Challenges and Strategic Choices in Business Model Evolution of European Digital Health Startups: A Qualitative Study

Sascha Noel Weimar
Institute for Entrepreneurship, Technology Management and Innovation
Karlsruhe Institute of Technology
Karlsruhe, Germany
sascha.weimar@kit.edu

Rahel Sophie Martjan
Institute for Entrepreneurship, Technology Management and Innovation
Karlsruhe Institute of Technology
Karlsruhe, Germany
rahel.martjan@kit.edu

Orestis Terzidis
Institute for Entrepreneurship, Technology Management and Innovation
Karlsruhe Institute of Technology
Karlsruhe, Germany
orestis.terzidis@kit.edu

***Abstract*—Startups are crucial in driving digital transformation in healthcare, with business modeling being essential for their success. However, these digital health startups face challenges in the healthcare sector, including stringent regulations and multiple stakeholders. As a result, they must make unique business model choices. This study investigates the challenges of digital health startups and systematically maps the resulting business model choices in the European Union. Through 32 expert interviews with founders and leaders, the study identifies key challenges and develops a catalog of business model choices across critical dimensions: value proposition and customer segments, medical device and regulatory compliance, evidence generation and clinical studies, revenue model and cost structure, key resources and funding, and key partnerships and customer engagement. Medical device regulations were identified as the major barrier for many startups, followed by related challenges regarding revenue models and funding. The findings emphasize the importance of addressing medical device regulatory requirements early in the business model design process and adapting related components such as funding or revenue models. The study further generalizes these insights into a conceptual model of the temporal evolution of digital health startup business models. This work contributes to the ongoing discussion on sustainable business models in digital health and provides a catalog of business model choices for digital health startups.**

Keywords—digital health, business model, challenges, choices, entrepreneurship

I. Introduction

Business models act as a mediating construct between technologies and the achievement of strategic goals and objectives of organizations, including economic value creation [1]; therefore, they are a crucial component in the commercialization of technologies. For digital technologies applied in healthcare, business modeling has been described as a crucial element [2]. Startups play a significant role in commercializing these digital health technologies. They can use their flexibility to explore new market segments that have been barely explored [3]. Therefore, they can transform established business models and, by joining strategic forces with other players, drive the digital transformation of the healthcare sector [3].

However, the healthcare sector is tightly regulated [3]. Additionally, the industry has many stakeholders [4]. Especially in the European Union (EU), more stringent medical device regulations have been introduced recently [5], potentially creating hurdles for many startups in the digital health domain. While general elements of business models in digital health have been described in the literature, there is a gap in understanding the challenges and related business model decisions of digital health startups. Especially the implications of regulations on the business model, reimbursement pathways, and funding strategies have been understudied [6]. While phenomena, such as skating the line between general wellness products and regulated medical devices [7], have been studied, a concrete understanding of their implications for business model choices remains limited. This understanding could help entrepreneurs identify key business model choices and advance the theoretical understanding of key business model strategies in digital health.

A. Objective

Based on this identified gap, the objective of this work is to shed light on the challenges and related business model choices of early-stage digital health startups that operate in the EU market, thereby creating a catalog of business model choices. We therefore formulate the following research question (RQ):

- RQ: Which challenges do early-stage digital health startups face, and how do they overcome these challenges through strategic business model choices?

The following work is structured as follows: The subsequent method section gives an overview of the research methods employed, the third section gives an overview of the results, and the results are discussed in the last section.

II. Relation to Existing Theories and Work

Digital health has developed into a broad term that refers to the use of information and communication technology to address health needs [8]. Key elements of digital health include electronic health (eHealth), mobile health (mHealth), and telemedicine, among others [9, 10]. Some digital health technologies are regulated as medical devices, often referred to as software as a medical device (SaMD) [11], while others do not qualify as medical devices.

The business model concept is well-established in the literature. A business model describes the design or architecture of how a business creates, delivers, and captures value [12]. In technology and innovation management, a business model is mainly described as a mechanism that connects a firm's technology to customer needs and other firm resources [13]. It is a conceptual framework that helps link a

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firm's strategy with its activities or strategy execution [14]. Therefore, the business model can be viewed as a reflection of the realized strategy [15]. Osterwalder [16] defines the business model as the "translation of a company's strategy into a blueprint of the company's logic of earning money".

Business models in digital health and related subareas have been described previously. Some conceptual work summarizes the key elements of such business models [17, 18]. To identify business model strategies, several studies have used qualitative approaches for specific digital health segments, such as telemedicine [19, 20, 21]. For example, Sterling and Lerouge [19] assessed telemedicine business models in the United States and found that business models closely aligned with a value-adding process model archetype were being deployed. Lin et al. [22] built on a case study to derive several business model choices for a telecardiology service. In addition to these contributions, another stream of literature discusses business model frameworks, such as those by Peters et al. [23] or processes for developing a business model strategy for eHealth [24].

In summary, while some conceptual work exists in this domain, and some challenges and business model choices were identified, they often rely on limited empirical data [20] or focus on specific digital health segments [22]. Additionally, the significant impact of medical device regulations and related strategic choices remains understudied. Therefore, a systematic understanding in the form of a catalog of business model choices for entrepreneurs and researchers in this domain is lacking.

III. Research Approach

We employed a qualitative research approach to understand the challenges and strategic business model choices of digital health startups. Through the use of qualitative research in the form of interviews, researchers can potentially gather more details and insights into a field than they can with quantitative research methods [25], which aligns closely with the objectives of this study. Therefore, we interviewed 32 experts, including digital health co-founders in the role of chief executive officers (30/32), and other senior leaders (2/32), all of whom have been or are currently involved in digital health startups across the EU. Most of the startups were founded in Germany (27/32), but often operated in multiple EU countries. Besides their expertise, the expert sample was chosen to represent various digital health startups with different focuses. For instance, the sample includes startups that build patient-facing mobile applications targeting specific diseases but also general well-being, software supporting administrative and communication purposes, desktop applications used by physicians for decision support, and software related to in vitro diagnostics, to name the most frequent ones. Additionally, the sample was chosen to include startups developing medical devices (26/32) and non-medical devices (6/32). We created an interview guideline to incorporate key aspects of business modeling [1, 16] and took into account the specifics of digital health business models as identified from the literature. Following the aim of the work, we asked about the startup challenges and afterward went through business model elements to understand strategic choices. Interviews were conducted and recorded using video conference software and were then transcribed and anonymized. All participants gave their informed consent for the anonymized data to be used in the scope of this work. Afterward, one researcher analyzed the data using the inductive Gioia methodology [26]. Following this approach, first-order concepts were derived from the textual data, which are closely linked to the original language, and were then grouped into second-order themes. These were then further combined into aggregate dimensions. Another researcher independently reviewed the codings, and disagreements were solved until a consensus was reached. This had the underlying goal of ultimately reducing potential biases.

