Overcoming Legal Complexity for Commercializing Digital Technologies: The Digital Health Regulatory Navigator as a Regulatory Support Tool

Research Paper

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Abstract. The increasing regulatory complexity presents a major challenge for digital startups, particularly in the European Union (EU). To address this, we introduce a new type of tool called regulatory support tools, which assist startups in navigating complex regulations. Based on insights from digital health startups in the highly regulated EU market, we apply a Design Science Research approach to derive key meta-requirements and develop design principles. These principles guide the creation of the Digital Health Regulatory Navigator (EU), a regulatory support tool that helps startups understand EU medical device regulations and strategically leverage regulatory opportunities for smoother market entry. Evaluations with experts and target groups confirm its practical value. Beyond this case, our study contributes generalizable design knowledge for regulatory support tools, emphasizing their role in integrating regulatory requirements early in commercialization. Furthermore, we highlight the potential of such tools to enhance entrepreneurial activities when designed and used responsibly.

Keywords: digital health technology, regulatory requirements, design science research, medical device regulations, regulatory support tools

1 Introduction

Digital technologies offer significant potential in various industries by providing new business opportunities. For instance, healthcare systems struggle with problems such as rising healthcare costs (Denoo & Yli-Renko, 2019) and shortages of skilled workers (Tariq, 2023). To address these issues, entrepreneurs are increasingly leveraging digital technologies. These are referred to as digital health technologies (DHT) (International Organization for Standardization, 2023). DHTs can potentially lead to benefits such as cost reduction and time saving (Tariq, 2023), but could also transform the medical field by improving patient outcomes, empowering individuals, and increasing the quality of healthcare (Wulfovich & Meyers, 2020).

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However, as regulations become increasingly complex, companies face greater challenges in staying compliant (Cleven & Winter, 2009) and bringing their solutions to the market. This is especially true in the EU, where novel and stricter regulations for digital technologies have been introduced recently. For instance, EU medical device regulations present a major barrier, replacing the less stringent previous rules (Baines et al., 2022). Digital health startups often have limited resources and can face difficulties in considering and acquiring legal knowledge early on.

To overcome these challenges, startups must consider regulations from the beginning and develop an appropriate regulatory strategy. In some cases, it may be beneficial to avoid medical device regulations or to carefully select a specific subset of regulatory requirements within the legal framework to manage costs at different levels. Little research has explored how startups facing regulations, such as medical device regulations, can be supported in the early stages (Weimar et al., 2024).

Therefore, this study aims to develop a methodological tool that supports digital health startups early in their decision-making, enabling them to understand medical device regulatory requirements for DHTs and build regulatory strategies. Consequently, we propose a design science research (DSR) project to answer the following research question (RQ): *How can we design a regulatory support tool to enable digital health startups to navigate EU medical device regulations?*

In this work, we introduce the concept of regulatory support tools for startups to overcome regulatory complexity. Additionally, we build design knowledge for designing this type of tool and instantiate and evaluate a regulatory support tool that practically supports digital health startups in coping with EU medical device regulations for standalone software.

The remaining work is structured as follows: The next section gives an overview of the background and related work. The third section outlines the research methodology used. The fourth section presents the results of our design project. In section five, key findings and contributions are discussed, and the last section concludes the work.

2 Background and Related Work

Digital health is a broad term that encompasses the field of employing information and communication technology to address health needs (World Health Organization, 2019). DHTs are therefore primarily standalone software solutions. A subset of DHT, which is regulated as a medical device, is known as software as a medical device (International Organisation for Standardization, 2023). The intended medical purpose, declared by the medical device manufacturer, qualifies a solution as a medical device (Baumgartner et al., 2023).

