Business Modeling for Highly Regulated, Multi-Stakeholder Environments: Design Support for Software as a Medical Device Startups in the European Union

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***Abstract*—Digitalization holds the potential to address challenges in healthcare systems. In the European Union Software as a Medical Device sector, startups play a pivotal role in driving and shaping the digital transformation of healthcare sectors. However, the complexity of the sector, especially the European Union medical device regulations and the multi-stakeholder environment, poses challenges for startups. A sustainable business model can be essential to tackle these challenges. This study adopts a design science research approach. We design the Software as a Medical Device Business Model Canvas based on the derived meta-requirements and design principles. The canvas consists of thirteen components and aims to support startups in developing a business model for their Software as a Medical Device in the European Union. The canvas aims to reduce complexity by covering key aspects on a strategic level. This study derives a solution tailored to the unique needs of digital health startups in the European Union Software as a Medical Device sector. Still, it addresses global challenges in healthcare systems, such as the lack of human resources and the quality of health service delivery. The derived design principles and the artifact can be generalized and applied to industries similar to the European Union's Software as a Medical Device sector, characterized by strict regulations and multi-stakeholder settings.**

Keywords—software as a medical device, business model, entrepreneurship, startups, regulations, european union

I. Introduction

An app to treat migraines and software that monitors irritable bowel syndrome – the range of Software as a Medical Device (SaMD) in the European Union (EU) is constantly growing. SaMD in the EU are regulated under Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) [1]. The EU medical device regulations focus on the safety and performance of medical devices in the EU [2, 3]. SaMD bears the potential to address global challenges faced in healthcare, such as rising expenses, a lack of qualified professionals, and issues related to patient outcomes [4]. SaMD can enhance patient well-being, increase the range of healthcare choices, and promote patient empowerment. Startups considerably drive the EU SaMD industry. With their flexible and adaptive structure, they can leverage disruptive innovation [5].

However, despite the potential of SaMD in healthcare systems, startups in this field are confronted with significant challenges. The complexities associated with a multitude of stakeholders [6], regulations [7], and the resulting delayed time to market are just a few of the challenges these startups encounter. With its stringent requirements, the EU SaMD industry, especially the MDR and IVDR, poses obstacles that many startups struggle to overcome [7]. In this complex industry, startups are challenged to develop a sustainable business model. Aspects such as delayed revenue generation and the associated need for funding are often overlooked, leading to early market exits. Furthermore, startups often lack a structured approach and a clear starting point for transforming their ideas into viable business models. A business model tool tailored to the EU SaMD industry can help mitigate these challenges. With tailored guiding questions, it can ensure that no key aspects are overlooked, possibly preventing early market exits. Furthermore, the tool can provide guidance and, therefore, reduce complexity.

Consequently, we propose a design science research (DSR) project to address the following research question (RQ) for our study:

- RQ: How can we design a tool that supports early-stage startups in developing the business model for a SaMD in the EU?

Our study addresses the unique needs of SaMD startups in the EU and, at the same time, the global need for improved public health. Globally, healthcare systems are facing challenges that digital solutions can address. Based on meta-requirements (MRs), the derived design principles (DPs) in this study can be generalized and applied to industries similar to the EU SaMD industry that operate under strict regulations and involve multiple stakeholders. These include the healthcare industry in general, along with other sectors such as the financial sector.

Below, we first present the foundations of our research and related work. This is followed by a description of our research methodology in Section 3. Subsequently, we outline our results, including general design knowledge, the implementation of the artifact, and the artifact evaluation. Finally, we reflect on our findings and conclude with a summary.

A. Software as a Medical Device

SaMD is software intended to be used for at least one medical purpose, performing these purposes without being part of a hardware medical device [8]. The intended purpose

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refers to the specific use of the device as defined by the manufacturer [9]. A startup with a product that falls within the scope of a SaMD in the EU needs to fulfill the safety and performance requirements specified by the MDR or IVDR.

B. Business Model and Related Work

A business model can be defined as the framework through which a company creates, delivers, and captures value for its customers [10]. A well-designed business model can create and deliver value propositions that resonate with customers and meet their needs [10]. Business models have been linked to firm performance and are considered essential for the survival and success of the business [11]. Especially for startups, business models are crucial to focus beyond product design and ensure value reaches customers effectively [11].

A couple of business model tools exist in the literature to facilitate business modeling. A well-known business model tool is the Business Model Canvas by Osterwalder and Pigneur [12]. The canvas is widely applicable across industries due to its generic structure. However, this broad applicability comes at the expense of adequately addressing industry-specific requirements. For instance, it falls short in capturing the particular needs of the healthcare sector [13]. Thus, a few industry-specific business model tools can be identified, such as the modelH by Riley and Associates [14]. It is an adaptation of the Business Model Canvas [12] and is designed for the healthcare sector. The model names the components but does not include guiding questions. These could help provide direction and highlight key healthcare-specific aspects to consider. In this way, the model remains rather unspecific despite its industry focus. Lee and Chang [15] derive a business model for chronic kidney disease, thereby focusing on a specific use case and making it irrelevant for SaMD startups in general. To our knowledge, a business model tool tailored to the specific needs of SaMD startups in the EU is lacking.