IV. Findings

We identified the six aggregate dimensions: value proposition and customer segments, medical device and regulatory compliance, evidence generation and clinical studies, revenue model and cost structure, key resources and funding, key partnerships and customer engagement. These dimensions are then made up of 36 second-order themes and 597 first-order concepts. The first-order concepts represent challenges or concrete business model choices. The understanding of choices in the scope of business models stems from the work of Casadesus-Masanell and Ricart [15]. An overview of dimensions and themes is shown in Table 1.

A. Value Proposition and Customer Segments

This dimension encompasses ten second-order themes, including challenges related to the dimension, strategies for developing a strong value proposition, and the value propositions identified for seven potential customers in healthcare. It also includes targeting and entering other markets.

A primary (1) **challenge** highlighted by most interview participants was understanding the needs of multiple stakeholders (E16, E8, E20, E11), with a broad stakeholder landscape in healthcare and many gatekeepers (E27). Typically, at least three key stakeholders must be considered: doctors, patients, and health insurers. Therefore, it is crucial to identify early on who the stakeholders are and who will pay for and use the solution (E20). The value proposition for these stakeholders may evolve over time (E11). The highly regulated nature of this sector adds further complexity to the environment (E8). Other challenges mentioned include the discrepancy between theoretical results from medical research and the real customer needs (E9). Additionally, a further challenge was the slow adoption of new technologies by healthcare providers. As a result, startups often face barriers related to usability and workflow integration rather than technology itself (E17), which must be overcome through a strong value proposition.

Several strategies for (2) **building a strong value proposition** were discussed by the experts. One approach involves starting with a small personal problem and gradually expanding from there (E16). Another expert suggested having a clear "north star" while remaining flexible on the way (E8). A common strategy was to conduct early customer interviews to develop a solution that aligns with their needs (E7, E9, E8, E21, E24, E29, E10). In addition to customers, engaging with multipliers like doctors—who can later recommend the solution—was also considered valuable (E22). Some experts recommended using a "smoke test", such as a fake landing page, to assess potential willingness to pay (E27). The overall advice was to identify a problem, quickly build a minimum viable product (MVP), and validate it iteratively, following lean startup (E27, E12) or design thinking principles (E28). One expert emphasized the importance of listening not just to existing

TABLE I. OVERVIEW OF AGGREGATE DIMENSIONS AND RELATED SECOND-ORDER THEMES

Aggregate dimension	Second-order themes
Value proposition and customer segments	(1) Challenges in value proposition and customer segments; (2) building a strong value proposition; value proposition for: (3) health insurer and government, (4) healthcare provider, (5) non-healthcare commercial firms, (6) patients and private individuals, (7) research institutions, (8) indirect healthcare commercial firm; (9) entry into alternative markets
Medical device and regulatory compliance	(10) Challenges in medical device and regulatory compliance; (11) support to build a medical device; (12) medical or non-medical device; (13) complying with medical device regulations; (14) ensuring data security and protection
Evidence generation and clinical studies	(15) Challenges in evidence generation and clinical studies; (16) evidence generation execution; (17) mandatory premarket evidence generation; (18) non-mandatory evidence generation
Revenue model and cost structure	(19) Challenges in revenue model and cost structure; paying entity: (20) health insurer and government, (21) healthcare provider, (22) indirect healthcare commercial firms, (23) non-healthcare commercial firms, (24) research institution, (25) patient and private individual; (26) cost structure
Key resources and funding	(27) Challenges in key resources and funding; (28) key resources; (29) bootstrapping; (30) equity-based funding; (31) public non-dilutive funding; (32) funding timeline
Key partnerships and customer engagement	(33) Challenges in key partnerships and customer engagement; (34) key partnerships; (35) outsourcing approaches; (36) channels and customer relationships

customers but also to potential customers who have not yet made a purchase and questioning why that is (E21). Another recommendation is not to focus on small markets (E24). One expert further suggested ensuring that the main value proposition addresses the potential payer (E26). In the scope of the value proposition, it was also mentioned that it is essential to understand the unique selling proposition (USP) early on (E6, E21) to distinguish from competitors.

The (3-8) **value propositions** could be clustered according to their target groups: patients and private individuals, health insurers and government, healthcare providers, indirect healthcare commercial firms (including pharmaceutical companies and other medical technology firms), non-healthcare commercial firms (including firms not developing healthcare-related solutions), and research institutions. It is important to note that patients and private individuals remain the foremost priority in many startup activities, which has become evident throughout the interviews. For (6) **patients and private individuals**, value propositions include achieving better health and improved quality of life, accessing the best available therapy (E30, E25, E29), engaging with therapy and healthcare stakeholders from home (E5), and reducing the need for travel (E1). This is particularly valuable in areas where local doctors are unavailable (E29). For (3) **health insurers and the government**, the main value proposition was cost reduction (E8, E21, E22, E29). This can be achieved in several ways, such as by supporting patients with medical conditions early on (E8) or facilitating earlier diagnoses, which later on reduces costs (E21). Additional value propositions include the digitalization of patient data, which can be used by health insurers for later engagement (E21) or to gain a competitive edge over other insurers by attracting specific target groups, such as young people (E22). For (4) **healthcare providers**, value propositions typically include saving time and improving efficiency, which in turn allows more time for patient care (E6, E8, E17). Other benefits mentioned include providing additional or increased revenue (E8, E1), enabling remote work and greater flexibility (E1, E5, E31), improving the quality of care delivery (E2), and allowing healthcare providers to focus on key tasks (E5). Hospitals, in particular, require multiple value propositions to address the needs of different departments, including doctors, commercial teams, and IT or regulatory staff (E10). For (8) **indirect healthcare commercial firms**, particularly pharmaceutical companies, the key value propositions include gaining closer proximity to patients through companion apps and understanding why patients start or stop taking medications (E29, E11). Collecting real-world evidence, supporting digital clinical trials, and fostering connections between pharmaceutical companies and doctors are also significant benefits (E11). Additionally, these companies may seek to save time and resources (E15). For (5) **non-healthcare commercial firms**, especially those focused on occupational health, the value proposition is to reduce employee sick leaves and minimize doctor visits (E21). For (7) **research institutions**, the main value proposition is to assist with data collection for research efforts (E12).

