DELIVERABLE

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D7.2 – Requirements for disease patients self-management

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Revision History, Status, Abstract, Keywords, Statement of Originality

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Abstract (for dissemination)	This deliverable presents the patient user requirements for a SMASH-HCM patient platform to provide patients with personalised guidance on topics such as understanding the disease and the potential impacts of lifestyle choices, and to collect personally relevant health, lifestyle, quality of life and unmet needs. Design requirements have been developed to help software developers understand in depth how each requirement's implementation may affect patient behaviour and commitment to using the software. It utilises Behaviour Change Wheel (BCW) interventions and Octalysis gamification techniques to arrive at a comprehensive set of user requirements and implementation suggestions. This is complemented by areas of information content and interactivity that would be most useful to patients, obtained through direct interaction with cardiomyopathy patient organisation representatives in the consortium. The software developers in

	the project will utilise this material to design digital tools for patient use, through iterative cycles of consultation with end user representatives.
Keywords	Decision support, machine learning, diagnostic certainty, risk stratification, quality of life, lifestyle choices, user requirements

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Table of Content

List of Figures

Executive Summary

SMASH-HCM is going to develop a SMASH-HCM patient platform to provide patients with personalised guidance on topics such as understanding the disease and the potential impacts of lifestyle choices, and to collect personally relevant health, lifestyle, quality of life and unmet needs. These will primarily be for the patient's own benefit but might also at times be shared with their HCM clinical team.

This deliverable presents the patient user requirements for this SMASH-HCM patient platform. Section 1 introduces the scope of this work and Section 2 summarises the methodology adopted to develop the requirements.

Section 3 presents design requirements developed through research undertaken for a master's thesis, aiming to help software developers understand in depth how each requirement's implementation affects patient behaviour and commitment to using the software. It utilises principles from Behaviour Change Wheel (BCW) interventions and Octalysis gamification techniques to arrive at a comprehensive set of user requirements and implementation suggestions.

This design methodology is complemented in Section 4 by direct interaction with cardiomyopathy patient organisation representatives in the consortium, who are connected to cardiovascular or specifically cardiomyopathy patients. They discussed the challenges faced by patients in managing their disease and in following their plan of care in between clinic visits. The interviewees proposed areas of information content and interactivity that would be most useful. These are expressed as content requirements, not yet mature enough to be expressed as formal statements.

This deliverable is a companion to SMASH-HCM Deliverable 7.1, which presents functional requirements obtained from clinicians for decision support tools that would assist them in caring for HCM patients.

The software development partners in the project will utilise both deliverables to design digital tools for patient and clinician use, through iterative cycles of consultation with end user representatives, which may therefore evolve the requirements presented here. Their initial response to these requirements is presented in Section 5. The next steps are reported in Section 6.

1 Introduction

SMASH-HCM will develop a human digital-twin-based platform to dramatically improve HCM stratification and disease management, both for clinicians and patients. SMASH-HCM combines clinical research, cardiology, radiology, cell biology, -omics tools, biophysical computational modelling, artificial intelligence (AI) and machine learning (ML), biomedical signal and image processing, clinical decision support system development, innovation management, and social sciences to address unmet clinical and substantial societal and psychological needs. It will deliver digital twin driven deep phenotyping and risk stratification tools to support clinical workflows and decision making with a cost-efficient solution, enabling the development of effective personalised treatment, patient self-management, and preventive interventions based on risk stratification.

SMASH-HCM additionally intends to develop and pilot a SMASH-HCM patient platform, which might be implemented as a portal or an app, to provide:

- personalised guidance on topics such as understanding the disease and understanding the potential effects of various lifestyle options on the progressing of the disease, e.g. exercise and smoking.
- screens through which to collect personally relevant health, lifestyle, quality of life and unmet needs information for the patient's own benefit and which might at times be also shared with their HCM clinical team.

This deliverable presents the patient user requirements for a SMASH-HCM patient platform that HCM patients would find useful. It summarises formal research undertaken as part of a master's thesis on the *design requirements* for a patient platform (delivered as a portal, app etc.). It captures (and elaborates) the views of patient advocates, from organisations connected to cardiovascular or specifically cardiomyopathy patients. These are expressed as *content requirements*, not yet mature enough to be expressed as formal statements. This deliverable is a companion to SMASH-HCM Deliverable 5.1, which presents functional requirements obtained from clinicians for decision support tools that would assist them in caring for HCM patients.

The software developers in the project will utilise both deliverables to design digital tools for patient and clinician use, through iterative cycles of consultation with end user representatives, which may therefore evolve the requirements presented here.

2 Methodology

2.1 Development of the design user requirements

The process started with the creation of user personas, which utilised the information obtained from the "The Voice of the Patient" article about patients' experiences and needs and focused on various health literacy skills [1]. User personas were created with the help of artificial intelligence through a process described in the next section, by feeding it the points highlighted in the article, urging it to consider differences in health literacy, and asking it to create 6 user personas.

Clinicians' views from the three participating clinical partners organisations in Italy, Finland and France were an important part of the user story mapping process. The doctors' experiences and views on patient care and the use of the software helped determine which features and functions the application should contain, and what the user personas' needs and goals could be. Clinicians' ideas were used as a framework for creating user stories.

When analysing user stories, the Behavior Change Wheel (BCW) and the Octalysis framework were integrated into the process. BCW was used to identify users' capabilities, opportunities and motivation in terms of user stories. After the COM-B processing[1], requirements were formed from the grouped stories, which were then tried to be listed in such a way that those whose literacy and reasoning could be thought to have the greatest impact on commitment were highlighted. This (and the veracity of all claims) should be confirmed before starting the development work by conducting a patient survey.

In the end, Octalysis motivation factors were combined with the prepared requirements and clear gamification elements were searched for implementation proposals. Gamification techniques, such as point systems, achievements and visually appealing reports, increase user interest and engagement, which is essential in actively managing their health, they motivate and engage users to continue using the software.

The result is a table containing 19 design user requirements with proposed measures. These could be regarded as the “how” requirements: how the patient platform should function to maximize patient acceptance and use. Using the table and survey, developers can then prioritize activities that are central to meeting user needs and best promote self-care and patient engagement.

The table already helps software developers to understand in depth how the implementation of each requirement may affect the patient's behaviour and commitment to using the software. The table could also be used as a basis for research conducted on patients - go through it one requirement and one service proposal at a time and find out how important the patients feel each requirement/feature is or how meaningful they would find the use of a certain gamification technique.

A final step in this deliverable has been to invite clinician feedback on the personas and the analysis that gave rise to the table of requirements. For transparency this clinical feedback is shown in italics within Chapter 3, as these are not part of the original Master’s thesis.

2.2 Development of the content user requirements

The above design methodology, substantially informed by the literature, was complemented by direct interaction with cardiomyopathy patient organisation representatives in the consortium. The main focus was a virtual engagement meeting on 15 May 2024, at which the project’s objectives and in particular its intentions to develop digital tools for patient use, were presented and discussed. The

[1] The COM-B model of behavour change. Please see https://thedecisionlab.com/reference-guide/organizational-behavior/the-com-b-model-for-behavior-change

interactions considered the challenges faced by patients in managing their disease and in following their plan of care in between clinic visits. In order to enable an open discussion, the participants were not shown the prior work described above, so that their wishes could be captured in a "green field" context. These requirements could be regarded as the "what" requirements: what features the patient platform should contain to meet the patients' needs and expectations.

The overall methodology is shown diagrammatically below.

