D9.2 – ARTEMIs VALUE PROPOSITION FOR THE DIFFERENT TARGET GROUPS, LEARNT FROM INTERVIEWS AND QUESTIONNAIRES

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Disclaimer

The opinions stated in this report reflect the opinion of the authors and not the opinion of the European Commission.

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INTRODUCTION

The global objective of ARTEMIs Project is the development and the Proof of Concept evaluation of a clinical decision support system (CDSS) for the management of metabolic dysfunction-associated steatotic liver disease (MASLD).

By delivering the CDSS, ARTEMIs is expected to produce outcomes that will make significant and meaningful contributions to the work of healthcare professionals, and to the lives of patients and other target groups. Specifically:

1. Clinicians and other healthcare professionals with the required qualifications will have access to computational models of individual patients for delivering optimised and cost-effective management strategies superior to the current standard of care.
2. Healthcare professionals will benefit from enhanced knowledge of complex disease onset and progression by recourse to validated models.
3. Clinicians and patients will benefit from new, improved personalised diagnostics, medicinal products, devices, and therapeutic strategies tailored to the individual patient pathophysiology.
4. Citizens and patients will have access to validated 'virtual twin' models enabling the integration of citizen-generated data with medical and other longitudinal health data, and benefit from early detection of disease onset, prediction of disease progression and treatment options, and effective disease management.

Although the results will not reach the market within the project duration, their acceptance will largely depend on the current consortium's capacity to identify all the relevant stakeholders and learn the key features that the ARTEMIS CDSS should have to relieve their pains and satisfy their expectations.

This deliverable lays the foundations of the project *Exploitation Plan,* as described in D9.1. It reports the process and results of 3 activity blocks:

1. **Preliminary stakeholder characterization.** Definition of the expectations that the project initially attributed to the target groups.
2. **Learning from stakeholder groups**, external to the project consortium, about their needs and expectations.
3. **Co-creation of the value proposition** for the main project result, the CDSS, through the identification and prioritization of the product features.

To conclude this report, the conclusions and the future works are summarised in sections 4 and 5 respectively.

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1 PRELIMINARY STAKEHOLDER CHARACTERIZATION

1.1 Identification

The deliverable D9.1 identified and mapped the stakeholders (see figure). It also advanced a summary of the expected features of the CDSS in terms of the 4 use cases that it will be able to perform.

In this section of D9.2, the objective is to provide more details about how each stakeholder group is expected to get value from the CDSS, i.e., use it or benefit from it.

The description given in the next section for each stakeholder group is based on the knowledge of the project team and serves as the initial hypothesis that will be validated through questionnaires and interviews in subsequent sections.

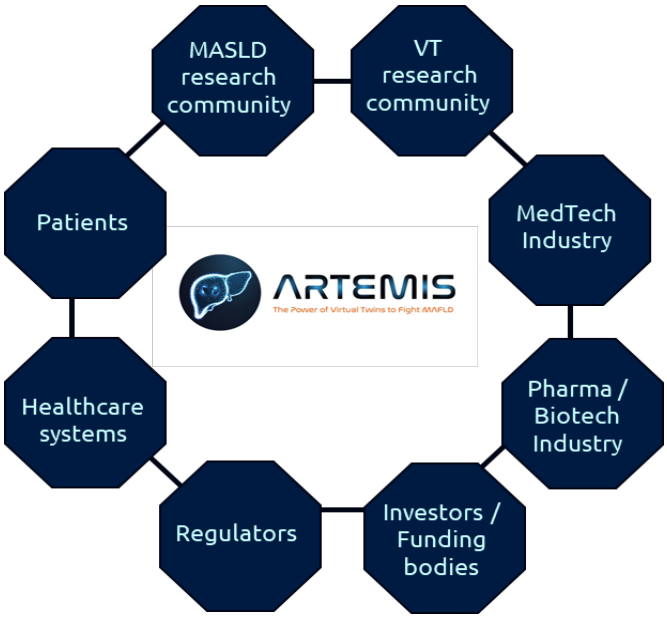

Figure 1. Artemis stakeholders

1.2 Hypotheses on stakeholder's expectations

MASLD research community

ARTEMIS project brings together specialists in MASLD from 13 clinical and medical research centres in 8 nations, including Key Opinion Leaders, participant in flagship European projects such as LITMUS and LiverScreen, and international consensus initiatives such as Delphi and Baveno.