Regarding (9) **alternative markets**, experts noted that markets outside the EU vary significantly (E19). Some considered entering the less-regulated United States market (E3), while others viewed the United Kingdom as an attractive entry point due to the language it shares with the United States, which could facilitate a later expansion (E23). In brief, the challenges are understanding stakeholder needs and developing a strong value proposition that aligns with different groups requiring unique value propositions. The United States and other markets are seen as attractive.

B. Medical Device and Regulatory Compliance

This dimension includes five second-order themes. These include key challenges and strategies related to medical device regulations, as well as data security and protection.

A key (10) **challenge** highlighted by interview participants was acquiring sufficient knowledge about regulations early on (E8, E20, E31). Healthcare is a highly regulated field, and understanding the specific requirements can be difficult (E6, E22, E25). It was described as a "regulatory jungle" (E30), with regulatory aspects being one of the most significant struggles for many startups (E19, E21, E1, E3, E4, E14). By far, the largest challenges identified stem from medical device regulations, which are seen as restrictive, time-consuming, and costly (E17, E19, E1, E3, E10, E11). Most experts mentioned these regulations several times as a significant

barrier during the interviews. The challenges induced extend beyond market entry (E17, E3), and there seems to be little available support (E17), with information often not freely accessible and expensive (E4, E5, E24, E13). This lack of clarity, combined with the novelty of the regulations, contributes to uncertainty (E22, E27). Key difficulties include understanding the regulatory requirements for medical devices, such as distinguishing between medical and non-medical devices (E9). There is no clear step-by-step guideline available (E1, E14), which makes it necessary to involve consultants (E5, E24). Specific challenges in implementing medical device regulations include finding the right personnel (E21), ensuring others adhere to the requirements (E4), and establishing a quality management system (E21). The potential need for clinical studies further complicates the process (E14). Another issue is the limited number of notified bodies (E8, E28, E31), as well as the variability in auditor standards (E1). These factors can cause companies to focus more on regulatory compliance than customer needs (E22), creating a "valley of death" where solutions not yet certified are unable to enter the market (E25, E14). Additionally, startups developing medical devices are, for this reason, not always venture capital cases (E2). Regarding data security and protection, it was reported that sometimes customers do not trust the solution, even if it is compliant with the General Data Protection Regulation (GDPR) (E18). Another challenge is that servers within the EU must be used (E2, E27). Still, GDPR was not seen as a big challenge. Besides these product-specific regulatory challenges, a few other issues mentioned include decisions about which business type to incorporate (E25) or tax-related concerns (E15). Also, besides medical device regulations, some specific certifications might be needed to enable usage by customers (E31).

Regarding medical device regulations, it was noted that the first critical step is (12) **determining whether the solution will or should be classified as a medical device**, as this decision underpins subsequent steps (E5, E6, E10, E13, E15). Several aspects of the business should be considered when making this decision (E21, E3). Importantly, it was emphasized that being classified as a medical device is not always required for working with hospitals or health insurers; this largely depends on the specific use case and application setting (E9). For the business-to-customer (B2C) segment, it was mentioned that a medical device may not always be necessary, as not all patients understand its significance, and they may simply recognize a Conformité Européenne (CE) mark (E21), which is also put on other products in the EU. The certification alone is not a compelling reason for using a medical device (E22). One expert mentioned positive aspects of the medical device regulatory requirements as they help minimize risk and establish solid company processes (E12). Some startups choose not to pursue medical device certification because it restricts product development and future changes to the solution (E23, E13) and introduces additional requirements (E26) that demand considerable time and resources (E26, E13). This decision is also influenced by whether the business case as a medical device is compelling (E31). Therefore, it is crucial to assess early on whether a non-medical device can still provide value (E4). Another strategy described is entering the market with a non-medical device to gather user feedback and eventually transition to a medical device in the long term (E9, E21, E7, E24, E12). Finally, an early decision to pursue medical device certification may be motivated by the desire to offer more complex features (E8, E24, E11), to serve as a gateway to hospitals in specific use cases (E17), or to establish trust by demonstrating the quality and benefits of the solution (E21, E24, E13). An early decision to become a medical device may also be driven by the specific business use case, such as in clinical settings (E19, E1, E7) where the device's functionality is critical, which may require it to be a medical device (E29). Some revenue pathways, particularly for reimbursement, may also require the solution to be classified as a medical device (E4, E22, E30, E13). It is important to identify early on if the solution will qualify as a medical device, as the medical device regulatory processes need to be established early on (E8). A requirement to pursue medical device certification is sufficient available funding (E25, E12) or revenue streams that are already established (E12). Still, these revenue streams must be established with a non-medical device, as a medical device can only enter the market after certification. It is also important to consider any claims that you wish to make related to the benefits of the solution, as these can influence whether the solution qualifies as a medical device (E7, E13). One final approach is to separate the solution into elements that are a medical device and that are not a medical device (E28).

