Interdisciplinary Research in Medical Sciences Specialty
ISSN: 3062-4401
2023, Volume 3, Issue 2, Page No: 36-63

Available online at: www.galaxypub.co/page/journals

Galaxy Publication

Examining Business Models for Navigating Uncertainty in the Healthcare, Medical Device, and Biotechnology Sectors

Sophie Laurent[1], Camille Durand[1], Élodie Marchand[1]*

[1]Department of Biomedical Innovation, Faculty of Medicine, University of Lausanne, Lausanne, Switzerland.

***E-mail** ✉ elodie.marchand@outlook.com

Received: 12 March 2023; **Revised:** 14 June 2023; **Accepted:** 21 June 2023

ABSTRACT

Innovation lies at the heart of healthcare, medical device, and biotechnology industries, where companies depend heavily on research, development, and the launch of novel products. However, innovation is often expensive and fraught with challenges in bringing products to market. Aligning business models (BMs) with these innovative processes is therefore essential for managing risk and supporting growth. This study investigates the role and design of BMs in innovative health-tech firms, focusing on how they can help navigate uncertainty and drive innovation. Through a systematic review of 34 recent papers, nine major BMs were identified: open innovation, sustainable, dynamic, dual, spin-off, frugal, high-tech entrepreneurial content marketing, back-end, and product-service system models. Among these, open innovation, sustainability, and dynamic approaches were found to form the foundational frameworks that can be integrated with other models. The study also presents a Dynamic Sustainable Business Model (DSBM) tailored for health-tech companies, emphasizing flexibility and long-term viability to better leverage emerging technologies. Furthermore, a framework of 28 uncertainty factors affecting BMs was developed to support strategic decision-making and risk mitigation. These findings provide actionable insights for health-tech organizations aiming to optimize innovation and value creation in a fast-changing environment.

Keywords: Innovation, Uncertainty, Healthcare, Sustainability, Health-tech, Business models

How to Cite This Article: Laurent S, Durand C, Marchand E. Examining Business Models for Navigating Uncertainty in the Healthcare, Medical Device, and Biotechnology Sectors. Interdiscip Res Med Sci Spec. 2023;3(2):36-63. https://doi.org/10.51847/PV3DytyT2t

Introduction

While business environments are inherently dynamic, the pace of change in recent decades has accelerated across most industries. Advances in technology and the proliferation of communication networks among firms have intensified global competition, prompting rapid shifts in production methods and service delivery. In this highly competitive and rapidly evolving landscape, organizations are compelled to continuously innovate by developing new services, adopting modern production approaches, and optimizing organizational and transactional processes. The rise of novel commercial activities not only fosters innovation but also boosts employment and enhances the overall efficiency of economic systems [1]. Researchers widely recognize the critical role of innovation in driving economic growth and development, with technological progress serving as a key determinant of social change. Consequently, “product development and innovation” has become a central factor in shaping the trajectories of both emerging and developed economies [2]. Within high-tech sectors, the healthcare industry—particularly medical and biotechnological equipment—stands out as a major domain of innovation. Industrialized nations increasingly support advancements in healthcare technologies, ranging from medical devices to biotechnological solutions. These areas depend heavily on scientific research and innovation, yet they are associated with high-risk environments; the inherent uncertainties in research and development (R&D) complicate the operational landscape for firms engaged in these fields [3].

The healthcare industry, often referred to as the medical or health economy, encompasses a broad range of sectors delivering patient care services, including curative, preventive, rehabilitative, and palliative interventions [4]. This

industry plays a vital role in developing and commercializing products and services aimed at preserving and restoring health. As one of the world's largest and fastest-growing industries, healthcare constitutes a substantial part of developed nations' economies, often exceeding 10% of GDP. In the United States alone, healthcare spending rose by 2.7% in 2021, reaching $4.3 trillion, which represented 18.3% of GDP [5, 6].

Within this extensive sector, biotechnology has emerged as a multidisciplinary field that integrates natural and engineering sciences to leverage organisms, cells, and molecular systems in creating innovative products and services. This convergence is critical in advancing healthcare through novel treatments and technologies [7]. Similarly, the medical device sector forms a cornerstone of healthcare innovation, encompassing products that range from basic instruments to complex machinery. Due to safety concerns, medical devices undergo stringent evaluation to ensure efficacy before entering the market [8]. The sector's importance is further underscored by robust growth projections, with global sales expected to rise over 5% annually, approaching $800 billion by 2030, highlighting its contribution to healthcare advancement and improved patient outcomes [9].

Despite this growth, significant mismatches persist between supply and demand in healthcare, with many regions facing critical shortages and underdeveloped commercial pathways for innovations [10]. Even countries with high scientific potential, particularly within the European Union, often lack effective mechanisms to translate new technological solutions into market-ready products [11]. Research indicates that the probability of a company successfully commercializing an innovation is only about 13% [12], and nearly 50% of registered medical equipment inventions never reach the market [13]. Numerous factors can impede implementation, resulting in the failure of otherwise viable innovations [1].

Hence, possessing a promising idea alone does not guarantee business success and, in some cases, may even threaten the firm's viability. What is crucial is the ability to transform technological opportunities into functional business models (BMs) that convert ideas into tangible products or services, deliver them to the market, and generate value for the company and its stakeholders. A well-designed BM provides a competitive advantage in complex and constantly evolving markets, enabling companies to secure favorable positions [14]. At its core, a BM outlines how a company generates value through its offerings, ensuring that customers are willing to pay for the product or service [15, 16]. A successful BM not only differentiates the firm from existing alternatives but also maximizes value for both customers and the organization.

Conversely, employing an unsuitable BM can hinder organizational performance and prevent a company from achieving its objectives [17]. Thus, a BM functions as a strategic tool that consolidates technological innovation and transforms it into economic value [18]. An effective BM should incorporate insights on target customers, value propositions, and business processes, clearly explaining the logic of economic activities and demonstrating how customer-desired value can be delivered efficiently [19]. Building a comprehensive BM that encompasses all critical aspects of a business is especially important during the early stages of a company or product development, as even the most innovative ideas hold limited value unless they are embedded in BMs capable of capturing and delivering their potential [20, 21]. Despite its importance, empirical evidence guiding entrepreneurs on the selection of appropriate BMs for innovative ventures remains scarce.

Examining business models (BMs) in the Healthcare, Medical Devices, and Biotechnology sectors is essential for effectively managing uncertainty. These industries function within complex ecosystems that involve multiple stakeholders, such as patients, healthcare providers, regulators, insurers, and investors [22]. Gaining insight into these dynamics is critical for responding to uncertainties arising from regulatory changes, shifting patient preferences, or technological advancements. Given the highly regulated nature of healthcare, adjustments in legislation can profoundly affect operations. Analyzing BMs enables firms to anticipate regulatory shifts, maintain compliance, and reduce the potential disruptions caused by evolving regulatory landscapes.

Moreover, medical technology and biotechnology are fast-evolving domains [23]. Studying BMs allows organizations to evaluate their ability to adapt to emerging technologies or modifications in existing ones, maintaining competitiveness and capitalizing on new opportunities. As patient expectations and demands evolve, BM analysis ensures that offerings remain patient-centered and aligned with current healthcare trends. Uncertainties also affect the availability and allocation of resources. By examining BMs, companies can strategically manage resources for R&D, innovation, and risk mitigation, enhancing organizational resilience. In summary, exploring BMs in these sectors supports proactive planning, innovation, risk management, and strategic adaptation, all of which are crucial for navigating the dynamic environments of healthcare, medical devices, and biotechnology while delivering effective healthcare solutions [24].

Despite the critical role of BMs in these industries, there remains a notable research gap. There is limited comprehensive understanding of corporate behavior in these markets, particularly regarding how different BM components interact. Systematic studies analyzing how BMs guide product management and the factors influencing their performance are scarce. Therefore, it is necessary to describe and compare BMs in these industries from the perspective of innovation management and new product introduction. Companies in medical devices, biotechnology, and other high-tech healthcare sectors operate as complex, dynamic, and uncertain systems due to multiple internal and external interactions. As knowledge-intensive businesses, these sectors experience heightened levels of uncertainty. Empirical evidence suggests that identifying the primary sources of uncertainty enhances companies' decision-making effectiveness [25]. Understanding these sources allows for more realistic BM design and implementation. Given the limited consideration of risk and inherent uncertainty in current BM studies for these sectors, this article proposes a framework to outline the causes of uncertainty and their impact on BMs in medical devices, biotechnology, and high-tech healthcare industries. The central question addressed is: what are the roots of uncertainty and risk in different aspects of BMs within these industries?

This systematic review seeks to advance knowledge of BMs applied in medical devices, biotechnology, and healthcare industries for new product innovation. The study has three objectives: (1) synthesize existing literature on BMs, identify and categorize key models, and compare them across critical dimensions such as infrastructure, offerings, customers, and financial aspects; (2) contextualize BM characteristics in medical and biotech markets, particularly regarding new product commercialization; and (3) develop conceptual frameworks—one mapping the causes of BM uncertainty, and another proposing a tailored dynamic and sustainable BM for the health-tech sector. The overarching aim is to address gaps in empirical evidence on optimal BMs for firms commercializing new healthcare, medical, and biotech products, providing practical frameworks and updated insights to align BMs with innovation activities and mitigate uncertainty. This approach supports effective innovation management and maximizes value creation from emerging technologies in these knowledge-driven industries.

The study's guiding research question—investigating the roots of uncertainty and risk within BMs in medical devices, biotechnology, and high-tech sectors—is central to understanding how BMs can effectively manage challenges in these rapidly innovating industries. These sectors are inherently high-risk, particularly in R&D activities, making it crucial to explore how BMs can support strategic risk management and decision-making. Addressing this question enhances both practical and theoretical frameworks, deepening comprehension of how BMs should evolve to navigate the unique uncertainties and risks characteristic of technology-intensive healthcare fields.

This study examines the interrelated domains of healthcare, medical devices, and biotechnology, emphasizing their synergistic connections. These sectors are inherently linked through their reliance on advanced science and technology, which drives innovation and addresses critical health challenges. Progress in healthcare is often dependent on the development of novel medical devices and biotechnological innovations, underscoring the interdependent nature of these industries. Moreover, they share similar regulatory frameworks and market dynamics, which result in reciprocal influences across sectors. This interconnection is further reinforced by overlapping stakeholders, including healthcare providers and patients, whose engagement spans multiple industries, reflecting the intertwined operations of these fields. The focus on these sectors is motivated by their central role in technological and innovative advancement. Their high-risk, high-reward characteristics provide a unique perspective on how business models navigate uncertainty within environments that are continually shaped by technological developments and regulatory changes. The exploration of these industries aims to reveal how business models can be designed and adapted to thrive amidst the inherent complexities and dynamism of these critical areas.

The study proceeds by outlining the systematic approach used for the literature review, including screening and analysis procedures. The results section presents the main findings, including the identification and classification of nine key business models. In the discussion section, these models are compared across four dimensions—infrastructure, offerings, customers, and finances—with open innovation, sustainability, and dynamicity highlighted as foundational frameworks. The analysis also examines business model characteristics in the medical and biotechnology sectors using illustrative case studies. Additionally, a framework is proposed that categorizes 28 groups of uncertainty factors affecting business models. Building on these insights, the study introduces a tailored Dynamic Sustainable Business Model (DSBM) for the health-tech sector, integrating sustainability, adaptability, and innovation. Collectively, the results and discussion provide a thorough analysis of business models for medical and biotech innovation, offering actionable insights and practical frameworks to help

companies effectively leverage emerging technologies. The conclusion section then summarizes the study's primary objectives, reiterates its contributions, and discusses its broader implications.

Materials and Methods

This systematic review explored and compared business models (BMs) in the medical equipment, biotechnology, and high-tech sectors within the healthcare industry. These particular domains were selected due to their pivotal role in driving healthcare innovation, characterized by rapid technological advancements and substantial impacts on health outcomes. They also present unique challenges, including navigating complex regulatory frameworks, managing high R&D costs, and responding to fast-evolving technologies. These factors make them especially suitable for examining business models, offering a rich context to understand how organizations can manage uncertainty, promote innovation, and adapt to changing market conditions. Focusing on these areas also addresses gaps in existing research, particularly concerning the application and effectiveness of BMs in high-stakes, fast-paced innovation environments. The aim is to provide insights into the strategic and operational practices of organizations at the forefront of healthcare technology.