C. Institutional Theory

According to institutional theory, institutions shape behavior through established frameworks, oversight mechanisms, and the application of regulations [16]. These regulatory elements originate mainly from government laws, industry agreements, and established standards [16]. The impact of institutional regulations on entrepreneurs has been explored in the literature [e.g., 16, 17]. The institutional environment impacts entrepreneurial activities, thereby affecting new venture creation. Regulations can discourage entrepreneurs by imposing excessive compliance requirements, often demanding significant time and financial resources to meet [18]. Regulations significantly shape entrepreneurial activities in the healthcare sector, specifically the medical device sector, with the challenging EU medical device regulations. The EU medical regulations lead to increased costs, delays in revenue generation, and associated difficulties in securing funding [7]. Additionally, extensive regulatory-related activities are required to meet requirements, such as setting up and maintaining a quality management system [3]. Experts are needed to implement these requirements effectively. Equally, the SaMD sector, like the health sector in general, is characterized by a multitude of stakeholders [19, 20] that directly or indirectly impact startups' operations [17]. Therefore, from the perspective of institutional theory, in highly regulated industries characterized by a multitude of stakeholders, regulations and the stakeholder landscape exert a profound influence on entrepreneurial behavior. As a result, these factors should be directly considered when developing a business model for a SaMD in the EU.

II. RESEARCH APPROACH

We employed the DSR approach described by Kuechler and Vaishnavi [21]. The DSR approach was selected because it is suitable for tackling real-world challenges [22]. Furthermore, the approach facilitates iterative build-and-test cycles, enabling continuous refinement and assessment of the developed solution. Figure 1 depicts the design science research cycles of our work. Following the approach proposed by Kuechler and Vaishnavi [21], we structured our study iteratively along the five phases: awareness of the problem, suggestion, development, evaluation, and conclusion. In total, our study comprises three design cycles.

In the first cycle, we conducted a systematic literature review and expert interviews to understand the problem [23]. For the systematic literature review, we followed the approach by Kraus et al. [24]. The goal of the review was to identify business model tools in the healthcare sector. We extracted and synthesized the components used for the identified business model tools and identified the lack of a SaMD-specific business model tool [23]. The conducted interviews confirmed this research gap. We conducted 13 interviews with experts and SaMD startups [23]. We ensured that each expert had expertise in one or more of the following areas: business modeling, entrepreneurship, and the SaMD industry, including EU SaMD startups. In the interviews, challenges in the context of SaMD business modeling were identified [23]. These included aspects, such as the lack of guidance and unique customer constellation, that should be considered [23]. We derived MRs and DPs for an artifact based on the theoretical and practical input. The DPs were instantiated in the form of an initial artifact. The artifact was evaluated following the Framework for Evaluation in Design Science Research (FEDS) suggested by Venable et al. [25]. It was integrated into three university entrepreneurship seminars, which aimed to develop the business model for a SaMD. In the form of a survey, in total, 70 students evaluated the initial artifact after applying it to their use case. Based on the evaluation, areas for improvement were identified and accounted for in design cycle two.

In the second design cycle, we specified the problem space by conducting an additional 31 interviews with experts and SaMD startups. Experts covered the fields described in the design cycle one. We refined the MRs and DPs accordingly and instantiated a second artifact version. The evaluation was conducted through a focus group comprising three experts, 14 interviews with experts and SaMD startups, and a survey conducted during a university entrepreneurship seminar. Additionally, a digital, interactive prototype of the artifact was developed in parallel during the second design cycle. This clickable prototype was evaluated through 13 expert interviews. Insights from these evaluations related to the artifact itself were incorporated into the further development of the non-interactive version focused on in this paper, thereby justifying its mention at this point. Questions pertaining to aspects such as the appearance or positioning of buttons, which were irrelevant to the non-interactive version, were intentionally excluded. The interactive prototype differed from the non-interactive version, for example, by allowing

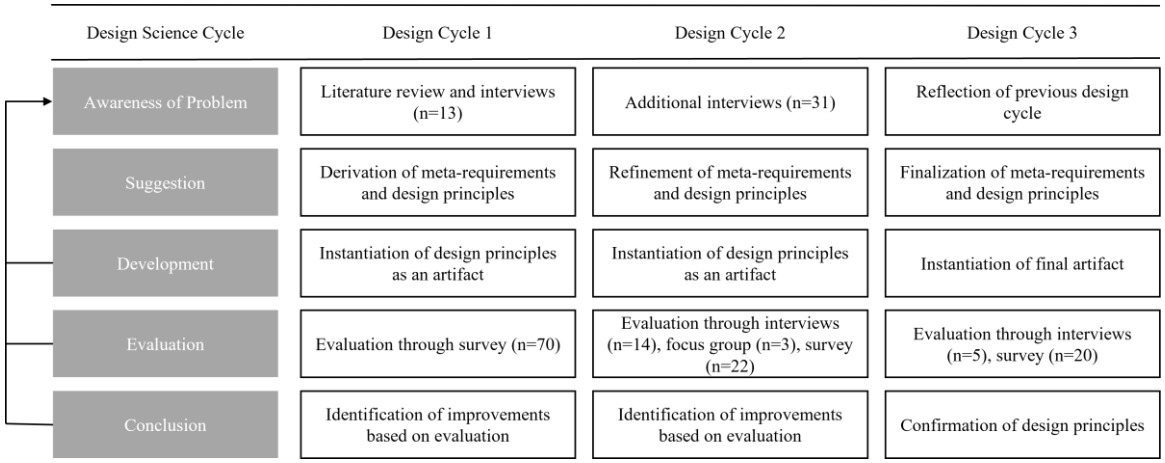

Fig. 1. Design science research cycles based on Kuechler and Vaishnavi [21].

users to type their responses directly after each question, rather than using sticky notes.

