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Effective Requirements Engineering in Early-Stage Digital Health Startups

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Abstract: This case study examines the implementation of a requirements engineering process in early-stage digital health startups developing software as a medical device. We demonstrate a four-phase process that integrates systematic requirements gathering into product development while preparing for approval as a medical device. The study shows that even resource-constrained startups can effectively implement requirements engineering processes that support future regulatory compliance, potentially serving as a model for other digital health startups.

Keywords. Requirements engineering, digital health startups, medical software, medical device, product development, regulatory compliance

1. Introduction

The digital healthcare market is experiencing strong growth, particularly in the European Union (EU) and Germany, where long-overdue digitization is entering the healthcare system [1]. This presents unique opportunities for digital health startups (DHS) to address customer pain points. However, DHS face challenges in developing Software as a Medical Device (SaMD) with limited resources, needing to rapidly develop, validate, and sell products while satisfying both customer expectations and regulatory requirements. This is essential for later CE marking in the scope of the Regulation (EU) 2017/745 on medical devices (MDR).

Standards play a crucial role in state-of-the-art software development and enable compliance with regulatory requirements. For SaMD, key standards include ISO 13485 for quality management systems [2], IEC 62304 for medical device software development [3], and ISO 14971 for risk management [4]. These standards address various aspects of requirements engineering (RE) processes and associated risk management: initial specification of requirements, tracing the requirements' origin, and the resulting product's risk management.

While the literature on product development methods is extensive, there is a lack of information demonstrating practical application in DHS [5]. The integration of RE in startups also varies significantly from one startup to another, with no uniform approach [6]. In part, this is due to the environment of the startup. Independent startups have no access to pre-existing resources such as in-house data protection, while spin-offs lack the freedom and agility from pre-existing processes. To identify how a DHS conducts this process and tackle the challenges, we pose the following research question (RQ):

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- RQ: How can early-stage DHS integrate systematic requirements engineering into their product development while laying the basis for later approval as a medical device?

2. Methods

We conducted a single-case study following the five components outlined by Yin [7]. The case study approach was chosen to provide in-depth insights into the specific context and conditions necessary for the successful implementation of a RE process within DHS. Therefore, the objective was to uncover approaches for systematic RE. Based on our research question, we proposed that a RE process could be effectively executed by DHS while laying the basis for medical device regulatory requirements.

The primary unit of analysis for this case study was the RE process developed and used within the product team of the DHS *Metis*. The data for this study were collected through documents used by the startup in the scope of their quality management system and through direct observations by participation in the RE process over three years. We employed a pattern-matching technique for evaluation, comparing the expected benefits of using the designed RE process to observed outcomes. Potential biases from our participatory role were mitigated by reflecting on our observations and external feedback from users of the RE process.

Metis is a spin-off project from the Karlsruhe Institute of Technology (KIT) in Germany. The spin-off consists of three full-time founders, part-time employees, and students. Where possible, *Metis* collaborated with external partners and experts, e.g., clinics and doctors. KIT does not house medical faculty or a clinic. The spin-off did not operate as a separate legal entity but from within the university during the case study. The aim of the spin-off was the identification of pain points in dementia prevention and treatment. The task was approached using tools such as the business model canvas, SWOT analysis, and value proposition canvas, among others. The resulting goal from this analysis is the treatment of risk factors identified by Livingston et al. [8] through a digital solution, which leads to a target customer group of dementia risk patients and their connected stakeholders in the German healthcare system. The team realized early that they would need to comply with MDR, as their solution will incorporate a medical purpose, and therefore, criteria for SaMD in the EU are fulfilled. This requires compliance with multiple regulatory requirements.

3. Results

The RE process observed was designed to gather and refine requirements for the mobile application supporting the patient in treating risk factors. The process aims to improve team communication and documentation for subsequent certification as SaMD. It was built around an interactive template that guides through all steps of requirements gathering and refinement. The template is published on GitHub[3]. For *Metis,* it was crucial that this template was easily accessible and modifiable, encouraging frequent

[3] https://github.com/mariusgerdes/requirementsengineering

engagement from all parties involved. Failing to do so may result in non-adherence by some employees with limited background knowledge and time.

The RE process is divided into four phases and builds on standards required for MDR conform product development, outlined in Table 1. Each phase yields results called artifacts. The team goes through these phases iteratively. *Metis* iterated on both the main application and submodules multiple times during product development. This enables co-creation with stakeholders and end-users. During all phases, all elements and sources are traceable through IDs. To allow the creation of technical documentation, *Metis* implemented design freezes of certain versions, which can be used for later CE marking.

Table 1. Phases of the requirements engineering process.

Phase	Description
1. User Needs Specification	Utilizes personas and various research methods to identify and prioritize user needs.
2. Stakeholder Requirements Definition	Translates user needs into formal requirements and incorporates additional stakeholder inputs as required by [2] and [3].
3. Software Requirements and Risk Analysis	Develops detailed software requirements according to [2] and [3], including risk assessment according to [4].
4. Prototype Development	Creates and iterates on a prototype based on gathered requirements.

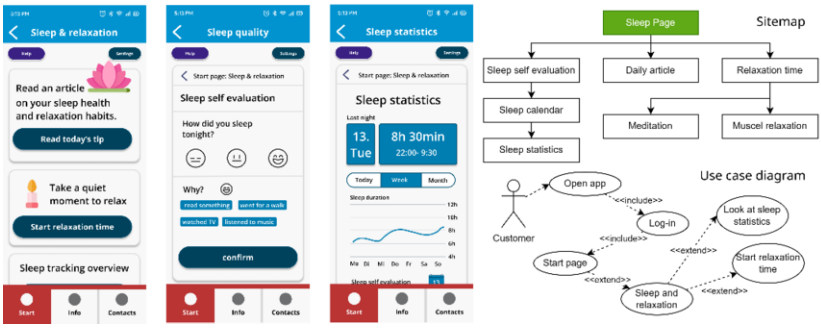

Figure 1. Research process from raw data collection to iterative qualitative data analysis.