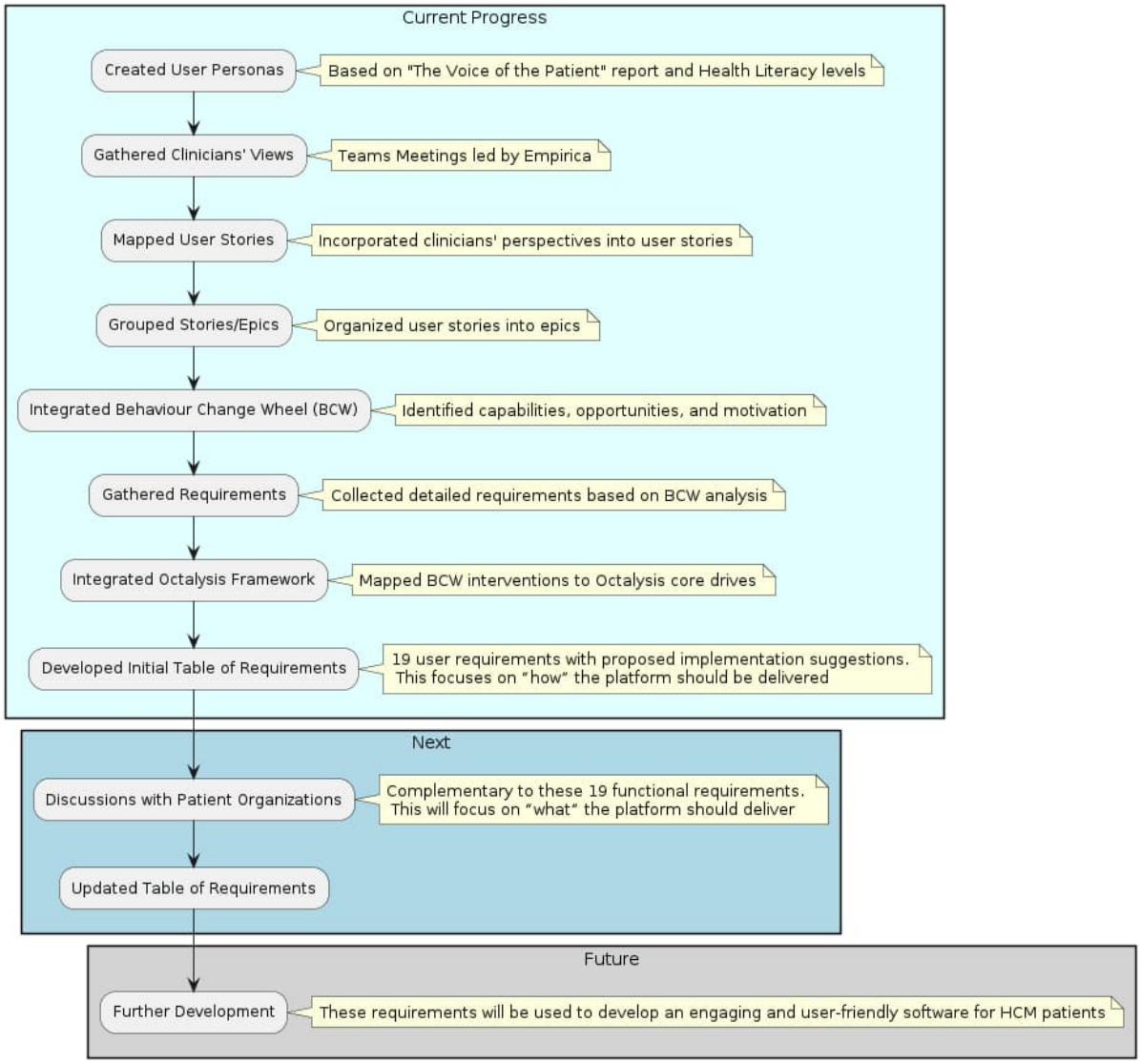

Figure 1: *Diagrammatic representation of the methodology pursued in developing the patient requirements*

3 Design Requirements

SMASH-HCM aims to develop a platform to enable HCM patients to access personally relevant and personally tailored education and guidance on their optimal lifestyle, care pathway, and precautions to reduce their risks of complications from cardiomyopathy. The platform will also enable some extent of data collection, the details of which are still to be determined at the time of writing this document. If this platform (which might be delivered as a web portal, an app, or via some other digital solution) is to be well used by patients, it has to deliver functions they would like to have and to meet their expectations regarding usability and usefulness.

In addition to exploring the SMASH-HCM-specific content wish list from the project's patient representatives, which is detailed in the next section, it has been valuable to capture and consider a more general and scientifically sound set of design requirements. The work to develop these requirements started within the SMASH-HCM project, but became focused more clearly when clinician interviews started. Using their inputs it was possible to go deeper into the literature and to develop the methodology for processing the clinicians' insights, to turn them into user requirements for improving patient engagement.

This section of Deliverable 7.2 reproduces and summarises, with permission, portions of the master's thesis titled as “Integrated requirements engineering for digital health: enhancing self-care in hypertrophic cardiomyopathy management” at the Faculty of Information Technology and Communication Sciences at Tampere University. The primary objective of the thesis was to define the requirements for a software application designed to enhance self-care in hypertrophic cardiomyopathy (HCM) management, with a particular focus on enhancing patient engagement through gamification techniques. By integrating Behaviour Change Wheel (BCW) interventions and Octalysis gamification techniques, the study developed a comprehensive table of user requirements and implementation suggestions. The goal was to create a list of requirements to guide further implementation of an engaging and motivating software that effectively supports patient engagement and self-care, based on literature research, patient insights, and clinician perspectives. For a more detailed exploration of the study and its findings, the full thesis will be published shortly by Tampere University.

3.1 From Clinicians’ Views to a Table of Requirements

The table of requirements created as a result of this research aims to help software developers understand in depth how each requirement's implementation affects patient behaviour and commitment to using the software. It could also serve as a basis for patient research, examining each requirement and service proposal to determine their importance and the perceived value of specific gamification techniques. Using the table and survey results, developers can then prioritise activities that best meet user needs and promote self-care and patient engagement.

The master’s thesis further extends the integration of BCW interventions and Octalysis core drives by providing detailed implementation suggestions. This next step involves creating a comprehensive table that outlines specific gamification techniques based on the identified core drives. These implementation suggestions are designed to go beyond theoretical analysis, offering practical and actionable strategies for enhancing patient engagement and motivation.

The process began with the creation of user personas, utilising information from the "The Voice of the Patient" report [1], which details patients’ experiences and needs, with a focus on various health literacy skills [2]. "The Voice of the Patient" report was produced by Lisa Salberg, Gwen Mayes and James Valentine following an Externally Led Patient-Focused Drug Development (PFDD) meeting

organised by the Hypertrophic Cardiomyopathy Association (HCMA) in June 2020. The meeting aimed to gather insights from patients and caregivers about living with hypertrophic cardiomyopathy (HCM) and managing the disease, discussing the burden of HCM, current treatment options, and future possibilities for better outcomes and needs.

User personas were created using artificial intelligence (AI) – based tools [3] that used points highlighted in the "Voice of the Patient" report and accounted for differences in health literacy. The researcher provided the AI with a summary of the report's key findings, as well as a detailed explanation of the importance of health literacy in this study. The AI was then prompted to develop personas that broadly reflect the demographics, skills and/or needs of HCM patients. The received proposals were checked and evaluated as acceptable by the researcher.

Clinicians' views captured in Deliverable 7.1 [4] were crucial to the user story mapping process [5]. Their experiences and perspectives on patient care and software use helped determine the necessary features and functions for the application and informed the user personas' needs and goals. These insights provided a framework for creating user personas' needs and goals before brainstorming stories.