In the third cycle, the MRs and DPs were refined based on previous evaluations, and a third version of an artifact was instantiated. The artifact was applied and evaluated by graduate students in a university entrepreneurship seminar focusing on the development of an EU SaMD business model. Furthermore, it was evaluated by five interviews with experts and SaMD startups. As the results of the third evaluation cycle did not prompt any significant changes to the artifact, this concluded the process.

III. FINDINGS

A. Meta Requirements

Based on the design cycles outlined in Figure 1, we identified five MRs to design the Software as a Medical Device Business Model Canvas, or short SaMD Business Model Canvas, for early-stage startups in the EU. The MRs are described below.

Existing business model tools insufficiently account for the intricate setting of early-stage startups aiming to develop a SaMD under EU medical device regulations (see section II). These startups need a tool tailored to their situation that supports them in developing an EU SaMD business model. Consequently, we formulate our first MR: *Support early-stage startups in developing a business model for a SaMD in the EU (MR1).*

SaMD startups in the EU are embedded in an intricate environment. Multiple stakeholders [6], regulations [7], delayed market access [26], and the need for comprehensive and precise cost and funding management characterize this environment. Despite these challenges, and in contrast to many other industries, the EU SaMD industry opens the door to new revenue opportunities. In particular, reimbursement by health insurers can be a popular revenue model for SaMD startups in the EU. At an early stage, potential revenue generation opportunities and, consequently, the respective market in the target country should be analyzed. Interviews revealed that the EU SaMD industry features a unique customer constellation. Whereas in a self-payment market, the user is often the product's payer, in the EU SaMD industry, this does not have to be the case. These EU SaMD specifics need to be considered for a respective business model. Thus, we formulate our second MR: *Cover all key business model components relevant to early-stage startups that aim to develop a business model for a SaMD in the EU (MR2).*

Given the complexity of the EU SaMD industry (see MR2) and the limitations of existing business model tools in addressing the specific situation of SaMD startups, these startups often feel overwhelmed when attempting to develop a business model for their SaMD. Many struggle with keeping all key aspects in mind and not forgetting essential aspects. Thus, we form our third MR: *Reduce cognitive complexity in the initial process of developing a business model for a SaMD in the EU (MR3).*

Communication among startup team members is crucial [27, 28]. At an early stage, when startups develop the business model for their SaMD, they set the basis for further entrepreneurial steps. All team members should align on the direction and agree on it to avoid potential future disputes. Hakanen and Soudunsaari [28] underscore the value of communication through ongoing engagement to build trust within startup teams. Therefore, we formulate our fourth MR: *Encourage communication within startup teams (MR4).*

To ensure that users can effectively utilize the canvas, clear instructions should be provided along with guiding questions that provide thought directions and clarify each component's focus. Therefore, we form the fifth MR: *Provide user guidance to facilitate the development of a business model for a SaMD in the EU (MR5).*

B. Design Principles

We formulate three DPs based on the derived MRs. Figure 2 provides the mapping diagram from MRs to DPs. To develop the DPs for our visual inquiry tool, we built on the three higher-level DPs suggested by Avdiji et al. [30] and applied them to the business model for SaMD startups in the EU.

A business model tool that aims to support startups in developing a SaMD for the EU market should include all relevant business model components, considering the particularities of the EU SaMD industry. Therefore, we combine MR1, MR2, and MR3 into our first DP: *Frame the problem of building a sustainable business model in the EU SaMD industry by considering the particularities and challenges of the EU SaMD industry (DP1).* DP1 should be incorporated as problem spaces, including guiding questions that capture the key challenges of early-stage startups in the EU SaMD industry. A central aspect is the integration of

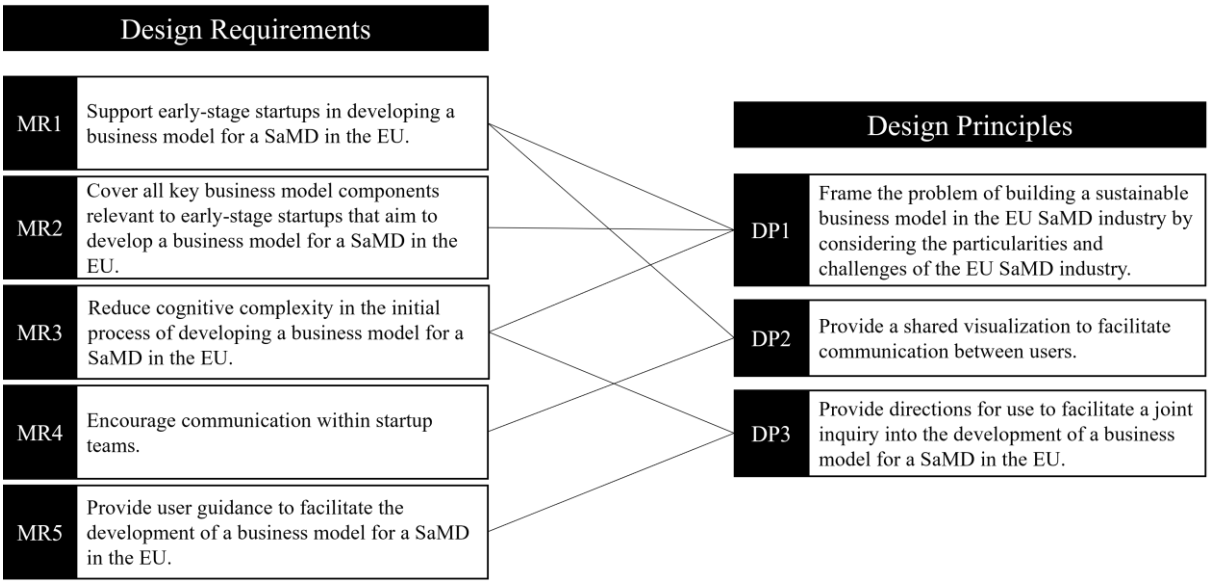

Fig. 2. Mapping diagram of meta-requirements and design principles adapted from Meth et al. [29].