In the EU, medical devices are governed by Regulation (EU) 2017/745 on medical devices (MDR) or Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) (Baumgartner et al., 2023; Baines et al., 2022). These regulations mainly aim to ensure that medical devices have been designed and manufactured in a way that they achieve the performance promised by the manufacturer under defined conditions of use and are safe, thereby not risking user health or physical integrity (Baumgartner et al.,

2023). Requirements include establishing a quality management system, developing the digital technology per state of the art, and collecting clinical evidence, among others (Baumgartner et al., 2023). Additionally, medical devices are classified into risk classes that have different conformity procedures. For instance, high-risk classes must involve a notified body, which is the designated authority responsible for overseeing compliance in the EU, when CE marking their product (Baumgartner et al., 2023).

The EU medical device regulations have been described as a barrier for many companies (Baines et al., 2022). Especially startups with limited resources and knowledge face significant hurdles in this environment. Therefore, companies often necessitate guidance from external consultants for compliance (Baines et al., 2022). The complexity leads to additional time and financial resources required (Hagen & Lauer, 2018). Although the EU has developed some regulatory guidelines, there is still a need to develop low-threshold support methods (Hagen & Lauer, 2018). Some researchers have responded by creating decision support tools to determine whether a product is regulated as a medical device (Lukas et al., 2021; Seifert et al., 2022).

Using the theoretical lens of institutional theory, scholars have explored how institutions and regulatory environments influence entrepreneurship (Bruton et al., 2010). Laurell (2018) investigated patterns in the commercialization of medical technology ventures based on the three pillars of institutional theory: regulative, normative, and cultural-cognitive. Another related stream of literature describes situations in which economic agents structure their activities to navigate between different levels of regulation under the concept of regulatory arbitrage (Coendet, 2021).

3 Research Methodology

We adopted the DSR approach as it enables addressing important unsolved problems in unique and innovative ways (Hevner et al., 2004). DSR projects "seek to produce knowledge about how to solve important problems in a defined application domain" (vom Brocke et al., 2020). Following Kuechler & Vaishnavi (2008), we structured our research iteratively across five phases: awareness of the problem, suggestion, development, evaluation, and conclusion. Their approach is recognized as an objectivist, positivist methodology and focuses more than others on the development of design theory (Venable et al., 2017). We conducted three design cycles, as shown in Figure 1.
Based on the problem understanding, we initially defined meta-requirements (MRs) for a regulatory support tool for digital health startups. These MRs served as the basis for deducting design principles (DPs). Subsequently, the first instantiation was created based on the proposed design principles: The Digital Health Regulatory Navigator (EU). For evaluation, we applied the Framework for Evaluation in Design Science Research (FEDS) (Venable et al., 2016), conducting three evaluations with experts, entrepreneurs, and graduate students experienced in digital health, entrepreneurship, and medical device regulation. Feedback from these sessions refined both the DPs and the instantiation.

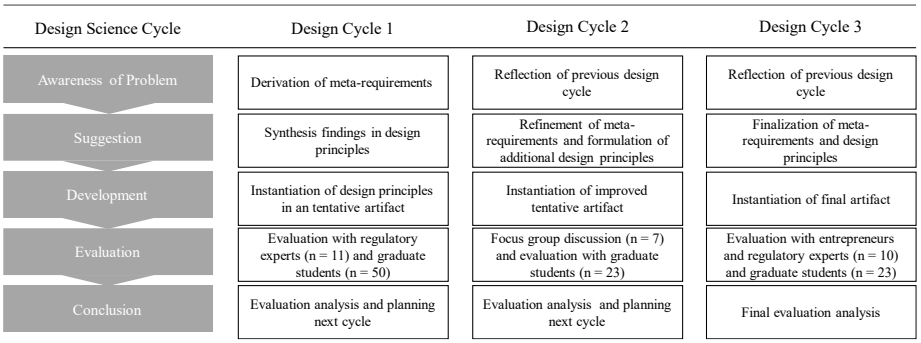

Figure 1. Design science research cycles based on Kuechler & Vaishnavi (2008).

4 Design

The results of the three design cycles are presented in the following.