After analysing and mapping user stories, the Behaviour Change Wheel (BCW) [6] and the Octalysis framework [7] were integrated into the process to gain a comprehensive understanding of users' abilities, opportunities, and motivations, and to identify ways to influence them. This approach not only aimed to recognize preliminary interventions but also focused specifically on using gamification techniques to increase user engagement.

The initial stages of the research focused on understanding these broader principles of engagement and the specific challenges faced by HCM patients. A literature review done during this research highlighted the importance of patient engagement in the effective management of chronic diseases like Hypertrophic Cardiomyopathy (HCM). Studies indicate that tailored interventions and personalised care plans significantly enhance patient adherence and outcomes. The review emphasized the importance of tailored interventions, clinical relevance, user-friendly design, social support, and behaviour change techniques. Insights from the "Voice of the Patient" report and clinician perspectives further supported this approach.It was seen that foundational understanding was necessary before applying a structured framework. The Behaviour Change Wheel (BCW) was introduced after the initial stages of user story development and mapping. The decision to incorporate BCW at this later stage was driven by the availability of extensive research data on patient engagement challenges.

The result is a table containing 19 prioritised user requirements with proposed measures.

3.2 Process

The development of user requirements for the patient-centered software application followed a structured process to ensure comprehensive and user-focused results.

3.2.1 Creation of User Personas

The first step involved creating user personas. These personas were generated by considering the insights obtained from the "The Voice of the Patient" report, which detailed patients' experiences and needs. User personas were created using artificial intelligence (AI) [3] that used points highlighted in the "Voice of the Patient" report and accounted for differences in health literacy. The researcher provided the AI with a summary of the report's key findings, as well as a detailed explanation of the importance of health literacy in this study. The AI was then called upon to develop personas that

broadly reflect the demographics, skills and/or needs of HCM patients. By utilising artificial intelligence the resulting user personas provided, according to the researcher's assessment, a comprehensive understanding of the diverse patient population.

Themes extracted to create user personas:

1. Challenges of daily life

• The report discusses the significant impact of HCM on patients' daily lives, including limitations in physical activity due to symptoms such as shortness of breath, fatigue and chest pain. Specific symptoms and their effects on daily activities are described throughout the document, especially in the sections summarizing the patients' experiences and symptoms.

• Sections "Overall impact of HCM on daily life" and detailed patient testimonials on several pages.

2. Social influence

• Patients expressed challenges in maintaining social activities and relationships. They highlighted how the symptoms and unpredictability of the condition can lead to social isolation and mental health problems such as depression.

• Discussion of social and emotional effects can be found in sections detailing patients' experiences of the illness, particularly when patients describe their social limitations.

3. Adherence to treatment

• The variability and side effects of treatments and the complexity of disease management make adherence to treatment difficult. This includes managing medications, understanding treatment options, and coping with side effects.

• Patients' perspectives on treatments and the challenges of adherence to treatment programs are discussed extensively, especially in connection with current and future treatment options.

4. Family and genetic concerns

• Many patients are concerned about the genetic aspect of HCM and how it affects their family members. This includes the stress of potentially passing the disease on to offspring and the wider family implications of genetic testing.

5. Emotional and psychological burden

• The report highlights the significant emotional and psychological stress associated with living with HCM, including anxiety, depression and the impact on patients' overall quality of life.

• Emotional and psychological effects are discussed throughout patient statements and in sections summarizing the overall burden of the disease.

6. Diverse patient profiles

• HCM affects many individuals of different backgrounds, ages and stages of the disease. This diversity affects how symptoms manifest and how individuals respond to treatment.

• The introduction and sections on participant demographics and experiences highlight the diversity of the patient population.

These themes emerged from the report as the main ways in which HCM affects different aspects of life. These themes provide a picture of the challenges faced by HCM patients and emphasize the need for individual and considerate approaches to care and support.

3.2.2 Clinicians' views

The views of the clinicians have been gathered in Teams Meetings, discussions led by Empirica/Malte von Tottleben and Dipak Kalra. The discussions have had a clear theme and a few leading questions, but mostly the discussion was informal.

It is important to understand that patients' and physicians' priorities often overlap only partially, sometimes not at all. Physicians focus on biological health, safety, long-term survival and efficacy of treatment. Patients focus on daily wellbeing, symptomatic improvement, remaining in the world of the "healthy", active and productive, as well as limiting medicalization and side effects.

A memo has been made of these discussions and a summary has been drawn up.

From this memo, the following points were extracted as the background story for user story mapping:

1. Patient orientation in treatment planning

• It is important to recognize patients' experiences and needs, especially pain and deterioration of quality of life.

• The importance of a patient-oriented approach

• The importance of patient involvement in shared decision-making and identification of treatment goals.

2. Patient follow-up and assessment of treatment effects

• Comparison of side effects and benefits - it is important to evaluate the side effects of treatments in relation to their benefits (for example by avoiding overuse of beta blockers).

• The importance of treatment processes and the use of software is emphasized in identifying patients' needs.

3. The patient's concerns and prospects

• Concerns about heritability of cardiomyopathies are discussed, especially in the context of parenting.

• The importance and support of patient associations as part of the treatment path are highlighted, offering social and emotional support.

4. Clinical challenges and treatment path development targets

• Tools that help to assess the stage of the disease and predict its progression are discussed.

5. Managing the patient's expectations and mental health

• Providing patients with information about their disease and prognosis can help them make informed decisions and manage their mental health.

The summary shows that the digital tools to be developed must be patient-oriented, supporting the monitoring of both quality of life and the physical management of the disease, and integrated into patient associations and support networks, offering comprehensive support to patients at different stages.

3.3 Analysing User Personas, Needs and Goals

User Personas were created first with the assistance of AI, and then the needs and goals of the user personas were formulated by incorporating clinicians' perspectives. The insights from healthcare professionals provided a deeper understanding of the essential features and functions that the application should include to support patients effectively. To achieve this, the researcher adopted the perspective of each user persona, reflecting on their potential needs and goals while considering the clinicians' views. Initially, the needs and goals were explored from the persona-driven perspective, ensuring a user-centred approach. Subsequently, the process was reversed to ensure that all the perspectives and insights provided by the clinicians were thoroughly addressed. This iterative process ensured that the application would meet both the explicit needs of the personas and the critical insights of the healthcare professionals.

1. A 68-year-old retired accountant with hypertrophic cardiomyopathy (HCM). Wants to remain as independent and active as possible despite illness. Has a need to manage daily symptoms and stay in touch with health care providers.

- Health awareness: Moderate
- Symptoms: Experiences increasing fatigue and shortness of breath from even the slightest effort. Worried about the worsening of symptoms and fears that ability to function will decrease.
- Motivation: Wants to understand illness, maintain independence, and actively participate in grandchildren's lives. Highly motivated to maintain independence and control over health but requires simple tools to manage symptoms effectively. Seeks to maintain a social life and interact with peers.
- Challenges: Fear of a sudden worsening of symptoms - need for quick access to medical help.

Needs and goals

- Maintaining independence - values ability to manage daily activities independently. Wants to be able to use tools independently.
- Monitoring and managing symptoms - wants to monitor heart function and symptoms such as shortness of breath and fatigue.
- Informed decision-making - wants to better understand illness and its treatment options.
- Feeling of security - It is important to know that contact to nurse/ doctor is available and help is available in an emergency. Wants to be sure that remembers to take medication.

- Maintaining a social life - wants to participate in social activities without being too limited by the disease. Wants to interact with peers.

2. A 35-year-old journalist with a special interest in the hereditary disease HCM, as it runs widely in family. Wants to gather and share information about HCM to relatives and help them understand the meaning of heredity. In this case, user story mapping focuses on gathering information, sharing, and raising the family's awareness of HCM.