Once the (13) **decision is made to pursue medical device certification**, several steps must be followed. It is crucial to consider regulations early on and to establish a regulatory strategy (E29, E17). Experts recommend having regulatory knowledge in-house, if possible (E4, E6, E14). The first step is to understand the importance of the intended purpose of the device, as this will inform many subsequent decisions (E19, E30). Then, classification rules for risk identification must be considered (E30). A lower risk class may not require a notified body, which can reduce time and costs (E8, E6). Another key step is to establish a quality management system, with experts recommending that businesses build their operations around this system (E17, E1). This is also an important step in proving reliability to other stakeholders if certifications for the quality management system are obtained by following standards (E27, E28). Using open-source information and seeking affordable consultations are recommended strategies for building a quality management system (E30). One expert mentioned that the quality management system needs to be integrated into the company culture (E24). Most experts agree that having internal personnel dedicated to compliance with medical device regulations is essential, as it can save money in the long term (E9, E20, E21), though a sufficiently large team may be required when starting to develop a medical device (E12). Some companies opt to outsource regulatory compliance activities (E19, E15), such as specific roles that are required, like the quality management officer or the person responsible for regulatory compliance (E30, E10). Another recommendation was to pay experts for a pre-review of technical documentation (E1).

It is common for companies to (11) **use external experts and consultants to build internal knowledge** for building a medical device (E8, E9, E21, E2, E4, E30, E10). Several experts advised selecting consultants carefully, as their expertise can vary significantly (E19, E1, E24). Consultants should be involved at different stages, such as formulating the intended purpose (E24), ensuring product development compliance (E25), or even confirming that a solution is not a medical device (E26).

While (14) **data protection and security regulations** are important, they were not viewed as a major challenge (E1,

E24, E13). Compliance can be achieved by adhering to standards (E1) and obtaining cybersecurity certifications (E18). One expert recommended implementing data security measures that exceed the minimum requirements (E26), while another emphasized that data protection requirements can vary depending on the healthcare providers, particularly for business-to-business (B2B) solutions, and cannot be generalized (E26).

In summary, the main challenge in this theme are the medical device regulations, which exert a strong influence on other areas such as funding. It is important to determine early on if the product qualifies as a medical device. Some startups avoid medical device regulations for flexibility, while others pursue them for market access. Early regulatory planning, quality management systems, and consultants are key to compliance.

C. Evidence Generation and Clinical Studies

This dimension encompasses four second-order themes: challenges related to evidence generation, mandatory and voluntary evidence generation strategies, and strategies for executing evidence generation.

Several (15) **challenges** related to evidence generation were mentioned. One common challenge is that conducting high-quality clinical studies is time-consuming (E8, E30) and can be costly, especially when multiple study centers are involved (E4). Often, studies are carried out in partnership with other organizations. For example, universities are typically slow, heavily regulated, and not very digital, which can delay the execution of studies (E9). University hospitals also have busy schedules, and multiple stakeholders are often involved, further extending the duration (E19). Other challenges include the difficulty of finding suitable partners and enough study participants (E20). Additionally, study participants may behave unexpectedly or fail to use the solution as intended, creating unforeseen challenges (E22, E30). Unexpected events such as COVID-19 also introduced complications (E30). Moreover, numerous additional requirements, such as ethical approvals, consume considerable time (E22, E30). Expert knowledge is also essential for generating evidence through literature reviews and clinical studies (E1). In terms of medical device regulations, there is some ambiguity regarding the sufficiency of clinical evidence required (E14). Finally, it was mentioned that creating something based on existing evidence could already be challenging, as healthcare systems are slow adapters of new solutions (E8).

Evidence generation can be categorized into (17) **mandatory premarket evidence** required by medical device regulations before a solution can enter the market and (18) **non-mandatory evidence** that can be collected pre- or post-market and is not required by regulations. Under (17) **mandatory premarket evidence generation**, there are two possibilities: building on existing evidence or conducting clinical studies. Existing evidence can be identified through scientific literature reviews (E12). This type of evidence is often used for marketing purposes later (E8). Building on existing evidence can be advantageous as it can already be difficult to bring existing evidence into the system just through a new digital channel (E8). For some solutions, relying on existing evidence may be sufficient to meet medical device regulatory requirements, while others may need to conduct their own premarket clinical studies. Experts mentioned that clinical studies are mostly conducted to meet medical device regulatory requirements (E22), but additionally, they can help to convince potential users, such as doctors (E19), or to expedite decision-making when negotiating with health insurers (E21). These studies also help build trust (E21) and demonstrate clinical effectiveness (E7). Premarket clinical studies in the context of medical device regulations are not always required to be completely randomized; they can be prospective (E21) or, in some cases, retrospective (E28, E10). As a result, clinical studies required for medical device regulations are often less expensive than high-quality clinical studies with multiple centers (E4). It is important to carefully select claims regarding the solution's benefits, as these claims will influence whether and which kind of premarket clinical study is necessary (E13). For some revenue pathways, such as the digital health application (DiGA) pathway in Germany, a high-quality, randomized controlled trial (RCT) may be required, exceeding the requirements of medical device regulations (E22, E30). In addition to mandatory evidence generation, it was also mentioned that (18) **voluntary evidence** can be collected that goes beyond regulatory requirements (E6), which can be in the form of clinical evidence for medical devices or non-clinical evidence for non-medical devices. Evidence generated through studies can be valuable for building relationships with potential partners (E9), such as hospitals, health insurers (E6), and investors (E23). It helps demonstrate the value of the solution (E3) and adds credibility (E11). Strong evidence can also prompt others to compare their solutions with the startup's solution (E3). Some experts conducted clinical studies to test their systems (E4). Finally, high-quality evidence has the potential to influence changes in official medical guidelines, which could open new reimbursement pathways in the long term (E26).

Regarding the (16) **execution of evidence generation and studies**, a common approach is to partner with clinics, university hospitals (E9, E19, E11, E14), and clinical research organizations (CROs) (E7, E22). Some experts fully outsourced their studies to university hospitals (E21, E2) due to the independence of results (E2, E26), a lack of internal expertise (E29), or limited funding (E26). However, these studies typically take longer than industry-led studies (E26). Other experts mentioned having an internal clinical team with the necessary expertise to conduct the studies (E3, E6, E15). A typical approach involves collaborating with a hospital to leverage their expertise and recruit patients while the startup’s team handles the study execution (E6, E28, E30). The benefits of this approach include gaining valuable insights at a lower cost (E22). Some experts outsourced parts of the study, such as statistical analysis, to maintain a neutral perspective (E30, E11). Additionally, one expert outsourced the literature review due to a lack of internal expertise (E1). One expert recommended conducting a feasibility study before the main study (E23).

