

Contributing challenge 3: Limited Resources for Continuous Monitoring and Response

Continuous threat monitoring and incident response capabilities are often beyond the reach of startups.

Solution 3.1: Implement Managed Security Services: Implementing Managed Security Services (MSS) provides startups with continuous threat detection and response capabilities, thereby reducing the burden on internal resources. MSS providers offer a range of services, including 24/7 security event monitoring, threat detection and response, and vulnerability management across various environments—public and private clouds, on-premises, and hybrid setups(134). The recommended Implementation strategy 3.1.1 is to Establish partnerships with leading MSS providers (see Appendix B).

Solution 3.2: Develop an Incident Response Plan: Comprehensive cybersecurity response plans equip startups with the necessary strategies to detect, contain, and recover from security incidents efficiently, minimizing potential disruptions and data breaches. Proactive incident response frameworks enable organizations to mitigate risks, protect sensitive information, and maintain operational resilience in the face of cyber threats. The recommended Implementation strategy 3.2.1 is to conduct regular incident response drills (see Appendix B).

Contributing challenge 4: Compliance with Regulatory Requirements

Navigating cybersecurity and data privacy regulations such as FDA standards can be challenging for startups.

Solution 4.1: Provide Regulatory Compliance Support: Offering regulatory compliance support helps startups navigate complex approval processes, meet industry standards, and ensure adherence to legal and safety requirements. Providing expert guidance, training, and resources enables startups to streamline submissions, reduce compliance risks, and accelerate market entry while maintaining high regulatory standards. The recommended Implementation strategy 4.1.1 is to develop compliance training programs (see Appendix B).

Solution 4.2: Develop a Compliance Management System: Creating a Compliance Management System (CMS) enables startups to systematically track, manage, and ensure adherence to regulatory requirements. A well-structured CMS provides real-time monitoring, documentation management, and automated alerts, helping startups stay compliant, mitigate risks, and streamline regulatory submissions for faster market entry.

The recommended Implementation strategy 4.2.1 is to develop automated compliance tracking tools (see Appendix B).

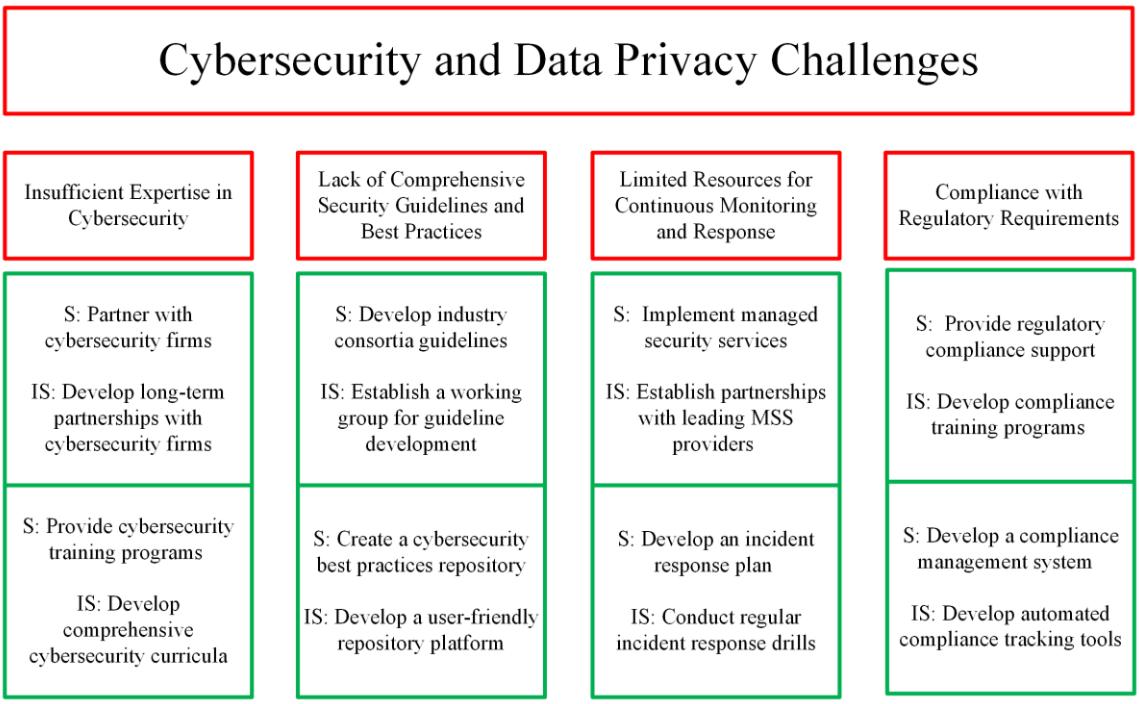


Figure 22 Cybersecurity and data privacy challenge, contributing challenges, and solutions

4.5.10. Resource Allocation

Effective resource allocation is vital for MedTech startups to access necessary facilities, equipment, and expertise without overwhelming incubators' capacities. Startups often encounter significant challenges, including limited access to lab facilities, poorly managed incubator resources, and inadequate infrastructure for collaboration, hindering their innovation and growth.

Contributing challenge 1: Lack of Access to Lab Facilities, Equipment, and Collaboration Between Incubators and Universities

Startups frequently lack access to advanced lab facilities and specialized equipment, compounded by insufficient collaboration between incubators and academic institutions.

Solution 1.1: Academic Institutions Offer Access to Lab Facilities and Create a Centralized Resource Directory: Universities can enhance startups' innovation capabilities by offering lab access and creating a centralized directory of available facilities and equipment. Stronger university-incubator partnerships maximize resource utilization and foster innovation (135). The recommended Implementation strategy 1.1.1 is to develop university-startup collaboration programs and create a centralized resource directory (see Appendix B).

Solution 1.2: Crowdsourcing and Open Innovation Platforms: Crowdsourcing and open innovation platforms foster collaboration between startups, researchers, and healthcare professionals, expanding access to diverse expertise and resources. Chesbrough highlights the value of open innovation in accelerating technological advancements, enabling stakeholders to co-develop solutions, share knowledge, and enhance problem-solving efficiency in the healthcare ecosystem(136). The recommended Implementation strategy 1.2.1 is to develop a digital collaboration platform (see Appendix B).

Contributing challenge 2: Inadequate Incubator Facilities

Resource constraints in incubators limit startups' access to essential tools and spaces.

Solution 2.1: Government Initiatives: Fund the Expansion of Incubator Facilities: Government initiatives that fund the expansion of incubator facilities provide startups with essential resources, mentorship, and infrastructure, fostering innovation and business growth. Kuhlmann & Edler emphasize the role of public investments in supporting entrepreneurial ecosystems, ensuring startups have the necessary support to develop, test, and scale their innovations effectively(137). The recommended Implementation strategy 2.1.1 is to establish a government-startup grant (see Appendix B).

Solution 2.2: Corporate Innovation Labs: Collaborating with corporate labs gives startups access to specialized technical expertise, funding opportunities, and valuable market insights, leveraging the infrastructure and resources of established healthcare companies to accelerate growth. Corporate partnerships in fostering innovation, enables startups to refine their technologies, navigate regulatory pathways, and enhance commercialization potential. The recommended Implementation strategy 2.2.1 is to develop corporate-startup partnership programs (see Appendix B).

Contributing challenge 3: Poorly Managed Incubator Facilities

Inefficient resource management in incubators leads to underutilization and misallocation of available assets.

Solution 3.1: Specifying and Managing Incubator Facilities: Clearly defining availability and improving management of incubator facilities enhance resource allocation, operational efficiency, and startup support. Effective facility management ensures that startups can plan, access essential resources, and optimize their use of space, equipment, and mentorship opportunities, ultimately

fostering innovation and business growth. The recommended Implementation strategy 3.1.1 is to develop an incubator facility management system (see Appendix B).

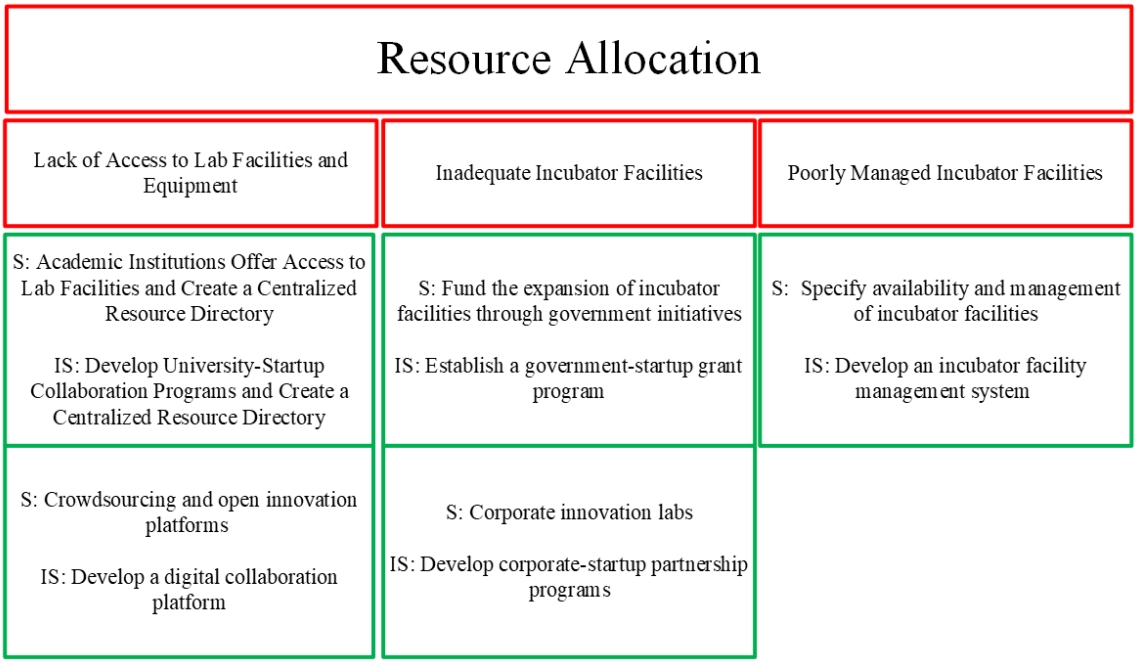


Figure 23 Resource allocation challenge, contributing challenges, and solutions

4.5.11. Mentorship Quality

High-quality mentorship is essential for MedTech startups to navigate the industry's unique challenges. Effective mentorship requires experienced, diverse, and specialized professionals who can provide tailored guidance and insights.

Contributing challenge 1: Lack of Experienced Mentors

Startups often lack access to mentors with relevant experience in regulatory affairs, clinical trials, and market strategies.

Solution 1.1: Engage Retired Professionals and Veterans: Retired professionals and veterans bring valuable expertise and practical insights from their extensive careers. Their mentorship can significantly enhance startups' strategic decisions. The recommended Implementation strategy 1.1.1 is to develop a mentorship program with retired professionals (see Appendix B).

Contributing challenge 2: Gender and Language Inequality

Mentorship programs often lack diversity, limiting inclusivity and relatability for entrepreneurs from diverse backgrounds.

Solution 2.1: Ensure Gender and Language Equality in Mentorship: Ensuring gender and language equality in mentorship fosters inclusive support networks, allowing startups to benefit from diverse perspectives that enhance innovation, creativity, and problem-solving. Professionals emphasize that a diverse mentorship pool strengthens entrepreneurial success by promoting equitable access to knowledge, experience, and opportunities across different backgrounds(138). The recommended Implementation strategy 2.1.1 is to develop a diverse mentorship pool (see Appendix B).

Contributing challenge 3: Lack of MedTech Expertise

Mentors without sector-specific expertise may provide generic guidance, which can be less effective for specialized industries like MedTech.

Solution 3.1: Specify Sector Expertise: Providing sector-specific mentorship ensures that startups receive targeted guidance on MedTech-specific challenges and opportunities, improving their ability to navigate industry complexities. Specialized mentorship programs enhance the relevance and effectiveness of support by aligning expertise with the unique needs of emerging healthcare technologies. The recommended Implementation strategy 3.1.1 is to develop sector-specific mentorship programs (see Appendix B).

Contributing challenge 4: Inadequate Entrepreneurial Experience Among Mentors

Mentors without firsthand entrepreneurial experience may lack the practical insights needed to guide startups effectively.

Solution 4.1: Provide Mentors with Entrepreneurial Experience: Engaging mentors with entrepreneurial experience allows startups to benefit from real-world insights, lessons from both successes and failures, and practical, actionable advice. St-Jean emphasizes that entrepreneurs-turned-mentors provide hands-on guidance, helping startups navigate challenges, refine strategies, and accelerate their growth with informed decision-making(139). The recommended Implementation strategy 4.1.1 is to develop entrepreneurial mentorship certification (see Appendix B).

Contributing challenge 5: Inadequate Industry Experience Among Mentors

Mentors without industry experience may not fully understand the complexities of market dynamics and regulatory environments.

Solution 5.1: Ensure Mentors Have Industry Experience: Mentors with industry experience can provide deeper insights into operational challenges and strategic opportunities, enhancing mentorship quality. The recommended Implementation strategy 5.1.1 is to develop industry-experienced mentor recruitment programs (see Appendix B).

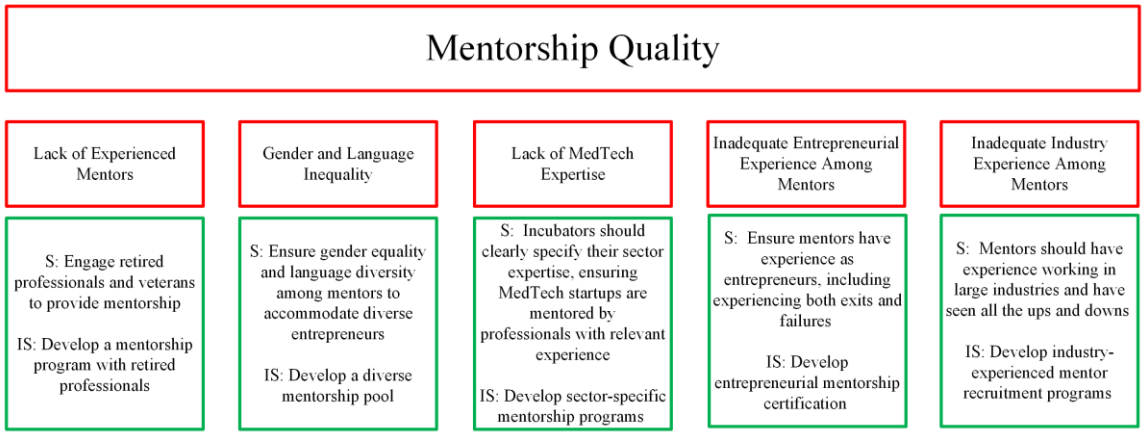


Figure 24 Mentorship quality challenge, contributing challenges, and solutions

4.5.12. Time Constraints

Time constraints pose significant challenges for MedTech startups in balancing resource allocation and achieving key milestones within tight deadlines. Effective project management strategies are essential to streamline operations and optimize time use.

Contributing challenge 1: Inadequate Project Management Skills Among Startups

Startups often lack the expertise required for effective project management, which can lead to delays and inefficiencies.

Solution 1.1: Assign Project Management Experts: Assigning project management experts ensures that startups receive structured guidance on timelines, resource allocation, and risk management, helping them stay on track and optimize operational efficiency. These experts provide strategic oversight, enhance productivity, and mitigate potential obstacles, enabling startups to

execute their projects effectively and meet key milestones. The recommended Implementation strategy 1.1.1 is to develop a dedicated team of project management experts (see Appendix B).

Solution 1.2: Provide Project Management Training for Founders: Providing project management training for founders equips them with essential skills, such as task prioritization, resource management, and the application of advanced methodologies. Tailored training programs help founders streamline operations, improve decision-making, and enhance efficiency, enabling them to effectively manage their startups and drive sustainable growth. The recommended Implementation strategy 1.2.1 is to develop a comprehensive project management training program (see Appendix B).

Contributing challenge 2: Lack of Structured Project Management Processes

Unstructured processes can hinder startups from effectively tracking progress and making timely adjustments.

Solution 2.1: Integrate Project Management into Coaching Plans: Integrating project management into incubator coaching plans, supported by tools like Gantt charts and milestone tracking systems, ensures consistent oversight, structured planning, and effective execution. Embedding project management practices into incubator support programs helps startups stay on schedule, allocate resources efficiently, and proactively address challenges, leading to improved outcomes and sustainable growth. The recommended Implementation strategy 2.1.1 is to develop a project management integration plan (see Appendix B).

Solution 2.2: Provide Standardized Project Management Templates: Providing standardized project management templates, such as project charters, task lists, and timelines, helps startups streamline planning, improve execution, and maintain consistency. These templates enable efficient resource allocation, clear goal-setting, and structured progress tracking, ensuring that teams stay organized and aligned with their strategic objectives. The recommended Implementation strategy 2.2.1 is to develop a comprehensive library of standardized templates (see Appendix B).

Contributing challenge 3: Insufficient Intensive Support for Rapid Progress

Startups often need focused support to accelerate development and meet market demands.

Solution 3.1: Implement Accelerator Programs: Implementing accelerator programs offers startups structured, time-bound support, providing access to mentorship, resources, and networking opportunities essential for rapid growth. These programs help startups refine their business models, secure funding, and accelerate market entry, fostering innovation and long-term success. The recommended Implementation strategy 3.1.1 is to develop a structured accelerator program (see Appendix B).

Solution 3.2: Introduce Milestone-Based Funding for Incubators Who Fund Startups Directly: Introducing milestone-based funding for incubators that directly fund startups ensures that financial support is tied to specific project achievements, promoting accountability, efficient resource utilization, and timely progress. This approach incentivizes startups to meet key development benchmarks, reducing financial risks while aligning funding with measurable outcomes(140). The recommended Implementation strategy 3.2.1 is to develop a milestone-based funding model (see Appendix B).

Contributing challenge 4: Need for External Project Management Support

In cases where incubators lack internal expertise, external support can fill the gap.

Solution 4.1: Engage External Project Management Firms If the Incubator Doesn't Have Experts Itself: Engaging external project management firms allows incubators without in-house expertise to offer startups high-quality guidance on planning, execution, and risk management. These partnerships ensure that startups receive specialized support, industry best practices, and structured methodologies, enhancing their ability to manage projects efficiently and meet key milestones. The recommended Implementation strategy 4.1.1 is to Develop a Partnership program with external project management firms (see Appendix B).

Solution 4.2: Schedule Regular Project Management Workshops: Scheduling regular project management workshops led by industry experts provides startups with ongoing education on best practices, tools, and methodologies, enhancing their ability to manage complex projects efficiently. These sessions ensure that founders and teams develop critical skills in planning, execution, and risk management, improving overall productivity and strategic decision-making. The recommended Implementation strategy 4.2.1 is to Develop a Schedule of regular project management workshops (see Appendix B).

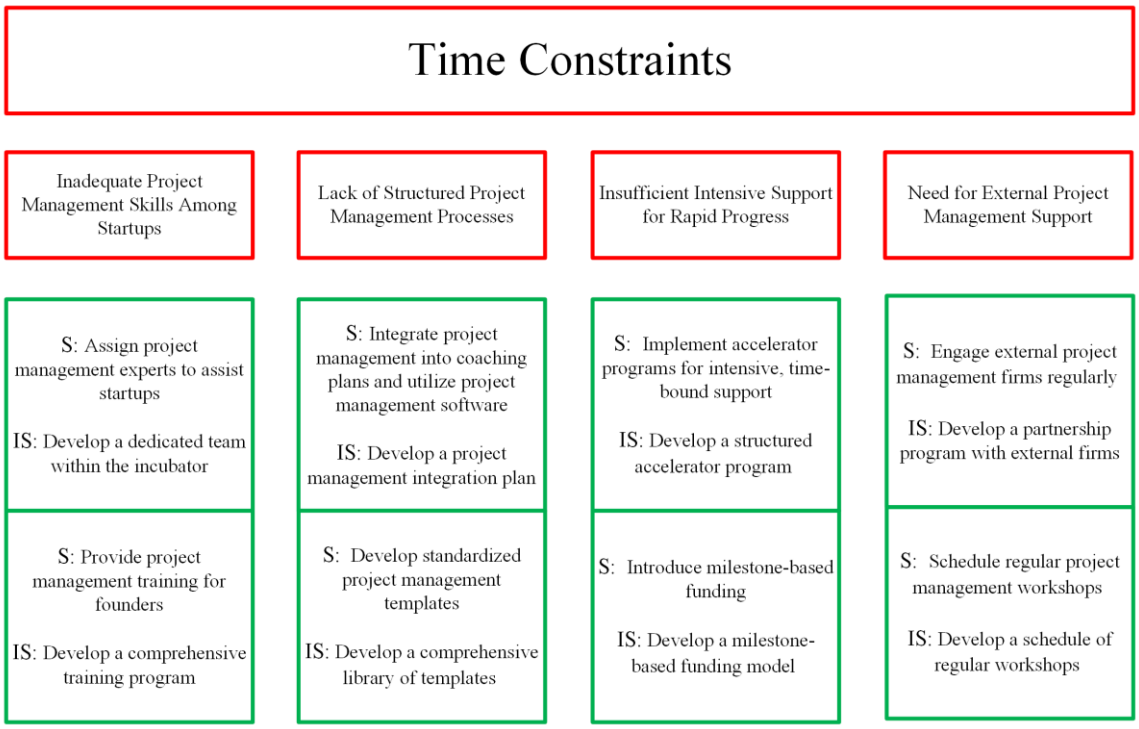


Figure 25 Time constraints challenge, contributing challenges, and solutions

4.5.13. Cultural Fit

Achieving cultural fit between startups, incubators, and third parties is crucial for fostering collaboration, innovation, and productivity. Misalignment in values, communication styles, and organizational practices can create barriers to successful partnerships, but these challenges can be mitigated through targeted solutions.

Contributing challenge 1: Misalignment of Organizational Cultures

Cultural differences in communication, work ethics, and values can hinder collaboration between startups and incubators.

Solution 1.1: Corporate Partners: Offer Cultural Training Programs: Corporate partners can offer structured cultural training programs through workshops, role-playing exercises, and interactive sessions, helping startups enhance cross-cultural understanding and alignment. These programs foster effective communication, collaboration, and adaptability, ensuring smoother integration into diverse work environments. The recommended Implementation strategy 1.1.1 is to develop and implement a cultural training program (see Appendix B).

Solution 1.2: Regular Cultural Exchange Sessions: Hosting regular cultural exchange sessions like monthly discussions, interactive workshops, or team-building activities, can foster mutual understanding and bridge organizational culture gaps. These sessions encourage knowledge sharing, adaptability, and stronger collaboration, ensuring that diverse teams align more effectively in a global business environment. The recommended Implementation strategy 1.2.1 is to schedule monthly cultural exchange sessions (see Appendix B).

Contributing challenge 2: Lack of Clarity on Cultural Expectations and Practices

Unclear expectations about cultural norms can lead to misunderstandings and inefficiencies.

Solution 2.1: HR Consultants: Assist in Cultural Assessments and Team-Building Activities: HR consultants can facilitate cultural assessments and team-building activities, helping organizations align expectations, improve communication, and strengthen collaboration. Through tailored evaluations, workshops, and interactive exercises, consultants can identify cultural gaps and provide strategic guidance to enhance workplace dynamics and team cohesion. The recommended Implementation strategy 2.1.1 is to partner with hr consultants for cultural assessments (see Appendix B).

Solution 2.2: Develop a Cultural Fit Checklist: Developing a cultural fit checklist for onboarding and performance reviews helps startups ensure alignment with incubator values, expectations, and best practices. This checklist can guide team integration, workplace adaptability, and long-term collaboration, fostering a cohesive and productive incubator environment. The recommended Implementation strategy 2.2.1 is to create and integrate a cultural fit checklist (see Appendix B).

Contributing challenge 3: Diverse Communication Styles and Languages Within Startups

Language barriers and varying communication styles may impede collaboration within startups.

Solution 3.1: Language and Communication Training: Implementing language and communication training programs enhances team dynamics, collaboration, and clarity in interactions, reducing misunderstandings in diverse work environments. These programs help startups improve cross-cultural communication and strengthen workplace relationships. The recommended Implementation strategy 3.1.1 is to develop a language and communication training program (see Appendix B).

Solution 3.2: Implement a Language Policy: Implementing a language policy ensures that official communications follow a common language, fostering clarity, inclusivity, and effective collaboration within diverse teams. This policy helps streamline internal and external interactions, reducing misunderstandings and enhancing workplace cohesion. The recommended Implementation strategy 3.2.1 is to develop and enforce a language policy (see Appendix B).

Contributing challenge 4: Inadequate Integration of New Employees

Onboarding processes often lack cultural orientation, delaying employee productivity.

Solution 4.1: Comprehensive Onboarding Programs: Implementing comprehensive onboarding programs that include cultural orientation and mentorship helps startups integrate more effectively into the incubator ecosystem. These programs provide structured guidance, facilitate team cohesion, and enhance alignment with organizational values, accelerating the adaptation process and improving overall collaboration. The recommended Implementation strategy 4.1.1 is to develop a comprehensive onboarding program (see Appendix B).

Solution 4.2: Peer Mentorship Programs: Establishing peer mentorship programs allows experienced employees to guide newcomers, fostering smoother transitions, knowledge sharing, and stronger team integration. This approach helps new members adapt quickly, build confidence, and align with organizational culture, enhancing overall collaboration and productivity(139). The recommended Implementation strategy 4.2.1 is to develop a structured peer mentorship program (see Appendix B).

Contributing challenge 5: Inadequate Cultural Fit Between Startups and Third Parties

Third-party collaborators may lack alignment with startups' values and practices.

Solution 5.1: Government Incentives for Cultural Alignment: Incentives encourage third parties to collaborate and align culturally with startups(125). The recommended Implementation strategy 5.1.1 is to develop a government program for cultural alignment incentives (see Appendix B).

Solution 5.2: Cultural Fit Evaluation Criteria: Establishing cultural fit evaluation criteria is essential when selecting third-party partners, as it ensures alignment in core values, beliefs, and behaviors between organizations. This alignment fosters effective collaboration, smooth communication, and mutual trust, ultimately contributing to the success of the partnership (141). The recommended

Implementation strategy 5.2.1 is to develop and integrate cultural fit evaluation criteria (see Appendix B).

Contributing challenge 6: Lack of Transparent Feedback Mechanisms

Without feedback systems, identifying and addressing cultural misalignments is challenging.

Solution 6.1: Develop a Feedback and Rating System: Implementing an anonymous feedback and rating system can significantly enhance transparency and accountability within organizations. Such platforms encourage honest communication, allowing individuals to express their thoughts and concerns without fear of retaliation(142). The recommended Implementation strategy 6.1.1 is to develop an online feedback and rating platform (see Appendix B).

Solution 6.2: Annual Cultural Fit Audits: Regular audits provide actionable insights for continuous improvement in cultural alignment. The recommended Implementation strategy 6.2.1 is to develop a structured audit process for cultural fit (see Appendix B).

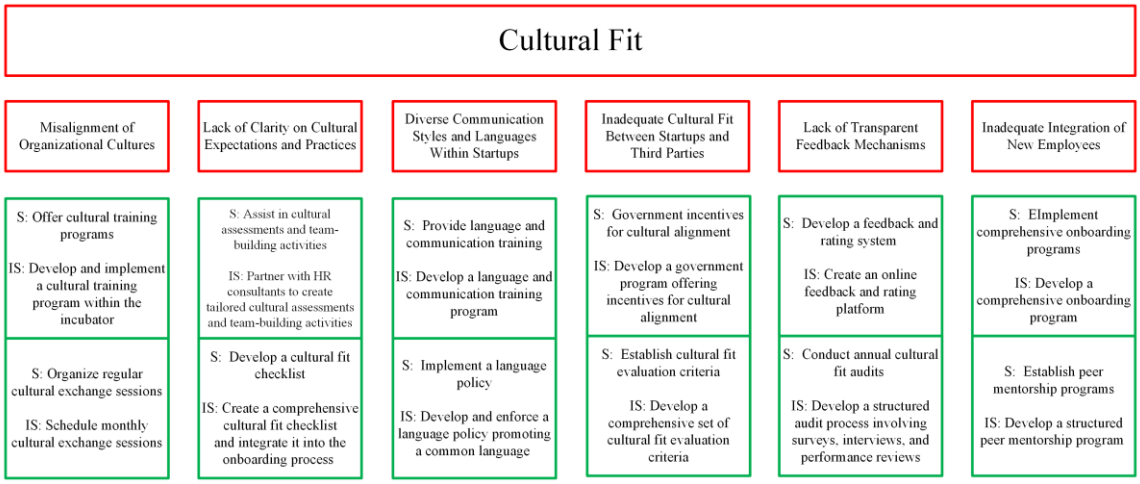


Figure 26 Cultural fit challenge, contributing challenges, and solutions

4.5.14. Follow-Up Support

Post-incubation support is critical for startups graduating from incubators that do not cover all nine Technology Readiness Levels (TRLs). Ongoing guidance, mentorship, and access to resources can significantly impact a startup's ability to scale, navigate new markets, and sustain growth.

