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Towards Value Creation with Artificial Intelligence in Healthcare: A Qualitative Study on User Requirements

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Short Paper

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Abstract

In recent years, artificial intelligence (AI) has emerged as a promising technology for healthcare. As a result, incumbents and startups entering the healthcare market with AI-enabled products need to explore the user requirements of medical professionals to enable reliable and satisfactory solutions. To overcome barriers and channel AI for value creation, we examine how startups and incumbents in the healthcare industry are innovating their business models to create value with AI. We conducted a qualitative interview study in which we investigate medical professionals from a provider perspective and representatives of medical companies. In the first round of data collection, we developed a holistic view of the specific requirements for AI-enabled medical devices in radiology (organizational, regulatory, product, communicative, and financial). In the second round, we plan to explore how companies can respond to the previously identified requirements through business model innovation and identified risks. We contribute to research and practice.

Keywords: Healthcare, Digital Health, Artificial Intelligence, User Requirements, Business Model Innovation, Radiology, Interview Study

Introduction

The urge to digitize value creation is challenging companies across various industries, including the medical landscape. In the healthcare industry, new digital technologies, such as computer-aided intelligent diagnosis systems, are pushing into the market and enabling an extension of traditional health information technology (Agarwal et al., 2010; Jussupow et al., 2021). This transformation has been most pronounced among incumbents, which have been forced to change their business models in response to shorter product life cycles, the appearance of innovative tech startups, and the emergence of new technologies, such as artificial intelligence (AI) (Garbuio & Lin, 2019). In this context, the U.S. Food & Drug Administration published a list of more than 521 AI-enabled medical devices to improve the quality of healthcare decisions in the United States (fda.gov, 2022). However, the majority of AI-enabled medical devices have not yet reached the level of maturity desirable to prove themselves in clinical practice while meeting the requirements and needs of medical professionals (Lebovitz et al., 2021).

In information systems research, we find first empirical studies of a user's perspective of medical professionals concerning AI tools. They demonstrate that opacity and its inhibiting effects on critical decision-making are a major burden on the utility of such tools in clinical practice (Lebovitz et al., 2022). In addition, Jussupow et al. (2021) show that a resulting lack of trust in AI-enabled medical devices leads to ambiguous decision paths, as medical professionals sometimes rely on their personal experience rather than on data or recommendations from modern AI tools. However, the performance of AI in practice also suffers, as in some cases "wrong" ground truth leads to poor recommendations by AI-enabled medical devices (Lebovitz et al., 2021). As a result, incumbents and startups aiming to provide AI-enabled products, need to carefully explore the user requirements of medical professionals to enable a reliable and satisfactory solution. This approach will also require companies to rethink their whole value creation paths leading to a need for business model innovation, especially in incumbent firms.

Business model innovation is defined as "*a significantly new way of creating and capturing the business value that is embodied in or enabled by IT*" (Fichman et al., 2014, p. 335). In recent years, business model innovation is increasingly driven by the implementation of AI in existing business models (Metzler et al., 2021) or the demand for AI-specific products or services (Gregory et al., 2021). However, in the healthcare market, companies face significant barriers, such as privacy or security concerns, that prevent them from revolutionizing the way of turning health data into value. (Garbuio & Lin, 2019). One common mistake of firms is a missing focus on user requirements when innovating their business models and providing new AI-specific products or services (Halecker et al., 2014). Overall, it is still unknown how AI will shape the business models of incumbents and startups in the future of healthcare.

User requirements and business model innovation are highly interconnected concepts. First, changing customer demands and the emergence of new digital technologies lead to the need to innovate existing business models (Garbuio & Lin, 2019). Second, to enable successful business model innovation, firms first need to carefully analyze and understand the underlying user requirements (Halecker et al., 2014) . Therefore, in the first step of this study, we need to understand user requirements for AI-enabled solutions in healthcare. We focus on the field of diagnostic radiology because it is a leading example of the kind of professional work that is expected to be dramatically transformed by AI (Lebovitz et al., 2021). Within this field, physicians deal with multiple sources of data to diagnose patients based on images or medical parameters. At the same time, we need to understand how firms can cater to these needs. Hence, in the second step, we aim to analyze how radiology firms cater to these requirements through business model innovation. Since business model innovation is a risky undertaking (Euchner & Ganguly, 2015; Taran et al., 2015), we further aim at analyzing arising risks including potential ways how to react to these risks. In our study, we investigate the field of radiology, a pioneering area in the development and provision of AI-specific healthcare tools, and add to the existing body of knowledge in the field of AI-specific healthcare solutions and business model innovation. We approach the topic with the following research questions:

RQ1: What are user requirements for AI-specific solutions in radiology and how can companies cater to these requirements through business model innovation?