- Health awareness: High
- Symptoms: Mild, but widespread HCM in the family is cause for concern.
- Motivation: *Worries about long-term survival and life span.* Wants to gather and share information about HCM to relatives and help them understand the meaning of heredity. *May wish to spread awareness about HCM and champion the delvelopment of new treatments.*
- Challenges: Finding reliable information and support related to heredity, and motivating relatives to participate in screenings.

Needs and goals

- Gathering and sharing information - wants to be able to gather reliable and up-to-date information about HCM and share this information easily with relatives.
- Understanding heredity - wants to understand how HCM is inherited and how it affects family members so they can make informed decisions about their health.
- Community Support - looking for ways to join or start support groups to help those with HCM and their families.
- Preventive measures and early detection - wants information on how to identify HCM early and what preventive measures are available; *wants to be up to date with ongoing efforts regarding novel treatments and research in HCM.*
- Developing communication tools - needs tools to help him communicate effectively and clearly with a large amount of information.

3. A 22-year-old university student and competitive athlete with newly diagnosed hypertrophic cardiomyopathy (HCM). Main challenges are related to how they can safely continue competitive sports and manage symptoms effectively. Highly motivated to stay competitive but wants to make sure health is not compromised.

- Health awareness: Low
- Symptoms: Newly diagnosed HCM affecting endurance and performance.
- Motivation: Wants to continue competitive sports as safely as possible and manage symptoms effectively, *to avoid social exclusion and reduce the risk of depression*.
- Challenges: Balance the demands of competitive sports and health maintenance and find applications and tools suitable for sports.

Needs and goals

- Safe sports - wants to continue playing competitive sports but needs tools to monitor heart condition in real time during sports performance, *leading to personalised exercise prescriptions*.
- Symptom management - important to recognize and manage risks and cardiac symptoms such as arrhythmias and shortness of breath.
- Personal health tracking - wants to track activity and health with an app that can help understand when it's safe to exercise and when to rest.
- Coaching and counselling - need for reliable information and guidance on how HCM affects sports and how the risks can be minimized.

- Finding community and peer support - appreciates the opportunity to connect with other athletes who suffer from the same illness.

4. A 45-year-old IT consultant who is very health-conscious and wants to actively use technology to manage health. Recently diagnosed with hypertrophic cardiomyopathy (HCM), wants to make sure that has the best tools possible to understand and manage condition.

- Health awareness: Very high
- Symptoms: Experienced cardiac symptoms that require constant monitoring and management.
- Motivation: Wants to actively use technology to manage health and optimize own condition.
- Challenges: Finding apps that provide tailored information and support to fit needs and lifestyle. Anxious about the illness, doesn't want others to know and doesn't see the benefit of peer support.

Needs and goals

- Collection of accurate and detailed health information - wants to collect and analyze extensive information about health *and to interact with highly trained healthcare personnel (as opposed to the majority who may not have specific training and competence)*.
- Information-based decisions - wants to make health-related decisions based on the collected data.
- Real-time monitoring and notifications - important to receive instant notifications about changes in the heart's condition.
- Self-control and independence in treatment - wants to be an active participant in own treatment process.
- Safety and risk management - wants to minimize potential health risks by using proactive tools.

5. A 30-year-old graphic designer who is active in social media and appreciates technology and the opportunities it offers to improve the quality of life. Has recently learned that has hypertrophic cardiomyopathy (HCM) and wants to use digital tools to manage disease, connect with others, and raise awareness about HCM.

- Health awareness: Low
- Symptoms: Often misunderstood heart symptoms, such as fatigue and shortness of breath.
- Motivation: Wants to better understand own health and learn to control symptoms.
- Challenges: Difficulty understanding medical language and treatment instructions, needs easy-to-use and clear tools.

Needs and goals

- Disease management - wants to use the app to track and manage daily symptoms, such as fatigue and shortness of breath.
- Social networking - wants to connect with other HCM patients, share experiences and get support.
- Raising awareness - wants to share information about HCM with a wider audience and promote awareness and understanding of the disease.
- Visual presentation - appreciates visually appealing and easy-to-use digital tools.
- Proactive Health Care - interested in proactive measures that can help minimize disease progression and improve quality of life. Needs clear and easy to understand material.

6. A 50-year-old engineer who is passionate about technology and actively enjoys cycling and other outdoor activities. Has been diagnosed with hypertrophic cardiomyopathy (HCM) and wants to actively use technology to monitor and manage disease, to maintain active lifestyle as safely as possible.

- Health awareness: Moderate
- Symptoms: Moderately severe, including chest pain and arrhythmia.
- Motivation: Wants to stay active and enjoy life despite the HCM diagnosis.
- Challenges: Manage your symptoms while maintaining an active and social lifestyle.

Needs and goals

- Safe activity tracking - likes to track activity to make sure it stays within safe limits for disease.
- Self-monitoring of disease symptoms - wants to identify and manage possible symptoms, such as arrhythmias and shortness of breath, in real time.
- Lifestyle Maintenance - wants to maintain an active lifestyle as much as possible and needs tools to help understand when and how one can safely engage in various activities *and to receive tailored exercise prescriptions*.
- Information sharing with healthcare - appreciates the opportunity to share health information directly with doctors or other healthcare professionals.
- Personalized health advice and instructions - wants to receive personalized instructions and advice based on the health information he collects.

3.3.1 Brainstorming and Theming User Stories

After creating user personas and analysing the needs and goals of each user, user stories were created through brainstorming instead of creating scenarios. This method enabled a more flexible and faster creation of user stories without the need for detailed and time-consuming scenario development. A leaner approach is justified in this initial requirement gathering phase, as it effectively utilises available information to form a clear picture of user needs and goals.

Although a deeper scenario-based approach could provide more comprehensive insights into complex user situations, the chosen method ensures that at least all the most relevant perspectives are considered. This approach has been seen to be sufficient at this point because the goal has been to create a preliminary list of requirements, which can then be used as a basis for a more detailed definition of requirements involving the users. After user stories were created, the stories were grouped according to how they seemed related to each other or emphasized the fulfilment of a similar need or goal, and five themes were established. Actual user stories are listed in the master's thesis – The list below is a collection of so-called core words extracted from "as a user… stories".

Monitoring and alerts

Heart rate monitoring

Safe activity tracking

Medication reminders

Heart function monitoring

Alarm function

Real-time heart monitoring

Real-time symptom tracking

Alerts and notifications

- Symptom recording and analysis
- Comprehensive health data collection

Social networking and support groups
- Social support network
- Finding and creating support groups
- Peer support network for athletes
- Community and peer support

Sharing information and raising awareness
- Facilitation of information sharing *with peers and healthcare professionals*
- Disease and treatment knowledge base
- Access to reliable, *understandable and relevant (filtered)* information
- Integration with other health applications
- Social media integration
- Data analysis and reporting
- Health data sharing
- Visualizing heredity

Anticipatory health care and personalized advice
- Activity tracking
- Personalized health advice
- Early detection tools
- Health report and activity analysis
- Risk management and anticipation
- Symptom tracking and self-care
- Risk assessment tool
- Symptom diary
- Proactive health monitoring
- Safe sports and activities
- Independent decision-making
- Guidance for safe sports

Ease of use and user experience
- Visually appealing reports
- User-friendly interface
- Ease of use and clarity of the interface

3.4 Analysing User Stories with COM-B Factors and Requirements Gathering

3.4.1 Identifying BCW Interventions and Integrating Octalysis Core Drives

In this research, the Behaviour Change Wheel (BCW) was introduced after the initial stages of user story development and mapping. The decision to incorporate BCW at this later stage was driven by the availability of extensive research data on patient engagement challenges. Literature reviews done during this research highlights the importance of patient engagement in the effective management of chronic diseases like Hypertrophic Cardiomyopathy (HCM). Studies indicate that tailored interventions and personalised care plans significantly enhance patient adherence and outcomes. The initial stages of the research focused on understanding these broader principles of engagement and the specific challenges faced by HCM patients. It was seen that foundational understanding was necessary before applying a structured framework like BCW.