Contributing challenge 1: Insufficient Advisory and Mentorship Support

Graduating startups often lack ongoing access to strategic advice and mentorship.

Solution 1.1: Venture Capital Firms: Offer Post-Incubation Support Through Advisory Role: Engage venture capital firms to provide strategic guidance, industry connections, and financial planning post-incubation. The recommended Implementation strategy 1.1.1 is to develop formal agreements with venture capital firms (see Appendix B).

Solution 1.2: Establish a Dedicated Post-Incubation Advisory Board: Establishing a dedicated post-incubation advisory board composed of seasoned entrepreneurs, investors, and industry experts provides startups with tailored mentorship, strategic guidance, and ongoing accountability. This board helps graduates of incubator programs navigate scaling challenges, refine business strategies, and secure long-term success through continued support and networking opportunities(143). The recommended Implementation strategy 1.2.1 is to form advisory boards with quarterly meetings (see Appendix B).

Contributing challenge 2: Lack of Structured Alumni Networks

Alumni networks are underutilized for mentorship and resource sharing.

Solution 2.1: Alumni Networks: Provide Ongoing Mentorship Leveraging Successful Graduates: Leverage successful graduates to mentor new alumni foster knowledge transfer and networking. The recommended Implementation strategy 2.1.1 is to develop a structured alumni mentorship program (see Appendix B).

Solution 2.2: Develop an Alumni Platform for Continuous Engagement: Develop online platforms to facilitate continuous interaction, discussions, and collaboration among alumni. The recommended implementation strategy 2.2.1 is to develop an online alumni engagement platform (see Appendix B).

Contributing challenge 3: Inadequate Infrastructure and Resource Support

Graduating startups often lose access to essential facilities and tools for R&D.

Solution 3.1: Provide Access to Specialized Facilities Post-Incubation: Establish partnerships with universities and research institutions for continued facility access at reduced rates(144). The

recommended implementation strategy 3.1.1 is to establish partnerships for facility access (see Appendix B).

Solution 3.2: Establish a Resource Directory for Graduates: Establishing a comprehensive and regularly updated resource directory for graduates of incubator programs is crucial in providing ongoing support as they transition into the broader business ecosystem. Such a directory serves as a centralized repository of facilities, services, and opportunities available to emerging businesses, facilitating their continued growth and development. The recommended implementation strategy 3.2.1 is to develop an online resource directory (see Appendix B).

Contributing challenge 4: Insufficient Visibility of Post-Incubation Support Programs

Graduates may not be aware of the support programs and resources available.

Solution 4.1: Develop a Centralized Platform for Post-Incubation Support Information: Developing a centralized platform for post-incubation support provides startups with an online hub that aggregates mentorship opportunities, funding resources, and facility access programs. This platform ensures that incubator graduates can easily navigate available support, stay connected with advisors, and access critical resources for continued growth and scalability(145). The recommended implementation strategy 4.1.1 is to develop a centralized online platform (see Appendix B).

Solution 4.2: Conduct Regular Webinars and Information Sessions: Regular webinars can educate graduates about opportunities and resources. The recommended implementation strategy 4.2.1 is to schedule regular webinars and information sessions (see Appendix B).

Solution 4.3: Virtual Incubation Programs: Digital platforms can extend mentorship and resources to startups in remote or underserved areas. The recommended implementation strategy 4.3.1 is to develop comprehensive virtual incubation programs (see Appendix B).

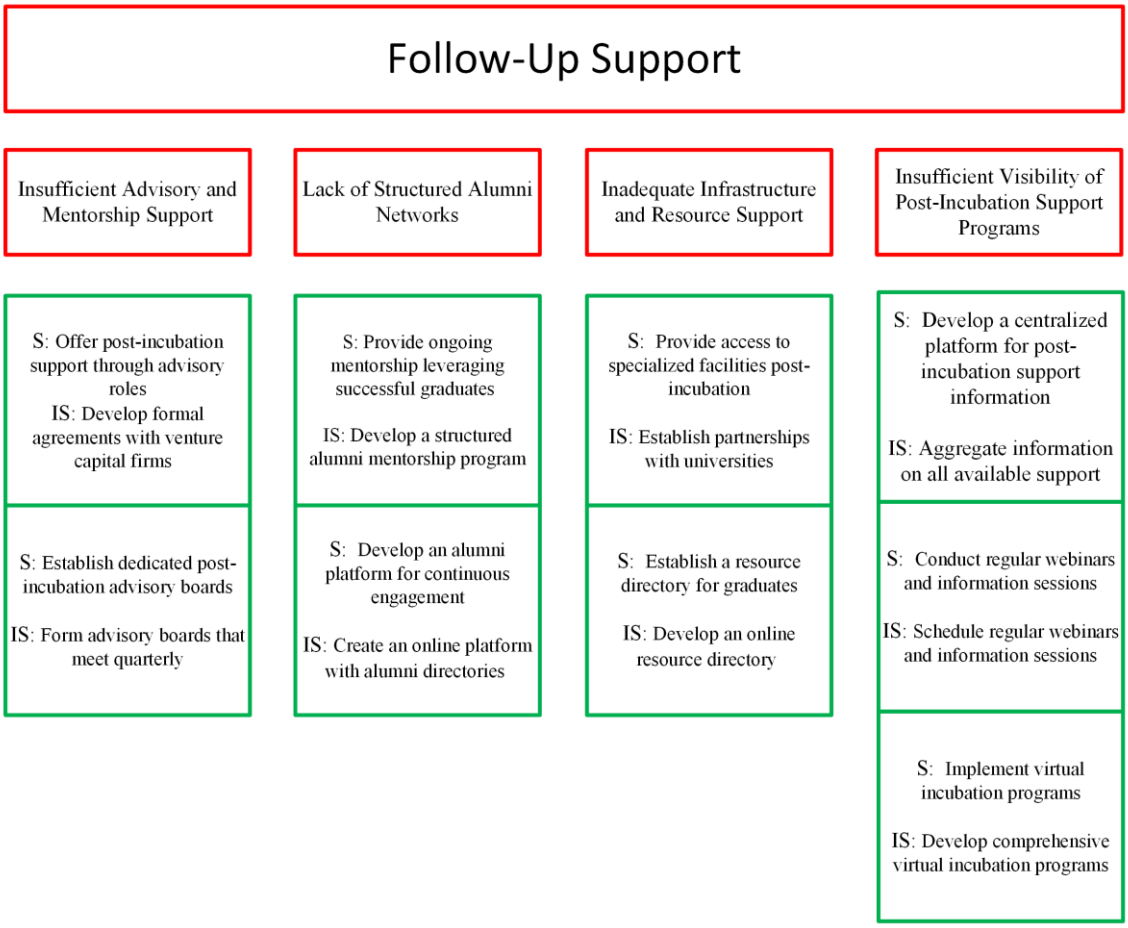


Figure 27 Follow-up support challenge, contributing challenges, and solutions

4.5.15. Tailored Business Development

MedTech startups face unique challenges that require industry-specific business development strategies. Generic advice often fails to address the complexities of the sector, including regulatory requirements, market access, and commercialization strategies.

Contributing challenge 1: Lack of Industry-Specific Knowledge

Generic business development guidance often overlooks the specific needs of MedTech startups.

Solution 1.1: Hire Industry-Specific Business Development Experts: Hiring business development experts with extensive experience in the MedTech industry can significantly enhance a company's strategic positioning and growth prospects. These professionals bring specialized knowledge and insights that are crucial for navigating the complex and rapidly evolving MedTech

landscape. The recommended implementation strategy 1.1.1 is to establish a recruitment initiative for medtech experts (see Appendix B).

Solution 1.2: Develop MedTech-Specific Training Programs: Develop focused training programs covering regulatory compliance, market access, and clinical trials(139). The recommended implementation strategy 1.2.1 is to design a comprehensive MedTech curriculum (see Appendix B).

Contributing challenge 2: Insufficient Understanding of Regulatory Requirements

Navigating the complex regulatory landscape is a significant hurdle for startups.

Solution 2.1: Offer Regulatory Strategy Workshops: Conduct workshops to help startups understand regulatory requirements and compliance strategies(12). The recommended implementation strategy 2.1.1 is to develop partnerships with regulatory agencies for workshops (see appendix B).

Solution 2.2: Provide Access to Regulatory Consulting Services: Partner with regulatory consulting firms to provide expert guidance on compliance and regulatory strategies (12). The recommended implementation strategy 2.2.1 is to create a network of vetted regulatory consulting firms (see Appendix B).

Contributing challenge 3: Limited Market Access and Commercialization Strategies

Startups often struggle to access markets and develop effective go-to-market strategies.

Solution 3.1: Establish Market Access Programs: Offer programs focusing on market research, partnership development, and sales strategies(115). The recommended Implementation strategy 3.1.1 is to develop a structured market entry Program (see Appendix B).

Solution 3.2: Develop Commercialization Partnerships: Collaborate with established healthcare companies to provide resources, market access, and credibility. The recommended Implementation strategy 3.2.1 is to establish a partnership framework for medtech startups (see Appendix B).

Contributing challenge 4: Insufficient Access to Industry Networks and Mentorship

Startups lack connections to industry veterans and mentors who can provide critical insights.

Solution 4.1: Create Industry-Specific Networking Events: Organize events to connect startups with investors, partners, and experts in the MedTech sector. The recommended implementation strategy 4.1.1 is to develop a calendar of regular networking events (see Appendix B).

Solution 4.2: Develop a Mentorship Program with Industry Veterans: Pair startups with experienced mentors to guide business development, regulatory navigation, and market strategies(139). The recommended implementation strategy 4.2.1 is to create a structured mentorship program with clear guidelines (see Appendix B).

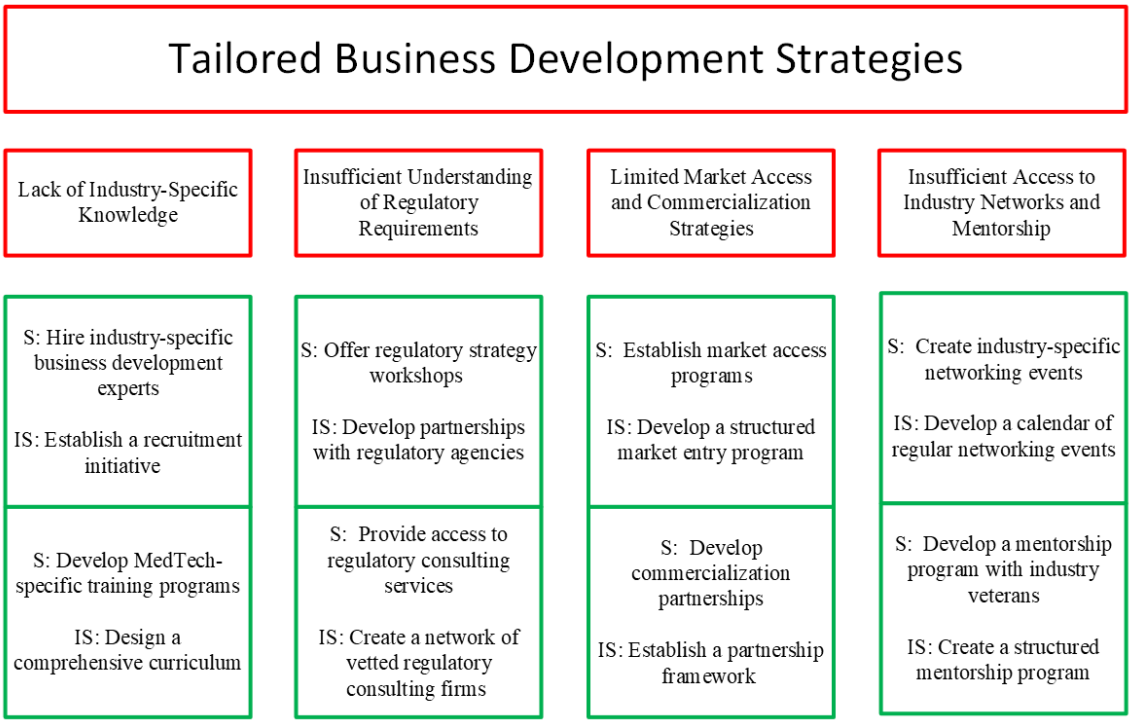


Figure 28 Tailored business development challenges, contributing challenges, and solutions

4.5.16. Clinical Trial Design and Management

Conducting clinical trials is a crucial step for MedTech startups but is often hindered by limited expertise, resources, and infrastructure within incubators. Effective design, management, and execution are vital for regulatory approval and market success.

Contributing challenge 1: Insufficient Expertise in Clinical Trial Design

Incubators often lack staff with specialized knowledge of medical device trials, leading to suboptimal trial planning.

Solution 1.1: Partner with Clinical Research Organizations (CROs): Collaborate with CROs for expert guidance in trial design, management, and regulatory compliance(130). The recommended implementation strategy 1.1.1 is to establish formal partnerships with leading CROs (see Appendix B).

Solution 1.2: Establish In-House Clinical Trial Design Teams: Develop dedicated teams within incubators to provide ongoing support and strategic advice. The recommended implementation strategy 1.2.1 is to develop a dedicated in-house clinical trial design team (see Appendix B).

Contributing challenge 2: Lack of Resources for Clinical Trial Management

Startups struggle with limited funding, infrastructure, and tools for managing clinical trials effectively.

Solution 2.1: Provide Access to Clinical Trial Funding Programs: Introduce funding initiatives with grants, subsidies, and investment opportunities to cover trial costs(146). The recommended implementation strategy 2.1.1 is to establish a clinical trial funding initiative (see Appendix B).

Solution 2.2: Develop Shared Clinical Trial Infrastructure: Create centralized resources such as data management systems and patient recruitment databases to reduce costs and improve efficiency. the recommended implementation strategy 2.2.1 is to establish shared clinical trial infrastructure (see Appendix B).

Contributing challenge 3: Challenges in Patient Recruitment and Retention

Recruiting and retaining participants for trials is a common hurdle for startups.

Solution 3.1: Utilize Patient Recruitment Services: Partnering with specialized patient recruitment agencies can significantly enhance enrollment efficiency in clinical trials. These agencies employ targeted strategies to identify and engage suitable participants, addressing common recruitment challenges(147). The recommended implementation strategy 3.1.1 is to establish partnerships with patient recruitment services (see Appendix B).

Solution 3.2: Implement Retention Strategies and Patient Engagement Plans: Develop plans including communication, education, and incentives to maintain participant involvement to help patient recruitment and retention process. The recommended implementation strategy 3.2.1 is to develop and implement patient retention plans (see Appendix B).

Contributing challenge 4: Difficulty in Data Management and Analysis

Efficient data management and analysis are critical but often challenging for startups.

Solution 4.1: Implement Advanced Data Management Systems: Implementing advanced data management systems, particularly Electronic Data Capture (EDC) systems, is essential for modernizing clinical trial processes. EDC systems facilitate the electronic collection, storage, and analysis of clinical data, offering significant improvements over traditional paper-based methods(148). The recommended implementation strategy 4.1.1 is to invest in and implement electronic data capture systems (see Appendix B).

Solution 4.2: Provide Biostatistical Support and Training: Providing biostatistical support and training is essential for ensuring accurate data analysis in clinical research. Access to experienced biostatisticians and comprehensive training programs enhances the quality and reliability of research outcomes(149). The recommended implementation strategy 4.2.1 is to establish a biostatistics support team and training program (see Appendix B).

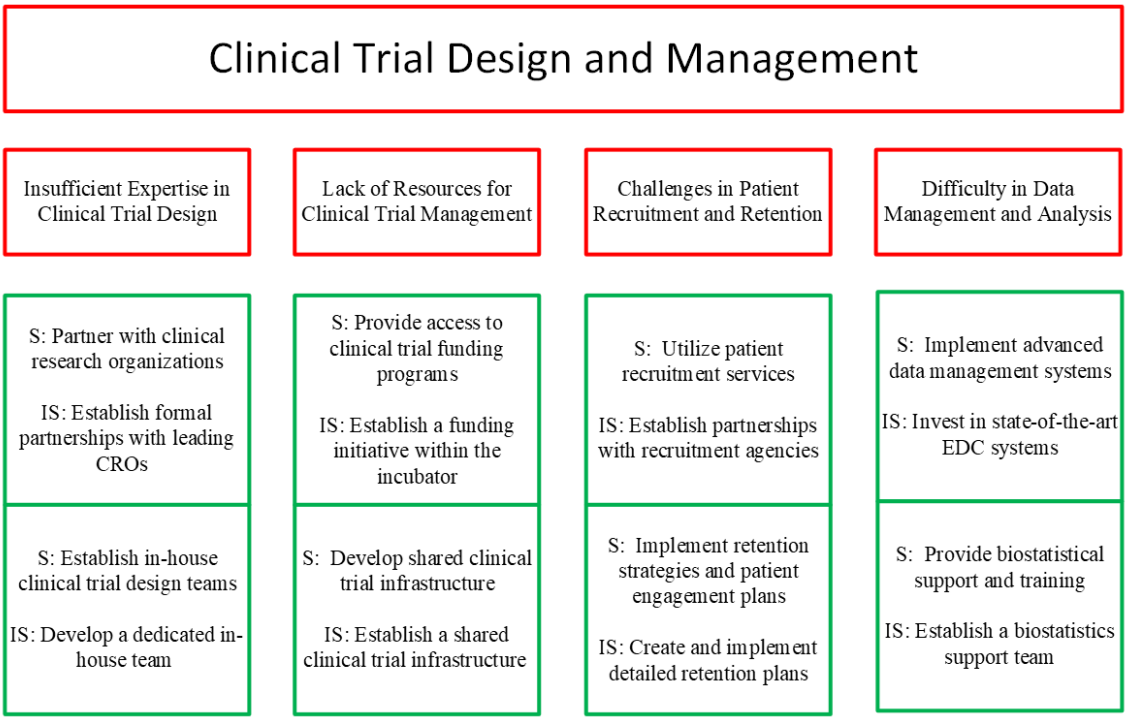


Figure 29 Clinical trial design and management challenge, contributing challenges, and solutions

4.5.17. Supply Chain and Logistics

Efficient supply chain and logistics management is essential for scaling MedTech startups. However, many incubators lack the necessary expertise, infrastructure, and regulatory knowledge to provide adequate support, creating significant barriers to efficient operations.

Contributing challenge 1: Lack of Supply Chain Expertise

Incubators often lack staff with specialized knowledge in supply chain management, limiting their ability to guide startups effectively.

Solution 1.1: Partner with Supply Chain Consulting Firms: Collaborate with consulting firms to provide tailored advice on procurement, logistics, and inventory management, ensuring efficient operations. The recommended implementation strategy 1.1.1 is to establish formal partnerships with supply chain consulting firms (see Appendix B).

Solution 1.2: Develop In-House Supply Chain Teams: Establish dedicated in-house teams to offer ongoing, customized support for startups, helping optimize supply chain strategies. The recommended implementation strategy 1.2.1 is to develop a dedicated in-house supply chain team (see Appendix B).

Contributing challenge 2: Inadequate Supply Chain Infrastructure

Startups often lack the necessary infrastructure, such as warehousing, transportation, and distribution networks, to efficiently manage their supply chains.

Solution 2.1: Provide Access to Shared Warehousing and Logistics Services: Facilitating shared access to warehousing and logistics infrastructure offers startups a cost-effective and scalable solution to manage their supply chain needs. By leveraging co-warehousing models, businesses can optimize operations, reduce overhead costs, and focus on core competencies(150). The recommended implementation strategy 2.1.1 is to establish partnerships with warehousing and logistics service Providers (see Appendix B).

Solution 2.2: Develop a Centralized Supply Chain Platform: Build a platform connecting startups with suppliers and logistics partners, offering tools for real-time tracking, inventory management, and

logistics coordination(107). The recommended implementation strategy 2.2.1 is to develop a centralized digital supply chain platform (see Appendix B).

Contributing challenge 3: Limited Expertise in Regulatory Compliance for Supply Chains

Navigating supply chain regulatory requirements, such as FDA and ISO standards, is complex and resource-intensive for startups.

Solution 3.1: Regulatory Compliance Training for Supply Chains: Offer training programs to educate startups on compliance standards, reducing risks and penalties(14). The recommended Implementation strategy 3.1.1 is to develop comprehensive regulatory compliance training programs (see Appendix B).

Solution 3.2: Develop Compliance Management Systems: Implement systems that automate regulatory checks, documentation, and monitoring to ensure adherence to compliance standards(33). The recommended implementation strategy 3.2.1 is to implement automated compliance management systems (see Appendix B).

Contributing challenge 4: Inefficient Logistics Coordination

Startups often struggle with coordinating logistics activities, leading to delays, increased costs, and operational inefficiencies.

Solution 4.1: Implement Integrated Logistics Management Software: Utilize software for real-time tracking, route optimization, and improved logistics visibility(107). The recommended implementation strategy 4.1.1 is to invest in advanced logistics management software (see Appendix B).

Solution 4.2: Develop Strategic Partnerships with Logistics Providers: Partner with logistics firms to access advanced networks, transportation resources, and operational expertise, enabling scalable logistics solutions(113). The recommended implementation strategy 4.2.1 is to establish strategic partnerships with leading logistics providers (see Appendix B).

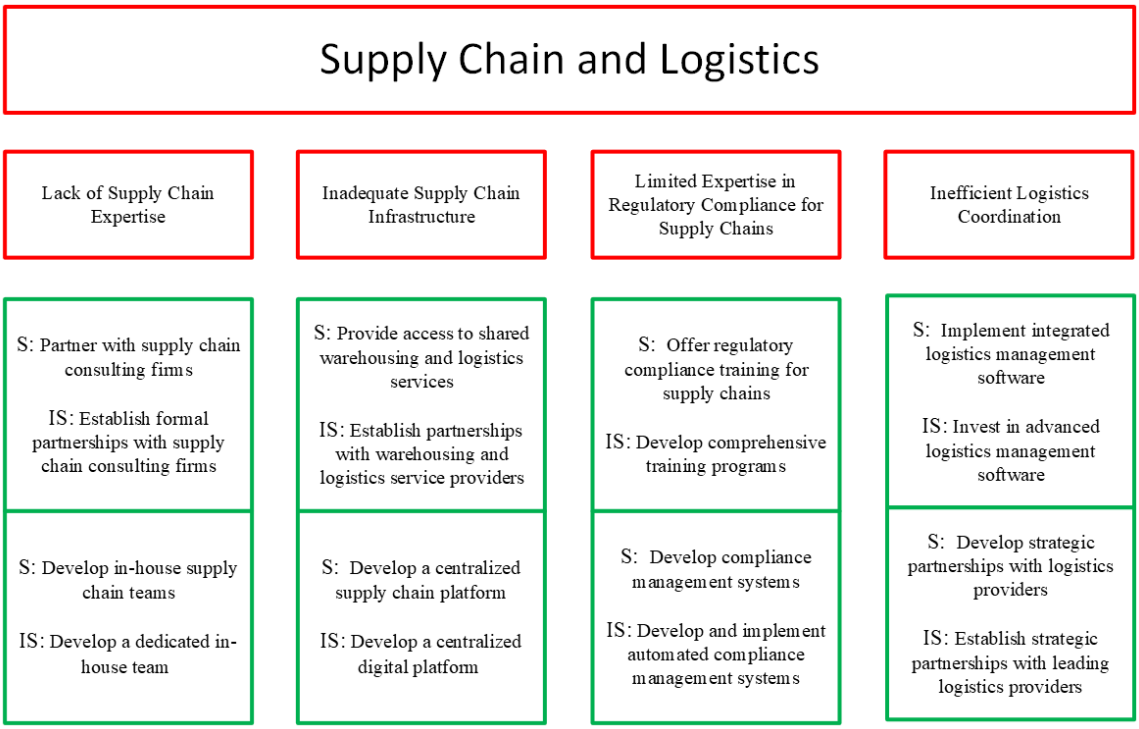


Figure 30 Supply chain and logistics challenge, contributing challenges, and solutions

4.5.18. Talent Acquisition and Retention

Attracting and retaining top talent in specialized fields like biomedical engineering is crucial for the success of MedTech startups. Incubators often lack sufficient expertise and resources to support effective talent acquisition and retention strategies, making this a critical area for improvement.

Contributing challenge 1: Limited Talent Acquisition Expertise

Incubators frequently lack specialized knowledge to develop effective recruitment strategies tailored to MedTech startups.

Solution 1.1: Partner with Recruitment Agencies Specializing in MedTech: Collaborating with agencies that possess extensive networks and expertise in MedTech recruitment helps talent acquisition(151). The recommended implementation strategy 1.1.1 is to establish formal partnerships with MedTech recruitment agencies (see Appendix B).

Solution 1.2: Develop In-House Talent Acquisition Teams: Establish dedicated teams within incubators to support recruitment efforts with tailored advice and strategies(151). The recommended

implementation strategy 1.2.1 is to develop a dedicated in-house talent acquisition team (see Appendix B).

Contributing challenge 2: Difficulty in Attracting Specialized Talent

Startups face challenges in competing with larger companies to attract highly specialized talent.

Solution 2.1: Offer Competitive Compensation and Benefits Packages: Offering competitive compensation and benefits ensures startups can attract and retain specialized talent. Providing equity options, flexible work arrangements, and industry-benchmarked packages enhance recruitment and long-term commitment. The recommended implementation strategy 2.1.1 is to benchmark compensation packages and include equity options (see Appendix B).

Solution 2.2: Develop a Strong Employer Brand: Highlight the startup's mission, culture, and impact to attract candidates motivated by meaningful work and innovation. The recommended implementation strategy 2.2.1 is to develop a comprehensive employer branding strategy (see Appendix B).

Contributing challenge 3: Retaining Key Personnel

High employee turnover disrupts operations, making retention a priority for sustained growth.

Solution 3.1: Create Clear Career Development Paths: Establish professional growth opportunities, including mentorship, training, and advancement plans, to retain employees. The recommended implementation strategy 3.1.1 is to develop and communicate clear career development plans (see Appendix B).

Solution 3.2: Foster a Positive and Inclusive Workplace Culture: Promote work-life balance, recognition programs, and team collaboration to create a supportive and engaging work environment to retain key personnel. The recommended implementation strategy 3.2.1 is to implement policies and practices to foster a positive workplace culture (see Appendix B).

Contributing challenge4: Limited Access to Talent Development Resources

Startups often lack the resources for extensive training and development programs.

Solution 4.1: Provide Access to External Training Programs: partner with educational institutions and professional organizations to offer workshops, certifications, and training opportunities help talent retaining. The recommended implementation strategy 4.1.1 is to establish partnerships with educational institutions for external training (see Appendix B).

Solution 4.2: Develop Mentorship and Coaching Programs: Implement structured mentorship and coaching programs to provide personalized guidance and skill development help talent retention(93). The recommended implementation strategy 4.2.1 is to develop structured mentorship and coaching programs (see Appendix B).