regulations, especially the EU medical device regulations, into the canvas. The interviews mentioned them as one of the biggest challenges for startups in the EU SaMD industry. Building on institutional theory, government regulatory requirements influence entrepreneurial behavior [16, 17] and should be considered early in the business model process. Furthermore, following contingency theory, the effectiveness of a business model depends on its ability to align with environmental circumstances, making the canvas tailored to the EU SaMD industry.

The canvas should be visually appealing, and the components should be organized logically and comprehensibly to lower the barrier to working with it and facilitate effective communication. To enhance user experience and ensure seamless integration, the shared visualization should be compatible with existing visualizations, such as the Business Model Canvas [12]. This compatibility can facilitate easier adoption and more effective communication among users. The problem spaces should be positioned logically, making their connections reasonable. Furthermore, icons should be included as metaphors that increase the affordance of the canvas [30]. Making the canvas visually appealing and logically structured prevents unnecessary cognitive load from being required to understand it [31]. Cognitive load can be used to process the questions instead. Thus, we combine MR1 and MR4 to form our second DP: *Provide a shared visualization to facilitate communication between users (DP2).*

With the canvas, early-stage startups should be supported in developing the business model for a SaMD in the EU. A guiding document should be provided to complement the canvas. This document should be kept concise to minimize complexity. It should include instructions for use and recommend supporting materials that can aid in answering the guiding questions. An exemplary filled-out canvas provides an orientation to the user, facilitating its usage. Furthermore, the guiding questions should include examples in parentheses, where necessary, to ensure the directions of the questions are clear. We combine MR3 and MR5 to form our third DP: *Provide directions for use to facilitate a joint inquiry into the development of a business model for a SaMD in the EU (DP3).* DP3 is based on decisional guidance theory, according to which guidance provides support and thereby enhances the decision-making process [32, 33].

Following the approach suggested by Gregor et al. [34], Table 1 depicts the three derived DPs based on the four building blocks: aim, context, mechanism, and rationale.

C. Instantiation

Based on the DPs, we instantiated the SaMD Business Model Canvas. To lower the barrier to working with the artifact, we decided on a canvas-based format that resembles the well-known Business Model Canvas [12]. The SaMD Business Model Canvas consists of thirteen components clustered into three layers, as illustrated in a simplified form in Figure 3. The first layer captures the components *Regulatory Compliance* and *Market & Competitors*. Both components are positioned at the top to indicate their pressure on layers 2 and 3 metaphorically. Regulations emanate from above, that is, the government, and are imposed on startups. Since regulations are market-specific, *Regulatory Compliance* is positioned next to *Market & Competitors*. Layer 2 consists of nine components, with *Value Propositions* being its centerpiece.

On the left side of Value Propositions are company-internal components, whereas on the right are company-external components. Starting with company-internal aspects, we derived *Financing*, *Key Partnerships*, *Key Activities*, and *Key Resources & Team*. Financing is required to cover the investments and make the value offering possible. Often, financial resources are received from partners, which are placed next to them. The activities performed by the partner and the resources, such as the team, contribute to the value offering. Whereas the company-internal side creates value, the company-external side receives the value offering. Via *Channels* and *Customer Relationships*, value is delivered to *Customer Segments*, thereby impacting the *Stakeholder Landscape*. Layer 3 consists of *Cost Structure* and the *Revenue Model*. The two components are the basis of business operations and enable it to function. Metaphorically, they can be seen as the walking legs of the business model. Contrary to

TABLE I. DESIGN PRINCIPLES FOR A SOFTWARE AS A MEDICAL DEVICE BUSINESS MODEL CANVAS IN THE EUROPEAN UNION

Building block	DP1	DP2	DP3
Aim	For designers and researchers, frame the problem of building a sustainable business model in the EU SaMD industry by considering the particularities and challenges of the EU SaMD industry.	For designers and researchers, provide a shared visualization to facilitate communication between users.	For designers and researchers, provide directions for use to facilitate a joint inquiry into the development of a business model for a SaMD in the EU.
Context	For early-stage startups that aim to develop the business model for a SaMD in the EU.		
Mechanism	Use components in problem spaces that capture the fundamental business model aspects of an EU SaMD at a high strategic level. Use terms established in the literature to reduce the barrier to working with the artifact.	Problem spaces should be positioned logically and include icons. Use different layers that structure the canvas, making it visually appealing and easy to work with.	Provide a guidance document with instructions for use and an exemplary filled-out artifact version as a reference to facilitate further usage. Use guiding questions to provide directions for thought.
Rationale	According to institutional theory, startups are shaped by external influences, including regulations and stakeholders' interests [16, 17]. Furthermore, according to contingency theory, organizations depend on environmental factors [35].	According to cognitive load theory, human cognitive resources are limited. Extraneous cognitive load should be minimized to free up time to focus on processing the questions [31].	Based on decisional guidance theory, guidance enhances decision-making by advising how to proceed [32, 33].