BCW helped identify users' capabilities, opportunities, and motivation in terms of themed user stories. The themed groups were analysed in detail using BCW interventions and Theoretical Domains Framework (TDF) areas (as a part of BCW). This step was essential to identify the most significant elements within each group that could be translated into user requirements. Each group was analysed for users' capabilities, opportunities, and motivations, with BCW providing a structured approach to explore these factors in terms of user skills and knowledge, environmental context and resources, and reinforcement and goal setting. Based on the BCW and TDF analysis, appropriate BCW interventions were identified for each group. These interventions included:

- Education and Training: To enhance user knowledge and skills.
- Enablement and Environmental Restructuring: To create supportive environments and resources.
- Persuasion and Incentivization: To motivate and encourage desired behaviours.

These interventions aimed to support behaviour change and enhance the user experience.

The final step involved combining BCW interventions with Octalysis [7] motivators to develop specific implementation suggestions for each user requirement. Octalysis, developed by Yu-kai Chou, is a framework for gamification that categorizes the core drives of human motivation into actionable strategies. Chou's method is further detailed in his work "Actionable Gamification", which provides concrete game techniques and design principles to effectively motivate and engage users. Octalysis identifies eight core drives of motivation, which are:

- Epic Meaning & Calling: Users are motivated because they believe they are part of something bigger than themselves.
- Development & Accomplishment: Users are driven by a sense of progress, achievement, and mastery.
- Empowerment of Creativity & Feedback: Users are engaged when they can be creative and receive feedback.
- Ownership & Possession: Users feel motivated when they own something or feel ownership over their actions.
- Social Influence & Relatedness: Users are influenced by social factors and relationships.
- Scarcity & Impatience: Users are driven by the desire to obtain something that is scarce or exclusive.
- Unpredictability & Curiosity: Users are motivated by the element of surprise and curiosity.
- Loss & Avoidance: Users are motivated to avoid negative outcomes.

Mapping to Octalysis Motivators: Each requirement's intervention was then mapped to one or more of the Octalysis core drives. This mapping ensured that the interventions were not only practical but also engaging and motivating for the users. For example:

- Education and Training interventions were linked with Development & Accomplishment to ensure users felt progress and achievement.
- Environmental Restructuring interventions were associated with Ownership & Possession to give users a sense of control.

User Requirement	BCW Intervention	Octalysis Motivator	Justification
Monitoring and alerts			
Interactive Educational Modules	Education and training	Development and Accomplishment	Enhances users' confidence and understanding of heart monitoring
Immediate Connection Feature	Enablement and environmental restructuring	Epic Meaning & Calling	Ensures rapid response in emergencies, enhancing safety
Real-time feedback	Persuasion and incentivization	Empowerment of Creativity & Feedback	Engages users through interactive challenges and progress tracking
Social networking and support groups			
Social Networking Guides	Education and training	Social Influence & Relatedness	Helps users effectively use and benefit from the platform's networking capabilities
User-Friendly Community Platform	Environmental restructuring and enablement	Social Influence & Relatedness	Provides an easy entry for discussions and support groups, enhancing social engagement
Recognitions and Community Events	Incentivization and coercion	Social Influence, Unpredictability & Curiosity	Strengthens community belonging and encourages mutual support, stimulates participation through events and recognitions that bring novelty and surprise
Sharing information and raising awareness			

Educational Materials and Resources	Education and persuasion	Development and Accomplishment	Helps users effectively develop their knowledge and skills, empowering users to manage their health
Easy Access to Information Repository	Environmental restructuring and enablement	Scarcity & Impatience	Gives users direct access to up-to-date and relevant information
Integration with Other Services	Environmental restructuring and enablement	Ownership & Possession	Encourages users to centrally manage their health information
Reward System for Sharing Information	Incentivization and persuasion	Development and Accomplishment	Motivates active participation and information sharing, increasing engagement and a sense of achievement
Personalized Reports	Education and persuasion	Development and Accomplishment	Provides concrete evidence of health progress, empowers users to track their health progress accurately
Anticipatory health care and personalized advice			
Educational Materials for Gathering Health Information	Education	Epic Meaning & Calling	Enables better understanding of health information – sense of control
Intuitive Tools like Symptom Diaries	Enablement	Empowerment of Creativity & Feedback	Facilitates easy recording and tracking of health information - tailored user experience
Personal Health Reports and Risk Analysis	Enablement	Development and Accomplishment	Helps users understand their personal health information - a sense of control over health
Training for Proactive Health Care	Training	Epic Meaning & Calling	Increases users' knowledge and skills to proactively manage health, giving a sense of purpose
Community and Peer Support in Healthcare	Incentivization	Social Influence & Relatedness	Increases peer support and community feeling

Ease of use and user experience			
Clear Instructions and Tutorial Videos	Education	Development and Accomplishment	Ensures users can easily understand how to use the application, improving user competence
Accessibility and Usability	Environmental restructuring	Ownership & Possession	Ensures the software is usable on all devices by all users, increasing personal attachment
Visually Attractive Reports	None	None	The appealing visual appearance increases willingness to use

3.4.2 Defining Actions and Goals

Specific activities were then defined based on the Octalysis analysis. These activities included for example developing interactive learning materials, building user-friendly platforms, incorporating gamification elements, and providing personal reports. The goals focused on enhancing the skills, opportunities, and motivation of users by leveraging the identified core drives. By mapping BCW interventions to Octalysis core drives, the research ensured that the application would not only address the functional needs of HCM patients but also engage and motivate them effectively. This approach helped in creating a balanced and holistic application that could support patients in their self-care journey.

3.5 Outcome

The process resulted in identifying 19 user requirements. These requirements are designed to guide software developers in creating a patient-centred application that enhances user engagement and supports self-care through gamification techniques, based on both BCW and Octalysis analyses.

Req No	User Requirement	Implementation Suggestion
1	*Personalized Reports	Develop a dashboard that automatically customizes, and updates based on user data.
2	Reward System for Sharing Information	Implement a system that randomly surprises users with unexpected rewards to enhance engagement.
3	Real-Time Feedback	Develop features that provide immediate feedback on users' health activities, such as instant alerts or immediate updates.
4	Interactive Educational Modules	Utilize interactive modules with real-time feedback to improve learning and retention.
5	Intuitive Tools	Develop user-friendly tools that are easy to navigate and provide immediate, actionable insights into users' health status.
6	Training for Proactive Health Care	Offer certificates and bonuses for completing training modules to motivate further learning.

7	Community and Peer Support in Healthcare	Use social features like group quests to foster community bonding and support.
8	User-Friendly Community Platform	Develop a platform that allows easy access to discussions and support groups.
9	Accessibility and Usability	Create tutorial levels that guide users through app features, catering to all skill levels.
10	Clear Instructions and Tutorial Videos	Use a skill tree approach for tutorial videos to let users choose their learning path.
11	Recognitions and Community Events	Implement leaderboards and achievement galleries to showcase and motivate users.
12	Integration with Other Services	Use power-ups as rewards for linking the app with other services, enhancing features or content.
13	Social Networking Guides	Incorporate role-playing elements to guide new users, enhancing social interactions.
14	Visually Attractive Reports	Design interactive visuals that users can explore to uncover health insights in an engaging manner.
15	Educational Materials and Resources	Include mini games related to health topics that provide educational content in an interactive format.
16	Easy Access to Information Repository	Implement a quest finder to recommend articles and resources based on user behavior and goals.
17	*Adjustable Personal Health Reports	Enable configuraton to allow users to personalize their health reports with themes that reflect their progress.
18	Educational Materials for Gathering Health Information	Offer challenge levels that users unlock by completing tasks, increasing structured learning.
19	Immediate Connection Feature	Integrate an SOS button that is easily accessible.