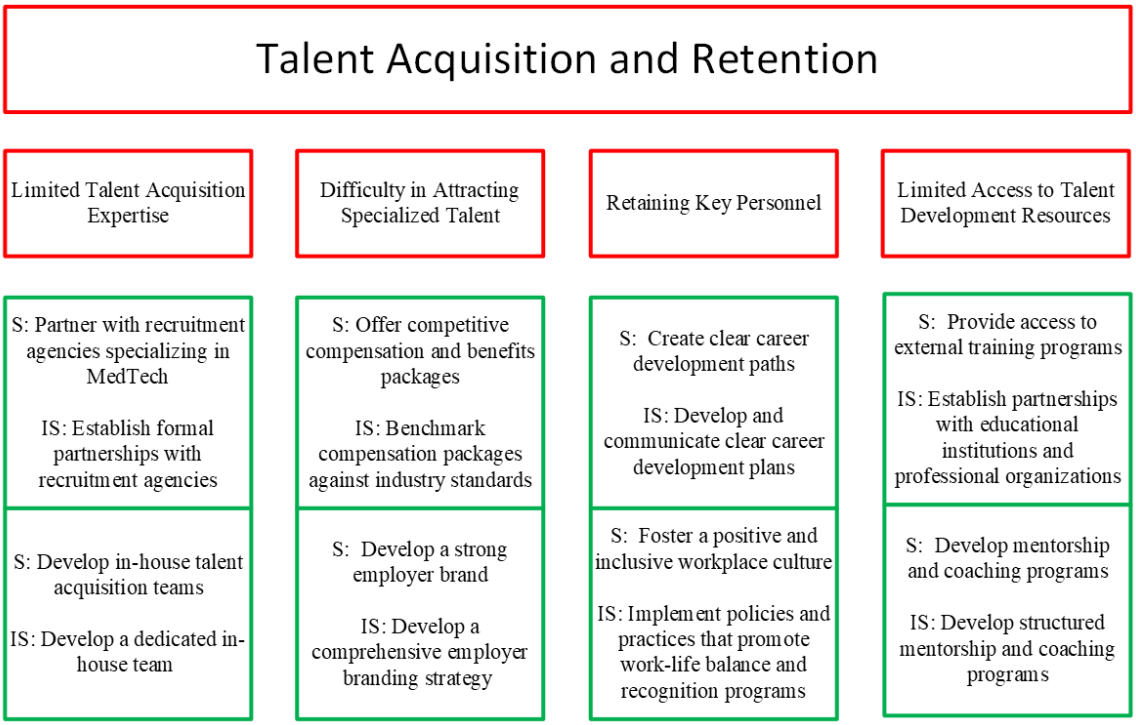


Figure 31 Talent acquisition and retention challenges, contributing challenges, and solutions

4.5.19. Integration with Healthcare Institutions and Workflows

Integrating MedTech devices into healthcare systems and workflows is a critical yet complex process. Many incubators lack the necessary expertise, networks, and resources to support startups in overcoming the challenges of healthcare integration effectively.

Contributing challenge 1: Limited Knowledge of Healthcare System Workflows

Incubators often lack a detailed understanding of healthcare workflows, which hinders their ability to guide startups in seamless device integration.

Solution 1.1: Collaborate with Healthcare Professionals: Partner with healthcare professionals to gain real-world insights into workflows and practical challenges, ensuring device designs fit seamlessly into existing systems(35,119). The recommended implementation strategy 1.1.1 is to establish formal partnerships with healthcare professionals (see Appendix B).

Solution 1.2: Conduct Workflow Analysis Studies: Perform in-depth studies to map out healthcare processes, identify integration points, and optimize devices for compatibility with current workflows. The recommended implementation strategy 1.2.1 is to conduct workflow analysis studies in collaboration with healthcare providers (see Appendix B).

Contributing challenge 2: Insufficient Connections with Healthcare Institutions

Startups often struggle to establish the partnerships necessary for device testing, validation, and adoption.

Solution 2.1: Establish Partnerships with Healthcare Providers: Establishing partnerships with healthcare providers enables startups to collaborate with hospitals and clinics, facilitating real-world testing, feedback collection, and iterative refinement of medical devices. These formal collaborations help ensure that innovations are clinically relevant, user-friendly, and aligned with regulatory and patient care standards(35). The recommended implementation strategy 2.1.1 is to establish formal partnerships with healthcare providers for device testing (see Appendix B).

Solution 2.2: Leverage Incubator Networks to Connect Startups with Healthcare Stakeholders: Use the incubator's network to introduce startups to healthcare stakeholders, fostering connections that facilitate integration and feedback. The recommended implementation strategy 2.2.1 is to utilize incubator networks to facilitate introductions and relationships (see Appendix B).

Contributing challenge 3: Challenges in Adhering to Regulatory Requirements

Navigating complex regulatory frameworks can delay or derail product integration efforts.

Solution 3.1: Provide Regulatory Support and Guidance: Providing regulatory support and guidance ensures that startups have access to expert advice on understanding and meeting regulatory requirements, including documentation, compliance strategies, and approval processes. This support helps startups navigate complex regulatory landscapes, reduce approval delays, and enhance market readiness for their innovations(14). The recommended Implementation strategy 3.1.1 is to develop a regulatory support team within the incubator (see Appendix B).

Solution 3.2: Develop Compliance Management Systems: Implement systems to monitor and ensure continuous adherence to regulatory standards reduces the risk of non-compliances. The recommended implementation strategy 3.2.1 is to develop automated compliance management systems (see Appendix B).

Contributing challenge 4: Integration with Existing IT Systems

MedTech startups often face difficulties ensuring their devices are compatible with healthcare IT systems like EHRs and HIS.

Solution 4.1: Develop Interoperability Standards: Collaborate with standards organizations to create protocols that ensure seamless communication between new devices and existing systems(128). The recommended implementation strategy 4.1.1 is to collaborate with standards organizations to develop interoperability standards (see Appendix B).

Solution 4.2: Provide Technical Support for IT Integration: Offer technical assistance to resolve compatibility issues, ensuring devices enhance healthcare IT systems without causing disruptions (126). The recommended implementation strategy 4.2.1 is to establish a technical support team within the incubator (see Appendix B).

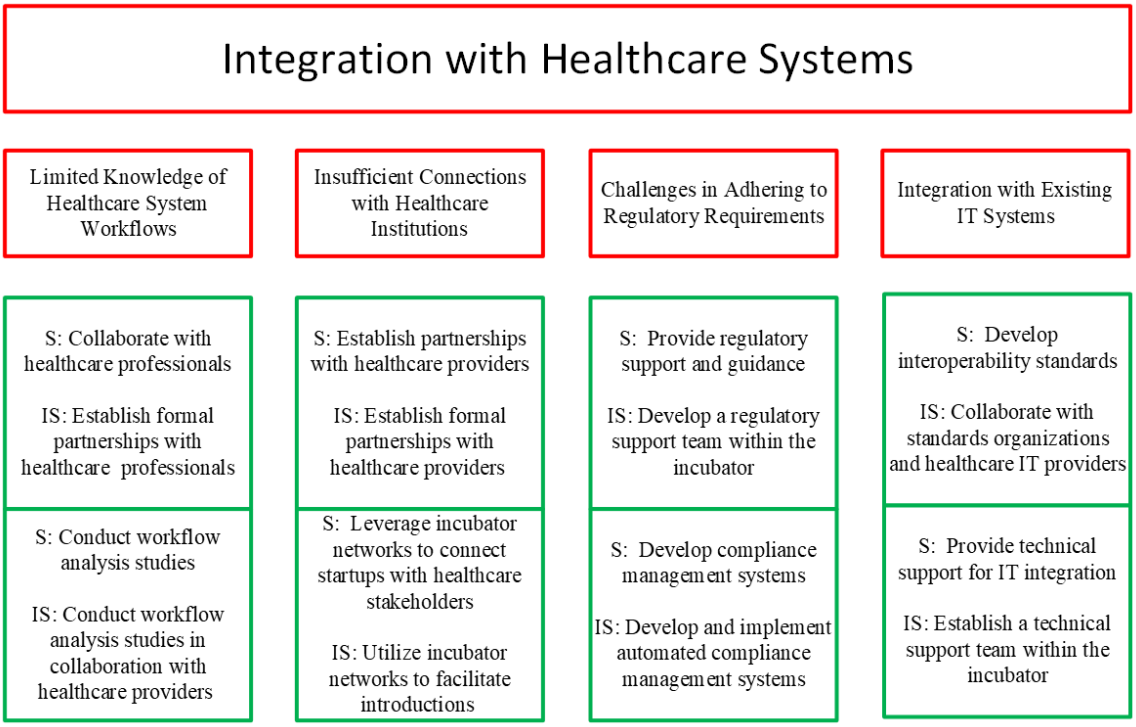


Figure 32 Integration with healthcare systems challenge, contributing challenges, and solutions

4.5.20. Feedback and Iteration Cycles

Regular feedback and iterative design processes are critical for refining medical devices to meet user and healthcare professional needs. Incubators often lack structured mechanisms to facilitate continuous feedback and improvement cycles, limiting the effectiveness of MedTech startups in optimizing their products.

Contributing challenge 1: Limited Access to Healthcare Professionals for Feedback

Startups frequently face barriers in obtaining valuable feedback from medical professionals.

Solution 1.1: Establish Feedback Panels with Healthcare Professionals: Create panels of doctors, nurses, and other healthcare experts to provide structured, periodic insights into device usability and functionality(152). The recommended implementation strategy 1.1.1 is to establish formal feedback panels (see Appendix B).

Solution 1.2: Implement Collaborative Platforms for Real-Time Feedback: Use platforms that enable immediate feedback through video conferencing, shared documents, and live comments,

expediting the iteration process. The recommended implementation strategy 1.2.1 is to implement collaborative platforms with real-time feedback features (see Appendix B).

Contributing challenge 2: Insufficient Engagement with End-Users for Feedback

Engaging patients and caregivers is essential to gather insights on device usability but is often overlooked.

Solution 2.1: Conduct User Experience (UX) Workshops with End-Users: Organize workshops for hands-on testing and feedback from end-users, ensuring devices meet their needs and preferences. The recommended implementation strategy 2.1.1 is to conduct regular UX workshops with end-users (see Appendix B).

Solution 2.2: Develop an End-User Advisory Board: Establish advisory boards of patients and caregivers to provide ongoing feedback and ensure user-centric design. The recommended implementation strategy 2.2.1 is to develop a formal end-user advisory board (see Appendix B).

Contributing challenge 3: Lack of Iterative Testing and Prototyping Facilities

Startups may lack access to resources needed for rapid prototyping and testing.

Solution 3.1: Provide Access to Prototyping Labs: Providing access to well-equipped prototyping labs featuring advanced tools like 3D printers is instrumental in facilitating rapid design iterations for startups and innovators. This infrastructure enables the swift transformation of digital concepts into tangible prototypes, allowing for efficient testing and refinement (153). The recommended implementation strategy 3.1.1 is to provide startups with access to advanced prototyping labs (see Appendix B).

Solution 3.2: Develop a Rapid Iteration Program: Create a program that includes regular feedback sessions, testing, and iterative workshops to refine designs systematically. The recommended implementation strategy 3.2.1 is to develop a rapid iteration program with regular feedback sessions (see Appendix B).

Contributing challenge 4: Inconsistent Feedback Implementation

Startups often struggle to integrate feedback due to a lack of structured processes.

Solution 4.1: Implement Agile Development Methodologies: Use agile practices, such as sprints and regular stand-up meetings, to incorporate feedback iteratively and flexibly(154). The recommended implementation strategy 4.1.1 is to implement agile development practices for continuous feedback integration (see Appendix B).

Solution 4.2: Use Feedback Management Tools: Employ tools to collect, prioritize, and monitor feedback implementation, ensuring systematic integration into the development process(107). The recommended implementation strategy 4.2.1 is to use advanced feedback management tools to integrate feedback systematically (see Appendix B).

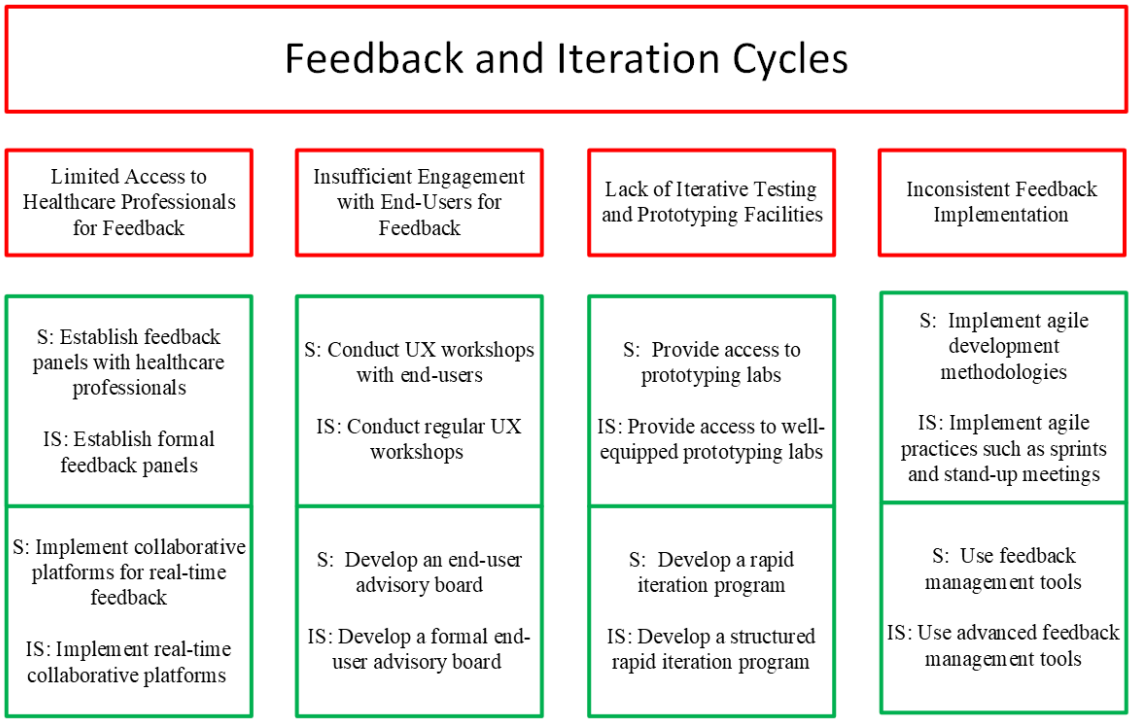


Figure 33 Feedback and iteration cycles challenge, contributing challenges, and solutions

4.5.21. Customizable Mentorship Programs

Tailored mentorship programs are crucial for addressing the unique needs of MedTech startups at various stages of development. Generic one-size-fits-all approaches often fail to meet the specific challenges of startups, particularly in the MedTech sector, where regulatory, technical, and market complexities require specialized guidance.

Contributing challenge 1: Lack of Tailored Mentorship for Different Development Stages

Startups have distinct needs at various stages, from ideation to scaling.

Solution 1.1: Develop Stage-Specific Mentorship Program: Create tailored programs for each development stage, ensuring relevant support for challenges such as prototyping, scaling, or market entry(139). The recommended implementation strategy 1.1.1 is to develop dedicated mentorship tracks (see Appendix B).

Solution 1.2: Implement Modular Mentorship Framework: Develop modular mentorship programs with customizable modules addressing specific topics like regulatory compliance, business development, and technical advice. The recommended implementation strategy 1.2.1 is to create a library of mentorship modules (see Appendix B).

Contributing challenge 2: Inadequate Matching of Mentors to Startups

Aligning mentors' expertise with startups' needs is critical to effective guidance.

Solution 2.1: Develop a Mentor Matching System: Use algorithms to match mentors based on expertise, industry experience, and startups' development stages, ensuring relevance and value(107). The recommended implementation strategy 2.1.1 is to develop a digital platform (see Appendix B).

Solution 2.2: Establish Mentor Training Programs: Train mentors to enhance their skills in communication, feedback, and coaching, improving the quality and impact of mentorship. The recommended implementation strategy 2.2.1 is to design a comprehensive mentor training curriculum (see Appendix B).

Contributing challenge 3: Inconsistent Mentor Engagement

Maintaining consistent communication between mentors and startups is challenging, leading to gaps in support.

Solution 3.1: Implement Regular Check-Ins and Progress Reviews: Schedule periodic meetings to evaluate progress, address challenges, and adjust mentorship strategies. The recommended implementation strategy 3.1.1 is to implement a digital calendar and notification system (see Appendix B).

Solution 3.2: Use Digital Platforms for Continuous Interaction: Leverage tools like video conferencing, messaging apps, and task management platforms to facilitate real-time communication and engagement. The recommended implementation strategy 3.2.1 is to develop a custom digital platform (see Appendix B).

Contributing challenge 4: Lack of Specialized Mentorship for the MedTech Sector

MedTech startups face unique challenges, such as navigating regulatory landscapes, clinical trials, and reimbursement strategies.

Solution 4.1: Recruit Mentors with MedTech Expertise: Actively seek mentors with specialized experience in MedTech to provide targeted advice on industry-specific challenges(155). The recommended implementation strategy 4.1.1 is to create a targeted recruitment campaign (see Appendix B).

Solution 4.2: Develop Sector-Specific Mentorship Modules: Create detailed mentorship content focusing on the MedTech sector's unique needs, such as regulatory pathways and clinical trial management. The recommended implementation strategy 4.2.1 is to develop a comprehensive set of sector-specific modules (see Appendix B).

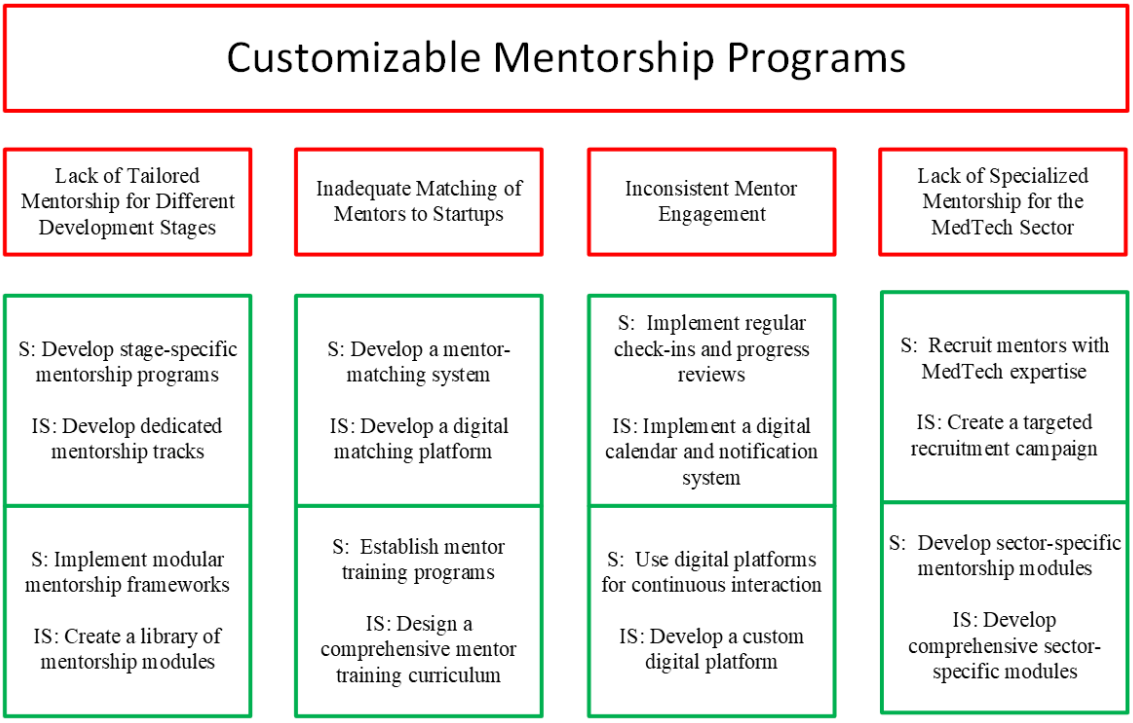


Figure 34 Customized mentorship programs challenge, contributing challenges, and solutions

4.5.22. Access to Advanced Manufacturing Technologies

Access to advanced manufacturing technologies is crucial for MedTech startups to develop cutting-edge medical devices. However, many incubators lack the facilities, expertise, and resources necessary to support startups in utilizing these technologies effectively.

Contributing challenge 1: Limited Access to Advanced Manufacturing Facilities

Incubators often do not have the state-of-the-art facilities required for advanced manufacturing.

Solution 1.1: Establish Partnerships with Advanced Manufacturing Facilities: Establishing partnerships with advanced manufacturing facilities through collaborations with universities, research institutions, and private companies can provide startups with access to cutting-edge technologies at discounted rates. This approach not only fosters innovation but also mitigates the high costs associated with acquiring and maintaining sophisticated equipment(156). The recommended Implementation strategy 1.1.1 is to develop a network of partnerships with local and international manufacturing facilities (see Appendix B).

Solution 1.2: Develop In-House Advanced Manufacturing Labs: Build in-house labs equipped with tools like 3D printers, CNC machines, and bioprinters, providing startups with direct access to essential technologies. The recommended implementation strategy 1.2.1 is to invest in building advanced manufacturing labs (see Appendix B).

Contributing challenge 2: Insufficient Expertise in Advanced Manufacturing Techniques

Startups may lack the skills to effectively utilize advanced techniques like 3D printing and bioprinting.

Solution 2.1: Provide Training Programs in Advanced Manufacturing: Providing training in advanced manufacturing ensures that startups gain expertise in cutting-edge techniques and technologies, enhancing their teams' capabilities. These programs help improve production efficiency, ensure quality standards, and accelerate the development of market-ready innovations. The recommended implementation strategy 2.1.1 is to design and implement comprehensive training programs (see Appendix B).

Solution 2.2: Employ Manufacturing Experts as Mentors: Recruit experts to mentor startups, providing personalized advice on manufacturing challenges and strategies. The recommended implementation strategy 2.2.1 is to establish a mentorship program (see Appendix B).

Contributing challenge 3: High Costs of Advanced Manufacturing

The significant costs associated with advanced manufacturing technologies can be prohibitive for startups.

Solution 3.1: Provide Subsidized Access to Manufacturing Technologies: Providing subsidized access to manufacturing technologies ensures that startups can overcome financial barriers and obtain essential equipment. Subsidies or grants help reduce costs, enabling startups to enhance production capabilities and accelerate innovation(125). The recommended implementation strategy 3.1.1 is to develop funding programs (see Appendix B).

Solution 3.2: Develop Cost-Sharing Programs: Developing cost-sharing programs through cooperative models including traditional cooperation, cost-sharing contracts, revenue-sharing contracts enable startups and small enterprises to access advanced manufacturing technologies and resources more affordably. By pooling resources and sharing infrastructure, these collaborations can

significantly reduce individual expenses while enhancing operational efficiency and scalability(157). The recommended implementation strategy 3.2.1 is to create a cooperative model (see Appendix B).

Contributing challenge 4: Integration of Advanced Manufacturing into Product Development

Startups may struggle to incorporate advanced technologies seamlessly into their workflows.

Solution 4.1: Develop Integrated Product Development Workflows: Design structured workflows that integrate advanced manufacturing from design to production, reducing time-to-market and improving quality. The recommended implementation strategy 4.1.1 is to develop a comprehensive product development framework (see Appendix B).

Solution 4.2: Utilize Advanced Manufacturing Software Tools: Providing access to advanced manufacturing software ensures that startups can enhance design precision and improve production efficiency. Utilizing tools like simulation and automation software helps streamline development and optimize manufacturing processes(107). The recommended implementation strategy 4.2.1 is to provide access to advanced software tools (see Appendix B).

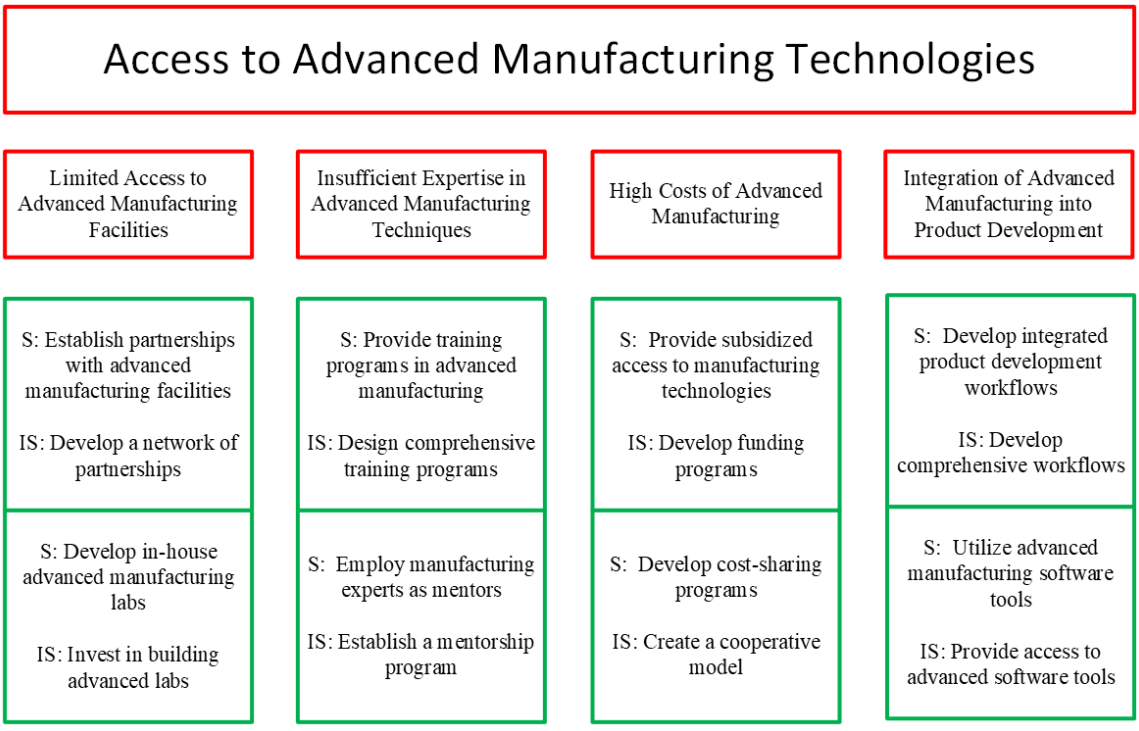


Figure 35 Access to advanced manufacturing technologies challenge, contributing challenges, and solutions

4.5.23. Long-Term Sustainability and Impact

Ensuring the long-term sustainability and impact of MedTech startups is critical for their success. While incubators often focus on short-term milestones, more comprehensive support is needed to help startups scale, maintain financial stability, and measure their impact on healthcare outcomes.

Contributing challenge 1: Focus on Short-Term Milestones

Incubators emphasize short-term goals like funding and exits, which can detract from long-term planning.

Solution 1.1: Implement Long-Term Strategic Planning Programs: Develop workshops on market trends, sustainability, and financial planning to foster sustainable business models. The recommended implementation strategy 1.1.1 is to create a series of strategic planning workshops (see Appendix B).

Solution 1.2: Encourage the Adoption of Viable Business Models: Guide startups to build adaptable and scalable models emphasizing operational efficiency and long-term financial stability(158). The recommended implementation strategy 1.2.1 is to develop a business viability framework (see Appendix B).

Contributing challenge 2: Limited Support for Scaling

Startups often struggle with scaling their operations due to a lack of resources, expertise, and strategic guidance.

Solution 2.1: Develop Scale-Up Support Programs: Developing scale-up support programs ensures that startups have access to resources and expertise for expanding operations. These programs help improve market entry strategies, enhance operational efficiency, and support sustainable growth. The recommended implementation strategy 2.1.1 is to establish a dedicated scale-up team (see Appendix B).

Solution 2.2: Foster Strategic Partnerships: Facilitate collaborations with larger companies, research institutions, and government agencies to access resources and market opportunities(135). The recommended implementation strategy 2.2.1 is to create a partnership office (see Appendix B).

Contributing challenge 3: Inadequate Focus on Impact Measurement

Measuring the long-term impact of MedTech solutions on healthcare outcomes is crucial for demonstrating value and securing ongoing support.

Solution 3.1: Develop Impact Measurement Frameworks: Developing an impact measurement framework is essential for quantifying the value of healthcare initiatives and securing stakeholder support. Such frameworks should encompass metrics that evaluate patient outcomes, cost savings, and overall healthcare improvements(159). The recommended implementation strategy 3.1.1 is to develop a standard impact measurement toolkit (see Appendix B).

Solution 3.2: Implement Continuous Improvement Processes: Establish feedback loops and performance evaluations to refine products and strategies, ensuring long-term relevance and impact. The recommended implementation strategy 3.2.1 is to incorporate agile methodologies (see Appendix B).

Contributing challenge 4: Lack of Long-Term Financial Planning

Startups may lack the financial planning required to ensure long-term sustainability, focusing instead on short-term fundraising goals.

Solution 4.1: Provide Financial Planning Workshops: Equip startups with skills in cash flow management, budgeting, and investment strategies through expert-led workshops(158). The recommended implementation strategy 4.1.1 is to develop and deliver financial planning workshops (see Appendix B).

Solution 4.2: Establish Long-Term Funding Strategies: Encourage diversified funding sources, including grants, venture capital, and public funding, to ensure financial stability(160). The recommended implementation strategy 4.2.1 is to create a long-term funding strategy template (see Appendix B).