RQ2: What are the relevant risks for firms arriving from AI-driven business model innovation in healthcare and how can firms react to these risks?

In this research-in-progress paper, we report initial findings from a larger research project. We conduct a qualitative interview study in which we investigate medical professionals from a provider perspective and representatives of medical companies. In the first round of data collection, we elaborated a holistic overview of specific requirements for AI-enabled medical devices in radiology (organizational, regulatory, product, communicative, financial) from a user perspective. In the next step of our research-in-progress paper, we plan to conduct a second round of interviews to (1) understand how companies react to these user requirements by performing AI-driven business model innovation, (2) identify risk factors of this process, and (3) find solutions on how to conquer such risk factors for future business. Our findings will contribute to research and practice for the future of value creation with AI in healthcare.

Conceptual Foundations

Fichman et al. (2014) divide digital innovation into (1) process innovation, (2) product innovation, and (3) business model innovation. Business model innovation is an interesting class that has received increasing attention in recent years from researchers across disciplines, such as management sciences and information systems research (Teece, 2010). We follow the definition of Teece (2010, p. 173), who defines a business model as "*how the firm creates and delivers value to customers and then converts the payments received into profits*". Existing literature suggests that companies should be constantly looking for new ways to improve their business model (Teece, 2010). Business model innovation enables companies to respond to changes in the marketplace and changing user requirements (Burström et al., 2021). The main change in the medical market is the emergence of new technologies such as AI, which is based on learning algorithms (Garbuio & Lin, 2019). In the medical market, we see a strong increase in such AI-enabled medical devices (Jussupow et al., 2021).

Following Berente et al. (2021, p. 12), we define AI as "*the frontier of computational advances that reference human intelligence in solving increasingly complex decision problems*". This frontier has two dimensions: (1) performance and (2) scope. Performance describes the *"ever-improving execution of tasks to which AI is applied"*, while scope describes the "*ever-expanding range of contexts to which AI is applied*" (Berente et al., 2021, p. 12). For example, in healthcare, AI at the MD Anderson Cancer Center assists in the development of new cancer diagnoses and treatments, while also helping to solve simple tasks such as making hotel recommendations or finding solutions to information technology problems (Davenport & Ronanki, 2018). In increasingly complex situations, AI promises to play a critical role in meeting the demand for faster and more validated decisions by making large amounts of data accessible, usable, and actionable. The role of humans in interacting with AI is not clearly defined, and AI can take a superior role in interacting with humans. More precisely, AI can outperform humans (Shen et al., 2019) or outperform human crowds (Fu et al., 2021). Viewing AI as a frontier expands our horizon of understanding by showing that AI is perceived not only as a phenomenon but rather as a moving target of evolving phenomena (Berente et al., 2021). In healthcare, AI offers new possibilities for medical diagnosis, reporting, and treatment. For example, in radiology, AI can be used to collect and analyze medical images to diagnose diseases and guide their treatment (Jussupow et al., 2022). This context reflects a core strength of AI.

The emergence and availability of new AI-specific tools in the healthcare industry lead to a rethinking of end users. First, end users require the use of new AI-specific tools to simplify their working routines (Grønsund & Aanestad, 2020). Second, the users of potential AI-specific tools have specific expectations from which a set of user requirements can be derived (Lebovitz et al., 2022). To remain competitive, firms need to provide new AI-specific solutions and at the same time meet the complex and ever-changing needs of end users. To reach this goal, companies need to rethink their value creation model and innovate their existing business model. In this context, we already know quite a bit about the user perspective of AI in clinical practice. In particular, we find several problems in radiology, which is a pioneering field for AI integration. We find initial evidence in the research of Jussupow et al. (2021), Lebovitz et al. (2021), and Lebovitz et al. (2022), where users perform complex tasks and interact with AI-enabled medical devices. These users perform different cognitive mechanisms when AI is characterized by an "untrue" ground truth, or the user feels uncertain due to the poor performance of the AI in practice (Jussupow et al., 2021; Lebovitz et al., 2021). As a result, medical professionals will have different requirements for an AI-enabled medical device. Companies in the market will have to take this into account. However, we know little about how AI will be commercialized and how Ai-specific medical devices can be established in the market. Therefore, in the first step of this study, we look at the requirements of medical professionals in the healthcare sector,

and in the second step, we want to interview incumbents and start-up companies that are transforming their business models based on these requirements. This approach helps us to understand and combine different perspectives in such a complex transformational industry. In the following chapter, we describe our research setting and our methodological approach.