They have an extensive network of collaborator researchers across European hospitals and health research institutes.

The MASLD research community would be mainly interested in accessing combined liver and cardiovascular data so they can elaborate data-driven hypotheses and continue generating knowledge that can ultimately be applied in clinical practice. Specific results considered highly relevant for this target group are:

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- **KER1** "Processing pipelines for omics and digital imaging data, for the extraction of quantitative metrics as inputs to the multiscale models".
- **KER4** "Advanced visualisation tool for multimodal data".
- **KER6** "Federated data exploitation infrastructure for some 7500 patients along the MAFLD spectrum".

VT research community

ARTEMIs partners have developed a set of heart and liver computational models (under the Virtual Liver network, LiSyM and LiSyM-Cancer projects). Some partners are participants in EDITH project and members of the Virtual Physiological Human Institute. ARTEMIs will align with EDITH, supporting the development of ecosystems for Digital Twins in healthcare in Europe. ARTEMIs, and the other projects funded under the Topic HORIZON-HLTH-2023-TOOL-05-03 "Integrated, multi-scale computational models of patient patho-physiology ('virtual twins') for personalised disease management", are requested to follow EDITH interoperability guidance.

The VT research community would be mainly interested in any progress expanding the limits of computational models on liver and heart through multi-organ integration, and mechanistic / machine-learning integration aimed to enhance explainability. The **KER3** *"Multiorgan Multiscale Multilevel model of liver-heart axis for MAFLD -Virtual Twin models"* could be especially relevant for this target group.

Patients

MASLD patients would expect early detection of disease onset, prediction of disease progression and effective treatment options, and effective disease management (**Outcome 4**). This entails receiving informative communications, so they are more aware of their condition, thus also serving an educational purpose, e.g. promoting positive reactions with respect to nutritional and lifestyle habits. Many patients would want to adopt a more active role in the management of their disease.

MASLD patients would also be interested in improved personalised diagnostics, therapeutic products, devices, and strategies tailored to their individual pathophysiology. Overall, they could expect lower uncertainty and more effectiveness of the therapeutic strategy chosen by clinicians (**Outcome 3**).

Medtech industry

The involvement of the MedTech industry would be interested in translating research results into technological solutions that can effectively penetrate the market and positively impact the targeted end-user community.

Medtech players may want to further develop the virtual twin computational model prototype for diagnostics and/or for clinical trials. In the first case, the final product needs to comply with the MDR 2017/745, while in the second case, it must also be compliant with ISO 14155.

In both cases, these stakeholders could expect a functional CDSS prototype (**KER5**) integrating the virtual twin model that can be or transferred to them (under a license agreement or other adequate mechanism) and further improved with their investment and development efforts with the objective of reaching the market and exploiting the system commercially.

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Pharma / Biotech industry

The pharma and biotech have a strong interest in addressing MASLD, considering its global prevalence. These industries are key stakeholders as potential buyers of the ARTEMIS CDSS, as it can assist in optimizing clinical trial designs, identifying patient populations most likely to benefit from novel therapies, and enhancing post-market surveillance efforts.

Therefore, this industry could expect, as the Medtech, a functional CDSS prototype (**KER5**) that can be licensed and further improved with their investment and development efforts with the objective of serving their R&D activities.

Healthcare services

Clinicians and other healthcare professionals would be mainly interested in having access to a CDSS with functionalities such as improved risk-based stratification of patients (using multi-modal clustering of patients and pattern identification **KER2**); access to data evidencing the disease mechanisms (e.g., liver-heart communication) in a more personalised way; or guidelines for the management of the disease and the treatment.

The healthcare professionals target group could expect new tools such as: 1) multi-scale computational models of individual patients to decide the optimal strategy for each patient (**Outcome 1**); 2) access to training contents or advanced models that can be used to improve the knowledge of complex disease onset and progression (**Outcome 2**); 3) diagnostics tools, medicinal products and therapeutic strategies that can be tailored to the individual patient pathophysiology (**Outcome 3**).