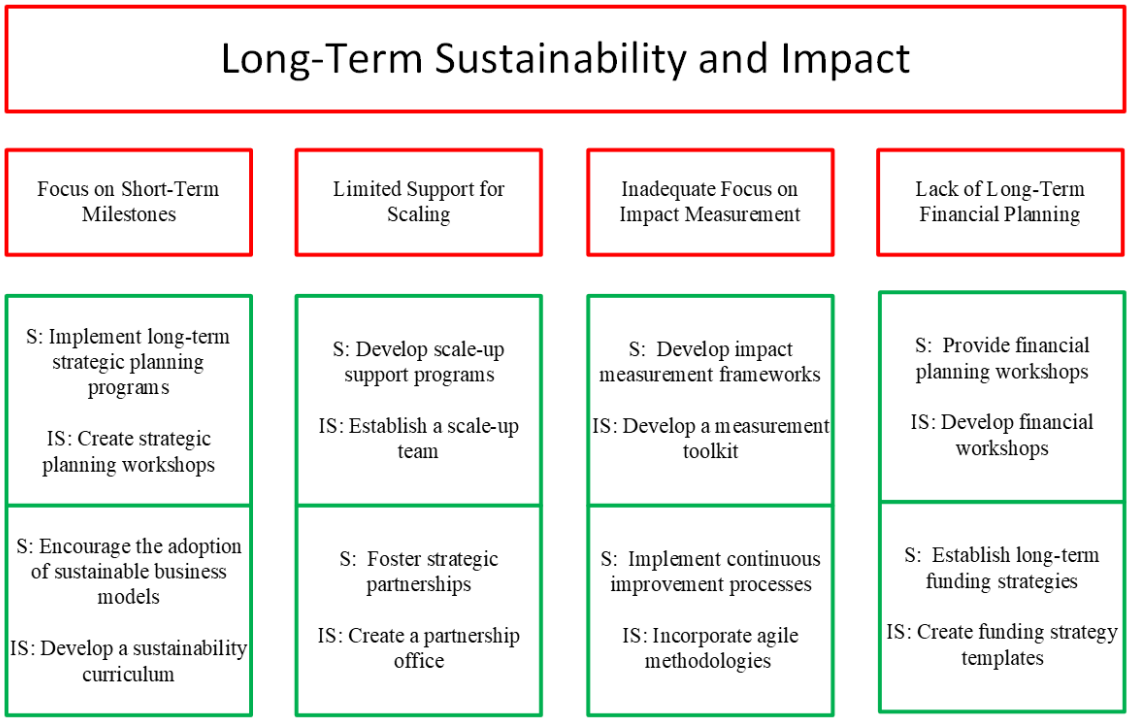


Figure 36 Long-term sustainability and impact challenge, contributing challenges, and solutions

4.6. MedTech entrepreneurship ecosystem model

The current MedTech entrepreneurship ecosystem model in Figure 38, is presented as a fragmented landscape characterized by weak connections and limited collaboration between key actors such as startups, incubators, universities, hospitals, and service providers. Startups often face challenges in navigating the complex ecosystem, limiting their growth potential and scalability.

Limited Access to Resources by Startups

Startups are often confined to the incubator in which they reside, restricting access to resources and services provided by other incubators. Innovation and growth are hampered by this insular approach, as the full breadth of facilities available within the broader ecosystem is unable to be leveraged (47). The network of VCs and angel investors known to startups is often sparse and difficult to navigate. Significant time and resources must be invested by startups in identifying lead investors, their past investments, and the sectors in which they operate, leading to inefficiencies in securing funding (60).

From the current model provided and the overall context of the MedTech entrepreneurship ecosystem, additional insights have been identified that highlight weak collaborations, lack of resource sharing, and the absence of solid networks and categorized lists of ecosystem actors.

Various nodes representing actors (startups, incubators, service providers, investors, etc.) are shown in the image, with lines indicating connections. However, relatively sparse connections are depicted. It is suggested that startups do not have direct access to a broader network of mentors, accelerators, and incubators beyond their immediate/resided incubator or accelerator, limiting collaboration and cross-pollination of ideas and resources across the ecosystem.

Independent Operations of Accelerators

Accelerators are typically functioned independently, with little collaboration observed among other incubators (hospital or university-based). The sharing of valuable resources and services that could be mutually beneficial is prevented by this isolation (26). Resource utilization could be enhanced by collaboration between accelerators and incubators, allowing startups to access accelerator programs at critical stages of their development. Fund optimization for both incubators and accelerators would be achieved through this collaboration.

The diagram shows accelerators loosely connected to incubators, particularly hospital and university incubators, acting separately and in parallel. It is indicated that missed opportunities arise for startups to utilize the specialized programs and services provided by accelerators. The separation between accelerators and incubators without structured collaboration leads to duplicated efforts and missed opportunities for efficiency and cost-effectiveness.

Gaps in Mentorship

Mentors are usually accessible only through specific incubators or accelerators, and specialization in certain sectors is often lacking. Additionally, many mentors may lack an entrepreneurial mindset, limiting their effectiveness in guiding startups (26). It is also observed that incubators and accelerators themselves face difficulties in finding sector-specific and expert mentors to join their programs, further compounding the issue. Better sector-specific advice and entrepreneurial guidance could be provided by a more structured and accessible mentorship network across incubators and accelerators (161).

The absence of a strong mentor network is evident from the image, as mentors are shown as separate entities, connected only to the incubators or accelerators they work with but not directly to startups or other ecosystem actors. It is indicated that the lack of a robust mentorship network, combined with the difficulty incubators and accelerators have in finding suitable mentors, constrains startups' access to practical guidance when needed.

Weak Collaborations Between Hospital and University Incubators

Collaborations between hospital and university incubators are limited to specific programs, with no consistent resource sharing observed. This results in inefficiencies, particularly in the area of clinical trials, where hospital incubators play a crucial role (161). Medical PIs are typically accessible only through hospital incubators, leaving startups with limited access to relevant medical expertise. A more integrated approach could facilitate smoother clinical trial processes and better access to medical professionals.

In the diagram, hospital and university incubators are depicted as operating separately, with limited and inconsistent interaction. Resource sharing across both types of incubators is inhibited, leading to inefficiencies in clinical trials and limited access to specialized research expertise.

Disconnect Between Service Providers and the Ecosystem

Service providers struggle to become known within the MedTech ecosystem, including those in the regulatory, legal, supply chain, market research, reimbursement, project management, market entry, human resources, health IT, business development, patient recruitment, MedTech recruitment, etc. A centralized list of service providers familiar with the ecosystem and willing to work with available funding programs is often unavailable to startups (47). Startups must spend additional time and resources identifying service providers who can meet their specific needs, creating barriers to growth.

The diagram shows service providers as a single entity but without a centralized directory. It is suggested that the lack of visibility into service providers specializing in MedTech makes it difficult for startups to find providers that understand the ecosystem's unique challenges and funding mechanisms, forcing startups to allocate extra resources to identify relevant providers.

Challenges in Collaborating with Large MedTech Companies

Access to large MedTech companies that are interested in working with startups is often a time-consuming process for startups, requiring potential collaborators to be identified on a case-by-case basis. No consolidated list of potential large MedTech companies categorized by sector exists, limiting the ability of startups to form strategic partnerships. Formal collaboration programs with large companies, which are often limited in scope and opportunity, are typically relied upon by startups.

The connection between startups and large MedTech companies is shown as particularly weak in the diagram. No categorized list of large companies interested in collaboration is available, and startups must independently identify potential partners, often resulting in missed opportunities for partnerships or access to critical resources.

Challenges with Venture Capital and Angel Investors

The connections between startups and VCs/angel investors are shown as weak, reflecting the challenge faced by startups in navigating the venture capital landscape. A condensed network or categorized list of investors that makes it easy for startups to find the right investor at the right stage is lacking. Significant resources must be invested by startups to identify relevant investors, investors who were lead investors, assess past investments, and determine alignment with their needs, leading to inefficiencies (60).

Search for Non-Dilutive Funding

Due to the high volum of tasks in startups that are assigned to the few employees they have, sometimes personnel must be allocated by startups to search for non-dilutive funding sources, including grants, awards, competitions, loans, and wage subsidies. A centralized or categorized list of funding opportunities is unavailable, forcing startups to look through each program's eligibility and criteria manually. This challenge is particularly pronounced for first-time entrepreneurs, leading to missed opportunities and wasted resources (60).

Bubbles representing non-dilutive funding (grants, awards, loans, etc.) in the diagram indicate that startups must independently search for and evaluate each funding source. A centralized list is lacking, meaning significant time and resources must be devoted by startups to identifying funding opportunities.

The current MedTech entrepreneurship ecosystem suffers from weak network connections, with limited collaboration across key actors and resource sharing deficiencies, which hinder the flow of resources and ideas. The ecosystem is also unstructured, lacking categorized lists of service providers, mentors, investors, and MedTech companies, making it difficult for startups to find relevant collaborators and resources. These challenges highlight the need for greater integration, structured collaboration, and categorization.

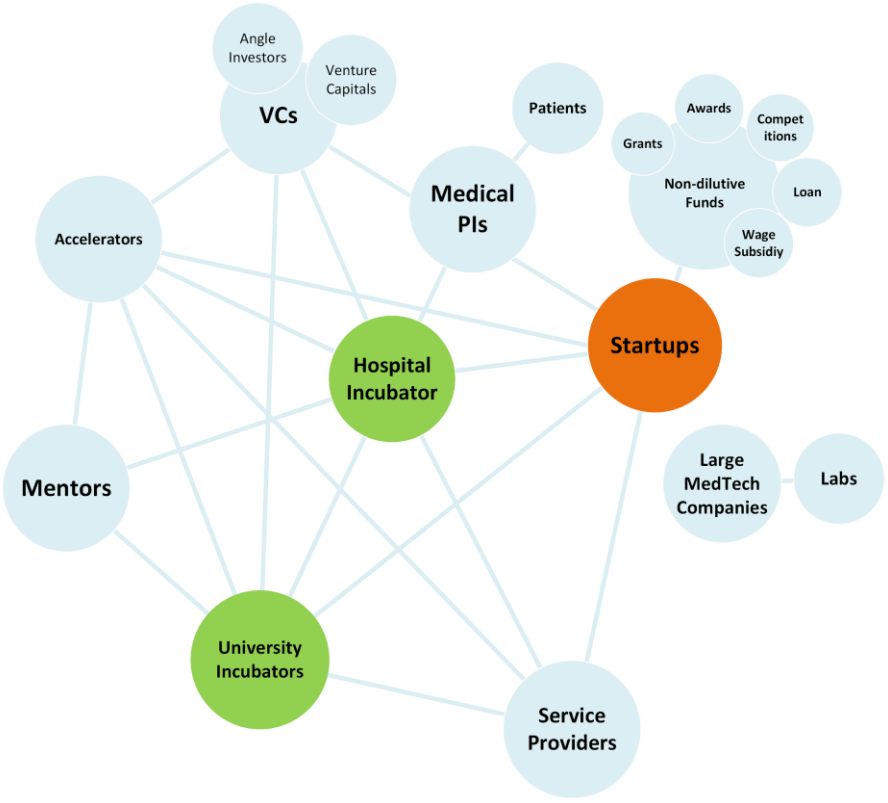


Figure 37 Current MedTech entrepreneurship ecosystem model

The proposed model of the MedTech entrepreneurship ecosystem in Figure39 reveals critical improvements in the network structure, addressing several deficiencies and challenges identified in the previous fragmented model. Below is an analysis based on each section of the current model described above:

Weak Network Connections

The proposed model demonstrates a significant enhancement in connectivity between key actors, including incubators, accelerators, service providers, and capital networks. In the current ecosystem, limited collaboration across actors is a significant challenge, but the proposed diagram shows the establishment of clear and structured links between these players. This enables a smoother flow of resources, information, and collaboration, fostering more robust interconnections that benefit startups.

Current model: Startups were confined to the incubators they resided in, with sparse connections to other actors in the ecosystem.

Proposed model: The model enables cross-incubator and cross-accelerator access, allowing startups to leverage resources from the entire network.

Limited Access to Resources by Startups

Previously, startups were constrained by their incubator's resources and services, which restricted innovation and growth. In the updated diagram, startups are now connected to a Hospital Incubator Network and a University Incubator Network, along with a Specialized Mentors Network and access to service providers through categorized networks. The platform addresses these issues by providing startups with more diverse access to expertise, facilities, and services beyond their immediate incubator.

Current model: Startups had limited access to resources outside their resident incubator.

Proposed model: Startups can now access facilities, services, and expertise across an integrated network of incubators, universities, and specialized mentors.

Independent Operations of Accelerators

The previous system was characterized by isolated accelerators operating independently of hospital and university incubators, leading to missed opportunities for resource sharing and collaboration. The new model fosters stronger connections between accelerators and incubators (both hospital and university); Accelerators are now integrated within the broader network, allowing startups to take advantage of specialized programs, services, and resources when necessary at the right time.

Current model: Accelerators worked in isolation with limited collaboration with hospital and university incubators.

Proposed model: Structured collaboration between accelerators and incubators is established, enhancing resource-sharing and efficiency.

Gaps in Mentorship

The initial model showed weak connections between mentors and startups, with incubators and accelerators struggling to find sector-specific mentors. In the proposed diagram, a Specialized Mentors Network has been introduced, connecting mentors to both startups and other ecosystem actors. This network allows incubators and accelerators to tap into a broader pool of experienced and specialized mentors, addressing previous gaps in mentorship and improving sector-specific guidance.

Current model: Mentors were only accessible through specific incubators or accelerators, with limited sector-specific expertise.

Proposed model: A dedicated Specialized Mentors Network provides more structured and accessible mentorship opportunities, including sector-specific and expert guidance.

Weak Collaborations Between Hospital and University Incubators

The previous model displayed weak collaboration between hospital and university incubators, with limited resource-sharing for critical activities like clinical trials. The updated ecosystem shows that hospital incubators and university incubators are now part of a cohesive network, enabling startups to access specialized resources such as clinical expertise, facilities, and research labs. This integration facilitates smoother collaboration, particularly in clinical trials and medical research.

Current model: Hospital and university incubators operated separately, resulting in inefficiencies.

Proposed model: The Hospital Incubator Network and University Incubator Network are connected, improving resource-sharing and facilitating clinical trials and other critical collaborations.

Disconnection Between Service Providers and the Ecosystem

Service providers were previously operating in silos, with no centralized directory for startups to access regulatory, legal, or market-entry services. In the updated model, service providers are integrated into the ecosystem through the Service Providers Network, making it easier for startups to find and collaborate with providers who specialize in MedTech and understand funding mechanisms. This centralized network increases visibility and reduces the time startups need to find relevant service providers.

Current model: Service providers were difficult to find, and startups lacked a centralized directory for specialized services.

Proposed model: The Service Providers Network offers a centralized system for startups to access relevant services, reducing barriers to growth.

Challenges in Collaborating with Large MedTech Companies

Collaboration with large MedTech companies was a challenge due to the absence of a categorized list of interested companies. In the updated diagram, large MedTech companies are now linked to

startups through the platform, providing easier access to market opportunities, credibility, and collaboration for product development. The platform makes these companies more visible and accessible, allowing startups to form strategic partnerships more efficiently.

Current model: Startups had to identify potential collaborators on a case-by-case basis, often leading to missed opportunities.

Proposed model: Large MedTech companies are more integrated into the ecosystem, offering startups structured collaboration opportunities.

Challenges with Venture Capital and Angel Investors

The previous ecosystem was characterized by a weak network of VCs and angel investors, making it difficult for startups to identify relevant investors and secure funding. The updated diagram shows the creation of a Categorized VC Network that connects startups with previous lead investors, venture capitalists, and angel investors. This structured network reduces the time and effort required for startups to find the right investors and increases their chances of securing appropriate funding.

Current model: Startups faced difficulties in identifying and securing funding from relevant investors.
Proposed model: A Categorized VC Network streamlines access to investors, providing startups with a more structured and efficient funding process.

Search for Non-Dilutive Funding

Previously, startups sometimes needed to allocate personnel to manually search for non-dilutive funding opportunities such as grants, awards, competitions, loans, and wage subsidies, resulting in wasted time and resources. The updated diagram includes a categorized non-dilutive funds section, making it easier for startups to navigate and apply for funding without requiring exhaustive searches. This centralized resource significantly reduces inefficiencies.

Current model: Startups had to manually search for non-dilutive funding, often missing opportunities.

Proposed model: A Categorized Non-Dilutive Funds section centralizes available funding sources, saving time and increasing startups' ability to secure appropriate funding.

Overall Improvements

The MedTech entrepreneurship ecosystem has been significantly enhanced with the proposed model, addressing critical issues such as weak network connections, resource-sharing deficiencies, and the lack of structured collaboration. Categorized lists of actors such as VCs, mentors, and service providers have been introduced, fostering greater transparency and efficiency. The ecosystem's overall efficiency and effectiveness have been improved by better integration and facilitation of collaborations through a more cohesive and structured network.

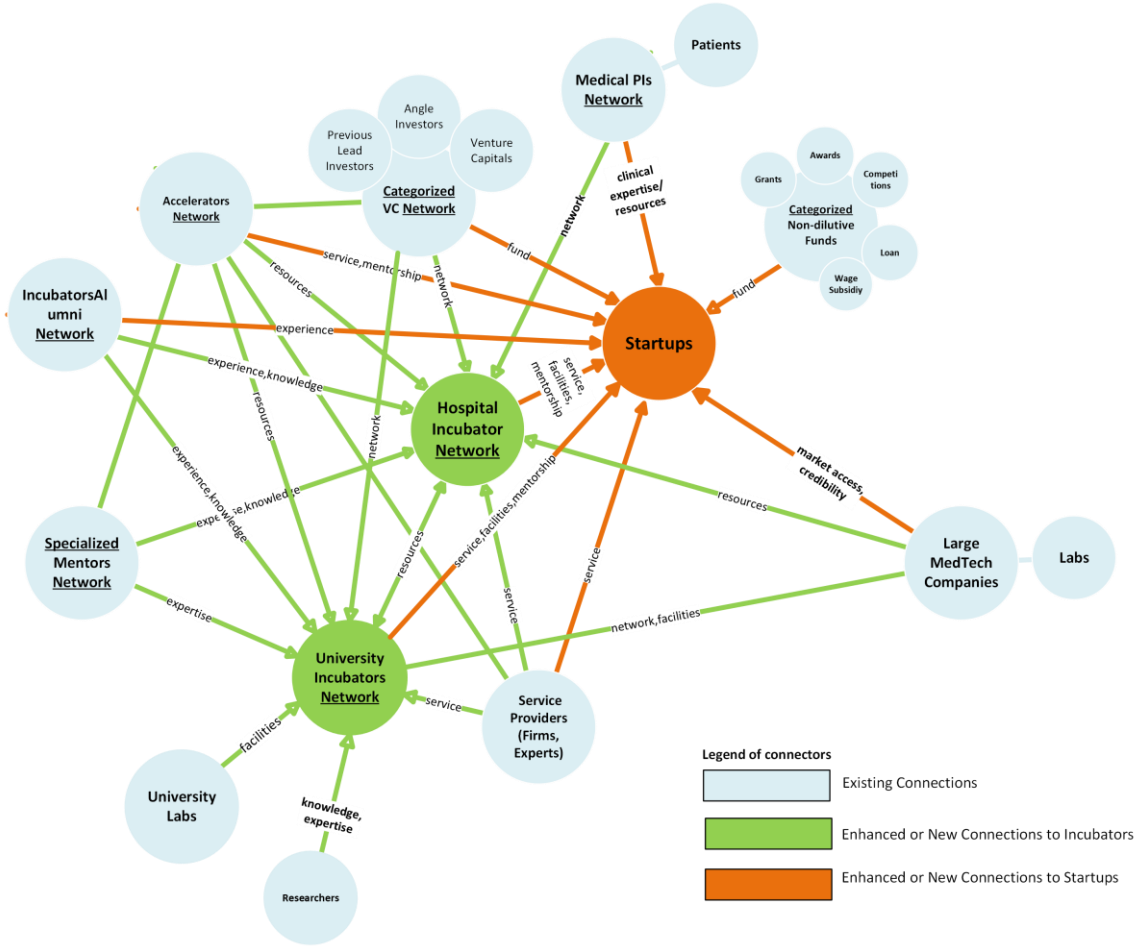


Figure 38 Proposed MedTech entrepreneurship ecosystem model

4.7. Addressing Challenges through the Proposed Model and Platform

Most of the challenges mentioned in the literature review and identified by the interview can be addressed through the proposed model applied in the platform as outlined below:

Fragmented Ecosystem: The platform connects key ecosystem actors within a centralized system. Offering tailored recommendations and fostering collaboration bridges gaps in communication and coordination, reducing fragmentation within the ecosystem.

Global Market Access: Navigating international markets becomes more manageable as the platform provides resources for regulatory guidance, cultural training, and logistical support. It connects users with international mentors and market entry experts to help manage complexities and promote global expansion.

Reimbursement and Health Economics: The platform offers training modules, expert consultations, and mentorship on health economics and reimbursement strategies. Centralizing these resources helps startups navigate the reimbursement landscape more easily and efficiently.

Regulatory Environment: By providing access to regulatory experts, training programs, and a repository of best practices, the platform enables startups to effectively address regulatory challenges. Tailored recommendations connect users to specific resources, streamlining regulatory compliance.

Access to Capital: Matching startups with investors open to high-risk ventures and connecting them to funding opportunities designed to cover regulatory costs, the platform helps mitigate financial barriers and simplifies the fundraising process.

Market Adoption: The platform facilitates connections between startups and healthcare providers who are early adopters of new technologies while also providing market entry strategies and success stories that help overcome resistance and penetrate the market.

Integration with Healthcare Systems: Providing resources on data integration and interoperability standards, the platform helps startups ensure their technologies are seamlessly integrated into existing healthcare systems, reducing friction during implementation.

Stakeholder Engagement: The platform enhances engagement by connecting startups with healthcare stakeholders, including those with real-world clinical experience. This allows startups to gain practical insights and build relationships with relevant stakeholders.

Cybersecurity and Data Privacy: Startups are supported with access to cybersecurity resources, expert consultations, and best practices for data privacy. The platform addresses security concerns and provides the necessary tools to meet compliance standards.

Resource Allocation Challenges: The platform connects startups to a wide network of physical and virtual lab facilities and incubators with the necessary resources, ensuring they have adequate support for development.

Mentorship Quality: The platform matches startups with mentors who have expertise in MedTech, entrepreneurship, and relevant industry experience. This improves the quality of mentorship and ensures startups receive sector-specific guidance.

Customizable Mentorship Programs: Tailored mentorship programs allow startups to specify their needs and be matched with mentors best suited to their development stage and focus area, providing better support and advice.

Time Constraints: Access to project management tools, training, and external support helps startups efficiently manage projects and meet deadlines, alleviating time management issues.

Cultural Fit: The platform offers resources on cultural fit and communication best practices, enabling connections between organizations with aligned values and communication styles and fostering better collaboration.

Follow-Up Support: Structured follow-up programs and alumni networks provide ongoing resources and mentorship beyond the incubation period, ensuring long-term support and development for startups.

Tailored Business Development: Industry-specific business development resources, including market access strategies and access to relevant networks, help startups successfully navigate market challenges.

Clinical Trial Design and Management: The platform connects startups with experts in clinical trial design and management while providing tools for addressing patient recruitment and data management, ensuring efficient and compliant trial execution.

Supply Chain and Logistics: Supply chain management resources and expert consultations are made available through the platform, helping startups navigate logistical challenges and streamline their operations.

Talent Acquisition and Retention: Access to talent pools, recruitment resources, and retention strategies helps startups attract and retain specialized personnel crucial to their success.

Feedback and Iteration Cycles: The platform facilitates connections with healthcare professionals for feedback and provides access to facilities for iterative testing and prototyping, enabling continuous product improvement.

Access to Advanced Manufacturing Technologies: The platform offers connections to advanced manufacturing facilities and funding opportunities to cover associated costs, ensuring startups have the tools needed to scale.

Long-Term Sustainability and Impact: Resources and mentorship focused on long-term planning and sustainability help startups move beyond immediate milestones, fostering lasting success and industry impact.

Mental Health Support: Mental health resources, support groups, and wellness programs tailored to the unique stresses of startup life are provided, helping entrepreneurs maintain their well-being.

Legal and Accounting Support: The platform offers access to legal and accounting services, including templates and consultations, ensuring startups remain compliant and managing their financial operations effectively.

Wrong Selection of Incubators: The platform's tailored matching process ensures that startups are paired with suitable incubators and resources, reducing the likelihood of mismatches and optimizing their chances of success.

By addressing these challenges, the platform offers comprehensive support to MedTech startups and other actors within the ecosystem, helping them overcome critical barriers and improve their chances of long-term success.

4.8. Survey Design and Analysis

To support the validation of the proposed collaboration model, a survey was designed and distributed to stakeholders across the MedTech entrepreneurship ecosystem. The aim of the survey was not to validate the digital platform itself, but rather to evaluate the relevance, practicality, and perceived effectiveness of the solutions and components outlined in the conceptual collaboration model. A total of 40 experts were contacted through LinkedIn and email, with 26 completing the survey. Respondents were selected using purposive sampling to ensure representation from key stakeholder groups, including MedTech startup founders, incubator managers, innovation program directors, investors, healthcare professionals, and regulatory consultants. The sample included individuals based in Canada, the Middle East, and Europe to enhance diversity and perspective. The survey included 15 multiple-choice and scaled questions alongside 3 open-ended questions, allowing for both quantitative and qualitative feedback. Responses were analyzed to assess stakeholder alignment with the proposed model, identify commonly supported solutions, and gather insights into areas requiring refinement. Detailed survey questions are included in Appendix C: Pre-Survey Description and Survey Questions.

The survey was distributed electronically through LinkedIn and Email to various MedTech ecosystem actors, including startups, incubators, investors, VCs, and non-dilutive funding providers. Participants represented a wide array of roles, from founders and CEOs to researchers, clinical trial managers, and technical experts. This broad selection ensured a comprehensive understanding of the platform's impact across various stakeholder groups.

The survey was open for responses over a period of several weeks, allowing ample time for participants to provide feedback. The closed-ended questions focused on evaluating the platform’s effectiveness in areas such as collaboration, capital access, resource availability, and partner selection. Meanwhile, the open-ended questions were used to collect qualitative insights on areas for improvement, innovation, and potential expansion beyond the MedTech field.

Data analysis involved the use of both descriptive and thematic methods:

- Descriptive percentages were used to summarize responses and provide an assessment of the platform’s perceived effectiveness. Key metrics, such as the percentage of respondents rating the platform as "Effective" or "Very effective," were calculated.

- Thematic analysis was applied to the qualitative responses to identify recurring themes related to collaboration, capital access, and regulatory challenges.

Ethical Considerations for Survey Participants

The survey in this study does not include sensitive questions or require participants to share personal information; ethical considerations remain essential.

4.9. Survey Analysis

The survey respondents represent a diverse range of job positions and roles across the MedTech ecosystem, primarily based in Canada, with some in Europe and the Middle East. Leadership roles, such as Founder & CEO, Cofounder, and Managing Director, highlight the platform's potential audience in the startup sector. Additionally, respondents from research and academia, including postdoctoral fellows, assistant professors, and research analysts, show the platform's reach to innovation and academia. Technical roles like UX Designers, Embedded Firmware Engineers, and Clinical Trial Managers further illustrate the variety of participants engaging with the platform. As Figure 39 The survey respondents' job positions presents, notably, 39.13% of respondents are involved in startups, with others from project management, VCs, and non-dilutive funding providers (4.35% each), indicating a broad spectrum of stakeholders.