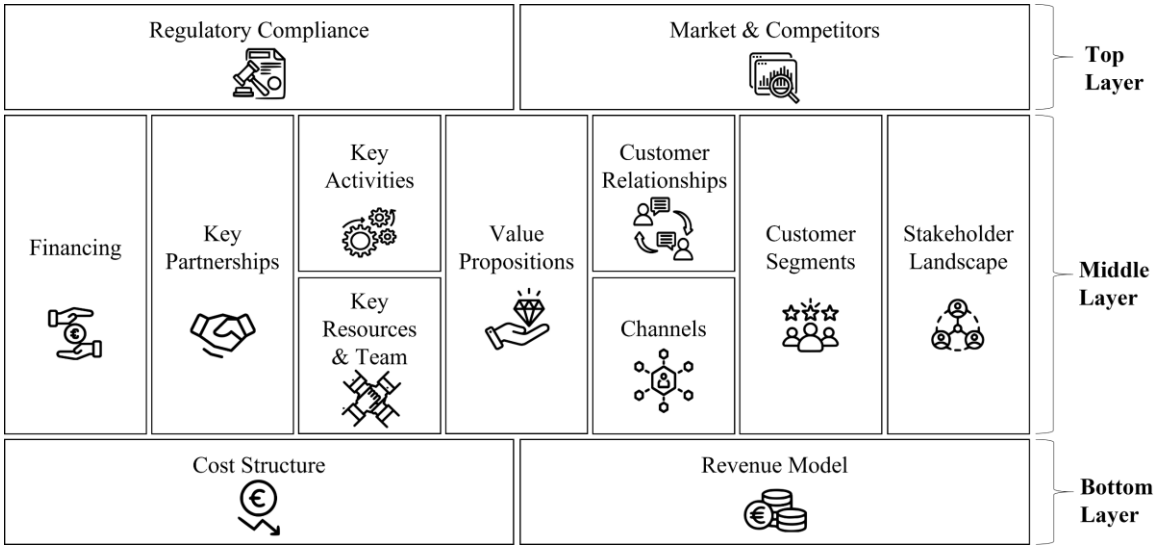

Fig. 3. A simplified overview of the Software as a Medical Device Business Model Canvas.

the Business Model Canvas [12], the SaMD Business Model Canvas accounts for SaMD industry specifics. The extensive regulatory requirements are reflected in the component *Regulatory Compliance* and the multi-stakeholder landscape in the component *Stakeholder Landscape*. Launching a SaMD involves a high financial burden, driven in part by regulatory requirements and the resulting long time to market. Therefore, funding must be considered early to prevent premature market exit. This is reflected in the component *Financing*. Lastly, contrary to the Business Model Canvas [12], we included the component *Market & Competitors* to account for characteristics of healthcare markets, including competitors.

The complete SaMD Business Model Canvas is depicted in Figure 4. It contains guiding questions for each component that explain the component and cover the key aspects startups should consider in the EU SaMD sector (DP1). The components are organized logically and comprehensibly, sharing a common visualization (DP2). Furthermore, recommendations are provided to answer the guiding questions (DP3). Part of the artifact is a guidance document (DP3). It includes information about the goal and scope of the canvas, instructions for use, and an exemplary filled-out canvas.

The SaMD Business Model Canvas can be used in various settings and by different stakeholders. Its main goal is to support the development of a business model for a SaMD in the EU. Startups in the SaMD industry can benefit from the canvas, especially in the early stages. Additionally, SaMD investors, partners such as pharmaceutical companies, and further stakeholders in that industry can use the canvas to get a holistic picture of the respective SaMD startup. Further target users are accelerators and incubators offering support to SaMD startups. Additionally, entrepreneurial seminars, such as those held in university settings that focus on teaching digital health and aim to derive the business model for a SaMD, can benefit from the canvas. The canvas can be