The analysis of BMs in innovative firms was structured around four main dimensions and nine components: (a) Infrastructure: key activities, key resources, and partner networks; (b) Offering: value propositions; (c) Customers: customer segments, channels, and customer relationships; and (d) Finances: cost structure and revenue streams. The review sought to identify and compare the most commonly adopted BMs among companies in medical devices, biotechnology, and high-tech healthcare industries, while also examining their strategies for managing new product development. To achieve this, a four-phase literature verification process was conducted: (a) identifying and selecting relevant studies; (b) re-evaluating selected papers; (c) confirming full-text papers against inclusion criteria; and (d) analyzing 34 papers that met the eligibility standards.

The decision to use a systematic literature review was deliberate, given the complex and multifaceted nature of BMs in these industries. This methodology enabled a comprehensive synthesis of existing literature, providing a holistic understanding of current knowledge in rapidly evolving fields. Systematic reviews are particularly effective in interdisciplinary domains, offering a reproducible, unbiased, and rigorous approach to aggregating and analyzing diverse studies. This approach ensures coverage of multiple perspectives and captures the intricate nuances of these sectors. Moreover, given the dynamic and continually changing nature of healthcare, medical devices, and biotechnology, a systematic review allows integration of the most recent research findings, keeping the study relevant and up-to-date. This methodology aligns with the study's objective of providing an in-depth understanding of BMs while addressing emerging trends and existing knowledge gaps.

Between January and June 2023, a comprehensive search was conducted in the Web of Science (WoS) and Scopus databases to identify relevant literature. The search focused on studies published and indexed from 2014 through the first half of 2023, covering a decade-long period. This timeframe was chosen to capture a recent yet sufficiently comprehensive era of healthcare, medical devices, and biotechnology development, reflecting both contemporary trends and significant historical context. This period encompasses substantial technological advancements and global shifts in healthcare, providing a solid foundation for analyzing modern business models and their adaptability to emerging challenges. The selection of articles was guided by the keywords detailed in **Table 1.**

Table 1. Paper distribution by property.

Keywords	Web of Science	Scopus
(Company OR Firm) AND ("Business model") AND "new product"	242	268
(Company OR Firm) AND ("Business model") AND "medical device"	22	24
(Company OR Firm) AND ("Business model") AND "high tech"	118	107
(Company OR Firm) AND ("Business model") AND "biotechnology"	63	73
(Company OR Firm) AND ("Business model") AND Healthcare	105	154
Total Publications (after removing duplicates)	**524**	**598**
Total Publications (Limit to English Articles or reviews)	**324**	**336**
Total Publications After Remove Duplicates in all data bases: 434		

The keywords for this systematic literature review were carefully chosen based on the assumption that they would efficiently guide the study toward relevant publications and support its objectives. Selection involved a combination of expert judgment and iterative refinement to ensure comprehensive coverage of pertinent literature.

Terms such as "new product," "business model," "medical device," "high tech," and "biotechnology" were selected due to their frequent occurrence in prior research focused on healthcare, medical devices, and biotechnology. Preliminary searches confirmed that these keywords effectively captured a wide spectrum of innovative practices and business models within the targeted sectors.

The inclusion of "new product," despite its broad scope, was intentional to encompass diverse innovations in healthcare, including those that might not explicitly reference "medical devices" or "biotechnology." Incorporating "high-tech" was necessary, as biotechnology represents a subfield of high-tech industries within healthcare. Quotation marks were used in the searches to retrieve exact matches, avoiding inconsistent or irrelevant results that could compromise the accuracy of the review.

The initial search yielded 1,176 publications, with 626 indexed in Scopus using the specified keywords and filtering through abstracts and titles. In Web of Science, 550 publications were identified using the keywords in the "TOPIC" field across all databases. **Table 1** presents the distribution of publications identified by keyword searches in both databases.

Following the initial search, duplicate records were removed, reducing the total to 434 publications. Titles, abstracts, and keywords were then screened for relevance to the study's objectives. Some studies initially appeared relevant based on titles or keywords but were ultimately outside the scope of medical, biotechnology, or high-tech healthcare industries and were excluded. After this initial screening, 218 publications remained, which were further refined to 115 after more detailed assessment. The full texts of these remaining studies were then (semi)manually examined according to the criteria outlined in **Figure 1**. This final stage of screening identified 34 studies that fully met the inclusion criteria and formed the core dataset for analysis in this systematic review.

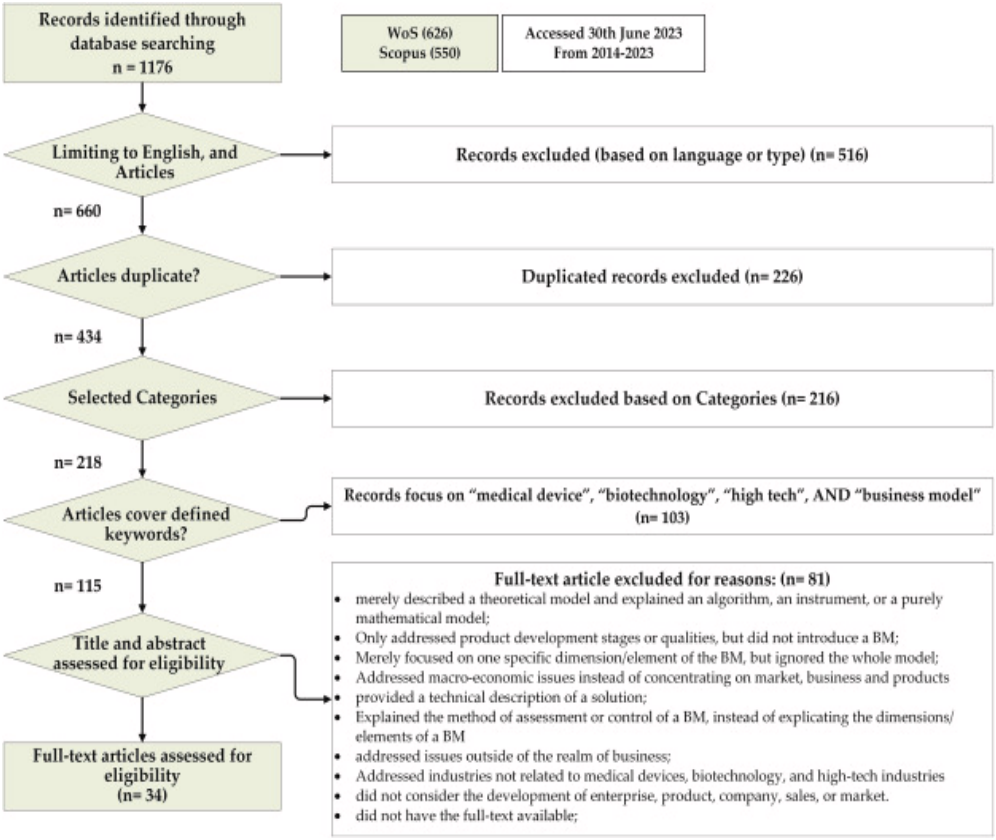

Figure 1. PRISMA-based flowchart illustrating the publication search and selection process.

Figure 1 depicts the number of papers identified and the stages of the screening process. For each publication, data were systematically extracted, including author(s), year, title, country or countries of study, the industry under investigation, objectives, methodology, main findings, the type of business model (BM) applied, and a concise description of the model. This study employed the PRISMA (2009) framework as the standard for searching, selecting, and analyzing publications. PRISMA was chosen because it provides an evidence-based minimum set

of items for reporting systematic reviews and meta-analyses, ensuring a rigorous and transparent process. **Figure 1** schematically illustrates the stages of publication search, selection, and analysis followed in this study [26].
To ensure the reliability and rigor of the systematic review, a comprehensive quality assessment (QA) process was implemented following the guidelines of Kitchenham *et al*. (2009) [27]. Each study was evaluated using four QA criteria: (1) clarity and appropriateness of inclusion and exclusion criteria; (2) comprehensiveness of the literature search; (3) quality and validity of the included studies; and (4) completeness of basic data and study descriptions. Studies were scored using a standardized scale: Y (Yes) for full compliance, P (Partly) for partial compliance, and N (No) for non-compliance. This scoring ensured that only high-quality and relevant studies were included in the review. Any discrepancies or uncertainties in scoring were resolved through team discussions, and authors of the original studies were contacted for clarification when necessary. This meticulous QA process strengthened the credibility and robustness of the review, aligning with established standards in systematic research.

Results and Discussion

After applying the screening procedures and inclusion criteria, a total of 34 papers were selected for analysis. **Table 2** presents these studies along with their key characteristics, including the industry examined, the BMs applied, and brief descriptions of the models. The studies are arranged chronologically by publication year. The selected papers covered diverse topics related to BMs in the medical devices, biotechnology, and high-tech healthcare sectors. From the analysis, nine general types of business models were identified, and their various dimensions were explored. Open innovation models emerged as the most frequently applied, followed by sustainable BMs, indicating that these two models are predominant in healthcare-related high-tech industries.
The findings are organized according to the BMs employed in each study. For clarity, the discussion of each BM is structured around four key areas: infrastructure, value proposition, customers, and finance, reflecting the main components used to compare and analyze the models across the selected literature.

Table 2. Summary of studies on business models in healthcare, medical devices, and biotechnology sectors

Study	Country	Industry	Business Model (short description)
[13]	Canada	Health technology	Spin-off BMs: Analysis of three Canadian spin-off companies
[18]	Finland	Healthcare technology	Open innovation BMs: Overview of BM functions for commercialization
[28]	UK, USA	Medical devices	Single-use BMs: Highlighting limitations of current medical device BM
[11]	Argentina	Medical healthcare	High-tech-low-cost BMs: Conceptualizing BM innovation across firm, environment, and customer dimensions
[20]	Poland	Biotechnology spin-offs	Spin-off BMs: Identification of BM components and associated attributes
[29]	Argentina	Biotechnology	Joint venture BMs: Illustrating BM decision-making in practice
[30]	Germany	SustainablySMAT	Sustainable BMs: Introducing a new environmentally sustainable value creation logic
[31]	UK, USA	Investment banks	Evolutionary and revolutionary BMs: Assessment of firm dominance levels
[32]	USA	"The Google of Healthcare"	Back-end BMs: 23andMe as a pioneering direct-to-consumer genetic testing company
[33]	UK, Portugal	High-tech entrepreneurs	Entrepreneurial content marketing BMs: Framework comprising five key elements
[34]	India, China	Medical and laboratory equipment	Frugal BMs: Exploration of value creation and capture for frugal innovation in emerging markets
[16]	Italy	EU Horizon 2020 ICT "i3 project"	Digital sustainable BMs: Role of digital platforms in sustainable BM development
[35]	Italy	Machinery, automation, transportation	Product-service systems BMs: Multi-step methodology for selecting and designing integrated product-service systems
[36]	UK	Biotechnology	Open innovation BMs: Identification of two distinct BMs in biotechnology

[37]	Brazil	Second-generation bioethanol	Open innovation BMs: Comparative evaluation of commercially scaled bioethanol BMs
[38]	China	Production and services	Open innovation BMs: Emphasizing alignment of BMs with open innovation strategies
[39]	Finland	Digital high-tech start-ups	Agile BMs: Assessment of alternative approaches under time-constrained settings
[1]	Italy	Mobile applications	Dynamic BMs: Application of the lean BM canvas
[40]	Italy	ICT, pharma, biotech	Ambidextrous BMs: Examining start-up BM evolution, design changes, and efficiency impact
[41]	Netherlands	General	Dynamic BMs: Focus on adaptive business approaches
[42]	Hong Kong	Software development	Dual BMs: Implementation in high-tech SMEs
[43]	Ireland	Medical devices	Collaborative and in-house NPD BMs
[44]	Korea	Medical devices, healthcare	Sustainable BMs: Activation strategy for medical device start-ups using AHP
[45]	Finland	Biomaterials, biotechnology	Circular bioeconomy BMs: Value creation, delivery, and capture by SMEs
[46]	Brazil	Medical devices	Circular BMs: Identification of circular business model innovation opportunities
[47]	Brazil	Pharmaceutical industry	Sustainable BMs: Eco-innovative BMs analyzed via product life cycle
[48]	Germany	Medical devices	Intelligence BMs: Converting research prototypes to market-ready products
[49]	Brazil	Biotechnology	Lean BMs: How biotechnology start-ups exploit market opportunities
[50]	Poland	Healthcare services	Development of a new healthcare market BM
[51]	Spain	Private healthcare	Impact of public resource desynchronization on BM sustainability
[52]	Russia	Healthcare	Exploring digitalization effects and BM innovation
[53]	Netherlands	Healthcare	Analysis of BM efficiency versus novelty
[54]	Mexico	Purified water	Combining Business Model Canvas with service blueprinting for process representation
[55]	Ireland	Biopharmaceuticals	Biopharmaceutical BMs and healthcare inequalities in low-income countries

Open innovation business models

Open innovation business models (BMs), highlighted in 9 of the 34 studies reviewed, are particularly influential in healthcare, especially in medical devices, biotechnology, and high-tech sectors focused on new product development. These models leverage both internal and external knowledge sources to drive innovation [3], breaking down traditional organizational boundaries and fostering a collaborative ecosystem where ideas are shared and co-developed across multiple entities [56].