Research Setting

Our study is situated in the healthcare industry with a focus on AI-specific applications in radiology. This is because the healthcare industry is known as a highly regulated industry where accurate decision-making (i.e., through AI) plays an essential role. Within this industry, the field of radiology is a pioneer in the development, implementation, and use of AI-enabled medical devices. This is reflected in the fact that 67% of all FDA approvals in 2022 are for AI-enabled medical devices in radiology (fda.gov, 2022). In addition, AI can be integrated into typical radiology core tasks such as workflow reporting, text analysis, image recognition, or analysis of patient data. Finally, since most radiological reports are written by one or multiple humans, an additional opinion provided by an AI-enabled medical device can be extremely helpful. However, the majority of solutions validated for the U.S. market are island solutions. Therefore, radiologists are demanding new approaches to meet their needs. Hence, we aim to (1) provide an overview of a collection of user requirements for AI in radiology, and (2) analyze how companies can develop and implement AI-enabled medical devices through business model innovation.

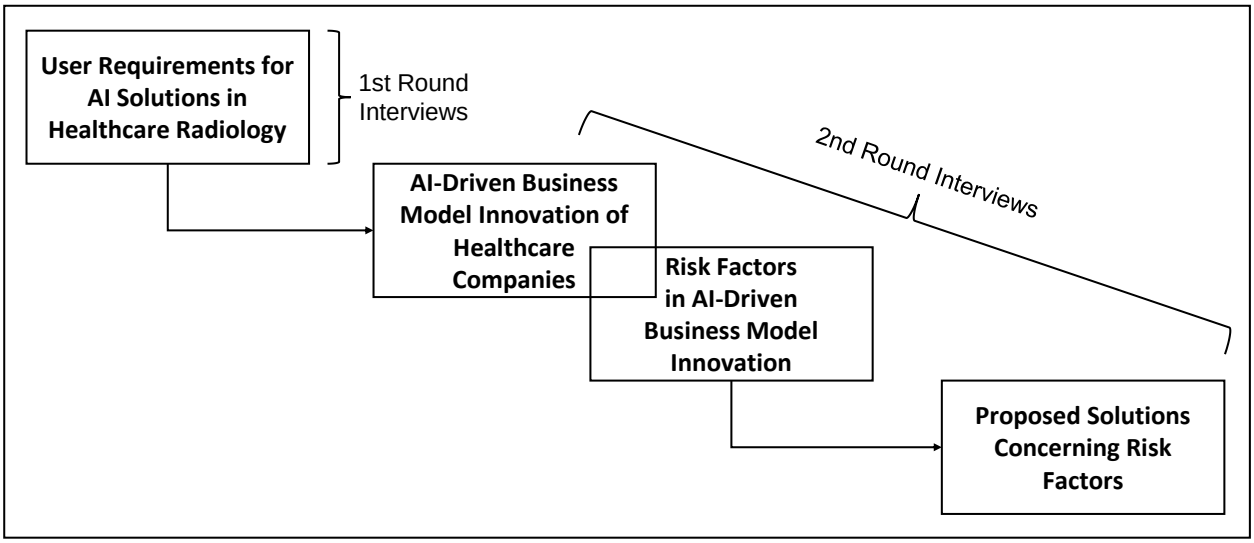

Figure 1: Anticipated Research Approach

As shown in Figure 1, our research approach is divided into three consecutive steps: First, our goal is to understand the user requirements for AI enabled medical devices in radiology. Based on the results of the first step, we will investigate how startups and incumbents targeting the healthcare market with AI-enabled medical devices can meet these requirements by transforming their business models. In this context, we also want to elaborate on which requirements can be implemented by innovating which specific business model element. Since AI-driven business model innovation is associated with high risk, in the third step, we aim to investigate the nature of the risk factors that arise and how companies can manage these risk factors. While the first round of interviews has already been conducted in late 2022, the second round of interviews is planned for early 2023. The following chapter describes our methodological approach.

Methodological Approach

To answer the underlying research questions, we are currently conducting an exploratory in-depth interview study (Myers & Newman, 2007). The advantage of interviews as a data collection method is that they focus directly on the topic under study and provide more (often sensitive) information than, for example, publicly available documents (Corbin & Strauss, 1990; Myers & Newman, 2007). In this study,

this is especially useful since user requirements for AI-enabled health solutions, as well as organizational strategic reactions to these requirements, are not publicly available.