4.1 Awareness of the Problem

Based on our understanding of the problem, we started deducting meta-requirements, which built a base for later deduction of design principles and an instantiated artifact. One of the initial steps for a digital health startup is to determine whether its potential DHT falls under medical device regulations. This crucial step can pose a significant challenge for digital health entrepreneurs (Lukas et al., 2021; Baines et al., 2022). Moreover, entrepreneurs can "skate the line" (Simon et al., 2022) between medical and non-medical devices. However, this decision should be made early in the startup lifecycle. Consequently, this leads to our first MR: *The tool should enable users to determine the applicability of EU medical device regulations for DHTs (MR1).*

Additionally, to make this determination feasible, entrepreneurs need to be aware of the key requirements of medical device regulations, such as risk classes, clinical evaluation, quality management systems, and standards, among others (Berensmann & Gratzfeld, 2018). Thus, the second MR reads: *The tool should present a summary of the key requirements of EU medical device regulations for DHTs (MR2).*

The medical device regulations and their requirements are perceived as complex (Baines et al. 2022). One strategy is to optimize the cognitive load for learning (Kirschner et al., 2011). It has been suggested that appropriately structuring legal knowledge can make it more accessible (Dickhaut et al., 2023), thereby reducing cognitive complexity. Therefore, our third MR is: *The tool should reduce cognitive complexity when starting to work with the EU medical device regulations (MR3).*

Al-Debei & Avision (2010) state that a business model must be compatible with external variables such as laws and regulations. In this way, institutions shape the strategy of a venture. It seems crucial, therefore, to incorporate regulations early on into the business strategy, leading to the fourth MR*: The tool should support early-stage digital health startups in the development of a regulatory strategy in the scope of the EU medical device regulations (MR4).*

Given the complexity of the regulations and the limited human cognitive load of individuals, the tool can serve only as an initial introduction to the regulatory requirements. This leads to the fifth MR: *The tool should serve as an introductory resource that facilitates the acquisition of in-depth legal knowledge (MR5)*.

Guidance design features promise to enhance performance and influence learning (Morana et al., 2017). In the context of the complex regulations, additional guidance is essential. Therefore, we formulate a MR regarding the inclusion of a guideline: *The tool should be supplemented by a guideline to support usage (MR6)*. Furthermore, instructions for use within the tool are essential (Avdiji et al., 2020): *The tool should include clear instructions to ensure successful application (MR7)*.

Finally, the artifact can also facilitate communication within the startup team (Avdiji et al., 2020). In complex settings, a common visualization is missing, which is a problem within startup teams. Therefore, we introduced the last MR: *The tool must enable communication within the startup team (MR8)*.

4.2 Suggestion

Building upon the derived MR and existing design knowledge (Avdiji et al., 2020; Dickhaut et al., 2023), we set out to deduct design principles for regulatory support tools that aim at bridging requirements and instantiation. Therefore, the principles conceptualize concrete mechanisms that describe acts, processes, forms, shapes, and architecture (Gregor et al., 2020). A mapping diagram from MR to DP is shown in Figure 2, as proposed by Möller et al. (2020). We formulated four DPs based on the schema of Gregor et al. (2020). The DPs are presented in Table 1.

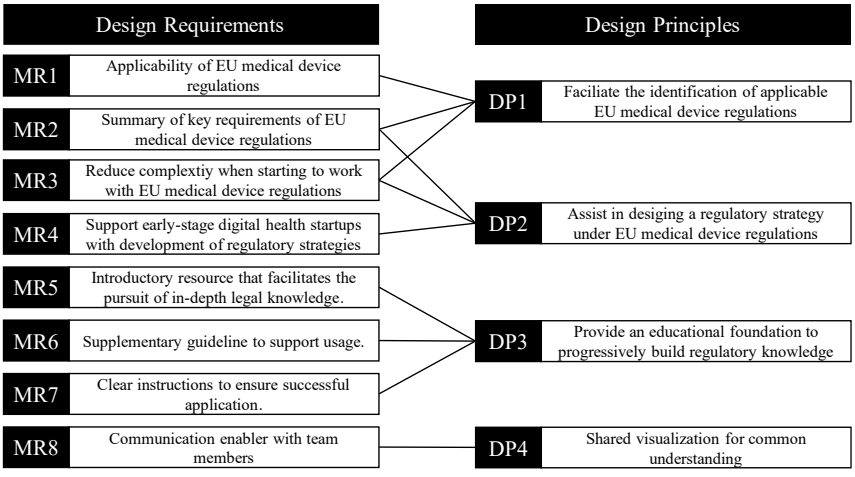

Figure 2. Mapping diagram from meta-requirements to design principle, visualization adapted from Möller et al. (2020)