In healthcare, open innovation BMs are instrumental in addressing complex challenges by integrating diverse expertise and resources. This approach helps manage the escalating costs of research and development (R&D) while accelerating product development cycles. Collaboration—even among competitors—facilitates the establishment of standards and institutional partnerships crucial for the healthcare industry [31]. Particularly in medical devices, open innovation encourages cooperation between hospitals, biotech companies, and other stakeholders, enabling faster creation of innovative solutions and enhancing the translation of external research into effective treatments [36].

A distinguishing feature of open innovation in healthcare is its dual approach: inbound and outbound innovation. Outbound open innovation involves sharing internal knowledge externally to leverage outside technological capabilities, while inbound innovation focuses on acquiring external ideas and expertise to strengthen the organization's internal knowledge base [43]. This two-way flow of information is vital in healthcare, where rapid technological advancements and evolving patient care practices demand constant adaptation.

Collaboration is a cornerstone of open innovation, providing access to specialized skills and resources that accelerate product commercialization. By pooling expertise, healthcare companies can respond swiftly to

technological changes and reduce dependence on fixed assets that may become obsolete [18]. Open innovation also optimizes resource allocation, cuts R&D time and costs, and increases productivity by sharing facilities, technical knowledge, and funding. In biotechnology, such collaborations enable tackling ambitious projects that would be difficult under closed innovation frameworks, expediting the development of breakthrough treatments and technologies [38].

Agility is another key element of open innovation BMs in healthcare, allowing organizations to quickly adapt to market or technological shifts. This flexibility supports continuous integration of external knowledge and emerging technologies, enabling faster development and implementation of medical solutions. Agile open innovation is particularly beneficial for startups and companies operating in rapidly changing healthcare environments, facilitating parallel commercialization processes and continuous adaptation to uncertainties [39].

In conclusion, open innovation BMs in healthcare extend beyond combining internal and external ideas—they emphasize flexibility, collaboration, and agility. This model accelerates product development, reduces R&D expenditures, and allows organizations to navigate the dynamic healthcare landscape effectively, ultimately improving patient outcomes and driving medical innovation.

Sustainable business models

Among the 34 papers included in this study, 9 specifically addressed sustainability-focused business models (BMs). In recent years, businesses and entrepreneurs emphasizing social objectives have gained prominence, and sustainable BMs are increasingly viewed as a source of competitive advantage. These models highlight shared values and sustainability principles that guide collaboration and innovation, making them a significant area of research within BM literature [55]. Sustainable BMs integrate social, environmental, and economic activities to create value not only for customers but also for society at large [57]. Ideally, a sustainable BM emphasizes creating and delivering long-term value for beneficiaries while capturing economic returns beyond organizational boundaries and maintaining or regenerating natural, social, and economic capital [45].

Value propositions in sustainable BMs often incorporate social and environmental benefits alongside economic ones. During the stages of value creation and delivery, sustainability can be expressed through renewable resources, technological innovation, responsible supplier engagement, and promotion of sustainable consumption. Capturing sustainable value involves fair redistribution of revenue among stakeholders [45, 58]. The value generated extends beyond financial returns, including benefits such as environmental preservation, resource savings via recycling, and broader societal advantages [30]. The healthcare and medical device sectors, in particular, require long development cycles—including technology advancement, clinical trials, regulatory approvals, insurance registration, and commercialization—which makes a sustainability-oriented strategy essential [44].

Many sustainable BMs identified in this review emphasize the circular economy, including product recovery and recycling. According to D'Amato *et al.* (2018), a central feature of these models is improving productivity and enhancing the recycling capacity of production and consumption systems through waste reduction, better practices, and reuse. In healthcare and biotechnology, circular economy principles are applied to the bioeconomy, giving rise to the concept of a "circular bioeconomy," which focuses on efficient use of renewable biological resources [45]. Moultrie *et al*. (2015) also addressed "single-use" BMs, proposing ways to convert them into sustainable models. Many medical devices are designed for single use, generating significant medical waste globally, highlighting the need to redesign BMs to support sustainability [28].

In some cases, single-use devices can be safely reused, and organizations—particularly in the US—have begun processing such devices. From this perspective, sustainable value propositions should consider environmentally friendly medical device design [28]. While evaluating innovations and developing BMs can be challenging, digital technologies provide infrastructure support by identifying previously unrecognized stakeholders and offering technical solutions that strengthen collaborative networks [3].

Overall, sustainable BMs are multidimensional, incorporating social, environmental, and economic objectives. Unlike conventional BMs focused primarily on financial gain, sustainable models seek to balance economic returns with social and environmental responsibility. Their value propositions emphasize economic profit alongside environmental stewardship and social impact. Companies adopting these models distribute products that are environmentally safer, recyclable, and reduce societal and environmental hazards. Their customers include not only the general public but also environmentally and socially conscious consumers, who may be willing to pay a premium for sustainable biotech or medical products.

From an operational perspective, sustainable BMs prioritize safety at corporate, social, and environmental levels, use recyclable or bio-based materials, and implement supply chain practices that enhance sustainability. In terms of value capture, these models aim to minimize environmental impact and address social responsibilities in addition to generating revenue and profit [28, 45].

Dynamic business models

Business models (BMs) can be classified as dynamically complex systems, a characteristic that complicates their analysis and predictability. The multitude of factors influencing different aspects of a BM, the intricate interconnections among these factors, and the central role of humans in shaping outcomes all contribute to the inherent complexity and uncertainty. Recognizing these challenges, researchers have developed a specific research stream focused on the dynamic aspects of business, particularly the exploration and explanation of dynamic BMs [3].

Within the 34 papers selected for this study, three specifically addressed dynamic BMs in the healthcare, medical devices, biotechnology, and high-tech sectors. The dynamic or transformational perspective treats a BM as a tool or framework for managing change and emphasizing organizational innovation, including innovation within the BM itself. Dynamic BMs are increasingly important because high-tech companies operate in markets and technologies that evolve rapidly. These models capture both internal and external changes over time, examining trends and the interactions among different BM components. Taking a systemic view, dynamic BMs evaluate various elements to enhance a company's alignment with environmental changes, customer behavior, competitors, technological shifts, and other relevant factors [41].

Dynamic BMs are termed "dynamic" because they explicitly consider temporal changes and the interdependencies among BM elements. They involve the ability to identify and act upon opportunities and threats, maintain competitiveness, and adapt or reconfigure tangible and intangible assets as needed. Firms with high dynamic capabilities can quickly implement, test, and refine updated BMs [41]. An essential aspect of a dynamic BM is the formulation of customer relationship strategies and performance metrics.

Customer segmentation is crucial because each segment has unique needs that influence value propositions, infrastructure, and service delivery. Five categories of customers are identified according to a product's lifecycle. First, innovators engage during the product development stage, typically comprising highly educated, risk-tolerant, financially capable, and technically skilled individuals with access to information. Second, early adopters participate in the product introduction phase, motivating the early majority to adopt new offerings and helping the company expand its market share [3]. Third, early majority customers appear during the growth stage; they have strong social networks, leadership potential, and rely on consultation to adopt innovations. Fourth, late majority customers engage at the maturity stage; they tend to be conservative, resource-limited, and slow to adopt new products. Finally, laggards are skeptical, socially isolated, and slow decision-makers. Recognizing these segments allows companies to tailor strategies at each stage of the product lifecycle, ensuring timely revenue generation [1].

A dynamic BM also incorporates key environmental variables affecting BM performance, while considering the company's impact on its surroundings. Such a framework must integrate internal company variables, external environmental factors, and those that may change as part of strategy or BM evolution, along with their interrelationships. Understanding these interdependencies and potential causal links is central to the dynamic nature of these models. Operating within networks, firms coordinate the development, production, and delivery of interrelated products and services. Over time, interactions among network participants can drive the growth or decline of advanced companies. Awareness of these relationships enables managers to detect environmental changes more efficiently. Core attributes of dynamic BMs include adaptability, realignment of relationships, and the evolving function of the BM over time [41].

Dual BMs

In today's complex business environment, many companies operate multiple business areas simultaneously, each guided by distinct management objectives. Dual business models (BMs) describe situations where an organization concurrently pursues two strategies or organizational goals that may appear conflicting but are equally important and strategically valuable [34]. This concept is often referred to as "organizational ambidexterity," which can be metaphorically likened to flying a plane while repairing its wiring. It illustrates a company's ability to balance exploration and exploitation, competing both in mature technologies and markets—where efficiency, control, and

incremental improvement are critical—and in emerging technologies and markets that demand flexibility, adaptability, and learning.

Ambidexterity has become essential, particularly for technologically advanced firms that must leverage existing strengths to gain immediate commercial benefits while simultaneously pursuing innovations for long-term growth [40]. For small- and medium-sized enterprises relying on advanced technologies, this requires pursuing distinct innovations to maintain a competitive edge while ensuring operational efficiency, as their economic resources are often more limited than those of larger corporations [42].

Research indicates that ambidexterity may negatively affect startup growth initially; attempting to pursue conflicting objectives too early can hinder development. However, once a startup matures—establishing organizational processes, clarifying its market position, and refining its revenue and cost structures—ambidexterity can unlock the organization's full potential and accelerate economic growth [40]. Collaborating closely with technology partners enhances a startup's internal capabilities, including knowledge absorption, creative processes, and innovation production, which in turn speeds up product innovation and marketing strategies. Evidence shows that productivity and novelty can coexist within a BM, allowing organizations to be both efficient and innovative simultaneously [42].

Dual BMs focus on two central aspects: efficiency and innovation. Efficiency emphasizes technology development to strengthen distribution channels and accelerate product innovation processes, while innovation focuses on collaboration with external partners, leveraging third-party technologies, and incorporating incremental improvements in products or services. Together, these approaches enable companies to create and capture value effectively while fostering continuous innovation [40, 42].

Spin-off BMs

A spin-off is a strategic approach through which a company creates an independent division from its parent organization. This new entity inherits assets, employees, intellectual property, or existing products from the parent company, while the parent's shareholders receive proportional shares in the spin-off, allowing them to buy or sell independently, which can make investment more attractive. This enables investors to focus on segments of the business that demonstrate higher growth potential. Beyond this structural separation, the spin-off business model encompasses strategic, operational, and innovative practices that guide the entity's market growth and success, particularly in healthcare and biotechnology [59].

Spin-off BMs combine innovation-driven strategies with operational frameworks essential for their sustainability in dynamic sectors. Academic spin-offs play a critical role in commercializing research ideas, as universities often focus on fundamental research without the mechanisms to effectively transfer their R&D outcomes to industry. Spin-offs bridge this gap by transforming academic technologies into commercially viable solutions [20]. However, these entities often lack commercialization expertise and face market uncertainties, highlighting the importance of a dedicated business model.

In healthcare and biotechnology, spin-offs typically originate from academic or research institutions and rely heavily on intellectual property. Their BMs focus on leveraging proprietary technologies, obtaining venture capital or government funding, forming industry partnerships, and strategically navigating commercialization paths. Spin-offs often target specialized niches where their innovative and technical expertise provides a competitive edge. Strategic collaborations, including partnerships with other research institutions, industry players, and academic bodies, are crucial for scaling, product development, and continuous innovation. Additionally, these BMs must address complex regulatory environments to ensure compliance, patient safety, and market acceptance. Compared to parent companies, spin-offs tend to be more agile, allowing rapid adaptation to emerging research, technological advances, or market shifts [59].