To summarize, key challenges include generating evidence, with clinical studies being costly and time-consuming. Premarket studies are often required for compliance, while voluntary studies help build trust and attract partners. Execution often involves partnering with clinics or outsourcing study elements.

D. Revenue Model and Cost Structure

Seven second-order themes emerged in this dimension, including challenges related to this theme and strategies employed for different paying entities and the most significant costs.

One common (19) **challenge** discussed was the difficulty in finding an appropriate revenue model, particularly in the early stages (E8, E9, E29), due to the many reimbursement pathways available (E4). Revenue models must also be tailored to specific country settings (E1, E26). Additionally, in some countries, the self-payer market is not very attractive, like in Germany (E29). Developing a revenue model is an iterative process, similar to creating a value proposition, involving frequent testing (E1, E7, E16). As one expert put it, medical device development and revenue model generation is "like clearing a path through the jungle with a machete" (E22). When creating value for multiple stakeholders, it can be unclear who will pay (E19). In the healthcare sector, it was stated that B2C revenue models can be difficult (27). On the other hand, healthcare providers have long sales cycles (E26), and monetization can also be restricted (E5). While medical professionals may be easier to convince to pay and use a solution, commercial and cybersecurity teams tend to be more difficult to persuade (E10). A significant pain point is understanding cash flows and budgeting within hospitals (E10). It was also mentioned that it takes a long time to generate revenue from health insurers (E21), and they often lack technological understanding (E21). Furthermore, the health insurer market is fragmented, meaning startups trying to secure selective contracts must negotiate with each insurer individually (E8). It can be difficult to reach healthcare providers when pursuing selective contracts, as insurers do not assist with this (E9). Private connections with health insurers can play a significant role (E22). Reimbursement can also be limited in certain applications; for example, physical doctor visits are sometimes easier to reimburse than virtual visits (E1). Alternative reimbursement pathways, such as digital health application (DiGA) in Germany, offer opportunities to get reimbursement through all health insurers but come with limitations, such as the need to convince doctors to prescribe these solutions (E2) and the pressure from insurers as they want to limit their costs (E2, E30). Additionally, DiGA is still relatively new, and there is limited experience with it (E2, E25, E11), which may require a larger sales force (E2).

A general recommendation was to approach revenue model development as a continuous process involving iterative testing and evaluation (E1). It was advised to understand how the entire system works early on (E12, E27), to "follow the money" (E29), and to make a decision about the revenue model early in the process (E6). One possible approach could be to start with a smaller solution to generate initial revenue and then expand to a more comprehensive solution (E9), such as starting with a non-medical device as a stepping stone for future solutions (E28). It is also important to adapt the revenue model to the context of the specific country (E1). In the long term, it is recommended to diversify and incorporate multiple revenue models (E3). While B2C self-payment or B2B models may be effective in the early stages, it can make sense in the long run to involve health insurers and other paying entities (E6).

In the case of **B2C self-payment**, where (25) **patients or private individuals pay** for the solution, several experts recommended this approach, especially in the early stages (E14, E9, E23). This can be useful for learning what customers want (E23). Regarding pricing strategies, experts recommended starting with a free solution and then offering a freemium model (E7). Subscription models are also commonly used (E5). While B2C self-payment can be a viable revenue stream, many experts suggested planning for additional revenue sources in the long term (E5, E23).

Experts frequently mention the approach of (21) **selling directly to healthcare providers as a B2B model**. The most common pricing methods include Software-as-a-Service (SaaS) with subscription models (E31, E16) or pay-per-use models (E17, E27, E31). Whitelabel solutions are also mentioned (E3). Selling primarily to large care facilities was recommended as it generates more revenue for the same acquisition cost (E18, E19, E3, E12). Additionally, charging an onboarding fee is common practice in this domain (E10, E12). Healthcare providers typically are not reimbursed for these costs, so they need incentives like saving time or reducing costs (E19).

Several experts proposed making (20) **health insurers or the government the paying entity** (e.g., E8, E21, E3). This is recommended if the B2C market is unattractive (E8) or there are no self-payers (E13). This might also be required to access larger markets, as only early adopters are willing to pay out of pocket (E13). Selective contracts with health insurers are viable in some target countries (E8, E31, E20, E21). Experts suggest starting with smaller insurers using an early prototype, refining the pitch, and later approaching larger insurers (E8). However, the solution must be deployment-ready before signing contracts (E8). Therefore, others suggest waiting until effectiveness is proven (E24). Building trust with health insurers is crucial, and it can be built through adhering to industry standards, engaging in partnerships (E31), or collecting clinical evidence (E8). While medical device certification or clinical evidence is not strictly required to secure selective contracts (E22), it can serve as an advantage. A startup might pivot from selling to healthcare providers to health insurers later (E12). Experts advise against setting prices too low initially, as raising them later can be difficult (E30). As selective contracts are made with each health insurer individually, multiple contracts may be required to achieve a sufficiently large revenue model (E21). Additionally, the process from selective contract to cash flow can take up to 18 months (E21, E27). Therefore, some experts cautioned against selective contracts despite the potential benefits (E30), though sometimes it may be the only viable option (E21). In some countries, selective contracts with health insurers do not exist, but other more centralized pathways with a governmental body exist to achieve reimbursement (E9). In Germany, the previously mentioned DiGA concept offers a model for specific digital health solutions where all health insurers reimburse the costs (E2, E22, E30).

Another approach is to (22) **sell to indirect healthcare commercial firms** like pharmaceutical companies (E20, E16, E3, E29). One reason for this can be because they have a network to market the solution (E20) and can embed the solution in their system (E3). They may also be interested in purchasing anonymized data from the solution (E11) to understand user behavior. Additionally, pharmaceutical companies typically have shorter sales cycles than health insurers (E4). The process of partnering with pharmaceutical companies becomes easier if there are sufficient references from other pharmaceutical partners (E29). Pricing is often based on a SaaS model with annual payments (E29). Another strategy is to sell directly to other medical device manufacturers and integrate the solution into their platforms (E6).