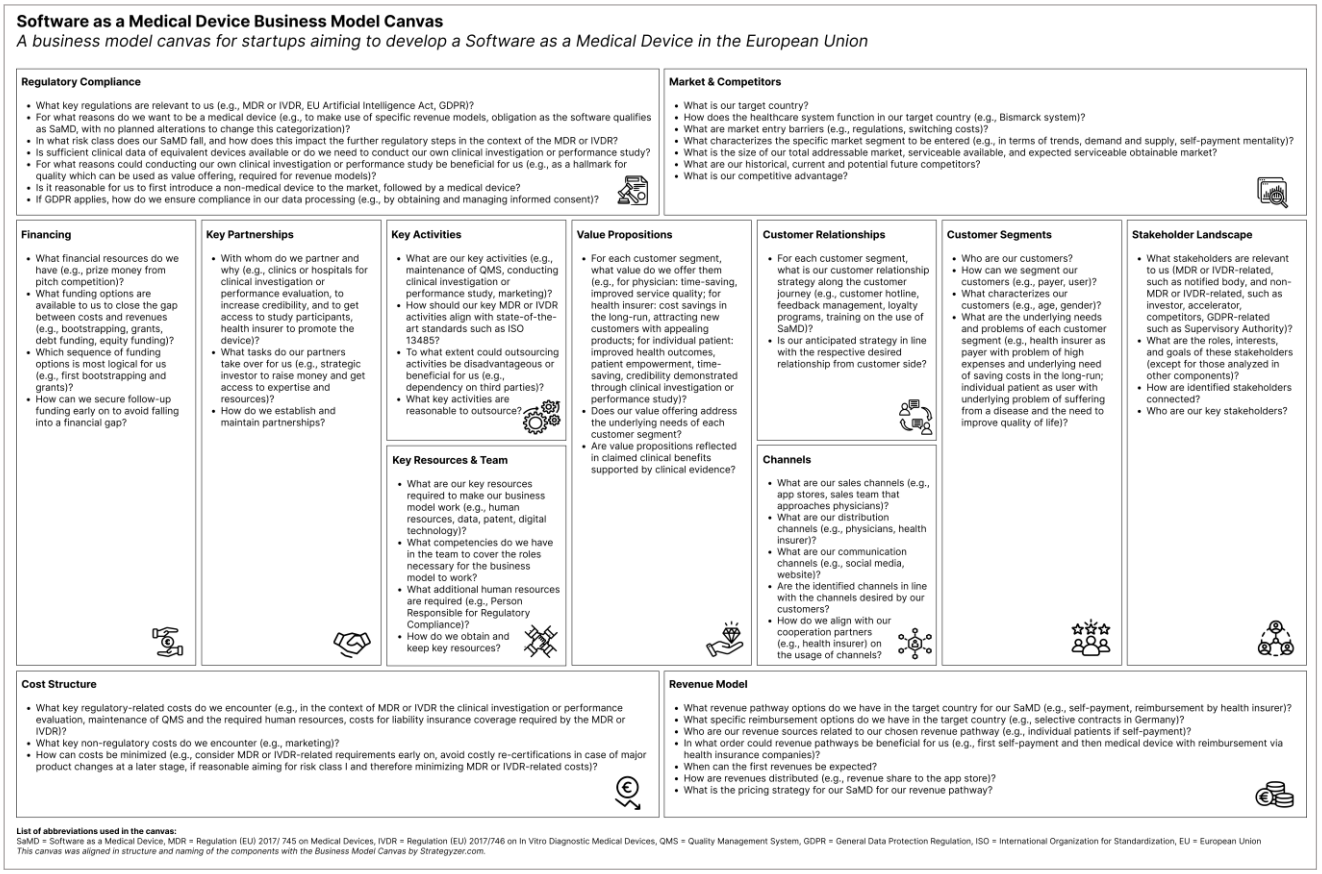

Fig. 4. Software as a Medical Device Business Model Canvas.

integrated digitally into collaborative tools or printed as a poster.

D. Evaluation

To evaluate the artifact, we followed the FEDS approach by Venable et al. [25]. We chose to adopt the human risk and effectiveness approach, which should be selected when a primary objective of the evaluation is to demonstrate that the utility or benefits will persist in real-world scenarios [24]. We applied the 5Es framework of efficacy, effectiveness, efficiency, elegance, and ethicality [36] as testable propositions for the evaluation. The 5Es provide a compromised list of evaluation criteria and were applied by Avdiji et al. [30] for visual inquiry tools. The 5Es are depicted in Table 2.

TABLE II: OVERVIEW OF THE 5Es AS TESTABLE PROPOSITIONS BASED ON [37] AND [30]

5Es	Description
Efficacy	The artifact must produce desirable effects under ideal circumstances.
Effectiveness	The artifact must produce desirable effects in practice.
Efficiency	The artifact must be efficient without wasting time.
Elegance	The artifact must be visually appealing and easy to use.
Ethicality	The artifact aligns with ethical norms and does not induce negative stress when working with it.

We conducted three evaluation cycles. In the first evaluation round, we conducted a survey filled out by graduate students. These students were a suitable target group since they were part of university entrepreneurship seminars that were specifically designed to fit the artifact and, therefore, focused on the development of an EU SaMD business model. During the seminar, the students learned the basics of the SaMD industry and entrepreneurship, making their situation comparable to early-stage startups. The graduate students had different academic backgrounds, such as computer science or industrial engineering. The sample included both males and females, with ages ranging from 16 to 42. They came from different countries, with the vast majority being from EU member states. Some of them already had work experience and were working at a startup. A couple of students indicated their interest in founding a startup in the digital health sector. This was also motivating their participation in the seminar. Thus, the seminar was an ideal situation to evaluate the artifact. In teams, the graduate students applied the artifact to their use case. In total, 70 students filled out the survey. We measured each 5E construct with a Likert scale ranging from 1 (fully disagree) to 5 (fully agree). The analysis yielded the following results: efficacy (mean (M) = 3.87; standard deviation (SD) = 0.75), effectiveness (M = 3.88; SD = 0.76), efficiency (M = 3,93; SD = 0.73), elegance (M = 3.98; SD = 0,86), ethicality (M = 3.87; SD = 0.85). The idea of having a tailored solution for SaMD business models that early-stage startups could use was well-received. However, the guiding questions in the initial version were perceived as insufficient and not adequately tailored to SaMD startups. The guiding questions were recommended to be further refined and customized to better suit early-stage startups aiming to develop a business model for an EU SaMD. This feedback was unambiguous and consistent. It matched the observations of the two researchers who conducted the seminars and watched how the teams used the artifact. Therefore, we

decided not to conduct further evaluations. Instead, we carried out 31 additional expert interviews to explore the problem space more deeply and adapt the artifact.