Regulatory bodies

The European regulatory approval procedure for ARTEMIs CDSS will need to contemplate the new medical devices regulation for software applications, and the regulation for high-risk AI systems, such as those for healthcare (AI Act proposal). The regulatory bodies involved, including the competent authorities for health technology assessment (HTA) in EU countries, and the competent consultation groups in HTA (CGHTA) of European Commission, will play a crucial role in the post-project time to market phase.

This target group could expect the project results to be aware of the applicable regulations and well oriented to comply with them. Specifically, the methodology applied to achieve the required models' performance, trustworthiness and usability (**KER7**), as well as the validation of the software as medical device, which will include verification of all software functionalities, including cybersecurity and penetration tests. .

Regulatory bodies may also be interested in being consulted or involved in new developments that may be among the first ones applying AI in Virtual Twins for use cases in liver disease management. It could be valuable feedback for their regulatory activity.

Private investors / Funding bodies

To reach market maturity, additional funding will be needed. The engagement with potential private investors and public funding bodies is essential to identify accessible opportunities.

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Investors could expect project results that have a large potential market, a large societal impact and a plan for their commercial exploitation. Depending on their investment thesis, they could be looking for higher or lower TRLs.

2 LEARNING FROM STAKEHOLDER GROUPS

2.1 Methodology

To maximize the chances of the CDSS being adopted by end-users and minimize market, technology or regulatory barriers, the project team adopted the *Lean Startup* principles.

Lean startup is a methodology for developing businesses and products that aims to shorten product development cycles and rapidly discover if a proposed technology is viable as a commercial product; this is achieved by adopting a combination of market-hypothesis-driven experimentation, iterative product releases, and validated learning.

Lean startup emphasizes customer feedback over intuition and flexibility over planning. This methodology enables recovery from failures more often than traditional ways of product development[1].

With the lean principles in mind, two actions were planned: 1) validate the stakeholders' needs, pains and expectations using questionnaires; and 2) elaborate a value proposition (solution) and validate it through interviews.

2.2 Questionnaire to learn about the users' needs and expectations

Questionnaire design for stakeholders out of the project consortium

The main objective of the questionnaire is to understand the stakeholder groups that will be using or benefiting from the CDSS, and their relationship with the MASLD. That means knowing in the first place their goals, their working environment, the needs that they explicitly report, or the trends that they can see in their sector. It also means inferring what they implicitly want to say, i.e., what are their pains (fears or frustrations) and their gains (needs and hopes).

To gather the information from stakeholders that are **external to the project consortium**, a single questionnaire was designed. It is generic enough to allow the respondents to think and reply freely. It is important to note that, at this point, ARTEMIS CDSS solution is not presented to the stakeholders to avoid interfering in their answers.

The questions follow the structure of the *Empathy Map Canvas*, which is a tool designed by Dave Gray, founder of the consultancy firm XPLANE and author of the book *"Gamestorming: A Playbook for Innovators, Rulebreakers, and Changemakers"*. This canvas aims to help teams develop deep, shared understanding and empathy for other people as part of customer experience improvement or product development activities.