Inspired by the existing literature on business models (Al-Debi et al., 2008; Teece, 2010) and AI-enabled medical devices in healthcare (Davenport & Ronanki, 2018; Lebovitz et al., 2021) we developed two semi-structured interview guidelines for two different interview groups. The interviews are not meant to be rigidly conducted according to the questionnaire, but rather situational and fluid, depending on the respondent's answers. The semi-structured approach allows us to easily deviate from the structure of the questionnaire to better follow up on interesting topics or statements (Galliers & Huang, 2012).

As a first step, we want to understand user needs for AI-enabled medical devices in radiology. In this context, we want to learn about specific user requirements for AI-enabled medical devices and their potential impact on healthcare business models. To this end, we decided to include a wide range of different viewpoints from potential users of AI-enabled medical devices in radiology, as well as from researchers focusing on such applications. In addition, we conducted interviews with business decision-makers (mostly from healthcare companies). In total, we conducted interviews with 13 individuals in the first round. We started with 10 interviews with practitioners from radiology and continued with a holistic understanding of 3 business decision-makers. All interviewees have extensive experience with the use, evaluation, or development of AI-enabled medical devices in radiology. Table 1 provides a detailed overview of the interviews conducted.

No.	Job Role	Field	Experience in the Field	Organization	Gender	Length
#1	Novice Physician	Radiology	Low (1-5 years)	Hospital	m	00:59:59
#2	Novice Physician	Radiology	Low (1-5 years)	Hospital	m	00:52:35
#3	Senior Physician	Radiology	High (5+ years)	Hospital	m	00:30:33
#4	Novice Physician	Radiology	Low (1-5 years)	Hospital	w	00:51:23
#5	Novice Physician	Radiology	Low (1-5 years)	Hospital	w	01:16:36
#6	Senior Physician	Radiology	High (5+ years)	Hospital	m	00:40:19
#7	Senior Physician	Radiology	High (5+ years)	Outpatient Practice	m	00:53:21
#8	Senior Physician	Radiology	High (5+ years)	Hospital	m	01:11:00
#9	Senior Radiographer	Radiology	High (5+ years)	Outpatient Practice	m	00:56:12
#10	Senior Radiographer	Radiology	High (5+ years)	Outpatient Practice	m	00:37:25
#11	Vice President of Medical Affairs (And Physician)	Radiology & Pathology	High (5+ years)	Healthcare Company	m	00:41:34
#12	Chief Information Officer	Health Information Systems	High (5+ years)	Hospital	m	00:45:17
#13	Head of Research & Innovation	Radiology & Pathology	High (5+ years)	Healthcare Company	m	00:52:31

Table 1. Overview of Interview Partners

After the data collection, each interview was transcribed and uploaded into the qualitative data analysis tool MAXQDA. As part of the data analysis, we conducted a qualitative content analysis of the interview transcripts. For the first sample of interviews, we used an inductive approach. First, we open-coded all interviews to identify (potential) application areas for AI in healthcare. In addition, we open-coded all interviews to identify the requirements for specific AI-enabled medical devices in each application area. After open coding, we engaged in axial coding to draw connections between the open codes and organize

them. In doing so, we came up with several categories that included several codes. Finally, we engaged in selective coding by organizing all the categories. In selective coding, we came up with the main categories "application areas" and "requirements". All subcategories were organized under these two main categories.

Based on the results of the first round of interviews, a second group of interviewees will be approached in the second step. This group of interviewees should primarily include CEOs (or persons in other leading positions) of healthcare companies that are currently engaged in AI-driven business model innovation to respond to changing user requirements for AI-enabled medical devices. With this group of interviewees, we aim to explore how companies can respond to the previously identified requirements for AI-enabled medical devices in healthcare radiology through business model innovation. In addition, we want to explore relevant risk factors arising from AI-driven business model innovation and potential ways to manage these risk factors. In this phase of research, we plan to conduct approximately 20 additional individual interviews to ensure a solid foundation for our inductive research approach.