*Req 1 and Req 17: Personalised Reports aim to educate and persuade users to stay engaged by showing immediate progress, while Personal Health Reports focus on enabling users to take control of their health with detailed, actionable insights and personalized visual enhancements.

The table of requirements aims to support developers of patient portal/app/software in several ways. It guides development focus, helps to understand user needs leading to the creation of relevant and beneficial features that are designed to effectively engage and motivate users, making the application enjoyable and rewarding.

The table offers a structured roadmap by breaking down user requirements into specific implementation suggestions, aiding in systematic planning and execution of development tasks. The suggestions provide a foundation for initial development, which can be refined based on user feedback and testing, continuously enhancing the application to better meet user needs.

In summary, the table bridges the gap between user requirements and practical development strategies, ensuring the healthcare software application is both functional and engaging.

The Master's thesis extends this by providing detailed implementation suggestions, creating a comprehensive table outlining specific gamification techniques based on Octalysis core drives. For instance, personalized reports may use "Progress Bars" and "Visual Storytelling" to enhance the Development & Accomplishment drive, while community support features might incorporate "Social Treasures" and "Group Quests" to boost Social Influence & Relatedness. Integrating these specific gamification techniques could ensure that the application is effective in meeting patient needs and motivates continuous use, enhancing self-care engagement.

These 19 functional requirements provide insight into the design features that the SMASH-HCM patient platform developers should endeavour to incorporate. It could be seen as presenting "how" the platform should deliver the desirable HCM patient support functions in order to optimise its overall usability and usefulness – including maximising retention of use by patients over time. The next section of this deliverable is complementary to these 19 functional requirements. It focuses on "what" the platform should deliver: the HCM-specific desirable content that patients would like in the platform.

The developers of the SMASH-HCM platform will need to interweave both of these sets of requirements, the "how" and the "what", balancing also what will be realistic to implement and pilot test within the resources and time frame of the project. Their initial response to the requirements in this deliverable is presented in Section 5.

3.6 References

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[4] Clinicians' views

Gathered in Teams meetings during the development of SMASH-HCM deliverable 7.1

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Patton, Jeff 2014: User story mapping: discover the whole story, build the right product.

[6] Behaviour Change Wheel

Michie, Susan and Atkins. Lou and West, Robert 2016: The Behaviour Change Wheel: a guide to designing interventions.

[7] Octalysis framework

Chou, Yu-kai 2019; Actionable Gamification.

4 Functional Requirements

Unlike the clinical functional requirements presented in Deliverable 7.1, for which the use cases for decision support are relatively clear, the main functions requested for the patient platform are topics about which patients wish to collect data primarily for their own benefit and use, and to have access to HCM educational resources and personalised care pathway and lifestyle guidance. These do not involve the use of computerised decisions support.

These areas are described below. Further work with patient representatives in the coming months will include developing the data elements and screen layouts that patient would like their platform to contain.

4.1 Data that patients would like to collect

These are the categories of data that patients would like to collect for their own use, and optionally to share with their clinicians.

- Risk factors: The collection of the status of risk factors for HCM, including monitoring their occurrence and quantity, such as smoking status and average quantity per day, alcohol consumption, the new occurrence within the family of an HCM diagnosis or HCM event such as arrhythmia, is considered valuable by clinicians and patients. The app needs to provide a screen where this information can be regularly updated, on a frequency determined by the patient.
- Presence of other diseases and continuous and temporary medication: a summary of the broader list of health conditions that the patient has, the regular medication across all of their health issues and a place to record short-term treatments including over-the-counter purchased treatments that the patient wishes to keep a record of.
- Exercise activity: a daily or weekly tracking screen through which a sporting or very active patient could monitor their activities: the nature, duration, and intensity (e.g., running 10km over 2 hours). This needs to balance the need for detailed information, which is best captured daily, and the pragmatic issues of the burden of using an app every day which patients may resent.
- Other lifestyle: The routine collection of certain HCM-influencing lifestyle factors not part of the above risk factors or exercise activity, such as diet. A patient and clinician could discuss and agree which lifestyle elements are most relevant to their individual care and decision-making, so as to focus attention on the important data that a patient might find valuable to track.
- Career planning: influences on and decisions the patient wishes to action regarding any change in career that may be necessary as a result of the new diagnosis of HCM, or any change in the health status such as the development of new symptoms or functional limitations.
- Disease progression: A diary of symptoms or other HCM related events, preferably encouraging regular (e.g. daily, weekly) recording of status rather than only capturing the occurrence of new health incidents, incorporating checklists to also prompt the recording of negative findings (things not experienced), and offering graphical displays of trends over time.
- Health (disease related) outcomes: Tracking the status of selected health outcome measures, discussed between the patient and their HCM clinician as being most relevant, captured using easy to use screen widgets and presented back as trends over time: possibly also including trigger thresholds when a patient should make direct contact with their clinical team because an outcome metric has become concerning.
- Wellness and lifestyle goals and desired outcomes: Tracking a patient's capability and comfort in achieving or maintaining levels of wellness and lifestyle in areas agreed upon by the patient

and clinician as the goals of treatment, or as satisfactory levels to defer treatment (e.g., we will only start treatment or perform a procedure if your wellness falls below an agreed level).

- Quality of life: This section refers to any additional aspects of life that are not directly related to assessing health or wellness, and aims to capture any negative impacts on the ability to fulfil a person's life expectations, possibly covering relationships, social life, work, driving, social activities, travelling abroad, etc. This section might not require regular monitoring or data entry but serves as a record of a person's life aspirations that are shared with the clinician and discussed when relevant, particularly if any of these are being prevented or impaired by the condition. Some assessment scores and scales, which might be useful to consult, have been published by Cardiomyopathies Matter and the Global Heart Hub.
- Mental health and wellbeing: possibly highlighting healthcare needs: this is an important area, potentially overlapping with wellness and with quality of life, but separated and highlighted here because of its importance and because this area is often overlooked when the patient-clinician focus is on physical health issues. This section might include a specified mental health questionnaire (e.g. SF-12) completed periodically by a patient (e.g. every 6-12 months), and/or specific monitoring items agreed between the patient and clinician.
- Communication (special) needs: This section might be used to list any special needs (e.g., if a patient is neurodiverse or is not proficient in the national language and may need translation help), mostly as a reminder for care team members to take into account. It might not need frequent updating.
- Support network: This section lists non-professional carers who support the patient, such as family, neighbours, and case workers, along with their contact details. It also indicates any logistical needs, such as transportation or accessibility issues. This section might also be used to highlight if the patient is quite isolated, although this might also be documented under mental health and wellbeing.

4.2 Monitoring data

This section describes the monitoring information that clinicians would find valuable and that could be collected by patients by entering data into a platform or using wearable technology.

SMASH-HCM is not issuing patients with wearable technologies as part of its planned pilots. However, it is possible that some of the patients will use wearable monitoring technologies because these have been advocated by their clinicians. This section is therefore a candidate area for inclusion in the patient platform, for further consideration.

When discussing patient monitoring with clinicians, the following wearable technologies have been highlighted as able to capture data on a frequent basis that enables them to make good decisions about the risks of arrhythmia or other complications such as high blood pressure, and to help determine when it is appropriate to intervene and when it is appropriate not to put the patient through an invasive process that might not be required. It is not expected that every patient with HCM or at risk of HCM would need to undertake these areas of monitoring, but rather they would be recommended by a clinician because of the need for accurate data for certain decision-making or risk monitoring purposes.