[1] https://hbr.org/2013/05/why-the-lean-start-up-changes-everything

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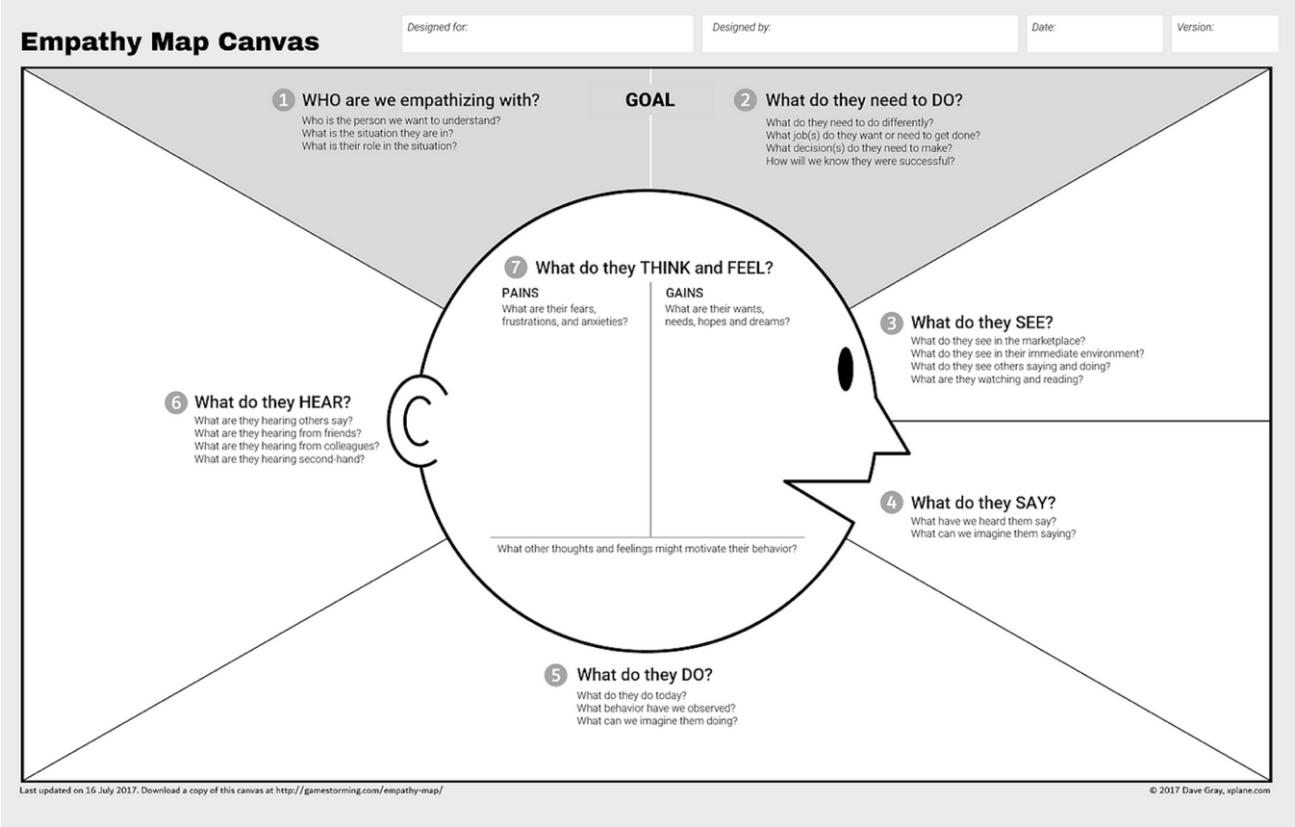

Figure 2. Empathy Map Canvas (source: Gamestorming)

The questionnaire was implemented using Microsoft Forms application, which makes it more user-friendly and can be filled in from any web browser either in a computer or a mobile device.