Key stages for spin-offs include idea conception, technology application, and commercialization. Strategic alliances, international collaborations, and experienced boards help mitigate risks and enhance global market entry. Financial stability, supported by grants or investments, is critical for navigating high-risk R&D environments [13, 20]. In essence, spin-off business models integrate innovation, funding, strategic partnerships, and operational agility, providing a comprehensive framework for success in the challenging healthcare and biotechnology sectors [13].

A growing trend in innovative business models targets the delivery of medical and health services to consumers at the base of the wealth pyramid. These BMs are structured around traditional notions of innovation, social impact, environmental context, labor, and end-user dynamics. Successfully implementing such models requires

extensive collaboration with customers, suppliers, distributors, and business partners across the various "structural blocks" of the BM. The approach prioritizes a customer-centric perspective over a product- or company-centric one, involving partnerships with non-profit organizations, social leaders, and trusted local entities. Through these collaborations, large companies can access previously neglected markets, while smaller firms can reach broader markets. Value propositions must consider cultural, psychological, behavioral, and socioeconomic characteristics of the target consumers [11].

In healthcare applications, strategies to deliver value in these models include removing intermediaries (e.g., insurance companies), adopting low-cost practices, outsourcing services, and offering scalable low-margin solutions such as annual membership programs. A subset of these models, known as frugal innovation BMs, further supports the creation of low-cost, high-value offerings, generating new markets and applications. Frugal BMs emphasize cost-effective innovations that balance affordability for consumers with value creation, enabling companies to compete effectively in emerging or resource-constrained markets [34].

Target customer segments for these BMs include those who benefit from increased healthcare productivity, improved clinic and doctor accessibility, and affordable solutions for urgent or routine care. Companies implementing frugal BMs optimize costs at each stage of value creation and tailor product development to meet specific customer needs, leveraging established technologies to deliver innovative and practical solutions [11].

High-tech entrepreneurial content marketing (HIT-ECM) BMs

HIT-ECM BMs emphasize the role of marketing as a strategic tool for value creation in high-tech enterprises, particularly small firms where technology lifecycles are short. These models focus on adapting marketing practices to rapidly changing technological environments, creating new business logics and innovative approaches to value creation. Content marketing is central to HIT-ECM BMs, enabling companies to engage with customers, deliver measurable value, and maintain ongoing communication. This approach treats mass media and content as strategic tools that shape consumer experiences while linking marketing directly to the entrepreneurial goals of the BM [33].

HIT-ECM BMs involve systematically designing marketing programs that identify customer segments, leverage social networks, and publish optimized content to attract and retain users. By emphasizing marketing as a core component, these BMs support the development of customer relationships, revenue generation, product promotion, and partnerships, integrating marketing into the very structure of the business model [33].

Back-end Business Models (BMs)

Back-end refers to the segment of a business's operations that is largely invisible to customers or the general public. Companies adopting a back-end BM typically feature two distinct value propositions: one directed at end customers, which forms the "front-end" of the business, and another oriented toward generating profit through back-end operations. For example, direct-to-consumer genetic testing kits allow users to perform basic medical analyses at home, appealing to ordinary consumers and encouraging purchase. In many cases, the company may not earn significant revenue from this front-end offering; instead, profit is generated through back-end activities such as partnerships, core operations, or key resources that remain unseen by the customer. A prime example in the healthcare domain is 23andMe, which was the first company to sell genetic test kits directly to consumers. Its business model consists of two main elements: the front-end, which involves selling personal genetic testing online, and the back-end, comprising one of the largest private genetic databases globally. Since 2007, 23andMe has provided affordable genetic tests to consumers, collecting extensive genetic data that is subsequently monetized. This dual approach has led to its reputation as the "Google" of personal healthcare [32].

Product-Service Systems (PSS) business models

The shift from conventional product-focused business models to Product-Service Systems (PSS) presents industrial companies with opportunities to enhance revenue and gain competitive advantages. In response to commoditization, shrinking profit margins, and increasingly complex customer demands, many manufacturing companies are transitioning from purely selling goods to providing integrated solutions. This shift not only improves customer satisfaction and revenue potential but also requires a fundamental transformation in how value is created, delivered, and perceived by customers [54].

PSS BMs integrate both products and services to deliver consistent value, moving beyond traditional product sales as the sole business activity [35]. The rationale behind PSS BMs lies in the recognition that simply manufacturing

high-quality goods is no longer sufficient for competitive differentiation [60]. Studies exploring the impact of PSS BMs on innovation highlight three key characteristics: (a) ownership of the product often remains with the provider rather than transferring to the customer; (b) the product functions primarily as a vehicle to deliver services, rather than as a standalone commodity; and (c) the revenue model differs significantly from companies that only manufacture and sell goods [49]. The core value proposition of PSS BMs typically emphasizes the service enabled by the product rather than the product itself. Companies must therefore adjust their internal mindset to help customers view services as valuable outcomes and sources of value creation [54].

To effectively communicate the new value proposition, companies need dedicated sales channels to deliver services directly to customers. Revenue can be generated based on service usage, product performance, or frequency of use. For instance, in medical devices, a test may incur charges for each administration rather than the device itself. Alternatively, PSS BMs can provide access to services for individuals unable to afford the full product, generating income while expanding market reach [35].

PSS BMs can generally be categorized into three types:

1. Product-oriented models: The company sells the product along with supplementary services such as maintenance, repair, consulting, or training.
2. Use-oriented models: The provider retains ownership but sells access to the product's utility over a period, through leasing, renting, subscription, or similar arrangements.
3. Result-oriented models: The company sells the outcome or performance delivered by the product rather than the product itself [54].

The advantages of PSS BMs are substantial. They enable continuous revenue streams, foster long-term customer relationships, and can enhance environmental performance, as service-oriented companies are incentivized to manage products responsibly over their lifecycle. Economically, PSS BMs can better satisfy customer needs, strengthen client relationships, differentiate offerings, increase revenue, open new markets, enable rapid responses, leverage service data, reduce ownership burdens for customers, improve technology utilization, mitigate risks, and lower product lifecycle costs. Socially, these models can also generate employment opportunities and create broader societal benefits [60].

This section covers four primary themes. First, it compares and elaborates on the business models (BMs) identified in the reviewed papers, examining their strengths, weaknesses, and focal areas within the medical device, biotechnology, and high-tech healthcare industries. This comparison draws on the core components of each BM. It should be noted that individual companies may employ multiple BMs across different areas of their operations, and some BMs may integrate elements of others. For example, one BM might emphasize open innovation or sustainability, while another could simultaneously incorporate principles of both sustainability and dynamicity. In this discussion, BMs are presented separately to clarify their distinct characteristics and dimensions rather than to suggest any conflict between them. Additionally, although many studies categorize spin-offs under open innovation models [48], in sectors such as medical devices, healthcare, and biotechnology, as well as in innovative start-ups, these BMs hold particular significance and are therefore treated as a separate category.

The second part focuses specifically on the medical device and biotechnology markets. Here, case studies from the selected papers are examined in detail, highlighting legal frameworks, types of financial support, target audiences, customer segments, and the products associated with each BM. A comparative summary of these studies is provided in **Table 3**, which emphasizes the most notable and relevant features of each model.

The third section addresses the dimensions of uncertainty inherent in business models. This analysis is essential for understanding how uncertainties affect BM performance and evolution, especially in fast-paced, innovation-driven sectors.

Finally, the fourth section introduces a novel Dynamic and Sustainable Business Model (DSBM) for the Health-Tech industry. This model synthesizes insights from the preceding analyses and provides a strategic framework that integrates sustainability, innovation, and adaptability. The DSBM is designed to effectively navigate the unique challenges and uncertainties that characterize healthcare, medical device, and biotechnology sectors.

Table 3. A summary of the comparison of the BMs.

Type of model	Infrastructure	Value proposition	Customers	Finances
Open innovation BMs	-	-	-	-

	Cooperation and partnership with companies, research institutes and universities to outsource various parts of a project - Create alliances, buy scientific services, invest in other companies, and use external knowledge networks - Buying or selling the intellectual property	Quality, "timely" delivery, differentiation, speed, accuracy, within the budget set and lean innovation	Companies that want to outsource their R&D and seeks innovation and efficiency in a product. Including global pharmaceutical companies, regional distributors, patients, professional hospitals, doctors and governments	Usually because of the project nature of the work, revenue will not be repeatable. - If innovation is successful, revenue can sustain a sales value stream for a long period
Sustainable BMs	- Using recycled materials - Developing hybrid business - Adopting innovative production process based bio-based material	- shifting from a consumer to a user logic - products using bio-based renewable material	- Market segments that are more concerned about the environment and society	- reducing costs, waste and virgin material use and minimizing enviromental impact
Dynamic BMs	- Designing feedback loops from the environment, competitors, and customers to get information - Designing agile processes	- The value proposition is not static, but it has a life cycle and changes in nature and value	- Customer segments can change over time	- revenue and cost sources are dynamic
Dual BMs	- Innovation in Processes and methods - Collaborating with other institutions and companies - Trying to increase efficiency and innovation at the same time	- Multiple value propositions based on innovation and efficiency	- Customers looking for incremental innovations along with efficiency and cost savings.	- revenue sources from innovations have higher risk but instead efficiency sector, support innovative financial needs
Spin-offs BMs	- Experienced managers Research teams - "star-scientist" Experienced manager	Entails both clinical and economic value for physicians	- Part of society seeks innovative value propositions	- Research partnering - Cost advantage due to research cooperation with university

High-tech-low-fee BMs	- Low-cost raw materials - Global sourcing for critical parts - Low-cost production - Decomposition of multipurpose machines into a focuses single purpose device	- Affordability and access to healthcare at low costs - Easy to use for rural general practitioner - Preventive screening	- Access to customers through new additional sales units for rural areas in Emerging markets, channels via distributors and direct selling	Cost minimization in each step of value chain and income is obtained by Product sales, Pay-per-use, Leasing, Software as a service.
The high-tech entrepreneurial content marketing BMs	- Engaging in discourses with customers through value-creating and measurable content through content marketing	- The approach is based on presenting a unique image that is independent of the value of the content	- Customers who are somehow active in social networks and social activities	- The cost of content marketing, especially on social networks, is the main difference between these models and others
Back-end BMs	- Create infrastructures to create value from the back end activities include big databases of front end customer's information	- Providing a value proposition based on company support activities to back-end customers	- Clients include patients, healthcare applicants for medical tests applicants, research organizations, governments, ministries and universities	- Back-end is generally the main revenue and profit making process - Main revenue is generally derived from the support activities
Product-service systems BMs	- Products with delivering part of their performance in the long term - Capture and use data generated by customers	- The goal is to deliver the performance of a product, not the product itself	- Customers include people who prefer to buy a product based on their usage	- Revenue is generally derived from the service units or performance of the product

Comparing and investigating the business models

Infrastructure: key partners, key resources, key activities

In high-tech sectors such as medical devices, biotechnology, and healthcare, competition increasingly revolves around knowledge, making the infrastructure of business models (BMs) in these fields heavily dependent on knowledge-based production and the commercialization of generated knowledge [46]. Open innovation BMs, frequently observed in the reviewed studies, derive value primarily through collaboration and partnerships, which are seen as both a source of value creation and a primary route for product development and commercialization. Companies within the same or different industries, including competitors, may collaborate to collectively provide resources for research and innovation projects [29]. Depending on their role, companies may engage in activities such as fundraising, contributing to study designs, securing permits and intellectual property rights, expanding networks by attracting new partners, and managing collaborative networks [36]. Inbound open innovation BMs, particularly in healthcare and biotechnology, often include activities like forming alliances, purchasing scientific services, acquiring rights to use or own intellectual property, investing in other organizations, and leveraging external knowledge networks.

A common approach in open innovation BMs involves the transfer or sale of usage or intellectual property rights for innovative products. For instance, a company may develop a medical device or pharmaceutical but lack the capacity to supply it globally; in such cases, it can transfer usage or sales rights to another firm capable of mass distribution. Here, the originating company functions as an outbound open innovation entity, while the acquiring firm operates as an inbound open innovation company [47]. In sustainability-oriented BMs, emphasis is placed on the outcomes of activities rather than the specific processes leading to them [47].