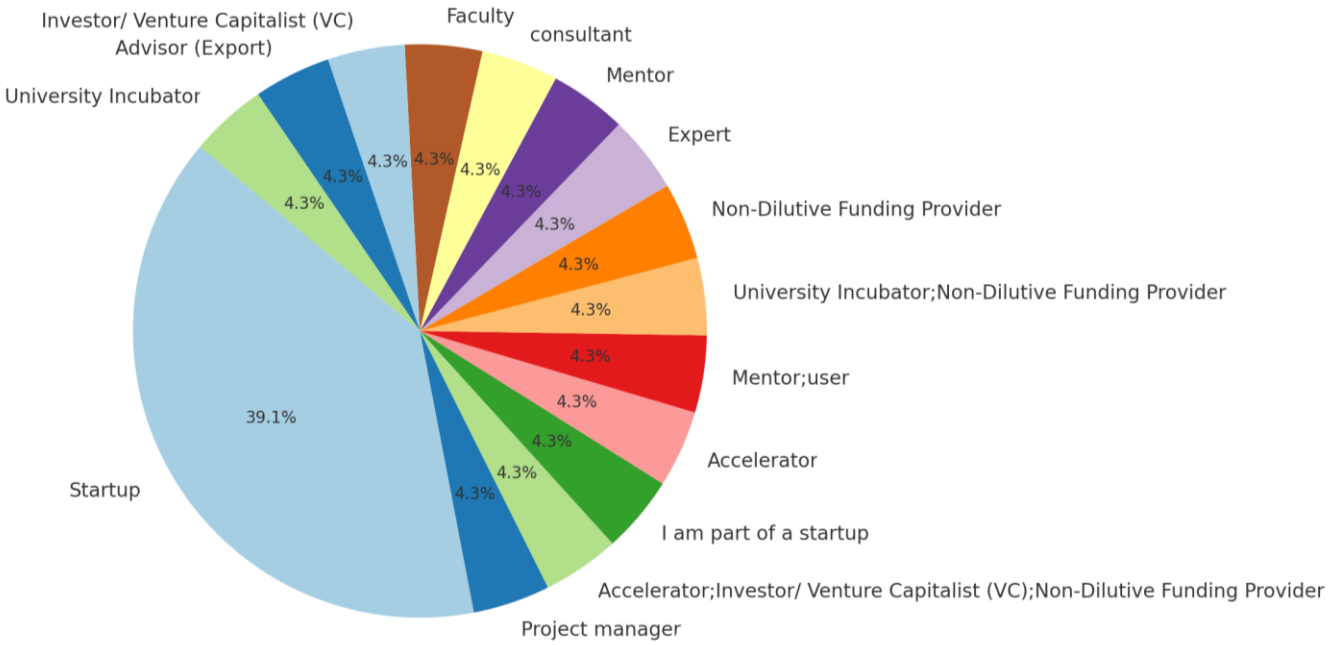


Figure 39 The survey respondents' job positions

Innovativeness of the Platform

The fact that 77.3% of respondents have not encountered a similar collaboration platform highlights the innovativeness of this platform in the MedTech ecosystem. This suggests that the platform is addressing a significant gap where a unified space for collaboration, networking, and resource access is either missing or underutilized.

For those who have used comparable platforms, the feedback referred to specific regional or specialized platforms (e.g., Nova Scotia Health, Admare), indicating that these may serve more niche or localized needs, whereas the proposed platform offers broader, more comprehensive solutions on a larger scale. The platform's novel approach to consolidating stakeholders and offering tailored support and resources fills an unmet need, particularly for startups and professionals who have not previously had access to such tools.

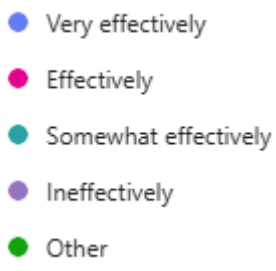
Effectiveness of the Platform

Survey participants provided mixed but generally positive feedback on the platform’s effectiveness in addressing key challenges:

Collaboration, as shown in Figure 40: A significant portion (54%) rated the platform as "Effective" and "Very effective", indicating its strong role in fostering collaboration and bridging gaps between startups and key stakeholders.

Access to Resources, as shown in Figure 42: The majority (35%) found the platform "Effective" in helping startups access resources, with 27% rating it as "Very effective." This indicates that the platform is perceived positively for supporting access to critical resources like mentors and services.

Capital Access, as shown in Figure 43: Respondents offered varied opinions on the platform's ability to support capital acquisition. While 46% rated it "Somewhat effective," 31% found it "Effective," and 15% rated it "Very effective," indicating that there is room for improvement in facilitating connections with investors.



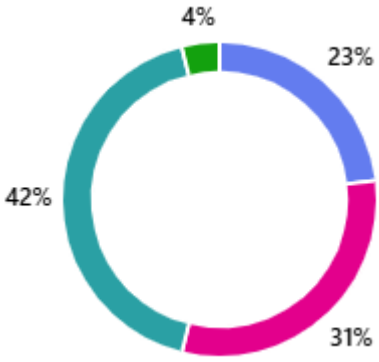


Figure 40 Effectiveness of the platform in facilitating collaborations

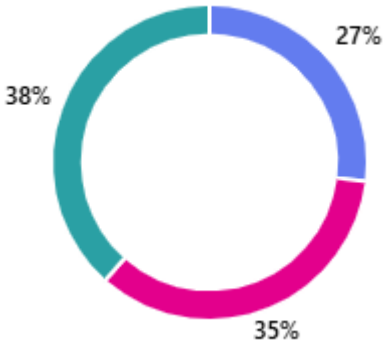


Figure 41Effectiveness of the platform in helping startups access resources

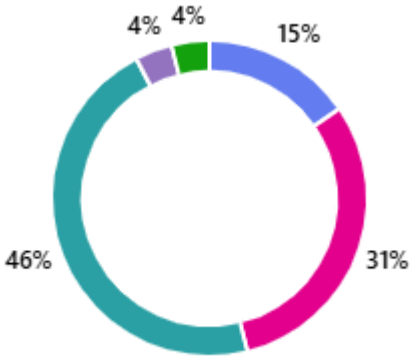


Figure 42 Effectiveness of the platform in supporting startups to secure capital

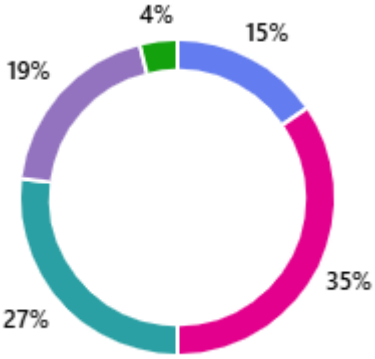


Figure 43 Effectiveness of the platform in bridging gaps between startups and large MedTech companies

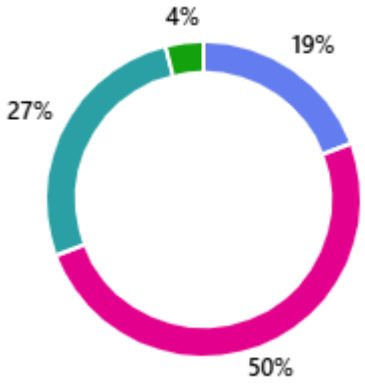


Figure 44 Effectiveness of the platform in facilitating ea access to service providers

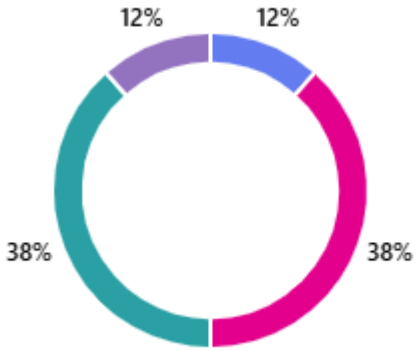


Figure 45 Effectiveness of the platform in minimizing wrong partner selection

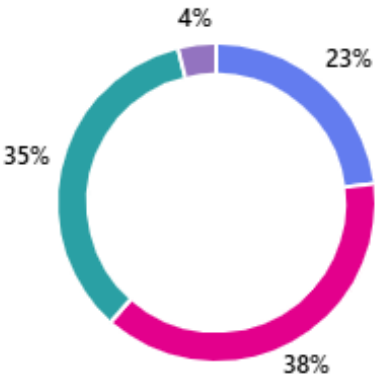


Figure 46 Effectiveness of the platform in assisting startups to identify and connect with suitable accelerators

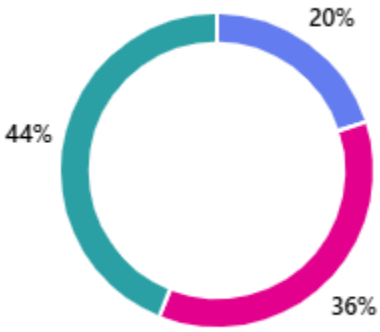


Figure 47 Effectiveness of the platform in transforming the MedTech ecosystem

Bridging Gaps with Large Companies, as shown in Figure 44: The majority (35%) believe the platform is "Effective" in overcoming barriers to market adoption. A significant portion (15%) rated it as "Very effective," while 27% felt it was "Somewhat effective." Interestingly, 19% rated the platform as "Ineffective," indicating room for improvement. Additionally, one respondent provided a simple "Yes," affirming the platform's potential without specifying the level of effectiveness.

Service Provider Access as shown in Figure 44: Nearly half (50%) of respondents found the platform "Effective" in improving access to service providers (e.g., regulatory, legal, and supply chain), though 27% rated it "Somewhat effective," suggesting that this area could be further refined.

Partner Selection, as shown in Figure 46: The platform's strength in minimizing wrong partner selection through better matching criteria received mixed feedback. While 38% rated it "Effective," an equal percentage found it only "Somewhat effective," indicating the need for further refinement.

As shown in Figure 47, the platform's ability to assist startups in identifying and connecting with the most suitable accelerators aligned with their development stage received largely positive feedback. The majority (38%) found it "Effective," with 23% rating it as "Very effective." A smaller percentage (35%) rated it as "Somewhat effective," while only 4% considered it "Ineffective."

The platform's effectiveness in transforming the overall MedTech ecosystem, by improving collaboration, access to resources, and efficiency received mixed responses as Figure 48. A significant portion (36%) of respondents rated the platform as "Effective," and a percentage (44%) rated it as "Somewhat effective." A smaller but notable group (20%) found the platform "Very effective."

The platform's potential to address key challenges within the MedTech ecosystem is highlighted by several areas where respondents see significant impact. The most identified challenge is the fragmented ecosystem (19 respondents, 73%), which indicates a lack of collaboration between key stakeholders. Additionally, integration with healthcare systems (15 respondents, 57%) and access to capital and funding (15 respondents, 57%) were seen as critical areas the platform could improve. Navigating regulatory environments (13 respondents, 50%) and access to global markets (10 respondents, 38%) also stand out as significant challenges the platform could help address. Other important areas include clinical trial design and management (11 respondents, 42%) and tailored business development services, supply chain, and cybersecurity (11 respondents, 42%).

Based on the responses, the most significant improvement brought by the platform regarding ecosystem collaboration appears to be its ability to bring all stakeholders into one place and categorize them effectively. This consolidated approach helps overcome the fragmented nature of the MedTech ecosystem by facilitating partnerships between health professionals and the private sector, accelerating innovation and translational research. Additionally, the platform’s role in streamlining communication between startups, funding providers, and medical researchers enhances networking opportunities and resource mobilization.

Several respondents highlighted the platform’s strength in matching partners more effectively, reducing the risk of wrong selections and ensuring better-aligned collaborations. However, some feedback indicates that large organizations might not fully engage with such systems and that human involvement remains essential for building trust and navigating the regulatory landscape. Overall, the

platform is recognized for improving access to critical resources, enhancing networking, and helping startups connect to global markets and government procurement opportunities.

In reviewing the responses regarding areas, the platform hasn't addressed or could improve, several key themes emerge:

Comprehensive Coverage: Many respondents believe the platform is already highly comprehensive, with no significant gaps in addressing actors or areas of the ecosystem. Some expressed satisfaction with the platform's breadth, with comments like "very comprehensive so far" and "It seems all sectors are already covered."

Venture Capital Access: A few respondents noted that access to venture capital could be an area of improvement. This highlights the need for enhanced connectivity to funding opportunities, particularly for startups seeking early-stage investment.

Political Influence and Decision Makers: One respondent pointed out the significant influence of political players in Canada, particularly in decisions related to core systems like EMRs and EHRs. This suggests that the platform could explore better integration or influence in these politically controlled areas.

Expanding User Base: There are suggestions for including non-hospital users or buyers of technology, as well as direct access for graduate students to help cultivate new entrepreneurs. Expanding the user base beyond traditional actors may offer new opportunities for innovation.

Healthcare Professionals: Another point raised was the need to focus on the time-saving benefits for healthcare professionals. Ensuring that the platform considers the needs of healthcare providers and how they can benefit from it could improve its overall utility.

Analysis of Additional Comments:

The feedback provided highlights several key themes and suggestions for improving the platform:

Challenges with Engaging Large Organizations: Several respondents noted that engaging large organizations and health players in such platforms can be challenging. One comment pointed out that many large health players aren't even on LinkedIn, suggesting that regulatory hurdles and pathways to commercialization are often the most difficult pieces to navigate.

Expansion Beyond the Medical Field: One respondent raised the question of how the platform could be applied to industries beyond the medical field. This indicates that the platform's potential for broader use could be explored, possibly adapting its framework for other sectors.

Importance of Human Relationships: Some responses emphasized that the platform alone may not be sufficient to foster true collaboration. Human relationships and motivation for engagement are critical, as many players in the ecosystem already face time and resource constraints. This suggests that the platform should focus on incentivizing engagement and building trust among users.

Design and Practical Alignment: A few comments suggested that the platform’s design and clarity could be improved. One respondent noted that language use and practical application were not fully aligned, and the platform’s usability needs improvement to ensure it meets real-world demands.

Diversity and Global Collaboration: Another common theme was the need to increase diversity in funding opportunities, especially for non-dilutive funding sources. Respondents also highlighted the value of international collaboration, suggesting that diverse perspectives could drive medical technology innovation forward.

User Engagement and Sustainability: For the platform to be truly effective, user engagement is vital. One respondent pointed out that the platform needs a large, active user base to thrive, with users consistently adding content and being engaged. Without this, the platform’s effectiveness could be limited.

Thematic analysis revealed recurring themes such as collaboration, capital access, government involvement, mentorship, and regulatory support. Collaboration stood out as a key improvement, with respondents appreciating how the platform consolidates the ecosystem and facilitates partnerships. However, capital access was frequently cited as needing more attention, particularly for early-stage startups. Government involvement was another concern, with respondents calling for better support in navigating regulatory and policy challenges.

Sentiment analysis showed a generally positive attitude towards the platform, particularly in its ability to improve ecosystem collaboration and create new partnerships. However, concerns were raised about capital access and regulatory challenges, which were seen as areas needing further improvement. Overall, the platform was recognized as a valuable initiative, but respondents emphasized the importance of engaging larger organizations and ensuring user participation for it to achieve its full potential.

4.10. Validity and Reliability

Internal Validity (Transparency)

To ensure internal validity, the research process—from data collection to thematic coding—was documented in detail. Interview transcripts, coding decisions, and theme development were tracked and reviewed systematically to maintain transparency in interpretation.

Construct Validity (Corroboration)

Triangulation was employed by integrating data from literature, interviews, and survey validation. This process helped corroborate key findings and ensured that the derived themes reflected multiple perspectives within the MedTech ecosystem.

Reliability (Replicability of Coding and Analysis)

A consistent coding process was followed using manual thematic analysis. While no software was used, the coding structure was developed iteratively and reviewed several times for consistency. Sample coded excerpts were revisited to confirm the theme alignment.

External Validity (Generalizability)

Given the study's focus on the Canadian MedTech ecosystem—particularly Quebec—the findings are context-specific. However, many challenges identified (e.g., regulatory gaps, mentorship needs) reflect broader issues reported globally, which may support cautious transferability to similar innovation ecosystems.

Chapter 5. Conclusion, Limitations, Future Study

This thesis has provided an in-depth exploration of the collaborative challenges and support gaps faced by MedTech startups within the broader entrepreneurship ecosystem, focusing on their interactions with incubators. The findings reveal that MedTech startups encounter specific obstacles related to regulatory requirements, fragmented resources, limited access to sector-specific mentorship, etc. These challenges hinder their ability to progress efficiently, highlighting limitations within incubation models that lack the tailored support MedTech startups require.

In response, a model and digital platform were developed to foster collaborative networks, streamline regulatory guidance, and centralize resource access for these startups. This model emphasizes structured support to bridge the gaps between startups and incubators, promoting a cohesive and effective environment for MedTech innovation. While the proposed platform holds significant promise, it remains theoretical; its practical impact and scalability have yet to be tested in real-world settings.

The study has limitations that should be considered. Findings were based on specific samples of interviewees and survey respondents, which may limit generalizability. The thematic analysis, while rigorous, involved subjective interpretation, and the research focused mainly on certain ecosystem actors, omitting perspectives from some stakeholders, such as policymakers and end-user healthcare providers. Additionally, as the model and platform have not been applied in practice, the research cannot fully assess their operational effectiveness.

As the recommendations were partially developed based on the researcher's synthesis of themes and contextual understanding, some degree of interpretive bias may be present. To minimize this, triangulation with interview data, literature references, and survey feedback was used where possible. Still, future research should aim to co-create strategies with stakeholders to further validate their applicability.

Given that healthcare in Canada is managed provincially, the feasibility of implementing some solutions—such as cross-institutional data sharing or regulatory alignment—may vary between provinces. The Quebec healthcare system's centralization presents both opportunities and limitations for enacting these recommendations.

Future research should focus on implementing pilot programs to evaluate the platform's real-world applicability across diverse regions and regulatory environments. Expanding the model's testing phase to include feedback from additional stakeholders, such as healthcare providers and

policymakers, would provide a more holistic view of its potential impact. Moreover, future studies could explore technological enhancements, such as remote mentorship and virtual resource access, to adapt the platform for an evolving digital healthcare landscape. These steps will be essential to validate and refine the model, ensuring it effectively supports MedTech startups in navigating complex challenges and advancing healthcare innovation.

References

1. Mark Wasmuth Secretary General GMDN Agency. Global Medical Device Nomenclature Gmdn Who Pdf. 2022.

2. Robert S Kaplan 1 MEP. How to solve the cost crisis in health care. 2011;

3. Stern S. Innovation and entrepreneurship in the medical device industry: A worldwide perspective. J Med Eng Technol. 2014;38(5):273–80.

4. Schumpeter JA. The Theory of Economic Development: An Inquiry into Profits, Capital, Credit, Interest, and the Business Cycle. Harvard University Press; 1934.

5. Oslo M. Guidelines for collecting, reporting, and using data on innovation: The measurement of scientific, technological and innovation activities. Luxembourg: OECD Publishing, Paris: Eurostat. 2018;

6. Damanpour F, Gopalakrishnan S. The Dynamics of the Adoption of Product and Process Innovations in Organizations. Journal of Management Studies. 2001 Jan 16;38(1):45–65.

7. Naidoo V. Firm survival through a crisis: The influence of market orientation, marketing innovation and business strategy. Industrial Marketing Management. 2010 Nov;39(8):1311–20.

8. Damanpour F, Aravind D. Organizational Structure and Innovation Revisited. In: Handbook of Organizational Creativity. Elsevier; 2012. p. 483–513.

9. Michael E. Porter and Thomas H. Lee. The Strategy That Will Fix Health Care. 2013;

10. Mullis KB. The Unusual Origin of the Polymerase Chain Reaction. Sci Am. 1990 Apr;262(4):56–65.

11. Torous JB, Chan SR, Yellowlees PM, Boland R. To Use or Not? Evaluating ASPECTS of Smartphone Apps and Mobile Technology for Clinical Care in Psychiatry. J Clin Psychiatry. 2016 Jun 22;77(06):e734–8.

12. Reis ME, Bettencourt A, Ribeiro HM. The regulatory challenges of innovative customized combination products. Front Med (Lausanne). 2022 Jul 22;9.

13. Rosen J, & MH. The driving forces behind the growth of the US medical device industry. Expert Rev Med Devices. 2015;12(1):1–4.

14. Torous J, Stern AD, Bourgeois FT. Regulatory considerations to keep pace with innovation in digital health products. NPJ Digit Med. 2022 Aug 19;5(1):121.

15. Zhang K, Kumar G, Skedgel C. Towards a New Understanding of Unmet Medical Need. Appl Health Econ Health Policy. 2021 Nov 18;19(6):785–8.

16. Collins FS, Varmus H. A New Initiative on Precision Medicine. New England Journal of Medicine. 2015 Feb 26;372(9):793–5.

17. Shaver J. The State of Telehealth Before and After the COVID-19 Pandemic. Primary Care: Clinics in Office Practice. 2022 Dec;49(4):517–30.

18. Sood R, BR, & VR. Improving sustainability in the healthcare sector: From theory to practice. J Environ Health Sci Eng. 2014;12(1):43.

19. Kaplan S. Discontinuities and senior management: assessing the role of recognition in pharmaceutical firm response to biotechnology. Industrial and Corporate Change. 2003 Apr 1;12(2):203–33.

20. Bosma N, Hill S, Ionescu-Somers A, Kelley D, Guerrero M, Schøtt T, et al. Global Entrepreneurship Monitor. 2020/2021 Global Report. 2021.

21. Hart MA. The Lean Startup: How Today's Entrepreneurs Use Continuous Innovation to Create Radically Successful BusinessesEricRies. New York:

Crown Business, 2011. 320 pages. US$26.00. Journal of Product Innovation Management. 2012 May 19;29(3):508–9.

22. Wolfe D. Knowledge, learning and social capital in Ontario's ICT clusters.

23. Deloitte. Innovation in MedTech: Key to Improving Health Outcomes. Retrieved from https://www2.deloitte.com. 2019;

24. Peters L, Rice M, Sundararajan M. The Role of Incubators in the Entrepreneurial Process. J Technol Transf. 2004 Jan;29(1):83–91.

25. Scanlon KJ, Lieberman MA. Commercializing medical technology. Cytotechnology. 2007 Apr 28;53(1–3):107–12.

26. Cohen S, Hochberg Y. Accelerating Startups: The Seed Accelerator Phenomenon. SSRN Electronic Journal. 2014 Jan 1;

27. Kulkov I, Hellström M, Wikström K. Identifying the role of business accelerators in the developing business ecosystem: the life science sector. European Journal of Innovation Management. 2021 Jul 13;24(4):1459–79.

28. Braly AR. The impact of angel investors on founders of new ventures in the medical technology industry. Massachusetts Institute of Technology; 2011.

29. Lehoux P, Miller FA, Daudelin G. How does venture capital operate in medical innovation? BMJ Innov. 2016 Jul;2(3):111–7.

30. Mas JP, Hsueh B. An investor perspective on forming and funding your medical device start-up. Tech Vasc Interv Radiol. 2017 Jun;20(2):101–8.

31. Bean J. Boulevard of broken dreams: why public efforts to boost entrepreneurship and venture capital have failed – and what to do about it. Bus Hist. 2010 Jul 23;52(4):688–9.

32. Manbachi A, Kreamer-Tonin K, Walch P, Gamo NJ, Khoshakhlagh P, Zhang YS, et al. Starting a Medical Technology Venture as a Young Academic Innovator or Student Entrepreneur. Ann Biomed Eng. 2018 Jan 10;46(1):1–13.

33. Medical Device Regulations. Retrieved. Food and Drug Administration (FDA). Retrieved from https://www.fda.gov/medical-devices; 2020.

34. EMA Regulatory Science to 2025. European Medicines Agency (EMA). Retrieved from https://www.ema.europa.eu; 2021.

35. Thangaratinam S, Khan KS. Participation in research as a means of improving quality of care: the role of a principal investigator in multicentre clinical trials. The Obstetrician & Gynaecologist. 2015 Jan 23;17(1):55–61.

36. Kulkov I. Medical Technology Innovation Ecosystems : Factors influencing the formation of new companies. Åbo Akademi universuty; 2021.

37. Gomis-Pastor M, Berdún J, Borrás-Santos A, De Dios López A, Fernández-Montells Rama B, García-Esquirol Ó, et al. Clinical Validation of Digital Healthcare Solutions: State of the Art, Challenges and Opportunities. Healthcare. 2024 May 22;12(11):1057.

38. Feldman M, Zoller T. Dealmakers in Place: Social Capital Connections in Regional Entrepreneurial Economies. Reg Stud. 2012 Jan 1;46:23–37.

39. Iyengar K, UGK, VR, & J V. COVID-19 and applications of telemedicine in the current pandemic. Diabetes & Metabolic Syndrome: Clinical Research & Reviews. 2020;14(5):733–7.

40. Gambardella A, GP, & LA. The impact of the COVID-19 pandemic on the global venture capital market. Res Policy. 2020;49(6).

41. Food and Drug Administration (FDA). Retrieved from https://www.fda.gov/medical-devices. 2020. Emergency Use Authorizations for Medical Devices.

42. 4. Arden C, BH, RS, & DC. How the COVID-19 pandemic has accelerated the adoption of digital technologies in healthcare. Future Healthcare. 2020;7(3):189–92.

43. Levitt T. EXPLOIT the Product Life Cycle. Harv Bus Rev. 1965;43(6):81–94.

44. Adnan Ashfaq. The Medical Device Development Process: A Deep Dive into the 5 Phases. Retrieved from https://www.greenlight.guru/. 2023;

45. Freeman J, Engel JS. Models of Innovation: Startups and Mature Corporations. Calif Manage Rev. 2007 Oct 1;50(1):94–119.

46. Birley S, Mosey S. Entrepreneurship and University Technology Transfer. J Technol Transf. 2004 Feb 1;29:235–46.

47. Chesbrough H. Open Innovation: The New Imperative for Creating and Profiting From Technology. Vol. 21, Journal of Engineering and Technology Management - J ENG TECHNOL MANAGE. 2003.

48. Hart M. The Lean Startup: How Today's Entrepreneurs Use Continuous Innovation to Create Radically Successful Businesses Eric Ries. New York: Crown Business, 2011. 320 pages. US$26.00. Journal of Product Innovation Management. 2012 May 1;29.

49. Josh Lerner. Boulevard of Broken Dreams: Why Public Efforts to Boost Entrepreneurship and Venture Capital Have Failed--and What to Do about It. Princeton University Press.; 2012.

50. Wang P, Kricka LJ. Current and Emerging Trends in Point-of-Care Technology and Strategies for Clinical Validation and Implementation. Clin Chem. 2018 Oct 1;64(10):1439–52.

51. Singh R, Lillard JW. Nanoparticle-based targeted drug delivery. Exp Mol Pathol. 2009 Jun;86(3):215–23.

52. Mukhopadhyay SC. Wearable Sensors for Human Activity Monitoring: A Review. IEEE Sens J. 2015 Mar;15(3):1321–30.

53. Bertrand AA, DeLong MR, Chandawarkar A, Robinson C. The Development and Commercialization of Medical Technologies. Aesthet Surg J. 2021 Nov 12;41(12):NP2020–9.

54. Mimi Polner. What Is An EHR? Everything You Need To Know. Forbes. 2022;

55. Nilmini Wickramasinghe JLS. Realizing Value Driven e-Health Solutions. IMPROVING HEALTHCARE SERIES. 2010;

56. Ginsburg GS, Willard HF. Genomic and personalized medicine: foundations and applications. Translational Research. 2009 Dec;154(6):277–87.

57. Mason C, Dunnill P. A Brief Definition of Regenerative Medicine. Regenerative Med. 2008 Jan 21;3(1):1–5.

58. Greenlight Guru. Greenlight Guru's 2023 MedTech Industry Benchmark Report: Provides insights into the funding landscape and challenges for MedTech startups. 2023.

59. Galen Data's 2023 Investor Environment for Medical Device Startups: Discusses various funding sources and their roles in different stages of MedTech startup development. 2023.

60. Gompers P, Lerner J. The Venture Capital Revolution. Journal of Economic Perspectives. 2001 May 1;15(2):145–68.

61. Gompers PA, Gornall W, Kaplan SN, Strebulaev IA. How do venture capitalists make decisions? J financ econ. 2020 Jan;135(1):169–90.

62. Filho PCS, Siluk JCM, de Freitas Michelin C, Rigo PD, Júnior ALN, Rosa CB, et al. A Measurement Tool for the Competitiveness of Startups' Innovation Ecosystem. Journal of the Knowledge Economy. 2023 Jun 14;15(2):8262–89.

63. Tan SN, Kim JM, Kim J, Sung CM, Kim HC, Lee J, et al. Head rotation improves airway obstruction, especially in patients with less severe obstructive sleep apnea without oropharyngeal collapse. PLoS One. 2022 May 24;17(5):e0268455.

64. mckinsey. How the medtech industry can capture value from digital health. 2021.

65. aviahealth [Internet]. 2021. By the numbers: The top KPIs to track in your health system’s digital transformation strategy.