- Heart rate and rhythm e.g. via a smart watch
- Smart watch ECG recording
- Blood pressure monitoring at home

For each of these three areas, there are recognised devices that measure data to a high quality and can be relied upon clinically. Each clinically issued device will have a method for making its data available to the clinical team. SMASH-HCM will need to explore further with the clinicians and patients

if it is appropriate to access and provide in the patient platform a view of this data, so patients also have a view of the state of their cardiac rhythm or blood pressure.

It will be a research question for the data analysis and decision support development experts in the consortium to determine if they could develop screening algorithms that would monitor incoming data streams to a clinical system from these devices, and highlight changes (either acute changes, or trends) that should warrant clinician review in the scope of this project. This is possibly essential in order to minimise clinician overload to need to monitor multiple patient complex data streams on a daily basis.

4.3 The provision of tailored lifestyle advice and education

Patient specific education and guidance could be provided in order to support:

- improved quality of life
- activities to reduce the risk of of co-morbidities and cardiovascular complications (staying active, controlling weight, not smoking etc.)
- avoidance of factors worsening obstruciton and HCM-related symptoms: weight control, hydration avoidance of vasodilators, avoidance of vigorous activities in the heat or after heavy meals, moderation in alcohol consumption.

This section refers to advice that has been personalised by the clinician. It is not intended in SMASH-HCM for this personalisation to occur in an automated way through decision support.

It was considered by the patient representatives to be helpful that they should have access to advice and education that is to some extent personalised to their health, disease, risk and lifestyle context. It may be premature to imagine that this personal guidance could be algorithmically managed, offering real time guidance to patients. It is likely that the underlying knowledge and data is insufficient to develop such algorithms. However, patients would value having access to (static) guiding information and links to educational resources that are considered relevant to their situation and needs. This might be handled through a clinician tool that contains a portfolio of self-management guidance and links to educational resources that a clinician could select from and push to that patient's platform in order to offer to the patient a personalised subset of the most relevant resources. This selection tool is specified in Deliverable 7.1.

4.4 A summary of the patient's personalised care plan

Since SMASH-HCM is hoping to use its clinician facing tools to support the customisation of care plans to maximise their relevance to individual patients (personalised care plans), the patients felt it would be valuable for them to have access to a copy of this care plan – as a personal *aide memoire* - so that they know the current plan and what might be the future options should they experience a change in their health situation. This could be a simple visualisation, such as a flowchart, and does not need to be interactive. If clinicians have access to a tool that allows them to define a personalised care plan, this could simply be implemented as a graphical export from that tool, that is incorporated into the patient app.

4.5 Support with taking medicines

Possible functions to support HCM patients with any medicines they are taking could inlcuded alarms to remember taking drugs, the possibility of checking for interaction with other medications, and a diary for side effects or for tracking improvements.

4.6 A display of risk scores

Patients would like to be able to see the risk scores that clinicians use, and trends in their values over time.

The HCM clinician experts have made clear that they use a number of guidelines and other checklist and scoring systems to help them to stratify patients into risk categories, and to make proportionate decisions about when to intervene, especially in patients who are asymptomatic but might have risks of arrhythmia or future deteriorations, and when they should monitor without intervention. Some patients felt that they would like to be able to see their own personalised scoring, not necessarily in order to challenge the decision but in order to feel an informed partner in those decisions. It is suggested that a section should be included in the platform that can provide a simple visualisation of the scoring systems that have been used in that particular patient, so they can see how the clinical thinking is being quantified through these scores. However, this information should only be given electronically to the patient if they wish to see it: some will be interested and some will find it too scary. Also, the concept of risk is hard to grasp for patients. Clinicians sometimes define high risk e.g. for sudden death as being less than 1% per year… which is fact is "relatively" high but low in absolute terms. This format of the information is hard for patients to handle.

4.7 Providing a visualisation of the patient's "human digital twin"

SMASH-HCM has introduced the concept of a human digital twin although at this stage it is rather loosely defined. As the project progresses to formalise what is a realistic set of digital metrics and projections that are person specific, to guide clinical understanding of the patient and to guide decision-making, patient would like to see what this looks like. The developers of the human digital twin concept in the project need to consider not only a clinician friendly way of understanding the digital twin, but also a patient friendly way of understanding it. At this stage it is premature to include these as functional requirements of any app, but as a stakeholder requirement that the digital twin innovators need to take on board.

4.8 A link to information pages

Patient organisations have a number of resources, not necessarily a huge number because of their budget limitations, but nevertheless developed with the patient or the family at the centre of their attention, that patients might find useful. The patient representatives in the meeting made clear that it would be useful if they could have a space within the platform where they could include pointers to their website (e.g. home page) and links to specific resources that might be useful for patients, in their own language and created by their own national HCM patient organisation. SMASH-HCM should plan for the development of such a resources page in collaboration with the patient organisations in the countries in which the project has pilots.

4.9 A method of communicating to the patient's clinician

The patient organisations indicated that individual patients would very much like the ability to use the platform to communicate with their clinical team members, especially with their consultant HCM cardiologist, to raise questions, highlight events or deteriorations that had occurred, and seek advice. We should document this as a wish from patients, but recognise that the provision of a two-way channel of communication through an app developed by our research project might not be endorsed by the healthcare provider organisations or by the professional associations guiding the clinicians. A simple option is for the patient to be able to use the app to compose a message or information that they would like to discuss with their clinician, which they can keep a record of through the app but communicate verbally when they meet their clinician at the next clinic visit. This is in effect a kind of memo to be stored through the app and used by the patient as a reminder of the points they want to raise when they next see their clinician. This could be a useful function even if it does not deliver the real two-way communication capability patients would ideally like. Sometimes patients forget to ask questions when they see the clinician. Of they might send an excessive number SMS or WhatsApp

messages which is not appropriate and leads to poor quality communication. This proposal might be a reasonable compromise.

4.10 General requirements

It should be possible for a patient to provide access to their clinical team to some or all of the information they have collected through SMASH-HCM platform, in case the patient has made observations or observed trends that they would like to discuss during a clinic visit. If a patient is undergoing regular monitoring, perhaps through a wearable device issued by the clinician, it may also be appropriate that clinicians have access to this ongoing monitoring information in near to real time (at least on a daily basis) so that they can detect any issues with a given patient that warrant bringing the appointment forward or telephoning the patient to discuss how best to handle a new cardiomyopathy issue or a deterioration. For this to be practical and scalable, an AI driven surveillance system will be needed for the incoming data streams that is able to direct to physicians in real time only to the really urgent or important situations.

There are inevitably non-functional requirements to take on board as well, to do with the accurate identification of patients, their authentication within the app and information security measures when any information is communicated from the app to the clinical environment.

5 Initial response from the SMASH-HCM decision support developers

In this section developers indicate their initial reactions to the patient wish lists, in terms of what may be in scope (time, resources, relevance) and areas of further detail they would need in order to design and implement a SMASH-HCM patient platform.

To implement a system that satisfies the user requirements specified in the table in Section 3.5, we will formalise both functional and non-functional requirements and select an appropriate technology stack for development, testing, and backend hosting. The system will ensure data security, scalability, and usability. The system will incorporate features such as personalised dashboards, reward systems, real-time feedback, and interactive personalised educational modules. It will be configurable by the user, allowing both patients and healthcare professionals to select the features most appropriate for each patient. We will adopt a hybrid methodology, incorporating elements of agile with regular sprints and user feedback loops, as well as elements of waterfall for user testing, early-stage clinical trial piloting, and preparations for larger-scale validations. Because the intended use may include both clinical decision support of healthcare professionals and supported self-management of HCM patients, the system is likely to be subject to the Medical Device Regulation. To facilitate future adoption, we will closely adhere to the general safety and performance requirements of the Medical Device Regulation during development.