In the second design cycle, we conducted the survey in one of the university entrepreneurship seminars with 22 graduate students. The setting of this seminar resembled the seminar description of the first iteration. The analysis yielded the following results: efficacy (M = 4.03; SD = 0.70), effectiveness (M = 3.98; SD = 0.73), efficiency (M = 4.09; SD = 0.70), elegance (M = 4.21; SD = 0.88), ethicality (M = 3.89; SD = 0.77). Comparing the two design cycles, the second evaluation cycle yielded improved results. Especially, the guiding questions were perceived as powerful. Besides the quantitative evaluation, we conducted five interviews with students from the university seminar to get more profound feedback. Additionally, we conducted nine interviews with EU SaMD startups and experts in one or more of the following fields: business modeling, entrepreneurship, and the SaMD industry. Furthermore, we led a focus group workshop with three experts that covered the fields just described. The qualitative analysis largely confirmed the positive results from the quantitative analysis. Experts from the EU SaMD industry and startups confirmed that these are the right questions to ask when developing a SaMD business model. An exemplary quote from the qualitative evaluation highlights the positive perception: *"So I found it definitely super helpful already. So I think the questions are really, really good. So I believe there is already super much covered."* (Translated from German by the authors.) While some target users initially found the artifact overwhelming due to the number of guiding questions, they did not feel this way once they began working with it. Instead, they appreciated the comprehensiveness and found the questions helpful. Some experts mentioned the added value of a guidance document, including instructions for use and recommended material as a starting point for addressing the open-ended questions. In the evaluation, a similar visual design to the Business Model Canvas [12] was perceived positively, making the artifact easy to use.

In the final design cycle, we conducted the survey in one of the university entrepreneurship seminars, which aligns with the description from the first design cycle. In total, 20 graduate students filled out the survey and applied the canvas to their use case. The survey yielded the following results: efficacy (M = 4.13; SD = 0.72), effectiveness (M = 4.43; SD = 0.64), efficiency (M = 4.15; SD = 0.63), elegance (M = 4.22; SD = 0.46), ethicality (M = 4.18; SD = 0.70). In the survey, the canvas was described as being "*precise, concrete but doesn't lose any essence*." It was perceived as being "*simple*" and "*easy to follow*". Furthermore, one student wrote a comment that *"[g]uidance through a difficult process [is] made easy*." The guidance document has been perceived as being a helpful optional document. Some students commented that they did not need it because they already had prior experience working with the Business Model Canvas [12]. Other students were happy to have it. One student wrote that "*[t]he guidance [document] is good*." The five interviews conducted with experts and SaMD startups yielded overall positive feedback. The canvas was perceived as having a clean and well-organized appearance. A few interviewees considered whether it might be useful to add color to the canvas instead of keeping the current plain black-and-white design. However, they were unsure whether this would add real value or possibly make it appear less high-quality. Other interviewees were opposed to the use of color altogether. In this interview round with the five interviewees, the guiding questions were again perceived as eye-catching and as one of the biggest strengths of the canvas.

IV. DISCUSSION AND CONCLUSION

A. Principal Findings

Primarily, our research revealed the profound effect of regulations, especially the MDR and IVDR, and the multi-stakeholder environment on the business of SaMD startups. While regulations in some industries may be considered external factors affecting the business model, in the SaMD industry, addressing the MDR or IVDR requires dedicated attention. Therefore, regulations need to be integrated as direct components in the business model of a SaMD in the EU. The multi-stakeholder environment, including the intricate customer constellation, partners, and further actors such as health insurers and notified bodies, all influence the operations of SaMD startups. Institutional theory serves as the foundation for understanding the profound influence of regulations and stakeholders on entrepreneurial activities. The EU SaMD sector's unique characteristics require both business models and respective supporting business model tools to address the specialties of this sector. This need is fulfilled by the SaMD Business Model Canvas, an artifact primarily designed for early-stage startups aiming to develop the business model for a SaMD in the EU.

A second key finding is the critical role of guiding questions in supporting effective use of business modeling tools. While the structure and naming of such tools can already convey valuable information, guiding questions help highlight the key aspects to consider within each component. This is particularly important for users such as early-stage startups, who might otherwise overlook critical elements. The importance of including well-designed guiding questions became particularly evident during the evaluation phase, especially in the interviews with experts and SaMD startups.

Lastly, while newly designed business modeling tools can offer advantages through novelty and differentiation, such decisions should be carefully considered. Our artifact intentionally follows the structure and naming conventions of the widely applied Business Model Canvas [12] to lower the entry barrier and allow users to begin working with the tool without requiring extensive prior instruction.
Our research, especially during the evaluation phase, showed that this approach was positively received. Therefore, the benefits of novelty should always be weighed against potential drawbacks, such as increased complexity or unfamiliarity for users.

B. Contribution

We consider the artifact to be valuable both for research and practice. The global crisis of the healthcare system is widely discussed in the literature. The shortage of human resources is especially profound in the literature [e.g., 38, 39]. In the EU, SaMD has the potential to address these issues by empowering patients and providing support to healthcare providers. However, the literature on SaMD primarily focuses on its challenges, such as the MDR or IVDR, which can be particularly demanding for startups. Solutions are missing to tackle these challenges and to support startups aiming to develop a SaMD for the EU market. Our research focuses on designing a canvas to support startups aiming to develop a

business model for a SaMD. Therefore, our research contributes to the literature on SaMD by providing a solution-oriented approach.