66. Mark Carol M. Why It Takes So Long to Develop a Medical Technology (Part 1). Retrieved from https://www.fusfoundation.org. Focused Ultrasound Foundation. 2022;

67. >75% of MedTech Startups Fail & This is Why. Retrieved from https://www.tti-research.com. TTi Health Research & Economics. 2021;

68. Li W. Science Business: The Promise, the Reality and the Future of Biotech. J Commer Biotechnol. 1969 Dec 31;13(4).

69. Aidan Petrie NCF. Why MedTech Startups Fail - Part 1. Retrieved from https://nemic.org/news/why-medtech-startups-fail-part-1. NEMIC. 2023;

70. New Strategies for MedTech Startups. Retrieved from https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/new-strategies-for-medtech-startups.pdf. Deloitte. 2022;

71. Pettersen IB, Aarstad J, Høvig ØS, Tobiassen AE. Business incubation and the network resources of start-ups. J Innov Entrep. 2015 Dec 3;5(1):7.

72. Jiang Q, Wang D, Wang Y, Wu B. Innovation Elements, Incubation Capacity, and Incubation Performance in Biomedical Incubation Platforms: Moderating Role of Customized Services. Front Public Health. 2022 May 11;10.

73. Al-Mubaraki HM, Busler M. Challenges and opportunities of innovation and incubators as a tool for knowledge-based economy. J Innov Entrep. 2017 Dec 24;6(1):15.

74. Barbero JL, Casillas JC, Wright M, Ramos Garcia A. Do different types of incubators produce different types of innovations? J Technol Transf. 2014 Apr 4;39(2):151–68.

75. Mejtoft T, Lindahl O, Öhberg F, Pommer L, Jonzén K, Andersson BM, et al. Medtech innovation guide: an empiric model to support medical technology innovation. Health Technol (Berl). 2022 Sep 23;12(5):911–22.

76. Hackett SM, Dilts DM. A Systematic Review of Business Incubation Research.

77. Grimaldi R, Grandi A. Business incubators and new venture creation: An assessment of incubating models. Technovation. 2005 Feb;25(2):111–21.

78. Kalinowska-Beszczyńska O, Prędkiewicz K. MedTech start-ups: A comprehensive scoping review of current research trends and future directions. PLoS One. 2024 Aug 6;19(8):e0307959.

79. Charlene Petuship. Top 8 Reasons Why Life Science and MedTech Incubators Fail. Mind Machine Retrieved from https://www.mindmachineco.com. 2023;

80. Pauwels C, Clarysse B, Wright M, Van Hove J. Understanding a new generation incubation model: The accelerator. Technovation. 2016 Apr;50–51:13–24.

81. Existing Co-innovation practices: What types of corporate-startup collaboration formats exist and how do they differ? Retrieved from CORSHIP.eu. CORSHIP. 2024;

82. Structured Mentorship and Networking Opportunities. Global Launch Base. 2023;

83. Phan PH, Siegel DS, Wright M. Science parks and incubators: observations, synthesis and future research. J Bus Ventur. 2005 Mar;20(2):165–82.

84. peekpublishers. Cultivating Innovation – The Role of MedTech Incubators. Retrieved from https://medtechpeek.com. 2023;

85. Erik Adams TH and JM. Medtech’s New Era of Collaboration and Innovation. 2023; https://www.bcg.com/publications/2023/medtech-era-of-collaboration-and-innovation

86. Wilson K, et al. Identifying Gaps and Challenges. Journal of MedTech Regulation. 2020;

87. Jones T, & SR. Mapping the Relationship Stages Between Startups and Incubators. Texas Medical Center. 2019;

88. MarkiTech. Role of Health Tech Incubators in Addressing Challenges. Health Technology Journal. 2023;

89. Nick Tippmann. Ultimate List of Medical Device Incubators and Accelerators (50+). Greenlight Guru Report. 2018;

90. PitchDrive. Enhancing Startup Support Through Structured Programs. PitchDrive Insights. 2023;

91. Kolabtree Report. Top Healthcare Incubators in the US. Kolabtree Report. 2023;

92. TBI MSMF. Role of Medical Associations in Supporting MedTech Startups. Journal of Medical Innovation. 2023;

93. MedTech Innovator. Mentorship and Networking Opportunities. MedTech Innovator Annual Report. 2021;

94. Tashakkori A, Teddlie C. SAGE Handbook of Mixed Methods in Social & Behavioral Research. 2455 Teller Road, Thousand Oaks California 91320 United States : SAGE Publications, Inc.; 2010.

95. Stebbins R. Exploratory Research in the Social Sciences. 2455 Teller Road, Thousand Oaks California 91320 United States of America : SAGE Publications, Inc.; 2001.

96. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006 Jan;3(2):77–101.

97. Savage J. One voice, different tunes: issues raised by dual analysis of a segment of qualitative data. J Adv Nurs. 2000 Jun 25;31(6):1493–500.

98. Richards L, Morse JM. Readme First for a User's Guide to Qualitative Methods. 1 Oliver's Yard, 55 City Road London EC1Y 1SP : SAGE Publications, Inc; 2013. 111–128 p.

99. King N. Using Templates in the Thematic Analysis of Text. In: Essential Guide to Qualitative Methods in Organizational Research. 1 Oliver's Yard, 55 City Road, London EC1Y 1SP United Kingdom : SAGE Publications Ltd; 2004. p. 256–70.

100. Aronson J. A Pragmatic View of Thematic Analysis. The Qualitative Report. 1995 Apr 1;

101. Tuckett AG. Applying thematic analysis theory to practice: A researcher's experience. Contemp Nurse. 2005 Aug 17;19(1–2):75–87.

102. Kehinde Feranmi Awonuga, Noluthando Zamanjomane Mhlongo, Funmilola Olatundun Olatoye, Chidera Victoria Ibeh, Oluwafunmi Adijat Elufioye, Onyeka Franca Asuzu. Business incubators and their impact on startup success: A review in the USA. International Journal of Science and Research Archive. 2024 Feb 28;11(1):1418–32.

103. Giaquinto AR, Grignolo A, Liberti L, Lim JCW, Salmonson T, Sauer F, et al. Improving access to quality medicines in East Africa: An independent perspective on the East African Community Medicines Regulatory Harmonization initiative. PLoS Med [Internet]. 2020 Aug 1 ;17(8):e1003092. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC7423065/

104. Edmondson AC, Harvey JF. Team Learning in the Field: An Organizing Framework and Avenues for Future Research. Small Group Res [Internet]. 2025 ; Available from: https://journals.sagepub.com/doi/10.1177/10464964251316877

105. Drover W, Wood MS, Zacharakis A. Attributes of Angel and Crowdfunded Investments as Determinants of VC Screening Decisions. Entrepreneurship Theory and Practice [Internet]. 2017 May 1;41(3):323–47. Available from: https://ideas.repec.org/a/sae/entthe/v41y2017i3p323-347.html

106. Lerner J, Nanda R. Venture capital's role in financing innovation: What we know and how much we still need to learn. Journal of Economic Perspectives. 2020 Jun 1;34(3):237–61.

107. Artificial Intelligence for the Real World | Harvard Business Publishing Education [Internet]. Available from: https://www.hbsp.harvard.edu/product/R1801H-PDF-ENG

108. Shared Leadership in Teams: Expanding Traditional Approaches to Leadership to Make Teams and Organizations More Effective Paul Tesluk Center for Leadership and Organizational Effectiveness UB School of Management.

109. Hines PA, Guy RH, Humphreys AJ, Papaluca-Amati M. The European Medicines Agency's goals for regulatory science to 2025. Nature Reviews Drug Discovery 2019 18:6 [Internet]. 2019 Apr 15 ;18(6):403–4. Available from: https://www.nature.com/articles/d41573-019-00071-2

110. Kramer DB, Xu S, Kesselheim AS. Regulation of medical devices in the United States and European Union. N Engl J Med [Internet]. 2012 Mar ;366(9):848–55. Available from: https://pubmed.ncbi.nlm.nih.gov/22332952/

111. Trompenaars Alfons, Hampden-Turner Charles. National Cultures and Corporate Cultures. Riding the waves of culture: Understanding diversity in global business [Internet]. 2012;389. Available from: https://primo.kb.dk/primo-explore/fulldisplay?docid=CBS01000609131&context=L&vid=CBS&lang=da_DK&search_scope=Blended&adaptor=Local Search Engine&isFrbr=true&tab=default_tab&query=any,contains,riding the waves of culture&sortby=date&facet=frbrg

112. Kotler P, Keller KL, Hall P, Columbus B, New I, San Y, et al. Marketing Management. 2012;

113. Christopher, M. (2016) Logistics and Supply Chain Management. 5th Edition, Pearson, London. - References - Scientific Research Publishing [Internet]. Available from: https://www.scirp.org/reference/referencespapers?referenceid=2455438

114. Supply Chain Management: Strategy, Planning, and Operation [Internet]. Available from: https://www.pearson.com/en-us/subject-catalog/p/supply-chain-management-strategy-planning-and-operation/P200000005863/9780137502844

115. Robles F, El-Ansary A, Root FR. Entry Strategies for International Markets. J Mark [Internet]. 1988 Oct ;52(4):128. Available from: https://www.researchgate.net/publication/274909151_Entry_Strategies_for_International_Markets

116. (PDF) CHAPTER 2 Internationalisation and International Entrepreneurship [Internet]. Available from: https://www.researchgate.net/publication/342883546_CHAPTER_2_Internationalisation_and_International_Entrepreneurship

117. Sorenson C, Drummond M, Burns LR. Evolving reimbursement and pricing policies for devices in Europe and the United States should encourage greater value. Health Aff (Millwood) [Internet]. 2013 Apr ;32(4):788–96. Available from: https://pubmed.ncbi.nlm.nih.gov/23569060/

118. Brogan AP, Hogue SL, Vekaria RM, Reynolds I, Coukell A. Understanding Payer Perspectives on Value in the Use of Pharmaceuticals in the United States. J Manag Care Spec Pharm [Internet]. 2019 ;25(12):10.18553/jmcp.2019.25.12.1319. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC10397793/

119. Makady A, Ham R ten, de Boer A, Hillege H, Klungel O, Goettsch W. Policies for Use of Real-World Data in Health Technology Assessment (HTA): A Comparative Study of Six HTA Agencies. Value Health [Internet].

2017 Apr 1 ;20(4):520–32. Available from: https://pubmed.ncbi.nlm.nih.gov/28407993/

120. Sorenson C, Drummond M, Khan BB. Medical technology as a key driver of rising health expenditure: disentangling the relationship. Clinicoecon Outcomes Res [Internet]. 2013 ;5(1):223–34. Available from: https://pubmed.ncbi.nlm.nih.gov/23807855/

121. Chan F. A Study of Social Media Influencers and Impact on Consumer Buying Behaviour in the United Kingdom. International Journal of Business & Management Studies [Internet]. 2022 ;03:2694–1449. Available from: www.ijbms.net

122. Robinson L. Enabling Change: A summary of Diffusion of Innovations. http://enablingchange.posterous.com [Internet]. 2009 ;1–10. Available from: www.enablingchange.com.au

123. Cervero RM, Gaines JK. The Impact of CME on Physician Performance and Patient Health Outcomes: An Updated Synthesis of Systematic Reviews. Journal of Continuing Education in the Health Professions [Internet]. 2015 Mar 1 ;35(2):131–8. Available from: https://scholar.usuhs.edu/en/publications/the-impact-of-cme-on-physician-performance-and-patient-health-out

124. Califf RM, Sugarman J. Exploring the ethical and regulatory issues in pragmatic clinical trials. Clinical Trials [Internet]. 2015 Oct 1 ;12(5):436–41. Available from: https://www.wcgclinical.com/insights/pragmatic-clinical-trials-what-you-need-to-know/

125. Lerner J. Government Incentives for Entrepreneurship. NBER Working Papers [Internet]. 2020; Available from: https://ideas.repec.org/p/nbr/nberwo/26884.html

126. Healthcare data integration: trends, benefits, and challenges [Internet]. Available from: https://innowise.com/blog/healthcare-data-integration/

127. (PDF) Health information exchange: persistant challenges & new strategies [Internet]. Available from: https://www.researchgate.net/publication/266908580_Health_information_exchange_persistant_challenges_new_strategies

128. Introduction | Interoperability Standards Platform (ISP) [Internet]. Available from: https://www.healthit.gov/isp/fhir-introduction

129. Consortium Formation Overview Focus Areas.

130. ACRO Health [Internet]. Available from: https://www.acrohealth.org/

131. Hall-Lipsy E, Barraza L, Robertson C. Practice-Based Research Networks and the Mandate for Real-World Evidence. Am J Law Med [Internet]. 2018 May 1 ;44(2–3):219–36. Available from: https://www.cambridge.org/core/journals/american-journal-of-law-and-medicine/article/abs/practicebased-research-networks-and-the-mandate-for-realworld-evidence/98B808B4FB0945DD01DBF8F47E8F6725

132. Risk D, Advisory F. The value of visibility: Cybersecurity risk management examination.; Available from: http://www.aicpa.org/interestareas/frc/

133. Cybersecurity Framework Implementation Guide Helps Healthcare Organizations Manage Risks | HIMSS [Internet]. Available from: https://gkc.himss.org/news/cybersecurity-framework-implementation-guide-helps-healthcare-organizations-manage-risks

134. Best Managed Security Services Reviews 2025 | Gartner Peer Insights [Internet]. Available from: https://www.gartner.com/reviews/market/managed-security-services

135. Leydesdorff L. The Triple Helix of University-Industry-Government Relations; Available from: http://www.leydesdorff.net

136. Chesbrough HW. The Era of Open Innovation. MIT Sloan Manag Rev [Internet]. 2003 Apr 15; Available from: https://sloanreview.mit.edu/article/the-era-of-open-innovation/

137. Kuhlmann S. Future governance of innovation policy in Europe - Three scenarios. Res Policy [Internet]. 2001 Jun;30(6):953–76. Available from: https://www.researchgate.net/publication/222831129_Future_Governance_of_Innovation_Policy_in_Europe

138. Gender Equality in the Workplace: What it Means and How We Can Get There [Internet]. Available from: https://www.beapplied.com/post/gender-equality-in-the-workplace

139. St-Jean E. Mentoring as professional development for novice entrepreneurs: maximizing the learning1. Int J Train Dev [Internet]. 2012 Sep 1;16(3):200–16. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/j.1468-2419.2012.00404.x

140. Gompers P, Lerner J. The Venture Capital Revolution. Journal of Economic Perspectives. 2001;15(2):145–68.

141. The Role of Cultural Fit in Vendor Selection [Internet]. Available from: https://inspirepreneurmagazine.com/the-role-of-cultural-fit-in-vendor-selection/

142. How Anonymous Employee Feedback Can Help Your Business Grow | Employment Hero [Internet]. Available from: https://employmenthero.com/blog/anonymous-employee-feedback/

143. What Are the Benefits of Advisory Boards for Startups? | BoardEffect [Internet]. Available from: https://www.boardeffect.com/blog/what-benefits-advisory-boards-startups/

144. van Stijn N, van Rijnsoever FJ, van Veelen M. Exploring the motives and practices of university–start-up interaction: evidence from Route 128. Journal of Technology Transfer. 2018 Jun 1;43(3):674–713.

145. Amezcua AS, Grimes MG, Bradley SW, Wiklund J. Organizational sponsorship and founding environments: A contingency view on the survival of business-incubated firms, 1994-2007. Academy of Management Journal [Internet]. 2013 Dec 1;56(6):1628–54. Available from:

https://experts.syr.edu/en/publications/organizational-sponsorship-and-founding-environments-a-contingenc

146. Chaturvedi J, Srinivas G. Grants, Funding, Awards and Recognition in Healthcare Innovation. Karnataka Pediatric Journal. 2021 Sep 6;36:76–81.

147. 15 clinical trial patient recruitment companies (and how to choose one) [Internet]. Available from: https://www.antidote.me/blog/15-clinical-trial-patient-recruitment-companies

148. Electronic Data Capture In Clinical Trials | Credevo Articles [Internet]. Available from: https://credevo.com/articles/2024/05/05/electronic-data-capture-in-clinical-trials-impact-advantages/

149. Services - Division of Clinical Trials and Biostatistics - Mayo Clinic Research [Internet]. Available from: https://www.mayo.edu/research/departments-divisions/quantitative-health-sciences/divisions/clinical-trials-biostatistics/services

150. Co-Warehousing: A Comprehensive Guide | Spacebring [Internet]. Available from: https://www.spacebring.com/blog/tips/co-warehousing-guide

151. Bank N, Kanda W. Tenant recruitment and support processes in sustainability-profiled business incubators. Industry and Higher Education. 2016 Aug 1;30(4):267–77.

152. Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff Preface Public Comment. 2000; Available from: http://www.regulations.gov

153. Why you need rapid prototyping solutions for hardware innovation [Internet]. Available from: https://www.ignitec.com/insights/why-you-need-rapid-prototyping-solutions-for-hardware-innovation/

154. What Is a Daily Standup In Agile Methodology [Internet]. Available from: https://www.aha.io/roadmapping/guide/agile/what-is-a-daily-standup

155. Keinänen AL, Lähdesmäki R, Juntunen J, Tuomikoski AM, Kääriäinen M, Mikkonen K. Effectiveness of mentoring education on health care professionals´ mentoring competence: A systematic review. Nurse Educ Today. 2023 Feb 1;121:105709.

156. Rybnicek R, Königsgruber R. What makes industry–university collaboration succeed? A systematic review of the literature. Journal of Business Economics [Internet]. 2019 Mar 8;89(2):221–50. Available from: https://link.springer.com/article/10.1007/s11573-018-0916-6

157. Wu Y, Liu P. Pricing strategies for shared manufacturing platform considering cooperative advertising based on differential game. PLoS One [Internet]. 2024 Jul 1;19(7):e0303928. Available from: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0303928

158. Finance for startups: essential strategies and tools for success [Internet]. Available from: https://onemoneyway.com/en/blog/finance-for-startups/?utm_source=chatgpt.com

159. Value-Based Care Needs to Measure What Matters to Patients - NCQA [Internet]. Available from: https://www.ncqa.org/blog/value-based-care-needs-to-measure-what-matters-to-patients/

160. Carroll DA, Stater KJ. Revenue diversification in nonprofit organizations: Does it lead to financial stability? Journal of Public Administration Research and Theory [Internet]. 2009 Oct ;19(4):947–66. Available from: https://www.researchgate.net/publication/228280972_Revenue_Diversification_in_Nonprofit_Organizations_Does_It_Lead_to_Financial_Stability

161. Powell WW, Koput KW, Smith-Doerr L. Interorganizational Collaboration and the Locus of Innovation: Networks of Learning in Biotechnology. Adm Sci Q. 1996 Mar;41(1):116.

162. A founder’s guide to non-dilutive funding - EmpowerRD [Internet]. Available from: https://www.empowerrd.com/resource/guide-to-non-dilutive-funding/

163. Premarket Notification 510(k) | FDA [Internet]. Available from: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k

Appendices

Appendix A: Interview Questions

The following questions were the foundation for the interviews conducted in this research. Each set of questions was customized for individual interviewees based on their roles and expertise. Below is the base set of questions used during the interviews, along with examples of how they were tailored to specific roles.

Collaboration Procedures:

How do typical collaborations between healthcare startups and incubators unfold, and what is the standard procedure?

Can you provide insights into how specific collaborations between healthcare startups and incubators developed? What was the process involved?

What criteria or protocols do organizations have regarding collaborative efforts within funded projects in healthcare? Is there a process to check applications and claims before agreements? How do these organizations establish and ensure trust in these collaborations?

Challenges in Healthcare Incubator-Startup Collaborations:

What challenges and specific points of friction are commonly encountered in the collaboration between healthcare incubators and startups?

How do funding agencies perceive collaboration challenges among healthcare startups and incubators?

What challenges and specific points of friction have you observed in healthcare incubator-startup collaborations? Could you describe these challenges in detail?

Were there any misalignments in expectations, communication breakdowns, or resource constraints that impacted the collaborative efforts between healthcare startups and incubators?

Addressing Collaboration Challenges:

How do you address the challenges faced in collaborations between startups and incubators in healthcare? Are there other key players in this process, and how do they contribute?

How can funding agencies further support and improve collaboration within the healthcare ecosystem between startups and incubators?

How do you envision the role of funding agencies or other actors in creating a conducive environment for collaboration between startups and incubators?

Success and Failure Stories:

Can you share success stories in healthcare startup-incubator collaborations, highlighting the key factors for success? Conversely, can you share failure stories and pinpoint the reasons for failure?

Reasons for Collaboration Failures:

What were the key factors that led to failures in previous collaborations between healthcare startups and incubators?

Lessons Learned and Preventing Collaboration Failures:

What lessons were learned from previous collaboration challenges? If you could go back, what actions would you take differently?

How have organizations adjusted their approach to collaborations since facing these challenges? What steps have been taken or are planned to improve the collaborative experience for startups and incubators in the future?

What procedures do you recommend to prevent potential reasons for failure in the collaboration between startups and incubators in the healthcare sector?

What are the differences between university-incubator and institutional-incubator approaches? Between non-profit and for-profit incubator approaches

Appendix B: Strategies for Implementing Solutions to the Presented Challenges

Global Market Access

Implementation Strategy 1.1.1: Develop a Global Regulatory Team

Establishing a specialized team within incubators for global regulatory affairs can improve compliance and reduce time to market. This team would provide consultations, prepare regulatory documents, and offer training on international updates. Whitaker (2018) underscores the importance of regulatory expertise in supporting startups.

Implementation Strategy 1.2.1: Create a Network of Regulatory Consultants

Establishing a network of vetted regulatory consultants can provide startups with specialized guidance across international markets. This approach ensures efficient resolution of regulatory challenges. Hynes, Lees, and Müller (2020) advocate for systemic thinking, aligning with this collaborative network strategy.

Implementation Strategy 2.1.1: Develop Interactive Cultural Workshops

Interactive workshops simulating real-world scenarios can help startups understand cultural differences and develop effective market strategies. Edmondson and Harvey (2018) highlight the role of cross-boundary teaming in fostering innovation. In Canada, the Trade Commissioner Service (TCS) supports international business expansion by offering guidance on cultural practices, investment environments, and regional strategies, such as conservative investor expectations in Japan. Programs like Investissement Québec provide local networks, while CanExport offers financial assistance of up to $75,000 for global expansion.

Implementation Strategy 2.2.1: Create a Local Expert Advisory Panel

To implement this solution, it is proposed that an advisory panel comprising local market experts from various regions be formed to provide ongoing insights and feedback to startups. An advisory panel ensures continuous access to localized knowledge, aiding in developing culturally appropriate strategies. Carson, Tesluk, and Marrone (2007) support the idea of the creation of a diverse advisory panel.

Implementation Strategy 3.1.1: Establish a Global Logistics Hub

A strategy involves creating a centralized logistics hub that coordinates international supply chain activities and provides real-time support to startups. A centralized hub can streamline logistics processes, reduce costs, and improve efficiency for international distribution. Chopra and Meindl (2016) highlight the significance of strategic planning in supply chain management.

Implementation Strategy 3.2.1: Create a Partnership Network of Distributors

To implement this solution, a network of trusted international distributors could be developed to support startups with local market entry and logistics. A reliable network of distributors can ensure smooth and compliant distribution, enhancing market penetration. Peters and Panayi (2016) discuss the potential of blockchain technologies to enhance the transparency and security of such networks.

Implementation Strategy 4.1.1: Develop a Regional Market Analysis Toolkit

A novel strategy involves creating a toolkit that includes resources and templates for conducting regional market analysis and developing entry strategies. A comprehensive toolkit can provide startups with the necessary tools and knowledge to create effective market entry plans. Hisrich (2010) supports the idea of providing startups with structured resources to facilitate international expansion.

Implementation Strategy 4.2.1: Establish a Global Mentorship Program

To implement this solution, it is proposed to create a mentorship program that pairs startups with international business experts for personalized guidance and support. A structured mentorship program ensures startups receive targeted advice and support tailored to their specific market entry needs. Gittell (2009) highlights the importance of relationships in achieving high performance, which aligns with developing a mentorship program.

Reimbursement and Health Economics

Implementation Strategy 1.1.1: Develop an In-House Reimbursement Team

A strategy to implement this solution is the establishment of a dedicated in-house team within incubators that specializes in reimbursement strategies. This team would provide consultation services, prepare reimbursement documents, and offer ongoing training on reimbursement updates. A specialized team ensures that startups receive expert advice tailored to their specific reimbursement needs, improving their chances of securing coverage. Whitaker (2018) underscores the importance of such specialized support in the pharmaceutical industry.

Implementation Strategy 1.2.1: Create a Payer Advisory Panel

To enhance this approach, a payer advisory panel consisting of representatives from major payers could be formed to provide ongoing feedback and guidance to startups. Continuous engagement with payers ensures that startups can adapt to payer requirements and increase their chances of successful reimbursement. Hynes, Lees, and Müller (2020) advocate for systemic thinking in policymaking, which supports the establishment of such collaborative panels.

Implementation Strategy 2.1.1: Establish an HEOR Center of Excellence

A potential implementation strategy involves establishing a Health Economics and Outcomes Research (HEOR) center within the incubator, supported through wage subsidies or cost-sharing between the incubator and the government. This center would provide startups with access to specialized resources and expertise needed to develop solid economic models and generate compelling evidence for the cost-effectiveness of their technologies. A dedicated HEOR center could help startups demonstrate the financial value of their innovations, increasing the likelihood of reimbursement and market adoption. Drummond et al. (2015) underscore the importance of having specialized resources for conducting thorough economic evaluations, which are critical in making a strong case for cost-effectiveness.

Implementation Strategy 2.2.1: Develop a Real-World Evidence Platform

To implement this solution, a digital platform for collecting and analyzing real-world data from various sources could be developed. This platform would enable startups to generate comprehensive real-world evidence. A dedicated platform can streamline the collection and analysis of real-world data, making it easier for startups to demonstrate the practical value of their products. Davenport and Ronanki (2018) discuss the potential of artificial intelligence in enhancing real-world data analysis.

Implementation Strategy 3.1.1: Create a Health Economics Advisory Board

A novel strategy involves establishing an advisory board comprising leading health economics experts who can provide ongoing consultation and support to startups. An advisory board ensures continuous access to top-tier expertise, helping startups navigate complex economic evaluations and reimbursement processes. Caffrey, Wolfe, and McKevitt (2016) highlight the value of embedding research and expert guidance in health systems.

Implementation Strategy 3.2.1: Develop a Health Economics Training Program

To implement this solution, a comprehensive training program for incubator staff should be developed, focusing on key aspects of health economics and cost-effectiveness analysis. A structured training program ensures that incubator staff are well-prepared to support startups in developing and executing effective health economics strategies. Edmondson and Harvey (2018) advocate for cross-boundary teaming, which is relevant for enhancing the capabilities of incubator staff.

Implementation Strategy 4.1.1: Develop Interactive Training Modules

A novel strategy involves creating interactive training modules that cover key topics in reimbursement and health economics, incorporating case studies and practical exercises. Interactive modules can enhance understanding and retention of complex topics, making it easier for startups to apply their learning in real-world scenarios. Cutler and Everett (2010) discuss the benefits of innovative educational approaches in healthcare reform.

Implementation Strategy 4.2.1: Create a Mentorship Matchmaking Platform

To implement this solution, a digital platform for matching startups with appropriate mentors should be developed based on their specific needs and challenges in reimbursement and health economics. A matchmaking platform ensures that startups can find and connect with mentors who have relevant expertise, improving the quality of mentorship and support. Freeman (1984) supports the strategic management of stakeholder relationships, which aligns with creating a mentorship matchmaking platform.

Regulatory Environment

Implementation Strategy 1.1.1: Develop a Fast-Track Approval System

A fast-track approval system for innovative medical devices could be established, allowing startups to navigate regulatory processes more quickly. This strategy, exemplified by the FDA's Breakthrough Devices Program, can significantly reduce the time startups take to bring their products to market.

Implementation Strategy 2.1.1: Develop Formal Partnerships with Regulatory Experts

Incubators could establish formal partnerships with regulatory consulting firms to ensure that startups receive expert advice throughout their product development cycle. This can help streamline the approval process and improve compliance outcomes.

Implementation Strategy 2.2.1: Form In-House Regulatory Advisory Boards

In-house advisory boards could be formed to provide startups with tailored regulatory advice, ensuring a clear understanding of approval processes and compliance strategies.

Implementation Strategy 3.1.1: Establish a Grant Program for Regulatory Compliance

A targeted grant program specifically designed to cover the costs of regulatory compliance could be developed. This program could help alleviate financial pressures and enable startups to focus more resources on innovation and market entry. The Small Business Innovation Research (SBIR) program is a good example of this approach.