(23) **Selling to non-healthcare commercial firms** in the area of occupational health (E21, E24) is another strategy, especially if the B2C self-payer market is not attractive and marketing costs are too high (E21). Pricing methods for this segment include subscription models or one-time payments for finite use of the solution (E13). A few experts also suggested (24) **selling the solution to research institutions** (E7, E28) for use in their studies (E7).

The elements relevant to the (26) **cost structure**, in addition to the ones mentioned previously, were primarily related to people (E6, E21, E20, E14, E16), particularly skilled software engineers (E9, E17), and high-profile personnel (E12). Other significant costs included medical device regulation compliance (E21, E5), clinical studies (E11), and consultants (E20). Office and IT infrastructure costs were also highlighted (E6, E16), along with marketing-related costs (E10, E4), which are often underestimated, as stated by the experts.

All in all, startups struggle to find the right revenue model due to complex reimbursement pathways and varying country contexts. B2C to patients and private individuals and B2B sales to healthcare providers are typically used. Health insurers and government contracts may be needed for larger markets but are slow and fragmented. Some startups explore partnerships with pharmaceutical companies or non-healthcare firms. Common pricing strategies include subscriptions and one-time payments. Key costs include personnel, regulatory compliance, clinical studies, and infrastructure.

E. Key Resources and Funding

Seven themes emerged in this dimension, revolving around the challenges in this dimension, strategies regarding the four main types of funding, time considerations of funding, and other key resources.

A primary (27) **challenge** mentioned by experts is that acquiring funding can be difficult for startups in the healthcare sector (E13, E7), especially in the early stages when business angels and investors may not be interested in the solution (E20). One reason for this is the lengthy time it takes to generate revenue in healthcare, particularly for medical devices (E6, E29, E30). Additionally, securing additional funding during the "valley of death" phase can be incredibly challenging for startups that must comply with medical device regulations (E20, E30). After securing initial funding, acquiring subsequent funding remains challenging, requiring continuous performance and strong pitches (E12). Experts had differing opinions on whether B2C or B2B models are better from an investor's perspective. Both models were seen as viable, though B2B was described as a better venture capital case due to its scalability (E5, E21, E24). Digital health, and specifically digital medical devices, are considered problematic venture capital cases because of delayed returns (E22, E23, E19). Another hurdle is the limited availability of venture capital, as it was mentioned that there is currently less funding in the market (E24, E27). B2C models were noted as difficult when scaling later on (E23). Investors may pressure startups to scale quickly to achieve high returns, but this focus on rapid growth can be risky (E12). Another problem is the potential need to change direction based on funding opportunities (E9). Regarding the internal resources, it was described as challenging to find a diverse startup team (E20, E22, E25, E24, E13, E16) and to identify suitable co-founders (E4, E31). Another valuable resource is the digital health technology itself. In the context of machine learning algorithms applied in digital health, concerns about data ownership when acquiring information from hospitals were mentioned (E29).

Regarding the (32) **order of acquiring funding**, most experts recommended starting with bootstrapping and smaller grants (E17, E1), followed by angel investors, bank loans (E21, E2, E24, E26, E27, E29), and eventually venture capital or convertible debt (E17, E11, E12). In the early stages, money from family and friends, prize money from competitions (E10), or research grants (E11) can also be used. It is important in the early stages not to dilute equity until significant costs, such as clinical studies, necessitate additional funding through grants or venture capital (E4). The EXIST grant from the German government was frequently mentioned as a viable initial funding option, with further funding from loans, angel investors, and eventually venture capital (E6, E22). While these funding patterns were common, there were cases where venture capital was acquired directly from the outset (E8, E13).

(29) **Bootstrapping** was cited as a strategy in the initial phase to keep the startup lean with a small team (E4, E18). This approach helps avoid bringing in additional investor goals (E25) and avoids taking on responsibility when business model pivots are necessary (E31). (31) **Public funding** was often acquired in the form of grants (E17) or crowdfunding campaigns (E9). However, experts cautioned that governmental grants can slow progress due to the reporting requirements involved (E20). Debt funding through bank loans was mentioned, often used in conjunction with other funding options (E21, E24). In the scope of (30) **equity-based funding**, angel investors were frequently mentioned as a first step before venture capitalists were introduced (E28). To attract the interest of venture capitalists, it has been recommended to have a senior team and a clear go-to-market strategy (E8). Furthermore, a good pitch and a strong team were emphasized as key factors to attract investors (E18). Another recommendation was to contact warm leads first to gain traction (E5). After initial investors are on board, it becomes easier to attract additional ones (E5). Finally, it was advised not to give away too much equity in the early stages, as even 10 % could become significant in the future (E7).

The (28) **key resources** mentioned by experts include the startup team, which should possess expertise in several areas, such as medical, technological, business, and regulatory aspects in healthcare (E8, E18, E21, E1, E6, E14). Other key resources include knowledge of how to build a medical device (E8), content creation as part of the solution (E9, E12), technology such as algorithms and data (E21, E28, E10, E14), knowledge of marketing (E21), office space (E13), and an established network (E15). Some startups also pay in-house doctors to offer specific services to the customers, making the doctors another key resource (E1). Patents were rare, with most experts not patenting anything since software is difficult to patent (E8). However, one expert mentioned their patented artificial intelligence technology (E6, E14). Some experts also mentioned keeping the core team lean and using freelancers (E27). Healthcare industry consultants are used to discuss ideas (E8, E4). Accelerators and incubators were also mentioned as sources of early-stage support (E23, E24, E16). Investors were also cited as additional advisors (E12).

In summary, digital health startups struggle to secure funding, especially early on, sometimes due to a long time to revenue.

Some investors prefer B2B models for scalability. Experts suggest starting with bootstrapping, grants, and angel investors and then moving to venture capital. Challenges also include building a team and stakeholder navigation. Key resources include a skilled team and technology

F. Key Partnerships and Customer Engagement

This dimension consists of four themes: challenges, key partnerships, outsourcing approaches, channels and customer relationships.