Dynamic BMs are distinguished by their underlying assumption that environmental conditions, customers, competitors, and other influencing factors are constantly changing, and the business must adapt accordingly [41]. Consequently, the infrastructure of these BMs is designed to be flexible and responsive, enabling rapid updates based on environmental feedback [1]. Dual BMs, in terms of infrastructure and value creation, focus on balancing efficiency and innovation. Efficiency typically involves leveraging technology to enhance distribution channels and accelerate product innovation [40, 42].

Spin-off BMs differ from other models in that their primary resources are not materials or equipment, but highly skilled personnel, such as prominent scientists, faculty members, inventors, and experienced system managers. In medical device and biotechnology spin-offs, knowledge itself is the core resource, with the firm often founded on a novel knowledge base. Key activities supporting survival include securing financial resources from governments, investment institutions, and knowledge commercialization grants, while growth strategies emphasize strengthening intellectual capital [13, 20].

Frugal BMs, or high-tech-low-fee models, prioritize cost reduction while maintaining advanced technological performance. Infrastructural strategies in these BMs include selecting cost-effective partners, relocating production to lower-cost regions, using inexpensive raw materials, sourcing critical components globally, employing digital tools to minimize errors and losses, simplifying multipurpose machinery into single-purpose devices, and collaborating with local small businesses or community organizations trusted by consumers [11]. Conversely, HIT-ECM BMs emphasize marketing as a core infrastructure for value creation, with activities designed to systematically introduce innovative products or services to customers [33].

Back-end BMs focus on infrastructural processes as their primary source of value creation, generating profit not from the products or services offered directly to end customers, but through supporting delivery processes that create value for secondary customers, such as third parties or government entities [32]. Finally, new Product-Service System (PSS) BMs integrate services and production within their infrastructure, as value emerges from the combination of products and services. Designing products with service integration in mind is a crucial activity for the successful implementation of these models [35].

Value proposition

The value proposition, the second core element of a business model (BM), serves as the crucial link between a company's infrastructure and its customers, representing a primary reason why customers choose to pay for a product or service. In open innovation BMs, value is delivered through attributes such as quality, timely delivery, differentiation, speed, accuracy, affordability, and the uniqueness of innovations and services, including proof of concept, final design, testing, and verification [43]. Such value propositions may either enhance efficiency and reduce transaction or coordination costs or emphasize the novelty of the product or service [38].

In sustainable BMs, the value proposition extends beyond economic gains to include social and environmental benefits. This can involve reducing resource consumption, minimizing waste and pollutants, recycling materials to create higher-value products, producing bio-based or recyclable products, promoting reuse, and lowering energy consumption [45].

Dual BMs balance multiple value propositions that integrate innovation and efficiency. Spin-off BMs focus on uncovering latent value in new technologies to attract forward-looking customers who recognize technology-driven benefits, emphasizing innovation, technological advancement, and uniqueness. Frugal BMs target cost reduction, delivering value by lowering unit prices while offering solutions that motivate customers to pay for essential benefits. In high-tech-low-fee models, value propositions aim to provide high-impact solutions for end users (e.g., patients) and B2B clients (e.g., doctors, small hospitals) while reducing overall healthcare system costs.

HIT-ECM BMs primarily deliver value through content marketing, with products offered independently and the distinctiveness of content forming the core value [33]. Back-end BMs feature layered value propositions: one directed at end customers to encourage service/product use and another, often covert, targeting specialized clients

that generate the company's primary revenue [32]. Finally, Product-Service System (PSS) BMs integrate value propositions through both products and services, focusing on the function or solution provided rather than the product alone, thereby offering a combined and functional-oriented value [35].

Customers: customer segments, channels, and communication

Across the reviewed business models (BMs), customers ranged from governments, large multinational corporations, and small startups to doctors, hospitals, patients, and caregivers. Customer segments and communication channels vary according to the BM type and corporate objectives. In the medical device and biotechnology sectors, outbound open innovation BMs serve a diverse clientele, including large multinationals, small and medium startups, and leading industry players, often consisting of companies seeking to outsource R&D outcomes [43]. Conversely, inbound open innovation BMs target customers from various societal levels or markets seeking innovation, efficiency, and novel initiatives, including international pharmaceutical companies, regional distributors, professional hospitals, doctors, patients, and governments [20].

Sustainable BMs differ from other models by prioritizing environmentally and socially conscious markets rather than focusing solely on consumers' immediate needs; they aim to engage customers guided by values and logic [44]. Dynamic BMs are shaped through continuous dialogue with customers, using feedback to adapt strategies and even redefine customer segments over time in response to shifting tastes or market demands [1]. Spin-off BMs target segments seeking high-tech, innovative value propositions, such as large international pharmaceutical firms, distributors, professional hospitals, patients, foreign governments, or any societal group interested in unique technological offerings [13].

High-tech-low-fee (frugal) BMs generally focus on emerging markets where cost sensitivity is high, targeting hospitals, clinics, and doctors in underdeveloped regions, as well as governments and NGOs [34]. In HIT-ECM BMs, customer interaction is driven by marketing and tailored content creation across commercial operations, with social media serving as a key communication tool for segmenting and engaging customers [33]. Back-end BMs categorize customers into multiple groups: ordinary end users, who may not directly contribute to profit, and organizations or institutions, such as research bodies, governments, and universities, that derive value from the firm's support activities [32].

Finances

Regarding finances, outbound open innovation BMs typically earn revenue immediately from collaborative services, though the project-based nature of such work means income is often non-recurring. In contrast, inbound open innovation BMs may pay collaborators upfront, while revenue collection can be delayed [43]. Sustainable BMs extend financial objectives beyond economic gains, aiming to minimize costs, waste, raw material consumption, and environmental impact, often emphasizing products requiring fewer resources [16]. Dynamic BMs enable firms to anticipate and respond to customer changes, creating more stable income streams; however, revenue sources may shift over time due to evolving products, value propositions, customer segments, or environmental factors [41]. Dual BMs, balancing innovation and efficiency, may generate income from multiple sources: higher-risk innovation-related revenues can be supported by more predictable efficiency-driven streams [40]. Spin-off BMs gain profitability through cost advantages in international markets, tax benefits, research partnerships, product design, and research projects [20].

High-tech-low-fee (frugal) BMs link financial outcomes directly to value creation activities, following a philosophy that low-cost products and business models can still yield healthy profit margins. These BMs may use alternative revenue mechanisms, such as pay-per-use, software services, or leasing, to address customers' financial constraints [11]. Back-end BMs split revenue generation into two components: the frontline, delivering goods to end customers with limited or no direct profit, and the backline, which produces the company's primary income by offering support services to organizations, governments, or institutions [32]. PSS BMs generate revenue primarily through services or product operations, often via joint services or pay-per-use arrangements [35].

Business models used in health-tech

This section examines BM specifications in medical devices and biotechnology as reported in the selected papers, focusing on legal requirements, financing methods, target groups, and product types. Among the 34 selected

papers, 52 business-related case studies were identified, involving companies in healthcare, medicine, biotechnology, and high-tech industries, most of which were innovative and knowledge-driven.

Customer groups for medical device and biotechnology companies can be classified based on activity and BM type: (a) end users, such as patients or the general public; (b) intermediate customers, including doctors, hospitals, clinics, and healthcare centers, who act as intermediaries between services and end users; and (c) wholesale customers, comprising larger corporations, academic or non-profit institutions, regional or international distributors, and governments, who facilitate service delivery without directly serving end users.

Financially, companies relied on diverse methods, including government subsidies, tax incentives, science and technology parks, and research grants. Given the high cost and initially low profitability of knowledge-based R&D, public funding can offset private project costs and increase the likelihood of success by lowering fixed expenses. Additional financing strategies included collaboration with large companies, joint investments, contracts, strategic partnerships, and use of private-sector consortiums. Legally, companies addressed intellectual property registration and patents, and obtaining regulatory approvals from the US Food and Drug Administration, the Department of Health and Human Services, as well as market certifications in Europe and Canada. Quality certifications from internationally recognized organizations (e.g., ISO) were also prioritized. Many studies emphasized that patents should cover detailed business aspects in addition to technical specifications.

Exploring uncertainty in health-tech business models

Given that this study focuses on companies inherently driven by innovation and knowledge development, understanding the sources of uncertainty is crucial, as innovation is inherently linked to unpredictable outcomes that require careful management. Knowledge-based businesses face higher levels of uncertainty and dynamism, meaning that any chosen business model (BM) must be equipped to handle these challenges effectively. In a business context, uncertainty refers to any unforeseen event that disrupts a company's performance [61]. The environments of medical devices, biotechnology, and high-tech industries—typically knowledge-intensive—are increasingly dynamic and uncertain due to factors such as disruptive digital technologies, deregulation, emerging BMs, new competitors, inventions, discoveries, and the intrinsic fluidity of knowledge [25].

Through an extensive literature review, a framework was developed to help companies in these sectors identify and understand the sources of uncertainty within various parts of their BMs. This framework, illustrated in **Figure 2**, groups 28 factors contributing to BM uncertainty. Its purpose is to provide clear insights into uncertainties across different BM components, enabling companies to anticipate potential challenges and reduce the occurrence of unforeseen disruptions. Practically, this framework supports companies in navigating dynamic business ecosystems, allowing them to create and capture value from complex, emerging innovations. It also serves as a tool to identify and assess risk and uncertainty factors within existing BMs. By adapting BM design to address these risks, firms can foster new innovations and developments. As depicted in **Figure 2**, the causes of BM uncertainty are classified into six categories: customers, value propositions, infrastructure, financial capabilities, and the external environment [62].

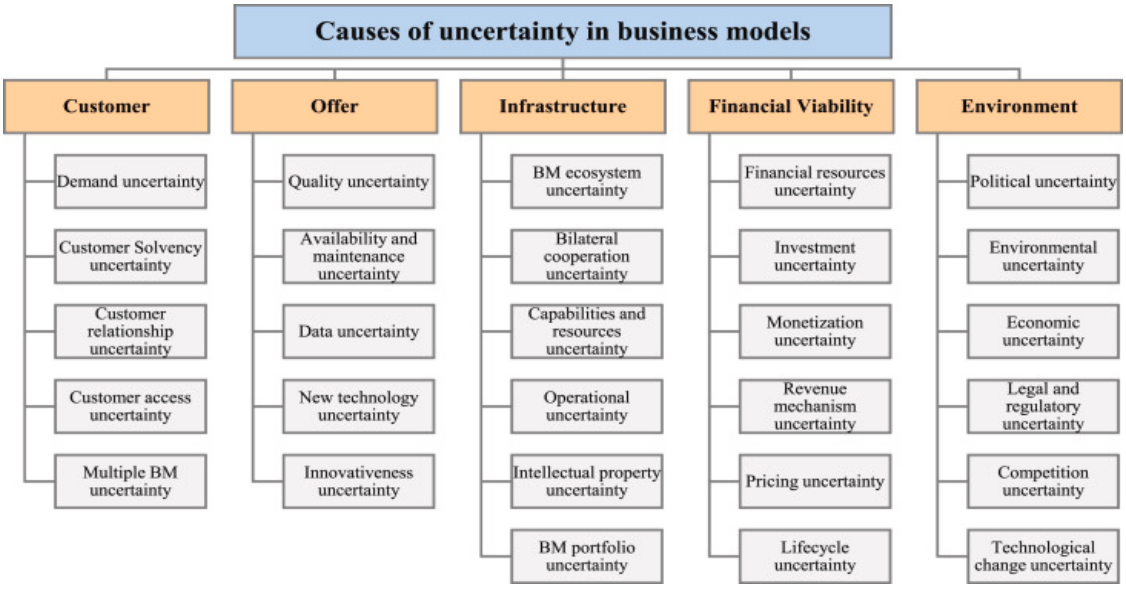

Figure 2. Framework of Causes of Uncertainty in Business Models

The first category, customers, encompasses all uncertainty factors associated with a BM's potential customer base. This includes aspects of customer relationships, solvency, market access, performance across multiple BMs, and demand dynamics. In medical devices, biotechnology, and high-tech sectors, rapid innovation and knowledge generation drive fluctuating demand, making forecasting challenging. Companies must remain flexible and responsive to such changes. Uncertainty may arise from failing to understand or meet customer needs, inability to attract or retain clients, or insufficiently addressing societal demands. Credit risks, such as misjudging customers' ability to pay, and factors affecting customer relationships—like loss of trust, opportunistic behavior, or rigid agreements—also contribute to uncertainty. Access-related challenges include limited market entry, weak intermediaries, high entry barriers, or strong competition. Additionally, the coexistence of multiple BMs can cannibalize the existing customer base, reduce loyalty, or convert current customers into competitors [25].