The content analysis of the second round of interviews will be conducted in a multi-step approach as a mixture of deductive and inductive category development. The business model framework of Al-Debi et al. (2008) will serve as the main conceptual lens for data analysis. As a first step, we aim to code all statements that refer to AI-driven business model innovation as a response to new user needs and sort the statements according to the four specific business model elements (i.e., value proposition, value architecture, value network, and value finance). The four business model elements thus serve as our main categories. In the second step, we aim to analyze these statements to find patterns regarding risks in each business model element. As a result, we expect that each business model element will be associated with several higher-level risk factors, which will then serve as our first order codes. In addition, we expect that the specific higher-level risk factors will be characterized by several lower-level risk factors. These lower-level risk factors will then serve as our second-order codes.

(Preliminary) Findings

Below we present some initial findings from our first round of interviews. Our data analysis revealed that (potential) users of AI-enabled medical devices in healthcare radiology have requirements in five different categories. These categories, including their specific characteristics, are shown in Table 2.

Requirements	Characteristics	Exemplary Quotes
Organizational Requirements	Holistic AI-enabled systems and interoperable interfaces for diagnosis and reporting	*"[...] if there is an intelligent solution that takes all interfaces with it, so to speak, and [...] works with text modules that are easy to insert or voice recognition, voice control, all this area is insanely underdeveloped in the clinic." (Interviewee 5, line 91)*
	Good integration of AI-enabled systems into the existing health system landscape	*"[...] it's all connected." (Interviewee 7, line 63). "[...] and of course, the technical interfaces, because everyone is so vendor-locked in his thoughts, the interfaces are always a mega mess [...]." (Interviewee 8, line 39)*
	AI alignment with existing software	*"[...] it has to fit into the existing systems." (Interviewee 12, line 55)*
Regulatory Requirements	Data protection compliance with learning-based AI	*[...] "Data protection and cybersecurity ...I think would definitely add value to that. And would be a totally interesting functionality." (Interviewee 7, line 96-98)*
	Clarified liabilities	*[...] "Who is responsible in the end? And the programmer will say, No, no, no, I'm not responsible for that" (Interviewee 7, line 27)*
Product Requirements	Reliability and trust	*"So, of course, it must somehow actually do what it promises." (Interviewee 8, line 17)*
	AI-enabled smart user interface with low additional interaction	*"And of course, you could imagine speech recognition software that would pop up tooltips for certain keywords." (Interviewee 8, line 61) "You can set as many filters as you like. I always set very few filters because I*

		want to keep track of everything." (Interviewee 7, line 63)
	A high degree of individualization and personalization	*"[…] I know that radiologists work individually and have individual needs. And as soon as they realize that the product doesn't cover their individual needs, they won't use it." (Interviewee 5, line 80)*
	Continuous smart voice control	*"[…] And for me, that's one of the reasons why I still dictate myself, because one of my strengths is that I can report incredibly fast." (Interviewee 7, line 82)*
	Economic efficiency per patient case	*"[…] the AI, of course, has to somehow actually do what it promises to do. I think the cost is always a factor, of course." (Interviewee 8, line 17)*
	Time efficiency	*"So we physicians in general, I would say now, are afraid of every lost second." (Interviewee 8, line 155)*
Communicative Requirements	Addressing customers at conventions with AI roadshows	*"Congresses are a big topic." (Interviewee 5, line 96) "[…] you can show software relatively easily and it's uncomplicated, you don't need this initial contact via email or telephone acquisition." (Interviewee 5, line 98)*
	Building trust through scientific evidence	*"[…] And we get that by doing research, by showing people: Hey, for example with the AI sequence, just for your understanding, this is an MRI sequence that takes four minutes, we can do it faster with AI, with the same image quality in two minutes." (Interviewee 6, line 32)*
Financial Requirements	Marketplace/Platform solution for AI services	*"There is DeepC from Munich. There is Black Ford Analytics from the UK. They do exactly that, they say okay, we have here, we offer you a contract partner, that's us. And in the background, there are 15, 20 AI companies that you can integrate through our platform." (Interviewee 13, Line 115)*
	Subscription model	*"[…] Let's say it's a little bit like $500 rent per month per user. That's a lot easier to sell than if I say, "We need to spend 1.3 million over the next five years." (Interviewee 12, line 73)*
	Cost efficiency	*"[…] the investment volume available to you as a hospital or radiology department is probably small anyway." (Interviewee 8, line 37)*

Table 2. Overview of User Requirements for AI-Enabled Medical Devices in Healthcare