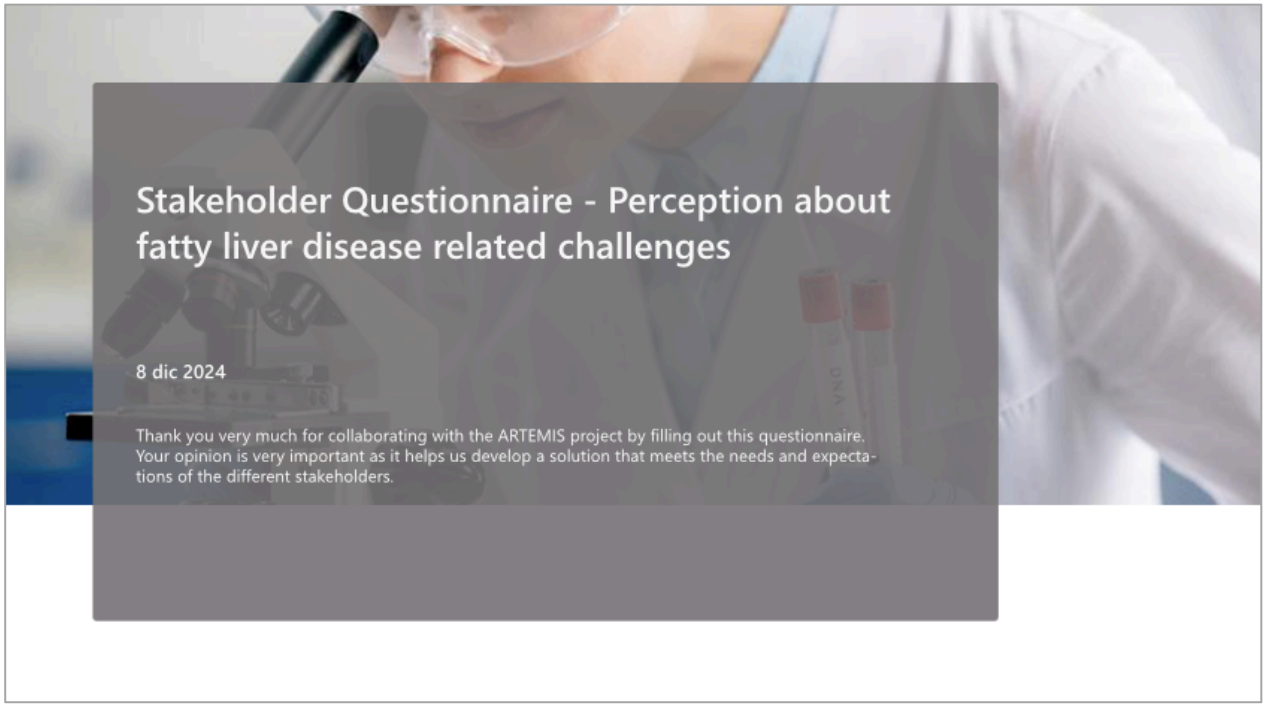

Figure 3. Screenshot of the introductory text of the questionnaire

The first section of the questionnaire introduced the problem of MASLD explaining the cause of the disease and the main associated disorders. The relation of this liver disease with cardiovascular complications is also pointed out.

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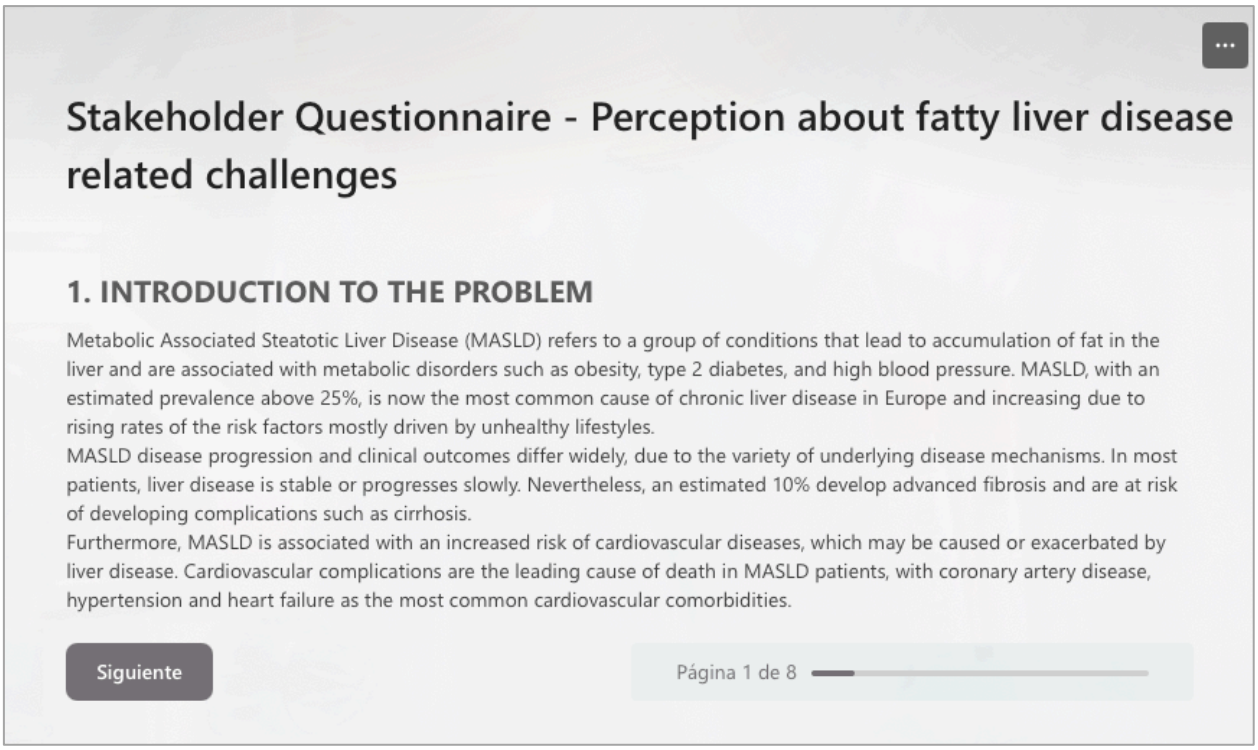