The second category, value proposition, covers uncertainty related to the quality, availability, and maintenance of offerings, as well as technological and data-related factors. Quality-related uncertainty includes discrepancies between expected and actual performance, durability, and overall effectiveness. Availability and maintenance uncertainty concerns ensuring offers remain functional and reliable, especially in models providing rental or service-based products. Data-related risks involve security, ownership, privacy, and quality, which are particularly relevant for digital BMs or companies selling products online. Failure in these areas may result in customer dissatisfaction, churn, reduced profits, and reputational damage [61].

The third category, infrastructure, addresses uncertainty in production and commercialization processes. In knowledge-based sectors, infrastructure relies heavily on key resources such as prominent scientists, faculty, and inventors. This category also considers risks related to business ecosystems, networks, partnerships, critical capabilities, and intellectual property. Operational risks, human errors, or technical failures—especially in multi-stage manufacturing chains—can cause delays, bottlenecks, or process failures, threatening the delivery of the value proposition [62].

The fourth category, financial capability, includes factors influencing a BM's access to funding, costs, revenue generation, and revenue models. High capital requirements or large initial investments introduce additional uncertainty. In the medical devices, biotechnology, and healthcare sectors, revenue streams may be delayed or non-recurring, though successful research or scientific projects can produce long-term financial gains [25].

Finally, external environment uncertainty involves political, economic, environmental, and competitive risks, as well as technological changes. Natural disasters that damage production sites or disrupt supply chains can also affect the BM or the broader business ecosystem, potentially compromising partners or suppliers [63].

A dynamic sustainable business model proposition for health-tech

Healthcare, medical devices, and biotechnology are innovation-driven industries that face constant challenges from disruptive technologies, evolving patient needs, strict regulatory frameworks, sustainability pressures, and

inherent uncertainties. A review of the literature highlights the need for business models that are both dynamic and sustainable to address these challenges effectively. A dynamic and sustainable business model is crucial for these sectors for several reasons. In technology-driven environments, dynamism allows seamless integration of innovations into products and services, maintaining competitiveness and market relevance. The patient-centric nature of healthcare necessitates a model that can quickly adapt to changing patient demands and preferences, enhancing satisfaction and outcomes. Regulatory compliance also requires agility, with a dynamic model enabling swift adaptation to evolving laws and standards to ensure uninterrupted operations.

Healthcare uncertainties, amplified by market shifts and advances in treatment, demand models capable of navigating risks while seizing emerging opportunities. Environmental sustainability further underscores the need for eco-friendly practices, which dynamic models can incorporate to align with global environmental priorities. Complex stakeholder ecosystems in healthcare—ranging from patients and providers to regulators and investors—require a model that balances diverse interests and fosters collaboration, mutual growth, and ecosystem harmony. Continuous innovation is key for long-term competitiveness, with a dynamic model supporting ongoing product and service enhancement, differentiation, and strategic positioning. By emphasizing adaptability and sustainability, such a model enhances resilience against disruptions, economic volatility, and industry shifts. Rapid responsiveness is also critical, allowing companies to recalibrate and address urgent healthcare challenges efficiently.

In summary, combining technological dynamism, patient-centricity, regulatory agility, sustainability, stakeholder integration, innovation, and crisis responsiveness establishes the rationale for a Dynamic Sustainable Business Model (DSBM) for Health-Tech. This model aims to foster agility, sustainable innovation, and long-term success. Unlike traditional static approaches, the DSBM emphasizes adaptability, interconnectedness, and sustainability as foundational principles, enabling strategic responses to evolving circumstances while accounting for economic, environmental, and social impacts. The proposed DSBM for Health-Tech is illustrated in **Figure 3.**

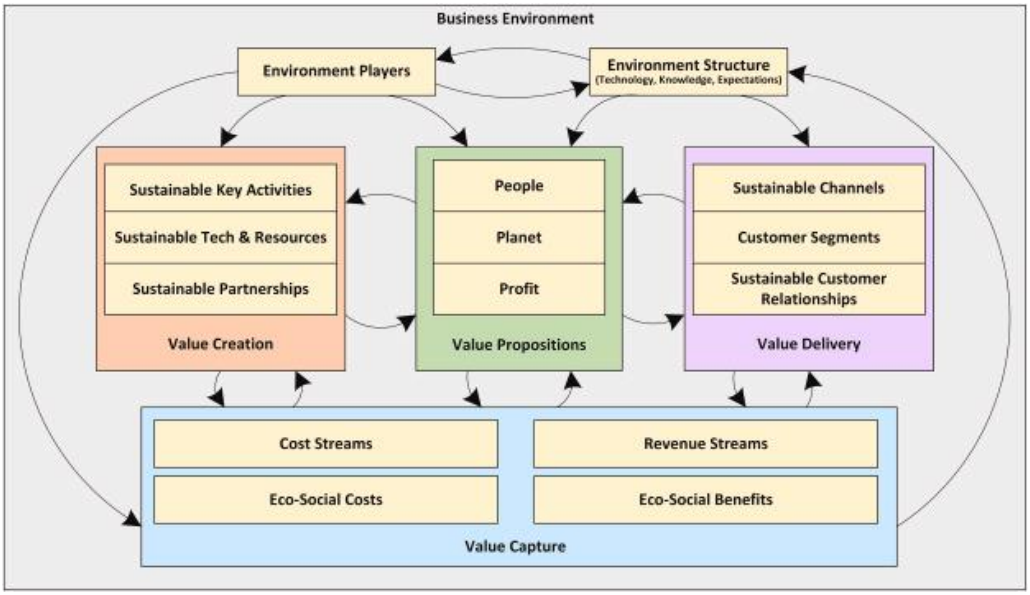

Figure 3. Visual representation of the DSBM for health-tech.

Figure 3 outlines an early conceptual version of the Designing Sustainable Business Model (DSBM) for Health-Tech, offering a broad view of how sustainability and adaptability can be embedded within the healthcare, medical device, and biotechnology fields. The framework is organized around five interlinked pillars—Business Environment, Value Propositions, Value Creation, Value Delivery, and Value Capture—which together form an integrated structure that supports long-term viability within the rapidly shifting health-tech landscape.

The Business Environment pillar portrays a fluid, multistakeholder setting in which an extensive range of actors interact. This network spans universities, research centers, emerging and established companies, clinical institutions, patients, governmental and regulatory bodies, investors, distribution partners, suppliers of environmentally conscious materials, insurers, and broader societal groups. Continual advances in science and

technology, fast-moving expectations, and continuous knowledge sharing collectively shape this environment, making it a catalyst for ongoing evolution and innovation.

The dimension of Value Propositions is centered on balancing the three core sustainability pillars—People, Planet, and Profit. People-oriented values highlight individualized care, patient empowerment, and improved well-being. Planet-focused values stress environmentally responsible design, the adoption of circular-economy approaches, and reductions in ecological footprints. Profit-related values ensure that financial performance, growth strategies, and ethical resource management are aligned with sustainable business conduct.

Within Value Creation, the model integrates Sustainable Key Activities, Sustainable Tech & Resources, and Sustainable Partnerships. These elements collectively support the development of innovative solutions that remain both technologically advanced and environmentally responsible. Sustainable Key Activities involve continuous R&D, iterative improvement, and resource-efficient operational practices. Sustainable Tech & Resources emphasize the use of advanced digital tools, environmentally friendly materials, and cutting-edge technologies. Sustainable Partnerships reinforce collaboration across sectors to accelerate innovation and drive sustainable transformation in healthcare.

The Value Delivery dimension explains how health-tech solutions reach end users. Delivery mechanisms encompass direct commercial channels, digital platforms, distributor collaborations, and engagement in professional or industry-focused events. These routes ensure reliable and timely access for patients, clinicians, and other stakeholders while supporting long-term relationships and environmentally conscious distribution strategies.

Finally, Value Capture outlines how the business secures economic returns while maintaining positive social and ecological implications. Revenue may emerge from licensing agreements, product sales, service offerings, or subscription-based models. Cost structures, revenue mechanisms, and the balance between eco-social burdens and the eco-social benefits generated by the business are all considered to maintain an ethically grounded and sustainable financial system.

Overall, the DSBM for Health-Tech shown in **Figure 3** represents an integrated, sustainability-driven framework designed to help organizations remain resilient and innovative while addressing both healthcare demands and environmental priorities. The specific components and their extended explanations are summarized in **Table 4**, which provides a clear breakdown of each element within the DSBM structure.

The DSBM for Health-Tech operates within an ever-evolving environment, relying heavily on continuous feedback mechanisms and built-in flexibility to stay aligned with shifting market forces, technological progress, and user expectations. These feedback cycles gather insights from multiple sources—including customers, regulatory agencies, industry collaborators, and broader stakeholder groups—and convert that information into strategic refinements that shape more effective medical device and biotech solutions tailored to both patients and healthcare professionals.

Within the DSBM, feedback loops serve as engines of ongoing innovation. By consistently monitoring user experiences, competitive pressures, and scientific advancements, the framework ensures that offerings remain relevant and future-oriented. This constant flow of information reshapes how Health-Tech companies structure their business models, embedding a culture focused on continual enhancement. Real-time data becomes a central tool for guiding decisions in product development, marketing strategies, and resource deployment, ensuring that operations remain synchronized with emerging market realities. Maintaining this two-way dialogue with customers not only strengthens long-term relationships but also contributes to enhanced brand credibility, user loyalty, and overall satisfaction.

Because adaptability is woven into these dynamic loops, the model enables rapid responses to disruptions and unexpected changes in the healthcare landscape. Such agility enhances organizational resilience, sharpens risk-mitigation strategies, and supports competitive positioning, helping companies establish themselves as leaders in the sector. At its core, the DSBM for Health-Tech embodies sustainability by integrating environmental, economic, and social aims. Eco-conscious design, circular economic principles, and renewable materials reduce ecological burdens, while circular supply chains reinforce long-term environmental benefits.

Financial sustainability is maintained through diverse revenue pathways and operational efficiency. Multiple income streams create stability even when market conditions fluctuate. The model also upholds social commitments that extend to patients, clinicians, employees, and communities. Collaboration with universities, research groups, and startups cultivates knowledge exchange, fosters community involvement, and supports broader societal development. These sustainability commitments are embedded throughout the entire business

model. Feedback cycles continuously track key indicators to guide improvements and align activities with environmental, economic, and social benchmarks. Circular innovations, sustainable alliances, and eco-friendly technologies collectively highlight the model's dedication to protecting the environment, ensuring economic health, and promoting societal well-being. Ultimately, the DSBM harmonizes these three spheres—environment, economy, and society—into a unified, future-oriented system that propels responsible innovation in healthcare.

An essential aspect of the DSBM for Health-Tech is understanding the distinction between "eco-social costs" and "cost streams." Eco-social Costs refer to the environmental and societal implications of business operations, encompassing issues such as resource depletion, pollution, and negative community impacts. Addressing these costs is central to sustaining long-term corporate responsibility, encouraging the adoption of greener production methods, responsible resource use, and active community engagement.

Cost streams, in contrast, involve the direct financial outlays necessary for daily business activities—manufacturing, R&D, marketing expenses, employee compensation, and operational overhead. The DSBM emphasizes efficient management of these expenditures by promoting lean processes, optimized supply chains, and strategic investments in advanced, cost-saving technologies. While eco-social costs and cost streams differ in nature, they intersect within the DSBM: responsible handling of the former supports long-term sustainability, while effective control of the latter ensures competitive performance and financial resilience. The model is intentionally structured to balance both, helping Health-Tech organizations remain profitable while upholding environmental and social commitments.