During Phase 1, user needs are identified, as shown in Table 2. *Metis* gathered information in multiple ways, including user interviews, user testing, expert interviews, literature research, and competitor analysis. A first mockup version, as depicted in Figure 1, served as an aid for a user interview. Due to a strong stigma towards dementia, *Metis* faced the problem of finding potential users. A solution was the use of related user groups and literature, accepting an initial loss of quality, as it may be improved upon iteratively while sustaining fast progress. In Phase 2, *Metis* transferred the user needs into stakeholder requirements in Table 3. Additionally, in Phase 2, further requirements from other stakeholders, such as regulatory stakeholders, can be added. In the case of *Metis*, this includes adherence to MDR, data protection, and software development standards.

Table 2. User needs identified in phase 1 of the requirements engineering process.

User Need ID	Stakeholder	User Need Description	Thematic Area	Importance	Source
Unique ID for tracing	*Stakeholder in question.*	*Formulation as user story.*	*Thematic area of user need.*	*Rates the importance from 1-10.*	*State source of user need.*

UN_Sleep_01	Beneficiary of the application, is at risk for a precursor to or a mild form of dementia. 50+years.	I want to have a sleep tracker, to gain insights and improve sleep quality.	Sleep	10	Expert Interviews, User interviews (20/34 interested.)

Table 3. Stakeholder requirements identified in phase 2 of the requirements engineering process.

Requirement ID	Stakeholder	Requirement Description	Thematic Area	Type of Requirement	Source
Unique ID for tracing	*Stakeholder in question.*	*Formulate requirement: The <product> must <ensure X or provide Y>.*	*Thematic area of stakeholder requirement*	*Functional, non-functional, or technical requirement?*	*State source of the requirement.*
UR_Sleep_01	Elderly person with dementia risk (50+ years)	App must track user sleep cycles with a wearable, including sleep phases.	App feature sleep	Functional requirement	UN_Sleep_01

As shown in Table 4 and Table 5, Phase 3 contains the translation of stakeholder requirements into concrete requirements for the software. This also includes the evaluation of potential risks for the users and the integration of measures to mitigate the risks. *Metis* found it essential to include the software development team in the process at this stage so that technical issues could be addressed.

Table 4. Software requirements identified in phase 3 of the requirements engineering process.

Requirement ID	Requirement Description	Detailed Specification	Source	Related Risk IDs	Risk Control Measure?
Unique ID for tracing	*Brief description of requirement for overview.*	*Detailed specification of requirement, links to stakeholder requirements and mockups.*	*State source of the requirement.*	*Associated risk or harm.*	*Originates from risk or harm.*
SO_Sleep_01	Sleep tracking functionality to track and display sleep data.	Sleep data includes, e.g. sleep duration. Visual display equivalent to mockups. Entry and saving of subjective sleep rating included	UR_Sleep_01	RH_Sleep_01	No
SO_Sleep_02	Warn user of faulty sleep data.	User needs visible disclaimer on possibility of partially inaccurate sleep data be depicted in mockups.	RH_Sleep_01	RH_Sleep_01	Yes

Table 5. Risks and harms identified in phase 3 of the requirements engineering process.

Risk ID	Assets or Inputs	Failure Mode	Hazard	Harm	Risk Control Measure Needed?	Associated Requirement
Unique ID for tracing.	*What are we looking at to identify risk and harm? Software Systems, UI-Elements*	*How can it fail?*	*What hazard is linked to failure?*	*Associated risk or harm.*	*Do we need to address this risk through a software requirement?*	*Associated software requirement to counter risk*
RH_Sleep_01	Sleep tracking functionality and statistics display sleep data of the user.	Data may be of poor quality not reflecting actual sleep.	Users may incorrectly identify that he has a sleep problem.	Users may be stressed and sleep worse.	Yes	SO_Sleep_02

After deriving software requirements and conducting the risk analysis, *Metis* concluded the iterations with Phase 4. This includes the creation of, or updates to, the prototypes, as depicted in Figure 1. Potential prototypes are clickable mockups, sitemaps, and user case diagrams. These are then evaluated further together with stakeholders in an iterative process. For release milestones, which would later require approval, the final iteration is supplemented by a detailed requirement and design specification document, which is self-contained and does not cross-link to other resources. However, *Metis* deemed this too time-intensive for every iteration.

4. Discussion and Conclusions

The case study demonstrates the development of a systematic RE process in DHS. We could confirm better team communication and improved documentation through the systematic process. Challenges include the lack of resources and complicated standards. One key finding was that the process has to be used continuously, and bottlenecks have to be addressed swiftly. This can be done by adjusting the methods to align with current constraints while still following the overall process. One disadvantage is the difficulty in judging the impact a continuously adapting process might have on the product.

A limitation of this case study is that the solution developed by the DHS has not yet received a CE marking. Additionally, this case study focuses on the RE process, as it does not cover all medical device regulatory requirements, like those for related processes such as risk management. Furthermore, the study is limited to a single case and may not generalize to other cases.

Future work could look at the progress of *Metis* and the connection of RE with other product development processes. Further feedback for the RE process could be gathered with a larger number of DHS. Nonetheless, the case demonstrated encouraging results for implementing a RE process in a DHS, despite minimal available resources.

In conclusion, the case study demonstrates that even early-stage DHS with limited resources can follow a RE process, improving communication, transparency, and documentation. This also lays a successful foundation for developing a medical device and earlier CE marking.

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