Additionally, our research contributes to the literature on business models, such as the literature on the Business Model Canvas [12]. While this canvas is broadly applicable, this comes at the expense of specialty. We explore business modeling in a highly regulated, multi-stakeholder environment and design a canvas tailored to this context. Our canvas has been aligned in structure and naming of the components to the Business Model Canvas [12], which, therefore, provides a valuable adaptation for SaMD startups. Our work also contributes to the literature on healthcare business modeling tools such as the modelH [14]. Although the modelH uses healthcare-specific terminology for its components, no further healthcare-specific information is provided, making it a rather nonspecific tool. There are no guiding questions to provide additional context, clarify the meaning of the components, and ultimately support the user in applying the tool effectively. Due to the lack of guiding questions, the tool neither encourages critical reflection nor highlights the key aspects a startup should be aware of. Strategic issues crucial in the early stages of business modeling in the healthcare sector, such as funding and key regulatory considerations, are missing. The SaMD Business Model Canvas addresses these issues and provides a holistic business modeling tool tailored to SaMD startups. The components cover all aspects necessary to consider early on, while the included guiding questions help startup teams reflect on each topic. This not only ensures that critical factors are not overlooked but also provides concrete support and reduces complexity in the early phases of business development.

From a practical perspective, the derived canvas provides a hands-on solution tailored to SaMD startups in the EU. Current business model tools do not sufficiently consider the specific situation of SaMD startups. Our work addresses this gap. A sustainable business model can improve the performance and survival of SaMD startups, thereby positively impacting healthcare systems. A multitude of actors can use the derived canvas. Apart from startups, especially those in the early stages, the canvas can be used by accelerators, incubators, investors, and partners such as pharmaceutical companies and health insurers. Furthermore, it can be applied in university seminars focusing on the SaMD industry. Due to the generalizability of the DPs, our work can be applied by researchers and designers focusing on business modeling in highly regulated and multi-stakeholder industries in general. Our derived artifact offers a solution tailored to the specific needs of SaMD startups in the EU while addressing the global challenge of struggling healthcare systems.

C. Limitations

Our research has some limitations. First, our work focuses on the EU and SaMD's specific needs. This approach allows for the derivation of tailored solutions and broadens the results to similar industries and the healthcare sector in general. However, the findings are less relevant for industries that are neither highly regulated nor characterized by a multi-stakeholder environment. Furthermore, as regulations continue to evolve, some of the guiding questions may become outdated and fail to address newly relevant aspects. Third, qualitative evaluations sometimes yielded mixed feedback, requiring compromises in design knowledge and implementation. We addressed these conflicts through researcher consensus. Lastly, in our first iteration, the artifact was evaluated solely with graduate students. While the university seminar was specifically designed for developing a SaMD business model, and the students' prior knowledge can be compared with that of early-stage startups, this does not replace insights from expert interviews or feedback from actual SaMD startups. We addressed this limitation in the two subsequent iterations, in which we conducted interviews with both experts and SaMD startups. Furthermore, the overall problem space was explored through a systematic literature review and 13 interviews in the first design cycle [23] and an additional 31 interviews in the second design cycle.

D. Future Research

For the third iteration, future research could evaluate the SaMD Business Model Canvas further. While five interviews with experts and SaMD startups have already been conducted, additional interviews could further strengthen the results and provide a more robust justification for not conducting an additional iteration. Future research could also include case studies in which early-stage EU SaMD startups apply the artifact to their specific business cases and provide feedback on its usefulness and applicability. This approach would offer valuable insights into how well the artifact works in practice. Additionally, the design knowledge and theoretical foundations developed in this work could be used to create adapted versions of the SaMD Business Model Canvas, suitable for other highly regulated, multi-stakeholder industries. These adaptations could retain the core structure and components of the original canvas while adapting the guiding questions to either align with the specific characteristics of each target industry or generalize them at a higher level.

E. Conclusion

In the wake of the digital transformation, SaMD can address global issues such as a lack of qualified healthcare professionals and healthcare quality. Yet, startups in the EU SaMD industry face challenges such as the MDR or IVDR and a multi-stakeholder setting. To tackle these challenges, this research derives theoretically grounded and practically validated MRs and DPs as a basis to develop a SaMD Business Model Canvas for the EU. The artifact provides a local solution tailored to digital health startups in the EU SaMD industry. At the same time, it tackles global challenges in healthcare systems, bridging the gap between localized innovation and worldwide healthcare demands.

MATCH & CONTRIBUTION

This contribution aligns strongly with the theme of the ICE IEEE 2025 conference, which focuses on how artificial intelligence (AI) is reshaping industries, as reflected in its title: "AI-driven Industrial Transformation: Digital Leadership in Technology, Engineering, Innovation & Entrepreneurship". The paper explores business modeling for SaMD startups in the EU. With the increasing amount and usage of SaMD, these digital health technologies considerably drive the digital transformation of healthcare systems. Several SaMD solutions are already AI-driven, such as apps that analyze patient data to recommend personalized treatments using machine learning algorithms. With the growing adoption of AI in healthcare, the number of such applications is expected to rise further. SaMD provides opportunities to tackle worldwide issues such as a shortage of healthcare professionals and the lack of personalized treatments. This paper aims to support

early-stage SaMD startups to develop a viable business model that prevents early market exits and thereby pushes the digital transformation of healthcare systems. This contribution aligns well with the conference's emphasis on data-driven methods to support innovation and entrepreneurial development, thereby representing a meaningful addition to the proceedings. Furthermore, our paper provides a holistic, practical business modeling tool that SaMD startups can use.

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V. REFERENCES

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