Compared with the traditional Business Model Canvas (BMC), the Designing Sustainable Business Model (DSBM) for Health-Tech introduces a more advanced and sustainability-driven approach tailored specifically to Healthcare, Medical Devices, and Biotechnology. Its core differentiator is the integration of sustainability across every dimension of the model. Eco-friendly production systems, circular economy concepts, and environmentally conscious product development are embedded as essential practices rather than optional components. Beyond sustainability, the DSBM introduces highly dynamic features absent in the standard BMC—such as continuous feedback cycles, adaptive responses to uncertainty, and scenario-based planning—that enable firms to stay agile amid rapid technological innovation, shifting market demands, and evolving regulatory landscapes. Innovation lies at the heart of the DSBM, supported by close collaboration with academic researchers, startups, and industry stakeholders. This collaborative orientation accelerates product development and embeds a mindset of persistent refinement. Furthermore, the model incorporates the triple bottom line—People, Planet, Profit—directly into its Value Propositions, ensuring that human well-being, ecological stewardship, and economic success are considered simultaneously and given equal importance.

The DSBM offers a wide range of strategic benefits, enabling companies that implement it to stand out as sustainability-driven organizations and attract stakeholders who prioritize ethical and responsible business conduct. Its inherently dynamic structure accelerates innovation, allowing firms to design advanced solutions that continuously reflect changing patient and market expectations. Flexibility and rapid adaptability become central sources of competitive strength, supporting organizations as they navigate shifting market conditions with greater stability and confidence. Because the model embeds long-term sustainability and ongoing innovation, it helps businesses maintain relevance throughout evolving technological cycles and periods of uncertainty. Its influence also extends beyond organizational performance: partnerships with healthcare professionals, academic institutions, and community groups generate broader societal value. The model's environmentally responsible practices further align firms with global sustainability agendas by reducing ecological burdens associated with their operations. In addition, the DSBM enables smooth regulatory alignment by incorporating ongoing monitoring and adaptive mechanisms, minimizing compliance risks and helping companies maintain their reputation as responsible industry leaders. Ultimately, the DSBM for Health-Tech provides a comprehensive and future-oriented blueprint for organizational growth. By weaving together sustainability, innovation, and adaptability, it supports improved healthcare outcomes, reduced environmental impacts, and enduring business performance.

In addition, the DSBM for Health-Tech is purposefully structured to manage uncertainty within the Healthcare, Medical Devices, and Biotechnology sectors. It leverages forward-looking scenario planning, built-in adaptability, continuous feedback systems, collaborative networks, strategic resource management, sustainability-driven practices, inclusive value frameworks, and systematic risk mitigation to address volatility. These features allow organizations to transform potential disruptions into opportunities for preparedness, creativity, and advancement. The model equips businesses to respond swiftly to emerging challenges by using real-time insights and external

partnerships. By integrating sustainability and inclusive decision-making, the DSBM enables companies not only to withstand uncertainty but also to convert it into long-term advantages, supporting meaningful innovation and sustained progress across the healthcare ecosystem.

Table 4. Components and descriptions of the DSBM for health-tech.

Main Components		Sub Components	
Business Environment	The environment of the DSBM for Health-Tech encompasses a dynamic ecosystem comprising academic collaborations, industry partnerships, regulatory influences, societal stakeholders, and innovative technology suppliers, all contributing to a holistic approach to healthcare innovation and sustainability.	Environment Players	The main players and stakeholders in the environment include academic institutions, research organizations, startups, industry partners, healthcare providers, patients, government bodies, investors, regulatory agencies, distributors, suppliers of sustainable materials, insurers, and societal stakeholders.
		Environment Structure	The Environment Structure incorporates rapidly evolving technology, cutting-edge knowledge dissemination, and dynamic expectations, creating a foundation that drives continuous innovation and adaptation.
Value Propositions	The Value Propositions in the DSBM for Health-Tech encompass the harmonious integration of People, Planet, and Profit, offering high-tech medical solutions that prioritize superior patient outcomes, environmental sustainability, and economic growth.	**People Values**	The People Values within the DSBM for Health-Tech emphasize patient-centricity, personalized healthcare solutions, and the well-being of individuals and communities.
		Planet Values	The Planet Values underscore the integration of eco-friendly practices, circular economy principles, and sustainable product design to minimize environmental impact.
		Profit Values	The Profit Values focus on achieving financial sustainability and growth while aligning with ethical business practices and responsible resource allocation.
Value Creation	The value creation in the DSBM for Health-Tech stems from the integration of Sustainable Key Activities, leveraging Sustainable Tech & Resources, and fostering Sustainable Partnerships to deliver innovative and environmentally conscious healthcare solutions that prioritize patient-centricity, environmental responsibility, and long-term economic viability.	**Sustainable Key Activities**	Sustainable Key Activities encompass continuous innovation, adaptable R&D, and circular economy practices, ensuring ongoing value creation while minimizing environmental impact.
		Sustainable Tech & Resources	The Sustainable Tech & Resources aspect in the DSBM for Health-Tech entails leveraging advanced technologies and eco-friendly resources to develop innovative medical solutions while promoting environmental sustainability.
		Sustainable Partnerships	The Sustainable Partnerships component involves collaborating with academic institutions, research organizations, startups, and industry players to pool diverse expertise, fostering innovation and driving sustainable healthcare advancements.

Value Delivery	The Value Delivery aspect involves efficient distribution of innovative healthcare solutions through direct sales, online platforms, strategic partnerships, and participation in industry events, ensuring timely access for patients, healthcare providers, and stakeholders. It ensures sustainable channels, reaching diverse customer segments, and nurturing long-lasting, ethical, and personalized relationships that prioritize patient-centric care and environmental responsibility.	**Sustainable Channels**	Sustainable Channels encompass direct sales, online platforms, partnerships with distributors, and active participation in industry events, all tailored to effectively engage stakeholders while maintaining environmental consciousness.
		Customer Segments	The Customer Segments encompass patients seeking advanced medical solutions, healthcare providers interested in cutting-edge technologies, government agencies seeking cost-effective options, and impact-driven investors looking to support innovative healthcare projects.
		Sustainable Customer Relationships	The Sustainable Customer Relationships involve personalized support for healthcare providers, continuous feedback loops with patients for ongoing improvements, transparent and ethical communication with stakeholders, and the cultivation of long-term partnerships that foster mutual growth and innovation.
Value Capture	Value capture in the DSBM for Health-Tech is realized by generating revenue through diverse streams, including product sales, licensing, services, and subscriptions, while aligning financial success with positive societal and environmental impacts. The Value Capture in the DSBM for Health-Tech encompasses the balance between cost streams, revenue streams, eco-social costs incurred by the business's operations, and the tangible and intangible eco-social benefits created by the business model, ensuring a sustainable and ethical financial foundation.	**Cost Streams**	The Cost Streams in the DSBM for Health-Tech involve the allocation and management of financial resources required for sustainable operations, innovation, and compliance within the healthcare, medical devices, and biotechnology sectors including production, R&D, marketing, and staffing.
		Revenue Streams	The Revenue Streams in the DSBM for Health-Tech encompass the diversified sources of income derived from the sale of innovative medical devices, sustainable biotechnological solutions, licensing of intellectual property, and subscription-based models for data-driven healthcare services.
		Eco-Social Costs	The Eco-Social Costs in the DSBM for Health-Tech account for the environmental and social impacts associated with business operations, ensuring a comprehensive assessment of both positive and negative externalities focusing on resource use, waste generation, and societal implications.
		Eco-Social Benefits	The Eco-Social Benefits encompass the positive contributions and outcomes that the business generates for the environment and society

	through its sustainable practices and innovations.

Conclusion

This systematic literature review provides an in-depth exploration of how business models support innovation and value creation across the medical, biotechnology, and broader healthcare sectors. By examining a wide range of academic studies and industry practices, the review identifies a nine-part taxonomy of commonly used models: Open Innovation BMs, Sustainable BMs, Dynamic BMs, Dual BMs, Spin-off BMs, Frugal BMs, High-tech Entrepreneurial Content Marketing BMs, Back-end BMs, and Product–Service System BMs. Comparing these models across the four foundational dimensions—infrastructure, offering, customers, and finances—revealed their unique characteristics and strategic orientations. The findings show that openness, sustainability, and adaptability are recurring pillars that consistently underpin effective business model design in these industries. The analysis highlights how these models interact in practice, demonstrating that their combined use can produce highly effective strategies for navigating the complexities of the medical device, biotech, and healthcare landscapes.

A key contribution of this work is its treatment of uncertainty. The study proposes a detailed framework consisting of 28 groups of uncertainty factors, offering organizations a structured method for anticipating and managing risks related to technological disruption, regulatory shifts, financial volatility, and environmental pressures. This framework acts as a strategic guide for health-tech firms striving to make informed decisions in the midst of complex and evolving conditions. The culmination of the review is the introduction of the Designing Sustainable Business Model (DSBM) for Health-Tech—a tailored model that integrates adaptability, continual refinement, and sustainability. By embedding iterative feedback mechanisms, responsiveness to emerging shifts, and a strong ethical and societal orientation, the DSBM provides a blueprint for business models that align innovation with long-term sustainability goals.

The research contributes to multiple fields, including healthcare management, medical devices, biotechnology, and business strategy. Its comparative analysis of existing business models delivers valuable perspectives for organizations operating in these sectors. One of the major outcomes is the development of a comprehensive uncertainty-management framework, offering practical tools for addressing sector-specific risks ranging from technology evolution to regulatory and environmental challenges. At the core of the study is the formulation of the DSBM for Health-Tech, an adaptable and sustainability-focused model that integrates innovation, stakeholder participation, and responsible resource use. This model responds directly to the increasing demand for environmentally conscious solutions. Furthermore, the study fills a significant gap by presenting the first extensive literature review and meta-analysis dedicated specifically to business models in the healthcare, medical device, and biotechnology fields, particularly with regard to uncertainty navigation. Its insights advance both scholarly understanding and real-world application.

The analysis also sheds light on risk-management strategies that help organizations confront the multifaceted uncertainties inherent in these industries. The study sets the stage for future research directions, encouraging deeper examination of real-world applications, evolving sustainability practices, industry-specific risk-mitigation approaches, enhanced mechanisms for stakeholder involvement, and the ethical issues associated with innovation. Overall, the research integrates innovation, business model theory, sustainability principles, and uncertainty management into a cohesive framework that helps organizations pursue sustainable growth and generate meaningful societal value.

Looking to the future, the study points to several promising research trajectories. Assessing the real-life application and performance of the DSBM across different organizational and national contexts is an important next step. Further investigation into how dynamic sustainability can be embedded within business models may reveal ways to balance adaptability with responsible practice. Developing risk-management tools tailored to healthcare, medical devices, and biotechnology will be crucial for strengthening industry resilience. Additional exploration of stakeholder engagement, the integration of emerging technologies, and the ethical considerations surrounding innovation will provide deeper insight into how business models evolve over time. Altogether, this work offers a comprehensive roadmap for empirical testing, enhanced sustainability integration, refined risk-management approaches, stakeholder analysis, technological advancement, and ethical inquiry.

Regarding global applicability, the study acknowledges that while healthcare, medical devices, and biotechnology industries differ across countries due to economic development levels and policy frameworks, they also share universal challenges—such as rapid technological advancement and global health pressures. The models and insights presented here are therefore designed to be adaptable. Although national conditions influence business behavior, the fundamental principles of innovation, sustainability, and strategic management apply across borders. By offering flexible frameworks rather than rigid prescriptions, the research enables firms in diverse regions to tailor the models to their regulatory environments, economic structures, and market realities. This adaptability ensures that the study's findings remain relevant and valuable within varied global contexts, supporting firms as they navigate both shared and region-specific challenges.

Acknowledgments: None

Conflict of Interest: None

Financial Support: The work was supported by the internal project "SPEV – Economic Impacts under the Industry 4.0/Society 5.0 Concept" and Excellence 2022, University of Hradec Králové, Faculty of Informatics and Management, Czech Republic. At the same time, the authors would like to acknowledge the support provided by the Economic and Management College of Nanjing University of Aeronautics and Astronautics, China.