Implementation Strategy 4.1.1: Implement a Real-Time Communication Platform

Developing a real-time communication platform that allows startups to interact directly with regulatory bodies could help resolve issues more quickly, expediting approval times. The FDA's Interactive Review Program is an example of a system that supports quicker communication and decision-making.

Implementation Strategy 5.1.1: Develop a Comprehensive Training Curriculum

A structured curriculum, including workshops, practical training, and hands-on experience, could be developed to prepare startups for regulatory challenges. The Global Harmonization Task Force (GHTF) guidelines serve as a model for this strategy.

Implementation Strategy 6.1.1: Develop and Implement Customized Regulatory Roadmaps

Incubators could offer tailored regulatory roadmaps for each startup, helping them stay on track with regulatory requirements and deadlines. Regulatory simulation programs could be introduced to allow startups to practice navigating these processes in a risk-free environment.

Access to Capital

Implementation Strategy 1.1.1: Develop a Government Incentive Program

To implement this solution, a government program could be established to provide tax incentives and matching funds to VCs who invest in early-stage MedTech startups. A formal incentive program can systematically reduce investment risk, encouraging more VCs to fund MedTech startups. The Small Business Investment Company (SBIC) program is a supporting principle for this approach.

Implementation Strategy 2.1.1: Develop a Centralized Funding Database

To implement this solution, a database that lists all available non-dilutive funding options, including grants, loans, and subsidies, could be developed and regularly updated. A well-maintained database can help startups quickly find and apply for the funding they need. Innovation Canada's funding platform serves as a model for this approach.

Implementation Strategy 2.2.1: Establish Innovation Hubs

To implement this solution, innovation hubs that provide funding, mentorship, and regulatory guidance to startups could be developed and supported by both the public and private sectors. Innovation hubs can offer a comprehensive support system, reducing barriers for startups. MaRS Discovery District in Toronto is a successful example of such a hub.

Implementation Strategy 3.1.1: Hire Financial Advisors in Incubators

To implement this solution, incubators could hire financial advisors specializing in grant writing and financial management to assist startups. Expert advisors can improve the success rate of grant applications, providing crucial early-stage funding. The role of financial advisors in business incubators is a supporting principle for this approach.

Implementation Strategy 4.1.1: Develop an Express Review Pathway

To implement this solution, an express review pathway for innovative medical devices should be established, providing a faster and more efficient approval process. Faster review times can significantly reduce the costs associated with regulatory approval, attracting more investors. The FDA's Breakthrough Devices Program is a supporting principle for this approach.

Market Adoption

Implementation Strategy 1.1.1: Develop Pilot Programs

A strategy involves creating structured pilot programs in collaboration with healthcare providers to test new technologies in real-world settings. Structured pilot programs can provide robust evidence of efficacy and safety, increasing the likelihood of adoption. This strategy is supported by clinical trial design and execution principles.

Implementation Strategy 1.2.1: Create a Shadowing Program Framework

A structured framework should be developed to ensure the effectiveness of shadowing programs. This framework would include guidelines, schedules, and objectives to ensure meaningful engagement between startups and healthcare providers. Experiential learning theories support the value of structured shadowing programs.

Implementation Strategy 1.3.1: Create a Testimonial and Case Study Repository

A strategy involves developing an online repository of patient testimonials and case studies that healthcare providers can access to learn about the benefits of new technologies. A centralized repository makes it easy for healthcare providers to find and review evidence supporting adopting new technologies. Evidence-based practice principles support the creation of such a repository and the implementation of supportive measures like these.

Implementation Strategy 1.4.1: Develop an Early Adopter Incentive Plan

To implement this solution, a detailed plan offering incentives such as discounts, extended warranties, or exclusive access to new features for early adopters should be developed. A well-structured incentive plan can motivate healthcare providers to try new technologies. Behavioral economics principles support the design of effective incentive programs.

Implementation Strategy 2.1.1: Integrate CME Modules

To implement this solution, CME modules focused on new technologies could be developed and made accessible through professional associations. These modules can effectively educate healthcare providers on the benefits and uses of new technologies, supporting their adoption. Adult learning principles underpin the effectiveness of CME in professional education.

Implementation Strategy 2.2.1: Establish Market Research Units

To enhance market entry success, dedicated market research units could be established within incubators. These units would assist startups with market analysis and strategy development, providing in-depth market insights and strategic guidance. Market analysis methodologies support the creation of such specialized units.

Implementation Strategy 2.3.1: Develop Reimbursement Workshops

Workshops focused on reimbursement strategies should be developed, covering key topics such as coding, coverage policies, and payer requirements. These workshops provide practical knowledge

and tools that startups need to navigate reimbursement challenges successfully. Instructional design theories support the development of effective workshops.

Implementation Strategy 2.4.1: Develop Market Research Access Program

A program could be established to provide startups with affordable access to market research databases and software. This will involve partnerships with market research providers and negotiating bulk licensing agreements to reduce costs. The program will also offer workshops to teach startups how to use these tools effectively, alongside continuous access to updated data and on-demand support for research interpretation.

Implementation Strategy 3.1.1: Develop Cybersecurity and Privacy Training Programs

Comprehensive training programs should be created, including practical exercises and case studies to help startups understand and implement cybersecurity and data privacy measures. These programs enhance startups' ability to meet regulatory requirements and protect patient data. Cybersecurity frameworks support the development of these training programs.

Implementation Strategy 3.2.1: Establish an Ethical Hacking Lab

An ethical hacking lab could be established within the incubator to provide startups with the resources and expertise needed to test their technologies. This lab ensures that startups have access to the necessary tools and support to secure their technologies. Penetration testing methodologies support the establishment of such a lab.

Implementation Strategy 3.3.1: Develop a Regulatory Compliance Handbook

A comprehensive handbook covering FDA and Health Canada regulations, including cybersecurity and data privacy requirements, could be created. This handbook provides startups with a clear and practical guide to regulatory compliance. Regulatory compliance frameworks support the creation of this handbook.

Implementation Strategy 3.4.1: Develop a Government Incentive Program

To implement this solution, a government program offering financial incentives to incubators that provide comprehensive regulatory and cybersecurity support to startups could be established. Financial incentives can enhance the support infrastructure available to startups, improving their chances of successful market entry. Public policy incentives support the creation of such a program.

Technical Integration with Healthcare Systems

Implementation Strategy 1.1.1: Establish Integration Partnerships

A novel strategy involves forming strategic partnerships with leading health IT companies to co-develop integration solutions tailored to specific healthcare systems. Strategic partnerships can leverage the strengths of both MedTech startups and health IT companies to create more effective integration solutions. Collaborative innovation in healthcare technology supports this approach.

Implementation Strategy 1.2.1: Develop a Compatibility Testing Framework

To implement this solution, a standardized framework for conducting compatibility testing should be created. This framework would include guidelines, tools, and metrics for evaluating integration with existing systems. A standardized framework ensures that compatibility testing is thorough and consistent, leading to more reliable integration outcomes. Systems integration testing methodologies support this strategy.

Implementation Strategy 2.1.1: Create Middleware Development Kits

A strategy is to develop and distribute middleware development kits (MDKs) that include tools, libraries, and documentation to help startups create integration middleware for their technologies. MDKs provide startups with the resources they need to develop effective integration solutions, accelerating the integration process. Software development kit (SDK) methodologies support this approach.

Implementation Strategy 2.2.1: Develop HIE Partnership Programs

To implement this solution, programs that facilitate partnerships between MedTech startups and HIEs should be created, including joint initiatives, funding opportunities, and shared resources. Partnership programs can provide startups with the support they need to integrate their technologies with HIEs successfully. Public-private partnership frameworks support this strategy.

Implementation Strategy 3.1.1: Participate in Standards Development Committees

To implement this solution, startups should actively participate in standards development committees and working groups to contribute to the creation and promotion of interoperability standards. Participation in standards development ensures that startups' needs and perspectives are considered, leading to more effective and relevant standards. Standards development processes support this strategy.

Implementation Strategy 3.2.1: Create an Interoperability Task Force

To implement this solution, an interoperability task force could be established. This task force would lead participation in consortia, monitor standards developments, and advocate for startups' needs. A dedicated task force ensures focused and consistent engagement with interoperability initiatives. Task force organizational models support this approach.

Stakeholder Engagement

Implementation Strategy 1.1.1: Develop PI Matching Portals

To implement this solution, online portals that match startups with medical PIs based on specific project needs and expertise could be developed. These portals can streamline the process of connecting startups with the right clinical experts, ensuring more efficient collaborations. Digital matchmaking and networking platforms provide the supporting principle for this strategy.

Implementation Strategy 1.2.1: Create CRO Partnership Programs

To implement this solution, formal partnership programs with CROs, including joint ventures and co-development agreements, could be developed. These programs ensure structured and ongoing support from CROs, enhancing the startup’s capacity for successful product development. Strategic alliance frameworks support this approach.

Implementation Strategy 2.1.1: Develop Multidisciplinary Matching Portals

Existing matching portals should be expanded to include a broader range of healthcare stakeholders, facilitating comprehensive engagement. A broadened portal ensures that all necessary stakeholders are involved in the development process, enhancing the chances of successful integration of new technologies. Comprehensive stakeholder engagement platforms provide the supporting principle for this strategy.

Implementation Strategy 2.2.1: Establish Regular Interdisciplinary Seminars

To implement this solution, regular interdisciplinary seminars focusing on emerging issues and collaborative solutions in MedTech should be established. These seminars foster continuous engagement and collaboration among diverse stakeholders, driving innovation in healthcare. Continuous professional development models support this strategy.

Implementation Strategy 3.1.1: Develop a Structured Shadowing Program

A structured shadowing program that includes defined goals, schedules, and evaluation metrics should be created. This ensures that shadowing experiences are meaningful and productive, providing actionable insights for startups. Experiential learning frameworks support the development of such a program.

Implementation Strategy 3.2.1: Create Feedback Integration Systems

To implement this solution, digital systems that collect, analyze, and integrate patient feedback into product development workflows could be developed. These systems streamline the feedback process and ensure that insights are actionable, contributing to more user-centered design. User-centered design methodologies provide the supporting principle for this approach.

Implementation Strategy 4.1.1: Develop Collaborative Research Programs

To implement this solution, programs that encourage joint research projects and data sharing between hospital research centers and other departments could be created. These programs enhance collaboration and integrate research insights into clinical practice, fostering continuous innovation. Collaborative research models support this strategy.

Implementation Strategy 4.2.1: Create Integrated Network Platforms

To support this solution, digital platforms that facilitate communication, project management, and data sharing within research-practice networks should be developed. These platforms streamline collaboration and ensure continuous interaction between researchers and clinicians. Integrated network management systems provide the supporting principle for this approach.

Implementation Strategy 4.3.1: Establish Military Collaboration Units

To implement this solution, collaboration with a retired military veteran could be created. These units would manage partnerships and technology transfer agreements, ensuring that military standards and experiences are effectively leveraged to enhance MedTech innovations. Technology transfer and collaboration frameworks support this approach.

Cybersecurity and Data Privacy Concerns

Implementation Strategy 1.1.1: Develop Long-term Partnerships with Cybersecurity Firms

Long-term partnerships with cybersecurity firms could be established to ensure continuous support and updates. These partnerships will help maintain sustained cybersecurity improvements and proactive threat management, providing startups with ongoing protection. Strategic alliances for continuous improvement support this approach.

Implementation Strategy 1.2.1: Develop Comprehensive Cybersecurity Curricula

Comprehensive curricula covering a wide range of cybersecurity topics, including threat assessment, incident response, and data encryption, should be created. These curricula ensure thorough training and preparedness for diverse cybersecurity challenges, equipping startup teams with the necessary skills. Structured educational programs provide the supporting principle for this strategy.

Implementation Strategy 2.1.1: Establish a Working Group for Guideline Development

A working group comprising cybersecurity experts, industry representatives, and regulatory bodies could be formed to develop comprehensive guidelines. A diverse working group ensures that the guidelines are well-rounded and practical, addressing the needs of all stakeholders. Collaborative standard-setting provides the supporting principle for this strategy.

Implementation Strategy 2.2.1: Develop a User-Friendly Repository Platform

An intuitive online platform that organizes best practices by category and provides easy resource access should be created. A user-friendly design ensures broad usage and accessibility, making it easier for startups to implement cybersecurity measures effectively. Accessible knowledge management systems support this approach.

Implementation Strategy 3.1.1: Establish Partnerships with Leading MSS Providers

Partnerships with leading MSS providers should be formed to ensure that startups have access to the best monitoring and response services. High-quality MSS providers offer robust and reliable security, essential for protecting startups from emerging threats. High-quality service provision supports this approach.

Implementation Strategy 3.2.1: Conduct Regular Incident Response Drills

Regular drills could be scheduled to practice the incident response plan to ensure readiness. These drills help teams stay prepared and ensure that the plan effectively mitigates potential threats. Regular practice and preparedness exercises provide the supporting principle for this strategy.

Implementation Strategy 4.1.1: Develop Compliance Training Programs

Training programs focusing on regulatory requirements and compliance strategies should be created to ensure that startup teams understand and can implement necessary compliance measures. Regulatory education and training provide the supporting principle for this strategy.

Implementation Strategy 4.2.1: Develop Automated Compliance Tracking Tools

Automated tools that track compliance status and generate reports in real-time could be developed. These tools streamline compliance management and ensure that startups can easily monitor and maintain adherence to regulatory requirements. Automation in compliance management provides the supporting principle for this approach.

Resource Allocation

Implementation Strategy 1.1.1: Develop University-Startup Collaboration Programs and Create a Centralized Resource Directory

To implement this solution, structured collaboration programs should be developed to facilitate regular partnerships between startups and university labs. These programs will ensure consistent access to cutting-edge lab equipment and foster collaboration with academic experts. Additionally, a centralized directory listing available lab facilities and equipment from universities and incubators should be created. This directory will allow startups to easily find and access the necessary resources to innovate and develop new technologies. Strategic alliances for resource sharing and centralized information systems provide the supporting principles for this approach.

Implementation Strategy 1.2.1: Develop a Digital Collaboration Platform

To support this solution, a digital platform should be created to facilitate collaboration between startups and external experts. This platform will provide startups with an efficient means to access a broad range of expertise and resources, fostering innovation through shared knowledge. Digital innovation in resource sharing supports the development of this platform.

Implementation Strategy 2.1.1: Establish a Government-Startup Grant Program

A targeted grant program should be developed specifically for expanding incubator facilities. This program would ensure the focused use of funds for infrastructure development, fostering an environment conducive to innovation. Public investment in innovation infrastructure supports this strategy.

Implementation Strategy 2.2.1: Develop Corporate-Startup Partnership Programs

Structured programs should be established to facilitate partnerships between startups and corporate innovation labs. These partnerships ensure consistent support and resource sharing, helping startups navigate the challenges of product development. Corporate engagement in startup ecosystems provides the supporting principle for this approach.

Implementation Strategy 3.1.1: Develop an Incubator Facility Management System

A system should be created to track and manage the availability and usage of incubator facilities. This management system ensures efficient use of resources and better planning, leading to improved startup outcomes. Efficient resource management systems support this strategy.

Mentorship Quality

Implementation Strategy 1.1.1: Develop a Mentorship Program with Retired Professionals

A structured mentorship program could be created that actively recruits retired professionals and veterans to mentor MedTech startups. Structured programs ensure consistent engagement and resource allocation, leveraging the extensive experience of these mentors for strategic guidance.

Implementation Strategy 2.1.1: Develop a Diverse Mentorship Pool

Initiatives should be created to recruit and retain a diverse pool of mentors in terms of gender and language. A diverse mentorship pool ensures a wide range of perspectives and support mechanisms, promoting inclusivity and better addressing the needs of diverse entrepreneurs.

Implementation Strategy 3.1.1: Develop Sector-Specific Mentorship Programs

Mentorship programs specifically for MedTech startups should be created, focusing on sector-specific challenges and opportunities. Tailored mentorship programs ensure relevant guidance and support, enhancing the chances of success in this specialized field.

Implementation Strategy 4.1.1: Develop Entrepreneurial Mentorship Certification

A certification program could be created for mentors to ensure they have significant entrepreneurial experience. Certified mentors with entrepreneurial experience can provide more relevant and practical guidance, improving the quality of support provided to startups.

Implementation Strategy 5.1.1: Develop Industry-Experienced Mentor Recruitment Programs

Targeted programs could be established to actively recruit mentors with extensive industry experience. Industry-experienced mentors provide deeper insights into the practical challenges of the MedTech industry, enhancing the effectiveness of the mentorship provided.

Time Constraints

Implementation Strategy 1.1.1: Develop a Dedicated Team of Project Management Experts

Develop a dedicated team of project management experts within the incubator to provide ongoing support to startups. This team would focus on project planning, risk management, and resource allocation, ensuring that startups receive continuous and structured project management support.

Implementation Strategy 1.2.1: Develop a Comprehensive Project Management Training Program

Develop a comprehensive training program that includes online courses, workshops, and mentorship opportunities focused on advanced project management techniques tailored for MedTech startups. This ensures that founders have access to both theoretical knowledge and practical skills.

Implementation Strategy 2.1.1: Develop a Project Management Integration Plan

Develop a project management integration plan within the incubator that includes mandatory coaching sessions, the use of project management software, and regular progress reviews. This approach ensures that startups are consistently guided in their project management efforts.

Implementation Strategy 2.2.1: Develop a Comprehensive Library of Standardized Templates

Develop a comprehensive library of standardized project management templates and make them available through an online portal, along with guidelines for their use. This resource library ensures that startups have easy access to essential tools for effective project management.

Implementation Strategy 3.1.1: Develop a Structured Accelerator Program

Develop a structured accelerator program within the incubator that includes a set curriculum, milestones, and regular progress reviews to ensure startups stay on track. The program would provide the intensive support necessary for rapid development.

Implementation Strategy 3.2.1: Develop a Milestone-Based Funding Model

Develop a milestone-based funding model within the incubator that ties financial disbursements to the achievement of specific, measurable project milestones. This model ensures that startups receive funding when they meet critical development milestones, keeping them on track.

Implementation Strategy 4.1.1: Develop a Partnership Program with External Project Management Firms

Develop a partnership program with external project management firms to provide regular consultancy and support services to startups within the incubator. This approach ensures that startups have access to high-quality project management expertise even if the incubator lacks internal resources.

Implementation Strategy 4.2.1: Develop a Schedule of Regular Project Management Workshops

Develop a schedule of regular project management workshops, including both online and in-person sessions, led by experienced project managers. These workshops would ensure that startups receive continuous support and are equipped with the latest project management techniques.

Cultural Fit

Implementation Strategy 1.1.1: Develop and Implement a Cultural Training Program

A structured cultural training program should be developed and implemented within the incubator, including workshops, role-playing exercises, and continuous learning modules to foster cultural understanding. These programs will help align the working styles of startups and incubators, improving collaboration and reducing potential conflicts.

Implementation Strategy 1.2.1: Schedule Monthly Cultural Exchange Sessions

Monthly cultural exchange sessions could be scheduled, including informal gatherings and structured activities facilitating open discussions about cultural differences and commonalities. These sessions will foster mutual understanding and improve the alignment of cultural values between startups and incubators.

Implementation Strategy 2.1.1: Partner with HR Consultants for Cultural Assessments

A partnership with HR consultants should be established to create tailored cultural assessments and team-building activities, ensuring they are integrated into the onboarding and ongoing development processes. These assessments will help startups and incubators align their cultural expectations, reducing potential conflicts.

Implementation Strategy 2.2.1: Create and Integrate a Cultural Fit Checklist

A comprehensive cultural fit checklist should be created and integrated into the onboarding process, with periodic reviews to ensure ongoing alignment with cultural expectations. This tool will help startups and incubators maintain a strong cultural fit throughout their collaboration.

Implementation Strategy 3.1.1: Develop a Language and Communication Training Program

A language and communication training program could be developed, including workshops, e-learning modules, and one-on-one coaching sessions. This program will help employees from diverse backgrounds improve their communication skills, enhancing collaboration within the startup.

Implementation Strategy 3.2.1: Develop and Enforce a Language Policy

A language policy could be developed and enforced within the startup, promoting the use of a common language for all official communications, with guidelines for multilingual support as needed. This policy will help create a more inclusive work environment and improve communication efficiency.

Implementation Strategy 4.1.1: Develop a Comprehensive Onboarding Program

A comprehensive onboarding program should be developed, including cultural orientation, training on organizational values, and continuous support through mentorship and feedback. This program will help new employees integrate smoothly into the startup's culture, improving their productivity and engagement.

Implementation Strategy 4.2.1: Develop a Structured Peer Mentorship Program

A structured peer mentorship program could be developed, pairing new employees with experienced mentors, including regular check-ins and feedback sessions. This program will support new hires in adapting to the startup culture and becoming productive team members.

Implementation Strategy 5.1.1: Develop a Government Program for Cultural Alignment Incentives

A government program could be developed to offer tax incentives, grants, or subsidies to third parties that demonstrate cultural alignment and collaboration with startups. This program will encourage third parties to align their cultural practices with those of startups, fostering better collaboration.

Implementation Strategy 5.2.1: Develop and Integrate Cultural Fit Evaluation Criteria

A comprehensive set of cultural fit evaluation criteria should be developed and integrated into the third-party selection process, with regular reviews and updates. These criteria will help ensure that third-party collaborators align with the cultural values and working styles of the startup.

Implementation Strategy 6.1.1: Develop an Online Feedback and Rating Platform

To implement this solution, a dedicated online platform should be developed where all stakeholders—startups, incubators, and third parties—can provide anonymous ratings and feedback on their collaborations. This platform will feature detailed comments and anonymized ratings to ensure honest assessments while improving the transparency and accountability of partnerships within the ecosystem.

Implementation Strategy 6.2.1: Develop a Structured Audit Process for Cultural Fit

A structured audit process should be developed, involving surveys, interviews, and performance reviews to assess cultural fit and provide actionable insights for improvement. This process will help maintain continuous alignment between startups, incubators, and third parties.

Follow-Up Support

Implementation Strategy 1.1.1: Develop Formal Agreements with Venture Capital Firms

Formal agreements could be developed with venture capital firms to provide structured advisory support post-incubation, including regular check-ins and strategic planning sessions. This structured approach will ensure startups receive continuous guidance as they scale.

Implementation Strategy 1.2.1: Form Advisory Boards with Quarterly Meetings

Advisory boards could be formed to meet quarterly, reviewing progress, providing guidance, and offering strategic advice tailored to the needs of post-incubation startups. This regular interaction will help startups stay on course as they grow.

Implementation Strategy 2.1.1: Develop a Structured Alumni Mentorship Program

A structured alumni mentorship program could be developed, where successful graduates commit to mentoring new alumni through regular interactions and support sessions. This program will foster ongoing connections and knowledge sharing within the alumni community.

Implementation Strategy 2.2.1: Develop an Online Alumni Engagement Platform

An online platform with features such as alumni directories, discussion forums, and event listings could be developed to facilitate ongoing engagement and collaboration. This platform will help maintain strong connections among alumni, supporting continuous growth and innovation.

Implementation Strategy 3.1.1: Establish Partnerships for Facility Access

Partnerships with universities and research institutions could be established to provide post-incubation startups with access to specialized facilities at reduced rates. This access will enable startups to continue their R&D efforts without significant financial strain.

Implementation Strategy 3.2.1: Develop an Online Resource Directory

An online resource directory should be developed and regularly updated with information on available facilities, services, and support programs for graduates. This directory will help startups quickly find the resources they need to continue their growth trajectory.

Implementation Strategy 4.1.1: Develop a Centralized Online Platform

A centralized online platform could be developed that aggregates information on all available post-incubation support programs, including funding opportunities, mentorship programs, and facility access. This platform will serve as a one-stop resource for graduates seeking support.

Implementation Strategy 4.2.1: Schedule Regular Webinars and Information Sessions

A schedule for regular webinars and information sessions could be developed, inviting experts to discuss various post-incubation support programs and answer questions from graduates. These sessions will ensure that graduates know and can access available resources.

Implementation Strategy 4.3.1: Develop Comprehensive Virtual Incubation Programs

Comprehensive virtual incubation programs could be developed, including remote mentorship, access to online resources, and virtual networking events. These programs will help startups access the support they need, regardless of their location.

Tailored Business Development

Implementation Strategy 1.1.1: Establish a Recruitment Initiative for MedTech Experts

A recruitment initiative could be established within incubators to attract business development professionals with proven experience in diverse sectors of MedTech. Offer competitive salaries and professional development opportunities to retain top talent, aligning with best practices in organizational design as outlined by Galbraith (2002).

Implementation Strategy 1.2.1: Design a Comprehensive MedTech Curriculum

A comprehensive curriculum could be designed with input from industry experts, covering topics such as regulatory compliance, market access, and clinical trial management. Incorporate leadership dynamics and sustainable entrepreneurship principles as suggested by Gill (2012) and Shepherd & Patzelt (2011).

Implementation Strategy 2.1.1: Develop Partnerships with Regulatory Agencies for Workshops

Partnerships with regulatory agencies should be developed to offer workshops led by current or former regulators who can provide insider perspectives. Utilize frameworks and case studies to illustrate successful regulatory strategies, as recommended by Chataway et al. (2007).

Implementation Strategy 2.2.1: Create a Network of Vetted Regulatory Consulting Firms

A network of vetted regulatory consulting firms should be created to offer discounted or pro-bono services to startups within the incubator. Leverage top management support principles, as highlighted by Young & Jordan (2008), to ensure regulatory compliance is prioritized.

Implementation Strategy 3.1.1: Develop a Structured Market Entry Program

A structured market entry program should be developed within the incubator that includes workshops on market analysis, customer segmentation, and go-to-market strategies. Apply strategic management principles from Covin & Slevin (1989) and Zahra & Bogner (2000) to tailor market access programs for MedTech startups.

Implementation Strategy 3.2.1: Establish a Partnership Framework for MedTech Startups

A partnership framework should be established within the incubator that facilitates introductions and collaboration agreements between startups and established healthcare companies. Utilize principles

of open innovation, as discussed by Chesbrough (2003), to foster successful commercialization partnerships.

Implementation Strategy 4.2.1: Create a Structured Mentorship Program with Clear Guidelines

A structured mentorship program could be created with clear guidelines and expectations, offering regular check-ins and feedback sessions to ensure productive mentor-mentee relationships. Leverage social exchange theory and mentorship dynamics as discussed by Ensher et al. (2001) to structure an effective mentorship program.

Clinical Trial Design and Management

Implementation Strategy 1.1.1: Establish Formal Partnerships with Leading CROs

Establish formal partnerships with leading CROs to provide startups with customized support packages that include trial design, management, and regulatory compliance services. Leveraging CROs' established protocols and expertise in handling complex clinical trials can significantly benefit startups.

Implementation Strategy 1.2.1: Develop a Dedicated In-House Clinical Trial Design Team

Develop a dedicated in-house team with a mix of experienced clinical trial designers and regulatory experts to provide continuous support to startups. Integrating in-house expertise can lead to more cohesive and responsive trial design and management processes.

Implementation Strategy 2.1.1: Establish a Clinical Trial Funding Initiative

Establish a funding initiative within the incubator that includes partnerships with government agencies, private investors, and non-profit organizations to create a diversified funding pool for clinical trials. Combining various funding sources can mitigate financial risks and ensure the availability of sufficient resources.

Implementation Strategy 2.2.1: Establish Shared Clinical Trial Infrastructure

Establish a shared clinical trial infrastructure within the incubator, including centralized data management systems, patient recruitment databases, and monitoring tools. Shared infrastructure can optimize resource utilization and streamline trial management processes.

Implementation Strategy 3.1.1: Establish Partnerships with Patient Recruitment Services

Establish partnerships with patient recruitment agencies and services specializing in digital outreach and community engagement to improve recruitment rates. Utilizing specialized recruitment services can significantly improve patient enrollment and retention.

Implementation Strategy 3.2.1: Develop and Implement Patient Retention Plans

Create and implement detailed patient retention plans that include regular updates, education sessions, and personalized engagement activities. Consistent engagement and communication strategies can significantly improve patient retention rates.

Implementation Strategy 4.1.1: Invest in and Implement Electronic Data Capture Systems

Invest in and implement state-of-the-art electronic data capture systems and train staff on their practical use. Advanced EDC systems ensure data quality and regulatory compliance, essential for successful clinical trials.

Implementation Strategy 4.2.1: Establish a Biostatistics Support Team and Training Program

Establish a biostatistics support team within the incubator and offer regular training workshops on data analysis and interpretation. Access to biostatistical expertise and training ensures accurate data analysis and supports successful regulatory submissions.