Table 1. The design principles derived, with elements specific to digital health startups in the European Union in brackets and generalized for startups in highly regulated domains without brackets based on the structure of Gregor et al. (2020).

Component	DP1	DP2	DP3	DP4
Aim	For designers and researchers to facilitate the identification of applicable (EU medical device) regulations by (digital health) startups.	For designers and researchers to assist (digital health) start-ups in designing a regulatory strategy in the context of (EU medical device) regulations.	For designers and researchers to provide an educational foundation that helps (digital health) start-ups build (medical device) regulatory knowledge.	For designers and researchers to facilitate communication and collaboration within (digital health) start-ups.
Context	For (digital health) startups that need to consider applicable (EU medical device) regulations.	For (digital health) startups where a (EU medical device) regulatory strategy impacts the business model.	For (digital health) startups with limited resources and expertise in regulatory affairs.	For (digital health) startup teams need to have a common understanding of their strategy.
Mechanisms	Facilitation through a structured approach with problem spaces and decision trees correlating product characteristics with regulations.	Summarisation of key regulatory requirements and regulatory strategy development and reflection through problem spaces and checkboxes.	Adoption of a simplified, step-by-step approach with clear usage guidelines and supportive resources.	Shared visualization that logically and visually organizes the relationships between building blocks, fostering communication within the team.
Rationale	Understanding qualification for (medical device) regulations can be challenging, has a strategic component, and is the basis for subsequent steps.	Based on institutional theory (Bruton et al. 2010), regulations influence business strategy and should be considered in early venture stages.	Human cognitive load can be optimized (Kirschner et al. 2011); thus, simplification and guidance help with understandability.	A shared visualization can foster and facilitate communication between users (Avdiji et al., 2020).

In the first cycle, building mainly on MR1 but also MR2 and MR3, we formulated DP1, which is aimed at facilitating the identification of applicable EU medical device regulations by digital health startups, achieved through decision trees and problem spaces that correlate DHT characteristics with regulations.

Building on MR4 together with MR2 and MR3, DP2 was formulated. This principle aims to assist digital health startups in developing a regulatory strategy in the context of the EU medical device regulations. The underlying mechanism is summarizing key medical device regulatory requirements and embedding problem spaces.

The next principle, DP3, is based on MR5, MR6, MR7. It is aimed at digital health startups within the EU with limited resources and expertise in regulatory affairs. Therefore, the mechanism is a simplified step-by-step approach with clear guidelines and supportive resources.

The last DP4 is aimed at early-stage startups that need a common understanding of the strategy. The mechanism is, therefore, a shared visualization that logically and visually organizes the relationships between building blocks. This can foster communication within the team.

4.3 Development

The Digital Health Regulatory Navigator (EU) was instantiated as a regulatory support tool for digital health startups based on the design principles derived. As illustrated in a structural overview in Figure 3, the tool comprises nine sections. The detailed final instantiation of the tool, which was developed through the three design cycles, is shown in Figure A1 in the Appendix and is available as a PDF together with an exemplary filled-out version via GitHub[1].

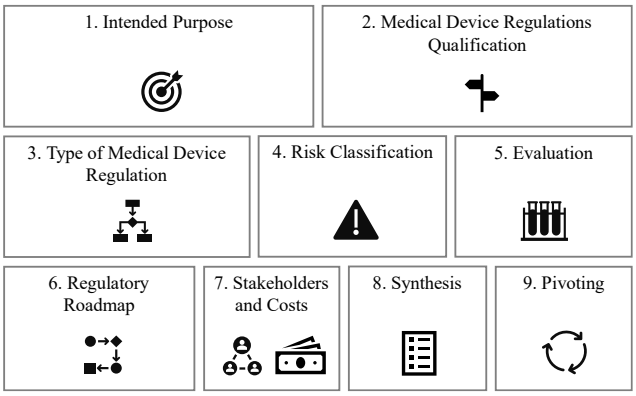

Figure 3. Overview of the structure of the Digital Health Regulatory Navigator with nine sections.