One of the (33) **challenges** mentioned within this dimension is that it was difficult to have partnerships with hospitals, as it is challenging to identify the real decision-maker (E1). Furthermore, gaining patient access through them is also challenging, as they cannot share and promote information (E9). Additionally, implementing and accepting technology (E23), particularly integrating technological interfaces in hospitals (E26, E31), presents further challenges. Other obstacles include internet and Wi-Fi connectivity issues at healthcare facilities (E13, E14). Promoting solutions through healthcare providers was also mentioned as a challenge because they needed to be educated (E9). In certain situations, when a solution needs to be prescribed to a patient before usage, it is especially challenging to convince the doctors (E2). Finally, it was also mentioned that working with a technological development partner can be difficult, as they do not always meet the required expectations (E12).

Regarding (34) **key partnerships**, some experts stated that no central partnerships were particularly relevant (E8, E6, E13). A primary motive for forming partnerships is to gain credibility (E9), for example, by partnering with large corporations (E18). Other reasons for partnerships include gaining patient access (E9), co-developing the solution (E19, E27), having additional channels (E21), testing the solution and receiving feedback (E7, E27, E26), securing resources and networks in the early stages (E12, E10), and leveraging additional multipliers to bring the solution to market (E20). These partnerships can take various forms, such as with hospitals, healthcare providers, pharmaceutical companies, patient organizations, and charities. Some companies partner with hospitals to collect data to train their machine learning models, which is a key resource (E10, E14), and partner with technology companies to access cloud infrastructure (E16).

The most common (35) **outsourcing approach** was to keep the most important processes, such as software development, in-house (E16). Besides outsourced roles mentioned in relation to medical device regulations, design activities (E16), development of a simple app without intelligence (E21), and some regulatory activities related to quality management were outsourced (E15). However, experts noted that someone from the team must be capable of managing these processes (E2). Only one expert mentioned fully outsourcing their technological development and part of their regulatory activities (E15).

Several strategies were identified for (36) **channels and customer relationships**. One approach is to use health insurers to directly reach patients, minimizing the need for additional marketing efforts (E8). Pharmaceutical companies can be leveraged similarly (E29, E11). Here, clinical evidence and reputation among healthcare providers can help to engage with these stakeholders (E11). Some experts reported success working with local distribution partners who have established field forces to generate traction (E17, E25, E30), attending trade shows (E1), using performance and social media marketing, running ads (E5), and collaborating with patient organizations for additional exposure (E11). Other strategies include partnering with charities to reach customers (E9) or using word-of-mouth marketing (E13). Some startups combine multiple channels like social media marketing and marketing through health insurers and providers (E6, E25). Healthcare providers are often approached through connections and networks, as some experts perceive cold acquisition as challenging (E18, E14). Channels used to engage these providers include trade shows (E1), online professional communities (as physical salesforces are expensive) (E4, E28), and conferences (E3, E11, E12, E16). Cold acquisition has also been successful for some companies (E1, E10, E12) if other healthcare providers recommend the solution (E10). Health insurers were typically engaged through fares (E21). Customer success managers employed by a startup and guiding the user through its customer journey are essential in making customers feel heard (E3), and educational academies for healthcare professionals have been successfully implemented (E15). Due to regulations, only specific claims can be used in marketing, as certain statements are prohibited (E25, E28). In some countries, certified medical device consultants must inform professionals about the solution (E28).

In short, partnerships help with credibility and access. Outsourcing is used for non-core tasks. Marketing strategies include partnering with insurers and pharmaceutical companies and using trade shows and social media to engage with the target groups.

V. Discussion

The principal findings of our work are that EU medical device regulations induce the most significant challenges. These regulations require significant additional time and resources. Other business model components also depend on the decision for or against a medical device. The additional time and resources stem from the additional personnel, evidence generation required, clinical studies, and further compliance activities. Therefore, an early decision on or against a medical device is important. Funding is connected to this hurdle, as it needs to be significantly higher for a medical device company to overcome the valley of death. Startups mostly turn to bootstrapping and grants before scaling to angel investors and venture capital later. Another challenge mentioned was finding the right revenue model that needs to be adapted to the country's context. While more standard B2B with health insurers or pharmaceutical companies or B2C models with the patient or private individuals can work, it can be crucial to, later on, mix these models with additional revenue through reimbursement from health insurers or the government. A key finding regarding value proposition was to understand user needs early on and consider the various value propositions that stakeholders require. Building skilled teams, leveraging partnerships, and outsourcing non-core tasks were further strategies for managing resources effectively. Interestingly, challenges regarding the development of digital technology were less frequently mentioned. It seems like for startups in this domain, especially regulatory problems, followed by revenue model and funding, dominate over technological challenges that are typically encountered in other digital startups.