Ethics Statement: None

References

1. Corallo A, Errico F, Latino ME, Menegoli M. Dynamic business models: a proposed framework to overcome the Death valley. J Knowl Econ. 2019;10:1248-71. doi:10.1007/s13132-018-0529-x
2. Pezeshkan A, Smith A, Fainshmidt S, Amini Sedeh A. National business systems and firm innovation: a study of developing economies. J Bus Res. 2016;69:5413-8. doi:10.1016/j.jbusres.2016.04.147
3. Maresova P, Javanmardi E, Maskuriy R, Selamat A, Kuca K. Dynamic sustainable business modelling: exploring the dynamics of business model components considering the product development framework. Appl Econ. 2022;:1-28. doi:10.1080/00036846.2022.2055740
4. Hasbollah HR, Hafizah N, Firdaus M. Introduction to healthcare industry. 1st ed. Kajang: Power Action Resources; 2015.
5. Centers for Medicare & Medicaid Services. National Health Expenditure Data: NHE Fact Sheet. Available from: https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet (accessed 8 Dec 2023).
6. Raghupathi V, Raghupathi W. Healthcare expenditure and economic performance: insights from the United States data. Front Public Health. 2020;8:156. doi:10.3389/fpubh.2020.00156
7. Clark DP, Pazdernik NJ. Biotechnology. 2nd ed. Amsterdam: Elsevier Academic Press; 2016.
8. Wreh E. Future of the medical device industry. In: Medical Device Regulation. Elsevier; 2023. p. 495-509.
9. Shalowitz J. The U.S. healthcare system: origins, organization and opportunities. 1st ed. Hoboken: Jossey-Bass; 2019.
10. World Health Organization. World health statistics: monitoring health for the SDGs 2019. Geneva: WHO; 2019.
11. Pels J, Kidd TA. Business model innovation: learning from a high-tech-low-fee medical healthcare model for the BOP. Int J Pharm Healthc Mark. 2015;9:200-18. doi:10.1108/IJPHM-02-2014-0011
12. Maresova P, Soukal I, Svobodova L, Hedvicakova M, Javanmardi E, Selamat A. Consequences of industry 4.0 in business and economics. Economies. 2018;6:46. doi:10.3390/economies6030046
13. Lehoux P, Daudelin G, Williams-Jones B, Denis JL, Longo C. How do business model and health technology design influence each other? Res Policy. 2014;43:1025-38. doi:10.1016/j.respol.2014.02.001
14. Gbadegeshin SA, Natsheh AA, Ghafel K, Mohammed O, Koskela A, Rimpilainen A. Overcoming the valley of Death: a new model for high technology startups. Sustain Futur. 2022;4:100077. doi:10.1016/j.sftr.2022.100077

15. Joyce A, Paquin RL. The triple layered business model canvas: a tool to design more sustainable business models. J Clean Prod. 2016;135:1474-86. doi:10.1016/j.jclepro.2016.06.067
16. Bellini F, Dulskaia I. A digital platform as a facilitator for assessing innovation potential and creating business models. Proc Int Conf Bus Excell. 2017;11:982-93. doi:10.1515/picbe-2017-0103
17. Urbinati A, Chiaroni D, Chiesa V, Frattini F. The role of business model design in the diffusion of innovations. Int J Innov Technol Manag. 2019;16:1950011. doi:10.1142/S0219877019500111
18. Pellikka JT, Malinen P. Business models in the commercialization processes of innovation among small high-technology firms. Int J Innov Technol Manag. 2014;11:1450007. doi:10.1142/S0219877014500072
19. Zott C, Amit R. Business model innovation: how to create value in a digital world. NIM Mark Intell Rev. 2017;9:18-23. doi:10.1515/gfkmir-2017-0003
20. Bialek-Jaworska A, Gabryelczyk R. Biotech spin-off business models for the internationalization strategy. Balt J Manag. 2016;11:380-404. doi:10.1108/BJM-11-2015-0223
21. Voigt KI, Buliga O, Michl K. Business model pioneers: how innovators successfully implement new business models. 1st ed. Cham: Springer; 2017.
22. Konopik J, Blunck D. Development of an evidence-based conceptual model of the health care sector under digital transformation. J Med Internet Res. 2023;25:e41512. doi:10.2196/41512
23. Wang Z, Lin S, Chen Y, Lyulyov O, Pimonenko T. Digitalization effect on business performance: role of business model innovation. Sustainability. 2023;15:9020. doi:10.3390/su15119020
24. Ishfaq R, Darby J, Gibson B. Adapting the retail business model to omnichannel strategy: a supply chain management perspective. J Bus Logist. 2023;. doi:10.1111/jbl.12352
25. Brillinger AS, Els C, Schafer B, Bender B. Business model risk and uncertainty factors. Bus Horiz. 2020;63:121-30. doi:10.1016/j.bushor.2019.09.009
26. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. J Clin Epidemiol. 2009;62:1006-12. doi:10.1016/j.jclinepi.2009.06.005
27. Kitchenham B, Brereton OP, Budgen D, Turner M, Bailey J, Linkman S. Systematic literature reviews in software engineering. Inf Softw Technol. 2009;51:7-15. doi:10.1016/j.infsof.2008.09.009
28. Moultrie J, Sutcliffe L, Maier A. Exploratory study of environmentally conscious design in the medical device industry. J Clean Prod. 2015;108:363-76. doi:10.1016/j.jclepro.2015.06.014
29. Feeney R, Perez C, Clay M, Bioceres P. AG biotechnology from Argentina. Int J Food Syst Dyn. 2016;7:92-114. doi:10.18461/IJFSD.V7I2.724
30. Regenfelder M, Slowak AP, Santacreu A. Closed-loop innovation for mobile electronics. In: Proc Electron Goes Green 2016+; IEEE; 2016. p. 1-6.
31. Velu C. Evolutionary or revolutionary business model innovation through coopetition? Ind Mark Manag. 2016;53:124-35. doi:10.1016/j.indmarman.2015.11.007
32. Spector-Bagdady K. The google of healthcare: enabling the privatization of genetic databanking. Ann Epidemiol. 2016;26:515-9. doi:10.1016/j.annepidem.2016.05.007
33. Mansour D, Barandas H. High-tech entrepreneurial content marketing for business model innovation. J Res Interact Mark. 2017;11:296-311. doi:10.1108/JRIM-03-2016-0022
34. Winterhalter S, Zeschky MB, Neumann L, Gassmann O. Business models for frugal innovation in emerging markets: the case of the medical device and laboratory equipment industry. Technovation. 2017;66-67:3-13. doi:10.1016/j.technovation.2017.07.002
35. Adrodegari F, Pashou T, Saccani N. Business model innovation: process and tools for service transformation of industrial firms. Procedia CIRP. 2017;64:103-8. doi:10.1016/j.procir.2017.03.056
36. Kamuriwo DS, Baden-Fuller C, Zhang J. Knowledge development approaches and breakthrough innovations in technology-based new firms. J Prod Innov Manag. 2017;34:492-508. doi:10.1111/jpim.12393
37. Neto AC, Guimaraes MJOC, Freire E. Business models for commercial scale second-generation bioethanol production. J Clean Prod. 2018;184:168-78. doi:10.1016/j.jclepro.2018.02.220
38. Zhu X, Xiao Z, Dong MC, Gu J. The fit between firms' open innovation and business model for new product development speed: a contingent perspective. Technovation. 2019;86-87:75-85. doi:10.1016/j.technovation.2019.05.005

39. Xu Y, Koivumaki T. Digital business model effectuation: an agile approach. Comput Hum Behav. 2019;95:307-14. doi:10.1016/j.chb.2018.10.021
40. Balboni B, Bortoluzzi G, Pugliese R, Tracogna A. Business model evolution, contextual ambidexterity and the growth performance of high-tech start-ups. J Bus Res. 2019;99:115-24. doi:10.1016/j.jbusres.2019.02.029
41. Khodaei H, Ortt R. Capturing dynamics in business model frameworks. J Open Innov Technol Mark Complex. 2019;5:8. doi:10.3390/joitmc5010008
42. Loon M, Chik R. Efficiency-centered, innovation-enabling business models of high tech SMEs: evidence from Hong Kong. Asia Pac J Manag. 2019;36:87-111. doi:10.1007/s10490-017-9558-4
43. Curtis E, Sweeney B. Flexibility and control in managing collaborative and in-house NPD. J Account Organ Change. 2019;15:30-57. doi:10.1108/JAOC-07-2017-0057
44. Lee M, Park S, Lee KS. What are the features of successful medical device start-ups? Sustainability. 2019;11:1948. doi:10.3390/su11071948
45. D'Amato D, Veijonaho S, Toppinen A. Towards sustainability? Forest-based circular bioeconomy business models in Finnish SMEs. For Policy Econ. 2020;110:101848. doi:10.1016/j.forpol.2018.12.004
46. Guzzo D, Carvalho MM, Balkenende R, Mascarenhas J. Circular business models in the medical device industry: paths towards sustainable healthcare. Resour Conserv Recycl. 2020;160:104904. doi:10.1016/j.resconrec.2020.104904
47. Barbieri R, Santos DFL. Sustainable business models and eco-innovation: a life cycle assessment. J Clean Prod. 2020;266:121954. doi:10.1016/j.jclepro.2020.121954
48. Homeyer A, Lotz J, Schwen LO, Weiss N, Romberg D, Hofener H. Artificial intelligence in pathology: from prototype to product. J Pathol Inform. 2021;12:13. doi:10.4103/jpi.jpi_84_20
49. Silva DS, Ghezzi A, de Aguiar RB, Cortimiglia MN, ten Caten CS. Lean startup for opportunity exploitation: adoption constraints and strategies in technology new ventures. Int J Entrep Behav Res. 2021;27:944-69. doi:10.1108/IJEBR-01-2020-0030
50. Vovk V, Kister A. Benefits of the on-line healthcare services. E3S Web Conf. 2021;307:08001. doi:10.1051/e3sconf/202130708001
51. Rodriguez R, Svensson G. The role of public resource desynchronization on business model sustainability in the private healthcare industry. Sustainability. 2021;13:6132. doi:10.3390/su13116132
52. Ivaninskiy I, Ivashkovskaya I. Are blockchain-based digital transformation and ecosystem-based business models mutually reinforcing? Eurasian Bus Rev. 2022;12:643-70. doi:10.1007/s40821-022-00209-0
53. Ijntema R, Barten DJ, Duits H, Tjemkes B, Veenhof C. The relations between business model efficiency and novelty and outcome in healthcare organisations. BMC Health Serv Res. 2022;22:990. doi:10.1186/s12913-022-08383-7
54. Garcia Lechuga A, Cortes Robles G, Arredondo Soto KC, Miranda Ackerman MA. Integration of business model canvas and service blueprinting. J Clean Prod. 2023;415:137801. doi:10.1016/j.jclepro.2023.137801
55. Geiger S, Gross N. Tech sharing, not tech hoarding: Covid-19, global solidarity, and the failed responsibility of the pharmaceutical industry. Organization. 2023;. doi:10.1177/13505084221145666
56. Foss NJ, Saebi T. Business models and business model innovation: between wicked and paradigmatic problems. Long Range Plan. 2018;51:9-21. doi:10.1016/j.lrp.2017.07.006
57. Geissdoerfer M, Vladimirova D, Evans S. Sustainable business model innovation: a review. J Clean Prod. 2018;198:401-16. doi:10.1016/j.jclepro.2018.06.240
58. Abdelkafi N, Tauscher K. Business models for sustainability from a system dynamics perspective. Organ Environ. 2016;29:74-96. doi:10.1177/1086026615592930
59. Juca-Aulestia M, Labanda-Jaramillo M, Guaman-Quinche J, Coronel-Romero E, Chamba-Eras L, Jacome-Galarza LR. Open innovation at university: a systematic literature review. In: Rocha A, Adeli H, Reis LP, Costanzo S, Orovic I, Moreira F, editors. Trends and innovations in information systems and technologies. Cham: Springer; 2020. p. 3-14.
60. Yang M, Evans S. Product-service system business model archetypes and sustainability. J Clean Prod. 2019;220:1156-66. doi:10.1016/j.jclepro.2019.02.067

61. Linder M, Williander M. Circular business model innovation: inherent uncertainties. Bus Strat Environ. 2017;26:182-96. doi:10.1002/bse.1906
62. Nair S, Blomquist T. Business model design in the case of complex innovations: a conceptual model. Technol Anal Strateg Manag. 2021;33:176-87. doi:10.1080/09537325.2020.1805103
63. Teece DJ. Business models and dynamic capabilities. Long Range Plan. 2018;51:40-9. doi:10.1016/j.lrp.2017.06.007