The first section of the tool focuses on the intended purpose, which is a term stemming from the medical device regulations for a description of what a DHT is intended for and is the basis for subsequent steps. The second and third sections expand on this by helping to determine whether EU medical device regulations are applicable and then choosing between the MDR and IVDR, which both make up the two EU medical device regulations (DP1).

Sections four and five offer guidance on risk classification and clinical or performance evaluations, respectively, which are both important steps to build a regulatory strategy in this domain. Subsequently, section six helps to outline the next required regulatory steps in the form of a roadmap. The roadmap opens the way for more strategic considerations, such as regulatory stakeholders and costs. Finally, sections eight and nine focus on the synthesis of results and consideration of pivoting, thereby adjusting the strategy and thinking about the next steps (DP2). Several guidance elements in

[1] https://github.com/sascha-weimar/digital-health-regulatory-navigator

the form of instructions and guidelines support the usage (DP3). The visual nature of the navigator supports communication within the digital health startup (DP4).

Digital health startups can use this regulatory support tool iteratively in the early stages to identify applicable EU medical device regulations and develop an appropriate regulatory strategy. Startup teams fill out the tool in digital or printed form, and results can be discussed internally within the team and externally with consultants.

4.4 Evaluation

We built our evaluation strategy for instantiations and the underlying DPs on the FEDS (Venable et al., 2016). We followed the human risk and effectiveness strategy, which should be applied "if a critical goal is to rigorously establish that the utility/benefit will continue in real situations and over the long run" (Venable et al., 2016). Following this approach, we conducted several evaluation episodes. While the first episode focused on a rather artificial setting with regulatory experts, the next episode included a focus group discussion with entrepreneurship experts. The final summative evaluation took place with digital health entrepreneurs as potential users, as well as regulatory experts. Each design cycle additionally included an evaluation in a university seminar on digital health entrepreneurship with graduate students.

We used the 5Es as testable propositions (TPs), which are summarised in Table 2 below. Stemming from Soft Systems Methodology (Checkland, 2000), they have been identified as suitable criteria for evaluating similar DSR projects (Venable et al., 2012; Johannesson & Perjons, 2014; Avdiji et al., 2020). The constructs were adapted for qualitative evaluations according to our use case with respective questions. Interviews and discussions were recorded, transcribed, and analyzed using the Gioia methodology (Gioia et al., 2013). For quantitative evaluations, a survey was employed using a 7-point Likert scale (1 = fully disagree; 7 = fully agree). Evaluations were slightly adapted for specific target groups; for instance, participants without expertise in regulatory knowledge can hardly judge the correctness of regulatory information within the tool.

Table 2. Testable propositions based on the 5Es with respective descriptions based on Johannesson and Perjons (2014) and Avdiji et al. (2020)

Testable Propositions	Description
Efficacy	The artifact must demonstrate high efficacy by producing desirable effects under ideal circumstances.
Effectiveness	The artifact must be effective as it can be successfully used in the context for which it was designed.
Efficiency	The artifact must be efficient without wasting time or requiring external resources.
Elegance	The artifact must be appealing and, consequently, easy to understand and use.
Ethicality	The artifact must align with ethical norms and not induce stress when working with it.