We will continuously monitor the system's performance in terms of usability, user engagement, and the efficacy of stratification and recommendation models/algorithms. We will implement an auditing process for the AI and machine learning models/algorithms that generate personalised alerts and recommend personalised interventions to ensure that predictions align with the latest clinical evidence. To maximise patient uptake, we will combine passive data collection with active learning where possible, minimising the frequency and volume of data entry required from patients without compromising prediction and recommendation quality. To enhance uptake by healthcare professionals, we will consider integrating the app's outputs and visualization dashboards within locally implemented IT systems using interoperable open application programming interfaces. Table 1 provides initial estimates of the resource requirements, as well as relevance to end-users and level of detail required for each specified feature of the decision support system. These initial estimates are likely to evolve over time.

Table 1 Initial estimate of time, resource, and relevance of the patient-facing features of the decision support system.

N	User Requirement	Implementation Suggestion
1	Personalised Reports	Time: long term, likely to evolve throughout the development. Resources: AI/ML specialists, HCPs, UX/UI designers, software developers. Relevance: high – patients benefit from tailored insights and personalized self-management interventions. Level of detail: high – customization, updates, adherence to clinical evidence are essential.
2	Reward System for Sharing Information	Time: medium term. Resources: PPIE experts, gamification experts, psychologists, software developers. Relevance: medium to high – enhances engagement of users interested in games. Level of detail: medium – need to clarify reward policies for different strata of users.

3	Real-Time Feedback	Time: long term. Resources: software developers, HCPs, interoperability experts. Relevance: high – immediate feedback can significantly improve user outcomes; however, to be practical, the feature may need to integrate with a plurality of health IT systems. Level of detail: high – need to define accurate, timely, and interoperable feedback mechanisms interfaced to legacy systems for clinical adoption.
4	Interactive Educational Modules	Time: medium to long term. Resources: educational content creators, HCPs, PPIE experts, software developers. Relevance: medium to high – Improves learning and retention for patients interested in self-education. Level of detail: high – need for engaging interactive materials consistent with the constantly evolving clinical evidence.
5	Intuitive Tools	Time: long term. Resources: UX/UI designers, software developers, AI/ML experts. Relevance: high – ease of use is critical for user adoption. Level of detail: High – need for minimizing effort for data collection (for example, through adoption of passive data collection and active learning aimed at minimizing data submission requests); intuitive navigation of every component of the system; actionable insights helping to move from predictions to personalized interventions.
6	Training for Proactive Health Care	Time: medium to long term. Resources: educational content creators, software developers, PPIE experts. Relevance: medium – motivates a subset of users interested in gamification to learn and improve. Level of detail: medium – defining bonuses and certificates.
7	Community and Peer Support in Healthcare	Time: medium to long term. Resources: social network developers, software developers, PPIE experts, social/community care providers. Relevance: medium to high – community support can enhance user experience for patients engaging with community support services and social network support groups. Level of detail: high – need for proactive involvement of community care providers and "patient champions" to enable the development of engaging social features.
8	User-Friendly Community Platform	Time: medium term. Resources: UX/UI designers, software developers. Relevance: medium to high – easy access to community / peer resources is crucial for patients engaging in social network support groups. Level of detail: medium to high – need for development and moderation of clear, accessible, and trustworthy discussion forums.
9	Accessibility and Usability	Time: medium term. Resources: UX/UI designers, accessibility experts, software developers. Relevance: high – accessibility of both the system and tutorial materials is vital for health equity and inclusivity. Level of detail: high – need for accessible features and tutorials aimed at diverse patient groups.
10	Clear Instructions and Tutorial Videos	Time: medium term. Resources: software developers, content creators. Relevance: high – every user should be able to understand and use the system effectively. Level of detail: high – need for detailed, structured, and configurable tutorial paths relevant to every patient.
11	Recognitions and Community Events	Time: medium term. Resources: software developers, PPIE experts. Relevance: medium – recognition in leaderboards can

		motivate a subset of users interested in gamification. Level of detail: medium – need to define intuitive leaderboards and engaging galleries.
12	Integration with Other Services	Time: long term. Resources: API developers, interoperability or integration experts. Relevance: high – enhances functionality and user experience; increases adoption by healthcare providers through integration with health IT systems. Level of detail: high – need for effective integration mechanisms, including possible integration with legacy health IT systems for clinical adoption and feedback.
13	Social Networking Guides	Time: medium term. Resources: social interaction experts, software developers. Relevance: low to medium – role-playing may enhance interactions for a subset of users interested in gaming and involved in thematic social network groups. Level of detail: medium – need for engaging role-playing elements.
14	Visually Attractive Reports	Time: medium to long term. Resources: UX/UI experts, data visualization experts, software developers. Relevance: high – engaging visuals improve user engagement. Level of detail: high – need to develop interactive and informative visuals.
15	Educational Materials and Resources	Time: medium term. Resources: Content creators, game developers. Relevance: medium – interactive educational mini-games may be effective for users interested in games. Level of detail: high – need for engaging mini-games.
16	Easy Access to Information Repository	Time: medium to long term. Resources: AI/ML experts, software developers. Relevance: high – helps to ensure that recommendations adhere to medial evidence, and helps users engaged in self-education find relevant trustworthy information. Level of detail: high– need for effective, trustworthy, and constantly growing knowledge base linked to the prediction and recommendation features.
17	Adjustable Personalized Health Reports	Time: medium term. Resources: AI/ML experts, software developers. Relevance: high – personalization and sparsity (without detriment to quality of recommendations) is key to user engagement. Level of detail: medium to high – customizable themes, elements of AI-powered ranking to focus attention on the most informative aspects.
18	Educational Materials for Gathering Health Information	Time: medium to long term. Resources: educational content creators, gamification experts, software developers. Relevance: medium to high – structured learning based on personalised tasks may be effective for users engaged in self-education and gamification. Level of detail: medium – need for personalized challenge levels relevant to patients and motivated by clinical evidence.
19	Immediate Connection Feature	Time: medium term. Resources: HCPs, software developers, integration or interoperability experts. Relevance: high – having a human in the loop is essential for patient safety. Level of detail: high – easy-to-use SOS button interfaced to HCPs via health IT systems or direct contact for rapid clinical response.

Throughout the development of the decision support system, our aim will be to create a robust platform that provides personalised health insights, engages users, and supports their health goals safely, effectively, and cost-efficiently.

6 Conclusion and next steps

This deliverable has presented the requirements for designing a platform for use by patients with HCM that can support them with better understanding, monitoring and managing their condition, including lifestyle choices that could make to optimise their health and minimise the risks of developing a complication from HCM.

Although the focus of this work was originally targeted at identifying areas of patient self-care for which decision support (personalised guidance) solutions may be useful, the feedback from patients and patient representatives during the meeting was that we should aim primarily to produce an informative platform which would really be consulted regularly by patients and into which they would be willing to enter data. This would need to offer some other areas of care support and information, not only to focus on aspects of self-care needing decision support. It has emerged from their feedback that the perceived role of decision support (the original intention) is rather limited.

The resulting requirements are divided into design requirements that will help to ensure that the platform is usable and engaging to use, to promote adoption and adherence, and content requirements that explain the areas of information, ideally personalised, that patients are expected to find useful: about their condition, their care plan, risks, lifestyle recommendations and links to external resources.

It is recognised that these might not all be capable of implementation within the resources and time available in the project. The first response from the development teams has been included in the previous section. This is the initial phase of an iterative and interactive process that will continue during the project. This deliverable will therefore be updated as the patient platform is designed and implemented.