Supply Chain and Logistics

Implementation Strategy 1.1.1: Establish Formal Partnerships with Supply Chain Consulting Firms

Establish formal partnerships with supply chain consulting firms to provide startups with customized support packages, including supply chain audits, process optimization, and strategic planning. Leveraging the extensive experience and best practices of supply chain consulting firms enhances operational efficiency.

Implementation Strategy 1.2.1: Develop a Dedicated In-House Supply Chain Team

Develop a dedicated in-house team of supply chain experts within the incubator, providing continuous support, training, and strategic planning for startups. Continuous in-house support ensures startups receive timely and tailored advice to optimize their supply chain operations.

Implementation Strategy 2.1.1: Establish Partnerships with Warehousing and Logistics Service Providers

Establish partnerships with warehousing and logistics service providers to create shared facilities accessible to startups within the incubator. Shared infrastructure reduces costs and enhances operational efficiency by providing access to essential logistics resources.

Implementation Strategy 2.2.1: Develop a Centralized Digital Supply Chain Platform

Develop a centralized digital platform that integrates supply chain management tools, providing real-time data and analytics for efficient logistics coordination. Centralized platforms improve visibility and coordination, leading to more efficient supply chain operations.

Implementation Strategy 3.1.1: Develop Comprehensive Regulatory Compliance Training Programs

Develop comprehensive training programs in partnership with regulatory experts to educate startups on supply chain compliance requirements. Thorough training programs ensure startups understand and adhere to regulatory standards, reducing compliance risks.

Implementation Strategy 3.2.1: Implement Automated Compliance Management Systems

Develop and implement automated compliance management systems that integrate with the centralized supply chain platform to ensure continuous regulatory compliance. Automated systems streamline compliance management, ensuring consistent adherence to regulatory requirements.

Implementation Strategy 4.1.1: Invest in Advanced Logistics Management Software

Invest in and implement advanced logistics management software that integrates all logistics activities and provides real-time data and analytics. Advanced software solutions enhance logistics coordination and operational efficiency.

Implementation Strategy 4.2.1: Establish Strategic Partnerships with Leading Logistics Providers

Establish strategic partnerships with leading logistics providers to ensure reliable and scalable logistics solutions for startups. Leveraging the expertise and resources of logistics providers enhances operational efficiency and scalability.

Talent Acquisition and Retention

Implementation Strategy 1.1.1: Establish Formal Partnerships with MedTech Recruitment Agencies

Establish formal partnerships with recruitment agencies specializing in MedTech to provide startups with access to a curated talent pool, recruitment process support, and industry-specific insights. Leveraging the networks and expertise of specialized recruitment agencies enhances talent acquisition.

Implementation Strategy 1.2.1: Develop a Dedicated In-House Talent Acquisition Team

Develop a dedicated in-house talent acquisition team within the incubator, providing startups with continuous support and strategic guidance in recruitment. Continuous in-house support ensures startups receive tailored advice and assistance in their recruitment processes.

Implementation Strategy 2.1.1: Benchmark Compensation Packages and Include Equity Options

Benchmark compensation packages against industry standards and include attractive benefits such as equity options and flexible work arrangements to appeal to top talent. Competitive compensation aligned with industry standards attracts high-quality candidates.

Implementation Strategy 2.2.1: Develop a Comprehensive Employer Branding Strategy

Develop a comprehensive employer branding strategy that includes digital marketing campaigns, social media presence, and employee engagement initiatives to highlight the startup's mission and culture. A well-crafted employer brand attracts passionate and mission-driven candidates.

Implementation Strategy 3.1.1: Develop and Communicate Clear Career Development Plans

Develop and communicate clear career development plans, including regular performance reviews, professional development opportunities, and leadership training programs. Clear career development paths enhance employee satisfaction and retention.

Implementation Strategy 3.2.1: Implement Policies and Practices to Foster a Positive Workplace Culture

Implement policies and practices that promote work-life balance, recognition programs, and team-building activities to foster a positive and inclusive workplace culture. A positive workplace culture enhances employee engagement and retention.

Implementation Strategy 4.1.1: Establish Partnerships with Educational Institutions for External Training

Establish partnerships with educational institutions and professional organizations to provide access to a wide range of training programs, workshops, and certifications for employees. Access to external training enhances employees' skills and professional growth.

Implementation Strategy 4.2.1: Develop Structured Mentorship and Coaching Programs

Develop structured mentorship and coaching programs within the incubator, pairing employees with experienced mentors and coaches to provide personalized career guidance. Structured mentorship and coaching programs enhance employee development and retention.

Integration with Healthcare Institutions and Workflows

Implementation Strategy 1.1.1: Establish Formal Partnerships with Healthcare Professionals

Establish formal partnerships with healthcare professionals to conduct regular meetings, workshops, and on-site observations, ensuring that devices are designed to integrate seamlessly into existing workflows. Collaboration with healthcare professionals provides real-world insights that improve device design and integration.

Implementation Strategy 1.2.1: Conduct Workflow Analysis Studies in Collaboration with Healthcare Providers

Conduct workflow analysis studies in collaboration with healthcare providers to map out existing processes and identify integration opportunities for new devices. Detailed workflow analysis ensures comprehensive understanding and smooth integration of new devices.

Implementation Strategy 2.1.1: Establish Formal Partnerships with Healthcare Providers for Device Testing

Establish formal partnerships with healthcare providers to enable ongoing testing and validation of devices in real-world healthcare settings. Real-world testing and validation refine device functionality and ensure practical applicability.

Implementation Strategy 2.2.1: Utilize Incubator Networks to Facilitate Introductions and Relationships

Utilize incubator networks to facilitate introductions and foster relationships with healthcare stakeholders, enabling startups to gain support and feedback from key industry players. Leveraging existing networks accelerates integration by connecting startups with key stakeholders.

Implementation Strategy 3.1.1: Develop a Regulatory Support Team within the Incubator

Develop a regulatory support team within the incubator to provide startups with guidance on documentation, submission processes, and compliance strategies. Dedicated regulatory support ensures compliance and smooth integration.

Implementation Strategy 3.2.1: Develop Automated Compliance Management Systems

Develop and implement automated compliance management systems to ensure continuous adherence to regulatory standards throughout the development and integration process. Automated systems streamline compliance management and reduce the risk of regulatory violations.

Implementation Strategy 4.1.1: Collaborate with Standards Organizations to Develop Interoperability Standards

Collaborate with standards organizations and healthcare IT providers to develop and implement interoperability standards for seamless device integration. Interoperability standards ensure seamless communication and integration with existing IT systems.

Implementation Strategy 4.2.1: Establish a Technical Support Team within the Incubator

Establish a technical support team within the incubator to assist startups with IT integration, addressing compatibility issues and ensuring seamless operation with existing systems. Dedicated technical support ensures seamless integration and reduces operational disruptions.

Feedback and Iteration Cycles

Implementation Strategy 1.1.1: Establish Formal Feedback Panels

Establish formal feedback panels that meet regularly to review and provide insights on device prototypes. Structured feedback from healthcare professionals enhances device usability and functionality.

Implementation Strategy 1.2.1: Implement Collaborative Platforms with Real-Time Feedback Features

Implement collaborative platforms with features for real-time feedback, enabling healthcare professionals to provide immediate insights. Real-time feedback accelerates device improvement cycles.

Implementation Strategy 2.1.1: Conduct Regular UX Workshops with End-Users

Conduct regular UX workshops with end-users to gather comprehensive feedback on device usability and functionality. User feedback ensures devices are designed to meet end-user needs.

Implementation Strategy 2.2.1: Develop a Formal End-User Advisory Board

Develop a formal end-user advisory board to provide continuous feedback and suggestions for device improvement. Continuous feedback from end-users ensures devices meet user expectations and needs.

Implementation Strategy 3.1.1: Provide Startups with Access to Advanced Prototyping Labs

Provide startups with access to prototyping labs equipped with the latest tools and technologies to facilitate rapid iteration. Access to advanced prototyping facilities accelerates design iteration and refinement.

Implementation Strategy 3.2.1: Develop a Rapid Iteration Program with Regular Feedback Sessions

Develop a rapid iteration program that includes regular feedback sessions and access to testing facilities to facilitate continuous improvement. Structured iteration programs ensure systematic and efficient device refinement.

Implementation Strategy 4.1.1: Implement Agile Development Practices for Continuous Feedback Integration

Implement agile development practices, including sprints and stand-up meetings, to facilitate continuous feedback integration. Agile methodologies enhance flexibility and responsiveness to user feedback.

Implementation Strategy 4.2.1: Use Advanced Feedback Management Tools to Integrate Feedback Systematically

Use advanced feedback management tools to collect, analyze, and integrate feedback systematically. Structured feedback management ensures the effective integration of user insights into product development.

Customizable Mentorship Programs

Implementation Strategy 1.1.1: Develop dedicated mentorship tracks

Develop dedicated mentorship tracks within incubators, focusing on different startup stages. Assign mentors with specific expertise relevant to each stage to provide targeted support. Mian, Lamine, & Fayolle (2016) highlight the benefits of tailored mentorship programs in technology business incubation.

Implementation Strategy 1.2.1: Create a library of mentorship modules

Create a library of mentorship modules that can be mixed and matched to address specific startup needs. These modules should cover key areas such as product development, market analysis, and regulatory compliance. Isenberg (2010) supports the use of modular frameworks in entrepreneurial ecosystems.

Implementation Strategy 2.1.1: Develop a digital platform

Develop a digital platform that utilizes AI to match mentors with startups based on detailed profiles and needs assessments. Regularly update the matching algorithm to reflect evolving requirements and feedback.

Implementation Strategy 2.2.1: Design a comprehensive mentor training curriculum

Design a comprehensive mentor training curriculum that includes workshops, webinars, and peer learning sessions. Incorporate feedback mechanisms to improve the training program continuously. Allen, Eby, & Lentz (2006) support the need for structured mentor training programs.

Implementation Strategy 3.1.1: Implement a digital calendar and notification system

Implement a digital calendar and notification system to schedule and remind mentors and startups of upcoming check-ins and reviews. Utilize progress tracking tools to document and review mentorship outcomes. Ensher & Murphy (2011) support using structured check-ins to maintain mentorship engagement.

Implementation Strategy 3.2.1: Develop a custom digital platform

Develop a custom digital platform specifically for mentor-startup interactions, incorporating features like virtual whiteboards, task management, and secure document sharing. Nowadays, Slack is popular and is being used by different incubators.

Implementation Strategy 4.1.1: Create a targeted recruitment campaign

Create a targeted recruitment campaign to attract experienced MedTech professionals as mentors. Offer incentives such as honorariums, recognition programs, and networking opportunities. Freeman & Engel (2007) highlight the need for targeted mentor recruitment in specialized sectors.

Implementation Strategy 4.2.1: Develop a comprehensive set of sector-specific modules

Develop a comprehensive set of sector-specific modules in collaboration with industry experts. Offer these modules through online courses, workshops, and one-on-one mentoring sessions. Kramer et al. (2012) support developing specialized training and mentorship programs for MedTech startups.

Access to Advanced Manufacturing Technologies

Implementation Strategy 1.1.1: Develop a network of partnerships with local and international manufacturing facilities

Develop a network of partnerships with local and international advanced manufacturing facilities. Create agreements that allow startups within the incubator to access these facilities at discounted rates or through a shared usage model. Chiu, Lai, & Lee (2015) support the creation of comprehensive collaboration models to drive sustainable innovation.

Implementation Strategy 1.2.1: Invest in building advanced manufacturing labs

Invest in building advanced manufacturing labs equipped with the latest technologies, such as 3D printers, CNC machines, and bioprinters. Offer workshops and training sessions to familiarize startups with the available equipment. Baglieri & Lorenzoni (2009) suggest that university research centers can act as knowledge brokers in these collaborations.

Implementation Strategy 2.1.1: Design and implement comprehensive training programs

Design and implement comprehensive training programs that cover advanced manufacturing techniques. Collaborate with industry experts to develop the curriculum and hands-on workshops. Gibson, Rosen, & Stucker (2014) advocate for developing specialized training programs in additive manufacturing.

Implementation Strategy 2.2.1: Establish a mentorship program

Establish a mentorship program where manufacturing experts are paired with startups to provide ongoing support and guidance. Host regular mentor-led seminars and Q&A sessions. Keupp & Gassmann (2009) support the concept of open innovation and the role of expert guidance in fostering innovation.

Implementation Strategy 3.1.1: Develop funding programs

Develop funding programs that provide subsidies or grants to startups for accessing advanced manufacturing technologies. Partner with government agencies and private organizations to secure financial support. Pisano & Shih (2012) argue for a manufacturing renaissance to support economic growth, emphasizing the need for accessible resources.

Implementation Strategy 3.2: Create a cooperative model

Create a cooperative model where multiple startups pool resources to share access to advanced manufacturing equipment. Develop a booking system to manage usage and ensure fair access. Von Hippel (2005) supports the concept of democratizing innovation through shared resources and collaborative efforts.

Implementation Strategy 4.1.1: Develop a comprehensive product development framework

Develop a comprehensive product development framework that includes stages for design, prototyping, testing, and production using advanced manufacturing technologies. Provide training and resources to ensure startups can effectively use the framework. Thomke (2003) emphasizes the importance of experimentation and structured processes in driving innovation.

Implementation Strategy 4.2.1: Provide access to advanced software tools

Provide access to advanced software tools through incubator facilities. Offer training sessions and support to help startups effectively use these tools in their product development process. Groover (2016) advocates for integrating computer-integrated manufacturing systems to enhance production efficiency and product quality.

Long-Term Sustainability and Impact

Implementation Strategy 1.1.1: Create a series of strategic planning workshops

Create a series of strategic planning workshops led by industry experts focusing on long-term market analysis, risk management, and sustainability initiatives. David (2011) supports the idea of structured strategic management processes.

Implementation Strategy 1.2.1: Develop a Business Viability Framework

A dedicated framework should be developed to guide startups in creating and maintaining viable business models. This framework would include resources on financial planning, market analysis, and scalability strategies. Startups would participate in workshops and mentoring sessions to refine their business models, ensuring they are equipped to handle market fluctuations and secure long-term sustainability. The lean startup methodology (Blank, 2013) provides a solid foundation for building adaptable and resilient business models to sustain long-term growth.

Implementation Strategy 2.1.1: Establish a dedicated scale-up team

Establish a dedicated scale-up team within the incubator that provides hands-on support for market expansion, operational efficiency, and strategic partnerships. Blank (2013) underscores the transformative impact of the lean startup methodology in scaling businesses.

Implementation Strategy 2.2.1: Create a partnership office

Create a partnership office within the incubator that actively seeks and facilitates strategic partnerships, providing a platform for collaboration and joint ventures. Chesbrough (2006) advocates for creating a system that supports open innovation and collaboration across organizations.

Implementation Strategy 3.1.1: Develop a standard impact measurement toolkit

Develop a standard impact measurement toolkit for MedTech startups, including templates, data collection methods, and reporting guidelines.

Implementation Strategy 3.2.1: Incorporate agile methodologies

Incorporate agile methodologies and continuous improvement practices into the startup development cycle, supported by regular training and feedback sessions. Deming (1986) advocates for the use of continuous improvement as a key driver of organizational success.

Implementation Strategy 4.1.1: Develop and deliver financial planning workshops

Develop and deliver a series of financial planning workshops led by finance experts, focusing on critical areas such as long-term budgeting, investment diversification, and risk management. Brigham & Ehrhardt (2013) support the importance of financial management education in sustaining business growth.

Implementation Strategy 4.2.1: Create a long-term funding strategy template

Create a long-term funding strategy template for startups, including guidelines for identifying and securing diverse funding sources and establishing financial milestones. Gompers & Lerner (2001) emphasize the importance of strategic funding in the growth and success of startups.

Appendix C: Pre-Survey Description and Survey Questions

Pre-Survey Description

Proposed Digital Platform to Improve MedTech Entrepreneurship Ecosystem

The proposed platform is designed to improve collaboration and streamline connections within the MedTech entrepreneurship ecosystem. It helps bridge gaps between startups and other key actors, either directly or through university and hospital incubators. The platform enhances incubators' access to facilities, services, and specialized mentors, making them better equipped to support startups.

Key Features:

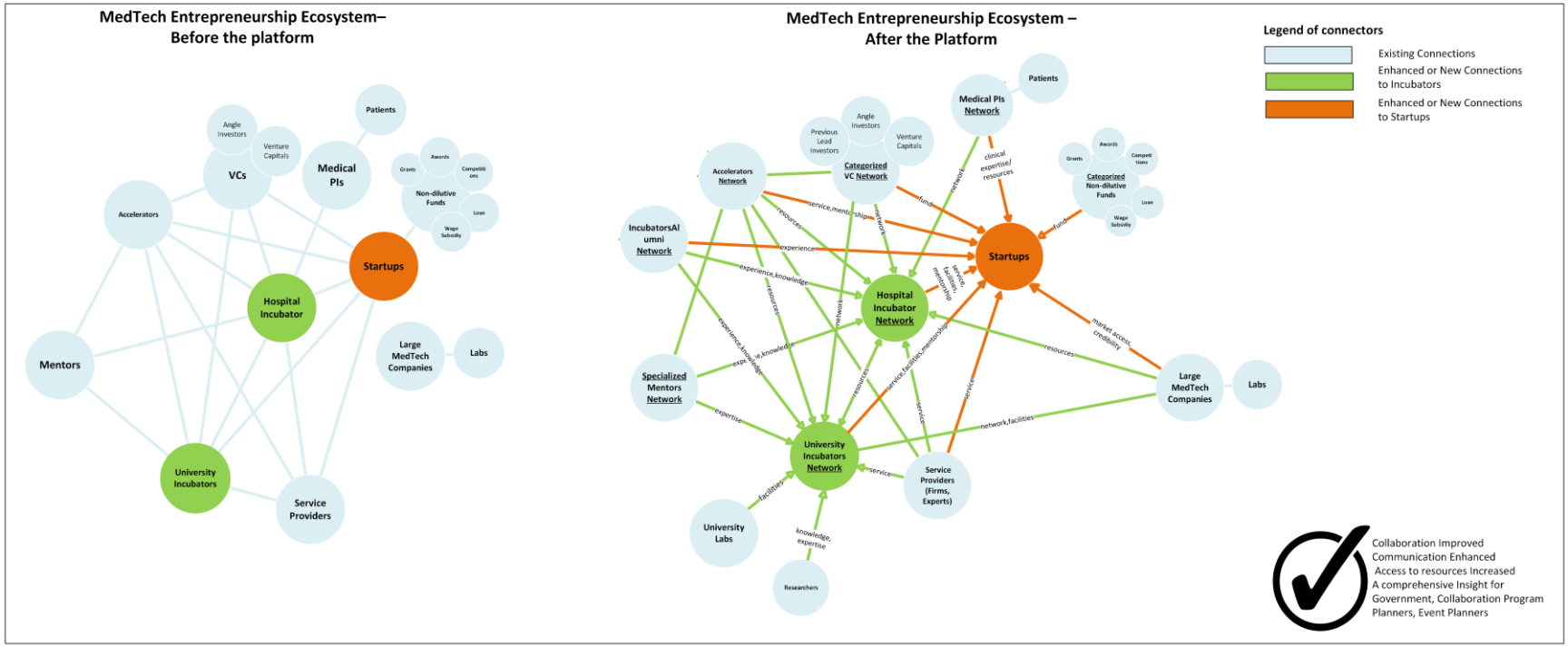
Personalized User Experience: Users specify their characteristics and needs, which the platform uses to match them with relevant partners, resources, and opportunities.

Filters and Features: The platform provides categorized resources for efficient exploration.

Program Use: Funding and collaboration planners can also utilize the platform to match the most suitable partners for their programs.

MedTech Entrepreneurship Ecosystem Diagram

The diagram illustrates the connections between key actors in the MedTech ecosystem, focusing on the resources and connections flowing toward incubators and startups. Elements directed toward other actors are not shown in the diagram.



Before the Platform: The ecosystem was fragmented, with weak connections and limited collaboration between key players such as startups, incubators, universities, hospitals, and service providers. Startups were limited to the incubator in which they were residents, restricting their access to facilities and services.

After the Platform: The platform strengthens the ecosystem by creating networks of incubators, accelerators, medical PIs, specialized mentors, and capital providers. Now, instead of being confined to a single incubator, startups can access a wide range of facilities and services across the entire incubator network, fostering greater collaboration and resource-sharing.

“Service providers” in the diagram include companies providing services in the regulatory, legal, supply chain, market research, reimbursement, project management, market entry, human resources, health IT, business development, patient recruitment, and MedTech recruitment.

The following survey was distributed to participants within the MedTech ecosystem to gather feedback on the proposed platform. The questions were the same for all participants.

1. **What is your primary role in the MedTech ecosystem? (Select all that apply)**

- ○ Startup
- ○ University Incubator
- ○ Hospital Incubator
- ○ Accelerator
- ○ Medical Principal Investigator (PI)
- ○ Investor/Venture Capitalist (VC)
- ○ Non-Dilutive Funding Provider (e.g., grants, awards, competitions)
- ○ Mentor
- ○ Other

2. **What is your current job position?**

3. **What company or organization are you affiliated with?**

4. **How many years have you worked within the MedTech ecosystem?**

- ○ Less than 1 year
- ○ 1-3 years
- ○ 4-6 years
- ○ 7-10 years
- ○ More than 10 years

5. **In which region are you primarily based? (Please specify the city)**

- ○ Canada
- ○ USA
- ○ Europe
- ○ Asia
- ○ Middle East
- ○ Other

6. **Have you previously used or been involved with any collaboration platforms like this in the MedTech ecosystem? (If yes, please specify the platform)**

- ○ Yes
- ○ No
- ○ Other

7. **How effectively could the platform facilitate collaborations between incubators and other actors (e.g., medical PIs, accelerators, service providers) to strengthen incubators' networks and resources, allowing them to better support startups?**

- ○ Very effectively
- ○ Effectively
- ○ Somewhat effectively
- ○ Ineffectively
- ○ Other

8. **To what extent could the platform help startups access necessary resources (e.g., mentors and services) directly or through incubators?**

- ○ Very effectively
- ○ Effectively

- Somewhat effectively
- Ineffectively

9. **How effectively could the platform support startups in securing capital (both dilutive and non-dilutive)?**

- Very effectively
- Effectively
- Somewhat effectively
- Ineffectively
- Other

10. **How effectively could the platform bridge gaps between startups and large MedTech companies, helping overcome barriers to market adoption?**

- Very effectively
- Effectively
- Somewhat effectively
- Ineffectively
- Other

11. **How effectively could the platform facilitate easier access to service providers (e.g., regulatory, market research, legal, health economics and reimbursement, supply chain, etc.) for key ecosystem players?**

- Very effectively
- Effectively
- Somewhat effectively
- Ineffectively

- Other

12. **How effectively could the platform help minimize wrong partner selection across all actors (e.g., mentors, investors, service providers) by providing better matching criteria and filters?**

- Very effectively
- Effectively
- Somewhat effectively
- Ineffectively

13. **How effectively could the platform assist startups in identifying and connecting with the most suitable accelerators aligned with their specific development stage?**

- Very effectively
- Effectively
- Somewhat effectively
- Ineffectively

14. **How effectively could the platform transform the overall MedTech ecosystem, improving collaboration, access to resources, and efficiency across all actors (e.g., startups, incubators, investors, service providers)?**

- Very effectively
- Effectively
- Somewhat effectively
- Ineffectively

15. **Which of the following challenges do you believe the platform could address through enhanced collaboration with service providers, specialized mentors, strengthened incubator networks, and other features? (Select all that apply)**

- Fragmented ecosystem (lack of collaboration between key stakeholders)
- Access to global markets
- Reimbursement and health economics
- Navigating regulatory environments
- Access to capital and funding
- Barriers to market adoption
- Integration with healthcare systems
- Resource allocation challenges
- Mentorship quality and customization
- Time management and constraints
- Cultural fit between partners and stakeholders
- Tailored business development services, supply chain, cybersecurity
- Clinical trial design and management
- Talent acquisition and retention
- Access to advanced manufacturing technologies
- Access to legal and accounting services
- Long-term sustainability and impact
- Mental health support for users
- Minimizing wrong partner selection through better matching criteria

16. **In your opinion, what has been the most significant improvement brought by the platform regarding ecosystem collaboration?**

17. **Are there any actors or areas in the ecosystem that the platform hasn't addressed or could improve further?**

18. **Additional Comments**

Appendix D: Proposed platform for implementation of the proposed model

The proposed platform is a comprehensive, user-centric tool designed to support the MedTech entrepreneurship ecosystem by connecting startups, incubators, researchers, investors, and other key stakeholders. The platform's primary goal is to foster collaboration, provide resources, and streamline processes for users across various stages of the MedTech lifecycle—from research and development to commercialization and scaling.

The platform's unique value lies in its ability to serve as a multi-functional hub, addressing the fragmented nature of the current MedTech ecosystem. By offering a wide range of resources, from regulatory support and funding opportunities to mentorship and global partnerships, the platform helps remove barriers to innovation, enabling users to connect with the right partners at the right time.

Key Platform Features

User Identification and Customization: Users are first prompted to define their role in the ecosystem, whether they are a startup, incubator, investor, researcher, or service provider. The platform personalizes the experience by gathering detailed specifications, such as the sector, development stage, geographic location, and specific needs. This tailored approach ensures that each user can find relevant resources, partners, and opportunities.

Dynamic Matching Process: The platform uses a two-phase approach to match users with the resources and partners they need. First, users specify their role and characteristics, and second, they define their needs (e.g., funding, mentorship, regulatory support). The platform continuously refines these matches based on user feedback, ensuring that users receive up-to-date recommendations and opportunities as the ecosystem evolves.

Funding and Grant Opportunities: A dedicated section for funding allows users to discover both public and private financial support tailored to their development stage. The platform provides access to venture capital, angel investors, government grants, and crowdfunding opportunities, all categorized by sector, geography, and eligibility criteria.

Regulatory Compliance and IP Support: MedTech startups face complex regulatory hurdles. The platform offers a regulatory hub that provides real-time updates on regional requirements (e.g., FDA, Health Canada), certification processes, and access to regulatory consultants. Additionally, there is a

section for intellectual property (IP) support, including templates for contracts, guidance on patent strategies, and access to legal experts.

Talent and Workforce Development: A talent pool and job board feature are included to help startups and other ecosystem actors recruit and develop the right teams. The platform also offers mentorship programs, career development resources, and internship opportunities to nurture early talent within the MedTech space.

Innovation Showcase: Startups and researchers can showcase their technologies, products, and research projects to attract investment and partnerships. The innovation showcase section allows users to upload pitch decks, participate in demo days, and receive feedback from peers and experts.

Supporting Collaboration and Resource Sharing

The platform strengthens the fragmented MedTech ecosystem by providing:

Networks for Incubators and Accelerators: Startups can now access services, facilities, and programs across an entire network of incubators rather than being confined to one. This encourages greater resource sharing and optimizes the use of funds supporting accelerators and incubators.

Specialized Mentor Network: A structured network of mentors, accessible across the ecosystem, ensures startups have access to sector-specific advice and entrepreneurial guidance. The platform helps incubators and accelerators find expert mentors for their programs, overcoming challenges in mentor recruitment.

Service Providers Directory: Startups can access a centralized list of service providers specializing in regulatory, legal, market entry, and other critical areas. This reduces the time and effort spent by startups in finding service providers familiar with the MedTech ecosystem.

Additional Key Features

Sustainability and Impact Initiatives: The platform promotes sustainability by offering best practices and impact measurement tools.

Global Partnerships: A section dedicated to international collaboration helps startups expand into global markets. The platform provides resources for navigating regulatory environments in different regions, cultural competency training, and access to trade missions and networking events.

Advanced Manufacturing and Prototyping: Startups can access shared lab spaces and prototyping facilities through a dedicated section for innovation labs and co-creation spaces. Virtual collaboration tools are also available for teams working on innovation challenges.

The proposed MedTech entrepreneurship platform bridges the gaps in the current fragmented ecosystem by offering a centralized, comprehensive solution that supports all phases of the MedTech lifecycle. It empowers startups to access the resources they need, fosters collaboration across a wide network of stakeholders, and provides personalized, dynamic matching to ensure users are continually connected with the right partners and opportunities. By consolidating resources and enhancing connectivity, the platform significantly enhances the efficiency and effectiveness of the MedTech ecosystem.