In the first iteration, the instantiation was evaluated by conducting 11 expert interviews with regulatory experts. Experts generally agreed on the effectiveness, elegance, and ethicality of the tool. Still, several improvements for the correctness of the regulatory information were proposed, and the idea of having a supporting guideline was positively received. With these adjustments, experts agree on the effectiveness of the tool for early-stage digital health startups. One expert mentioned that "most startups spend

weeks or even months searching for information, getting confused, and not knowing which documents to consult or how to make decisions properly. You clearly guide them through this, which is so helpful". In addition, the artifact was tested based on the TPs with 50 graduate students in a university seminar on the topic of digital health entrepreneurship resulting in metrics of effectiveness (M = 5.9, SD = 1.0), efficiency (M = 5.2, SD = 1.5), elegance (M = 5.7, SD = 1.2) and ethicality (M = 5.8, SD = 1.2). Hence, the first instantiation was well received by regulatory experts and graduate students. This evaluation resulted in the development of a guideline with an exemplary filled-out tool and improvements made to regulatory information in the instantiation.

Coming from this first evaluation, we conducted a focus group discussion with 7 entrepreneurship experts who commonly work with startups. The entrepreneurial experts noted the complexity of the medical device regulations and that some stress is involved when working with the tool; still, they agreed on the efficacy and effectiveness of the tool with some further adjustments to the elegance and layout. In this evaluation episode, the instantiation was also tested again with a sample of 23 graduate students resulting in metrics of effectiveness (M = 5.8, SD = 1.1), efficiency (M = 5.4, SD = 1.0), elegance (M = 5.9, SD = 1.2) and ethicality (M = 6.0, SD = 0.9). The supplementary guideline, which contains detailed information, was mentioned as positive, and an increased efficiency score was noted. Furthermore, the effectiveness and elegance of the tool were confirmed for most sections of the instantiation. Some improvements to the instantiation were made based on the feedback regarding the visual layout by streamlining design elements, restructuring some sections for clarity, and including a synthesis section to help users compile their results.

In the current final summative evaluation, 10 expert interviews with digital health entrepreneurs and medical device regulatory experts have been conducted. Participants received the tool before the interview and could test it. The participants did not mention any significant need for further improvements. One entrepreneur mentioned that he thinks the tool is "very suitable for early-stage startups, especially when used in combination with the guideline". Another expert noted that "in comparison to the regulations, I think the navigator is very simple and easy to use". Many entrepreneurs wanted to continue to use the tool, proving the value they saw in it. Additional evaluations with 23 graduate students resulted in metrics of effectiveness (M = 6.1, SD = 0.9), efficiency (M = 5.6, SD = 1.1), elegance (M = 6.3, SD = 0.7), and ethicality (M = 5.8, SD = 1.4). This concluded the design process with all TPs sufficiently fulfilled, and no further adjustments deemed necessary by the researcher team.

5 Discussion

A key finding is that the developed Digital Health Regulatory Navigator (EU) proved valuable across various contexts. As a regulatory support tool, it helps digital health startups navigate the complexities of EU medical device regulations for DHTs and simplifies early-stage decision-making. It especially benefits resource-constrained startups, supporting their understanding of regulatory requirements and the development of a regulatory strategy. This work also highlights the broader potential of such tools and proposes generalizable design principles.

Secondly, we discuss regulatory strategies for digital health startups within the developed regulatory support tool. Coendet (2021) distinguishes between regulatory avoidance, where regulations are bypassed entirely, and regulatory selection, where specific rules are chosen. Selection can occur within or across jurisdictions (Coendet, 2021). Regulatory avoidance under EU medical device regulations happens when startups adapt their DHT to avoid qualification as a medical device, instead positioning it as a wellness or research-only solution. Financial constraints, business strategy, or regulatory complexity may influence this choice. Regulatory selection within the EU framework takes various forms based on DHT design. One approach is adapting a DHT to fit a lower-risk class, thereby avoiding the need for a notified body. Another strategy involves minimizing clinical trial requirements by aligning product claims with existing clinical evidence. Additionally, regulatory selection can occur across jurisdictions, where startups choose markets with simpler regulatory pathways. By incorporating these strategies, the tool can help digital health startups navigate the EU medical device regulatory framework.