The first set of user requirements refers to **organizational requirements**. These requirements primarily concern the need for considering the organizational conditions of potential AI users (i.e., organizational conditions in hospitals). Here, we found that potential AI users expect a holistic AI system that covers several tasks of their daily work routines. These work routines include radiological workflows like image collection, analysis or recommendations for further treatment. For example, one interviewee said: "*My dream world would be an all-in-one solution. I would be able to open up one piece of software, write my findings there, pull up the images there, look at the patient's history there, dictate there, and do everything there. And not jump back and forth and open 1000 things." (Interviewee 6, line 76)* Furthermore, users want a good integration into the existing system landscape of their organizations such as a Radiology Information Systems (RIS). In that regard, AI firms should offer variable interfaces for different existing systems. This is also associated with the desire to be independent of existing software (no vendor lock) and provide dashboards for an overview of the landscape. For example, hospitals that combine different software systems such as RIS or Picture Archiving and Communication System (PACS) in several workflows replied with *"*[…] *to unify the approaches or develop some kind of dashboard." (Interviewee 6, line 22)*

Concerning **regulatory requirements**, we found that potential users of AI-enabled medical devices demand comprehensive data protection compliance. To fulfill this requirement, providers of AI solutions should communicate their efforts to protect data and follow new ways such as privacy-preserving AI.

Further, our interview partners stated that they require a clear clarification of liabilities. This, for example, concerns cases in which damages occur due to wrong decisions of the AI-enabled medical device, i.e., one interviewee said *"*[…] *I think this is a bit of a gray area. If I, as a radiologist, write and sign this report, electronically so to speak, I am liable for it." (Interviewee 5, line 30)*

Our interview partners further formulated various **product requirements**. These requirements primarily concern the design of AI-enabled medical devices and associated services. For example, all interview partners mentioned the need for high reliability of AI-enabled medical devices in radiology by the statement *"*[…] *For reporting questions, you may need heat maps or certain explanations of why this is now this thing* […] *because there are many things that look similar but are different." (Interviewee 3, line 44)* Additionally, they demand smart user interfaces with a high degree of individualization and continuous voice control with augmented text reporting by the help of AI. To become integrated into hospitals and other medical offices, AI-enabled medical devices further need to be efficient and need to reduce working time. This means that the AI should work accurately, i.e., it should be well trained on multi-center data or in the words of an interviewee: *"*[…] *and when the applications are used, they should also work and require little interaction." (Interviewee 3, line 31)*

We further found that potential users of AI-enabled medical devices require specific **communicative requirements**. For example, users demand to be contacted by developing firms at conventions or AI roadshows, instead of being contacted via e-mail or phone calls. Additionally, our interviews highlighted the importance of trust building through scientific evidence as mentioned "*So this trust came about differently, and that was once through academic research. That we have done research together and they know it." (Interviewee 6, line 44)*

Finally, users of AI-enabled medical devices demand specific **financial requirements**. In this context, our interview partners highlighted the need for a subscription model for AI-enabled medical devices, instead of buying models. This, especially, helps to reach financial freedom as one interviewee stated: *"*[…] *a monthly rent. That is the easiest thing, a rent that I can cancel, where everything is included in this rent." (Interviewee 12, line 71)* Further, the AI-enabled medical devices in use need to be as cost-efficient as possible per medical case.

Discussion, Next Steps, and Anticipated Contributions

As an initial step, we analyzed user requirements for AI-enabled medical devices in radiology. Our findings indicate that companies that want to offer AI solutions in this field have to address several issues, such as complex product requirements and regulatory requirements. In the next step, we aim to analyze how incumbents and startup companies in healthcare are addressing these emerging requirements through AI-driven business model innovation. In this context, we also want to analyze which requirements can be implemented by innovating specific business model elements. For example, the impact of the requirement for subscription models on the "value finance" element in companies' business models will be analyzed.

With this ongoing study, we aim to contribute to the literature on information systems and business model innovation in several ways. First, we aim to shed light on new user requirements that arise from the novelty of AI. In this context, we also highlight potential application areas of AI in radiology. Second, we aim to provide suggestions on how healthcare organizations can address new user requirements and develop AI-enabled medical devices that meet these requirements through business model innovation. Overall, these anticipated contributions aim at providing a new research perspective by combining the literature streams of business model innovation and healthcare information systems.

Furthermore, we aim to provide several practical implications for healthcare companies that aim to provide AI-enabled medical devices, as well as for potential users of such solutions. On the one hand, potential users of AI-enabled medical devices can learn about the potential to accelerate their daily workflows. On the other hand, companies and startups can learn about user requirements for AI-enabled medical devices in radiology and understand how they overcome challenges by innovating their business model.

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