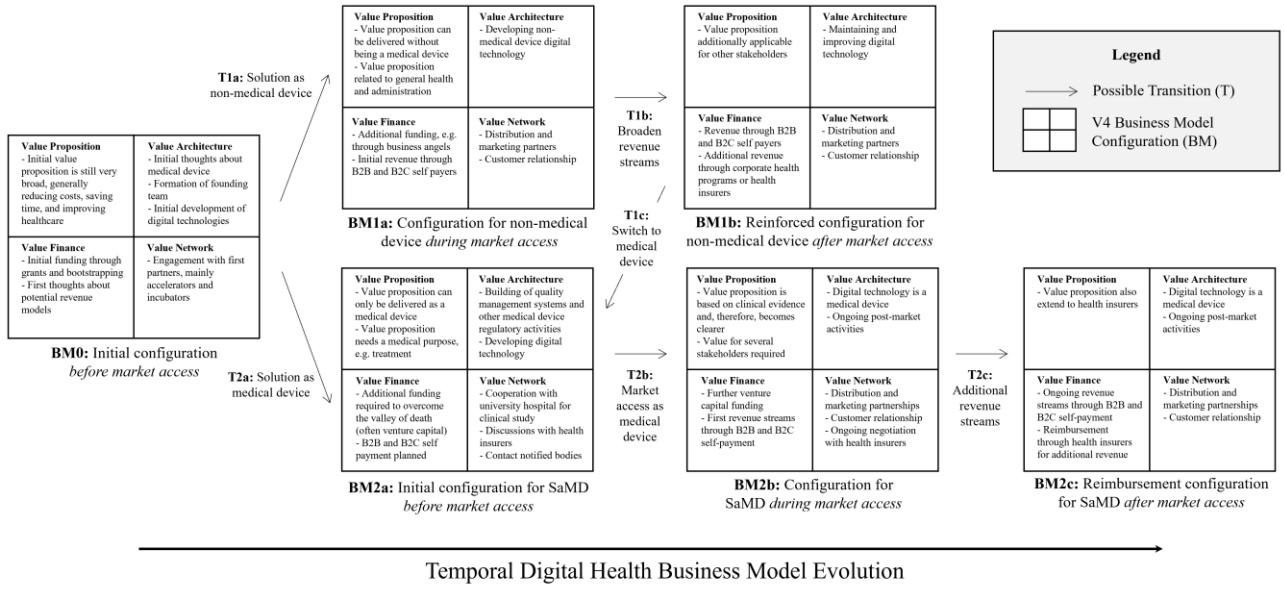

Fig. 1. Conceptual model of the temporal digital health business model evolution.

A generalization of the insights in the form of a conceptual model of the temporal evolution of digital health business models is shown in Fig. 1. To describe the evolution, we build upon the V4 business model dimensions introduced by Al-Debei and Avison [1] to describe the temporal business model configurations (BM) of digital health startups. Al-Debei and Avsion describe general business models through the 4 dimensions value proposition, value architecture, value finance, and value network as part of their hierarchical taxonomy of the business model concept. We use these dimensions to describe observed business model patterns in digital health. We also introduce possible transitions (T) between these configurations. Before market access, the business model and value proposition remain generic, and early considerations of revenue models begin to take shape. A critical early decision involves whether to pursue a medical device designation, as it significantly influences other business model elements. Funding at this stage often comes from bootstrapping or grants (BM0). If the decision against a medical device is taken (T1a), market access can be achieved quite quickly. In this case, the value proposition typically addresses general health or administrative support. Additional funding may come from business angels or venture capital, and initial revenues are generated through B2B and B2C self-paying customers (BM1a). Over time, this business model can then be adapted (T1b) to include corporate health programs or reimbursement from health insurers (BM1b). A switch to a medical device pathway can sometimes occur at this point (T1c). Alternatively, ventures may decide in the beginning to develop a medical device (T2a). This path necessitates compliance with medical device regulations, including establishing a quality management system, potential execution of clinical studies, and securing high additional funding, such as venture capital, to overcome the "valley of death" (BM2a). Once market access is achieved with a CE-marked medical device (T2b), revenues are often initially derived from B2B or B2C self-payments (BM2b), with additional revenue streams emerging later (T2c) through reimbursements from health insurers (BM2c).

Comparing the temporal evolution of digital health business models with those of general digital startups, it becomes evident that the T1 transitions resemble the trajectories of typical digital startups, where early market entry is possible and revenue models may evolve over time. In contrast, the T2 transitions are more akin to those seen in highly regulated, multi-stakeholder environments such as biotechnology. Nevertheless, digital health startups benefit from not needing to establish physical laboratories or production facilities, which can lower initial barriers to entry compared to traditional life sciences ventures.In summary, ventures not aiming to develop a SaMD often generate faster revenue and need less funding. Therefore, an early and strategic decision on configuring the business model is critical to the success of digital health startups. To bring a SaMD to the market, additional support through entrepreneurship support infrastructure, such as accelerators and incubators, is fundamental, as these entities can help to acquire knowledge that is more difficult to access, such as regulatory knowledge.

VI. Conclusion

While digital health holds significant potential to address challenges in healthcare systems, the complexity of the domain requires unique business model approaches, including medical device regulations and revenue pathways. This work offers a catalog of business model decisions and can serve as a base for entrepreneurial success in digital health.

A. Contribution

This research makes a significant contribution to the understanding of business models in digital health. We emphasize the profound impact of regulations, particularly medical device regulations, on the entire business model—an underexplored topic. By examining a sample of experts from startups developing medical and non-medical devices, we provide a comparative analysis of specific business model choices, an area that has received limited attention in prior research. Previous studies only built on a few case studies and a small amount of data, or did not discuss key elements such as medical device regulations. We also advance the

understanding of business model configurations in digital health while elaborating on the temporal evolution of these models with a strong empirical basis.

Practically, this work can support entrepreneurs of digital health startups in understanding key challenges and strategies relevant to their business model. It can also foster awareness of this sector's intricacies, such as medical device regulatory strategies and revenue models involving reimbursement. The business model choices catalog can help guide startups through this network.

B. Limitations

Limitations of our work are that we only focused on the EU, thereby highlighting business models in this context, which has the advantage of explaining the intricacies of this context in more detail, but misses aspects of other business models, such as in less regulated locations. Additionally, each country within the EU has some degree of regulatory and cultural differences. Therefore, some expert recommendations within this work might not apply in all countries. Still, the mentioned business model choices can help to guide startups through this network. Qualitative research methods can also induce biases, which we tried to minimize through a sufficiently large sample and a researcher consensus for derived themes.

C. Further Research

Further research could explore the business model choices for different types of digital health startups in greater depth. Additionally, regional variations could be examined. Further research could dive deeper into the role that entrepreneurship support organizations, such as incubators and accelerators, play in supporting digital health startups overcoming regulatory and market access barriers.

MATCH & CONTRIBUTION

This contribution aligns strongly with the IEEE TEMS research objectives. It addresses implementation challenges and management of emerging technology in the digital health sector by focusing on the evolution of business models in European digital health startups. The conceptual model of business model evolution can serve as a practical framework for navigating regulatory, financial, and market complexities. Therefore, the contribution directly supports IEEE TEMS objectives of advancing technology and engineering management practices in dynamic and regulated industries.

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