The structure of the Digital Health Regulatory Navigator draws on visual principles used in business model tooling, which can enable better communication and collaboration (Bouwman et al., 2020). Similar to visual tools like the Business Model Canvas (Avdiji et al., 2020), our navigator supports decision-making and team alignment, but focuses specifically on regulatory strategy in highly regulated domains. This domain-specific regulatory focus expands the general tooling landscape by addressing the legal complexity that is often underrepresented in existing tools. Still, using the navigator alongside business modeling tools can be beneficial to align business models with legal requirements. Compared to the method proposed by Dickhaut et al. (2023) for generally developing lawful design patterns, the navigator offers a concrete, domain-specific tool that guides digital health startups through regulatory decision-making, making it particularly actionable in early-stage entrepreneurial contexts.

Regulatory support tools must be designed and used responsibly. A key ethical boundary lies in distinguishing between legitimate regulatory strategy, such as aiming for a lower-risk classification by adapting the DHT design, and deliberate regulatory avoidance. For example, downplaying a product's medical purpose to evade qualification as a medical device may reduce regulatory burden, but risks bypassing essential safety requirements like clinical validation. This goes against regulatory intent, can endanger patients, or even violate laws. Used ethically, such tools help digital health startups navigate regulations while fostering innovation. Designers and users alike must ensure these tools uphold ethical and regulatory integrity.

Theoretically, we contribute to the discussion on how regulations and institutions shape company strategies through the lens of institutional theory. While traditional views emphasize compliance, digital health startups can also leverage regulatory strategy as a competitive advantage. With fewer financial resources than larger firms, startups can use such strategies to navigate highly regulated markets and foster innovation that benefits both consumers and society. Additionally, we introduce regulatory support tools as a novel type of tool and contribute to their design knowledge by formulating empirically tested design principles. Specifically, we identify key principles for entering highly regulated domains: understanding regulatory applicability, developing and reflecting on regulatory strategies, and incorporating visualization and guidance elements. These principles are generalizable to other regulatory contexts, providing a

strong foundation for future DSR projects at the intersection of regulation and entrepreneurship. For instance, in the context of the EU Artificial Intelligence Act, these principles could be applied to build tools that support startups in determining the applicability of the regulation, understanding associated obligations, and developing informed regulatory strategies.

On the practical side, we have instantiated the Digital Health Regulatory Navigator (EU) as a tool to help digital health startups navigate EU medical device regulations. Startups famously have the liability of smallness (Stinchcombe, 1965) and newness (Freeman et al., 1983). Therefore, it is a huge challenge to navigate strict regulations. The Digital Health Regulatory Navigator supports startups in the process. This can help them reduce compliance costs, enabling them to innovate more quickly, create new products, or provide services that might otherwise have been hampered by heavy regulation. The tool might also be beneficial for consultants and other stakeholders in the digital health industry.

This work has several limitations. First, qualitative evaluations sometimes yielded mixed feedback, necessitating design and implementation compromises that were resolved through consensus among researchers. Second, the tool is tailored to digital health startups developing standalone software in the EU, offering limited value in other markets. Additionally, as regulations evolve, the tool may become outdated. However, the underlying design knowledge enables future updates through additional design cycles, in line with the DSR approach. Thus, regulatory changes can be addressed, and a revised version of the tool could be released. Lastly, the current instantiation is limited to a paper-and-pencil format.

Further research could apply the design knowledge and theory developed in this work to design tools in the context of other industries or countries. Startups and entrepreneurs in various countries could benefit from easier access to regulatory knowledge in their early venture stages. In the future, the tool could also be implemented as a digital platform to enhance user interaction and accessibility.

6 Conclusion

With increasing regulatory demands, many startups, such as those in the digital health sector, face market entry barriers. This work shows that a regulatory support tool can help navigate EU medical device regulations, enabling startups to develop effective regulatory strategies. The design knowledge generated advances the understanding of how to build tools that support startups in navigating complex regulatory environments and can inform future design science research. Against the backdrop of growing regulations, especially for digital technologies, this study contributes to theoretical and practical discussions on how institutions influence startups and how startups can design and commercialize technologies that meet evolving regulatory requirements.

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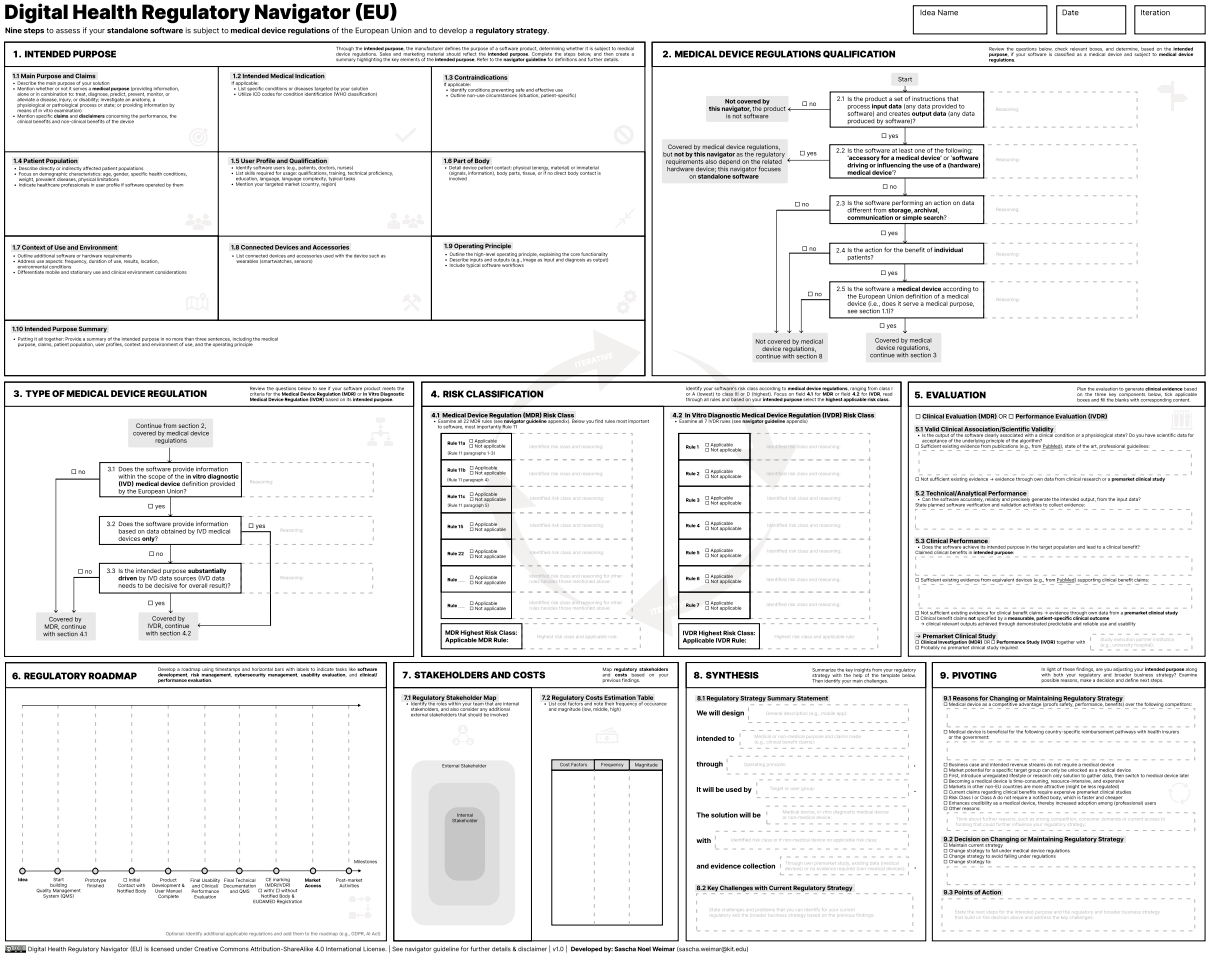

Figure A1. Final instantiation of the Digital Health Regulatory Navigator as a regulatory support tool.

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