Figure 4. Screenshot of questionnaire's *section 1: Introduction to the problem.*

The second section of the questionnaire, titled "Your Goals", aimed to fill in the two first fields of the Empathy Map Canvas (see Figure 2). I.e., who are we empathizing with? And what do they need to do?

Respondents identify themselves as part of one of the 8 predefined stakeholder groups. Then, an open text field allowed them to explain the kind of work that they need to do in relation to the management of MASLD.

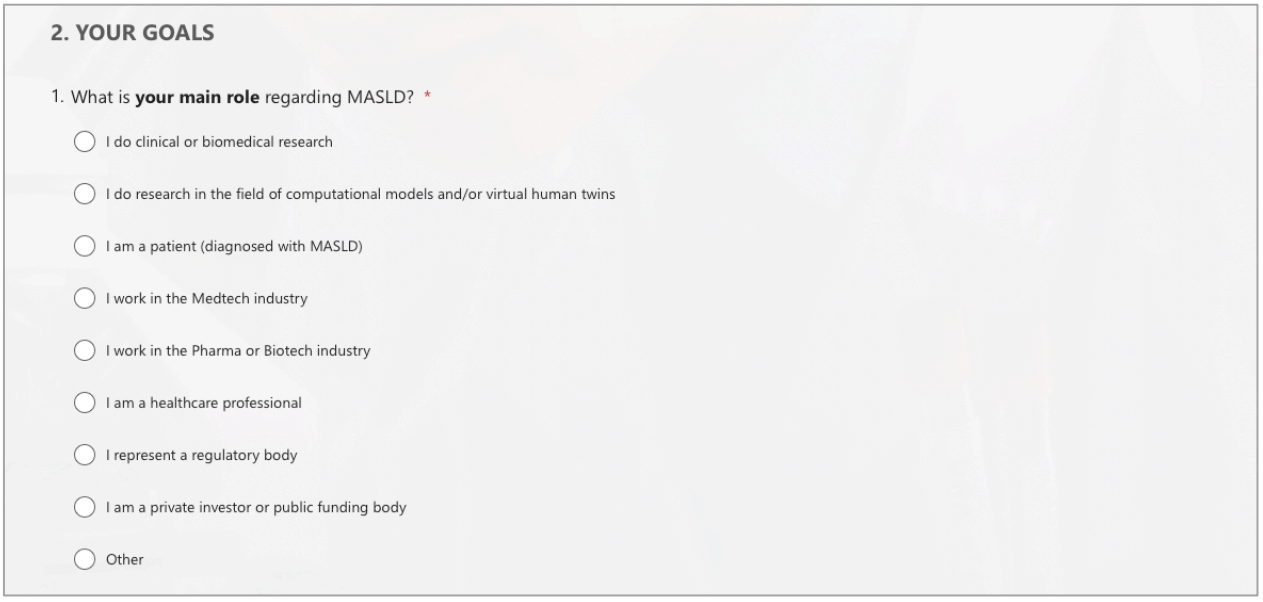

Figure 5. Screenshot of questionnaire's *section 2. Your Goals* (1 of 2).

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Figure 6. Screenshot of questionnaire's *section 2: Your Goals* (2 of 2).

The objective of the third section was to gather insights about questions 3 and 4 of the Empathy Map Canvas (see Figure 2): what do you see? and what do you say? These questions are intended to understand the direct interaction of the respondent with the problem (MASLD disease and/or its management).

To give a little context, the first question asked explicitly whether they suffered the direct impact of MASLD or its management and, if so, in what way. Then, the focus was put on the problems experienced and the awareness of existing or upcoming solutions.

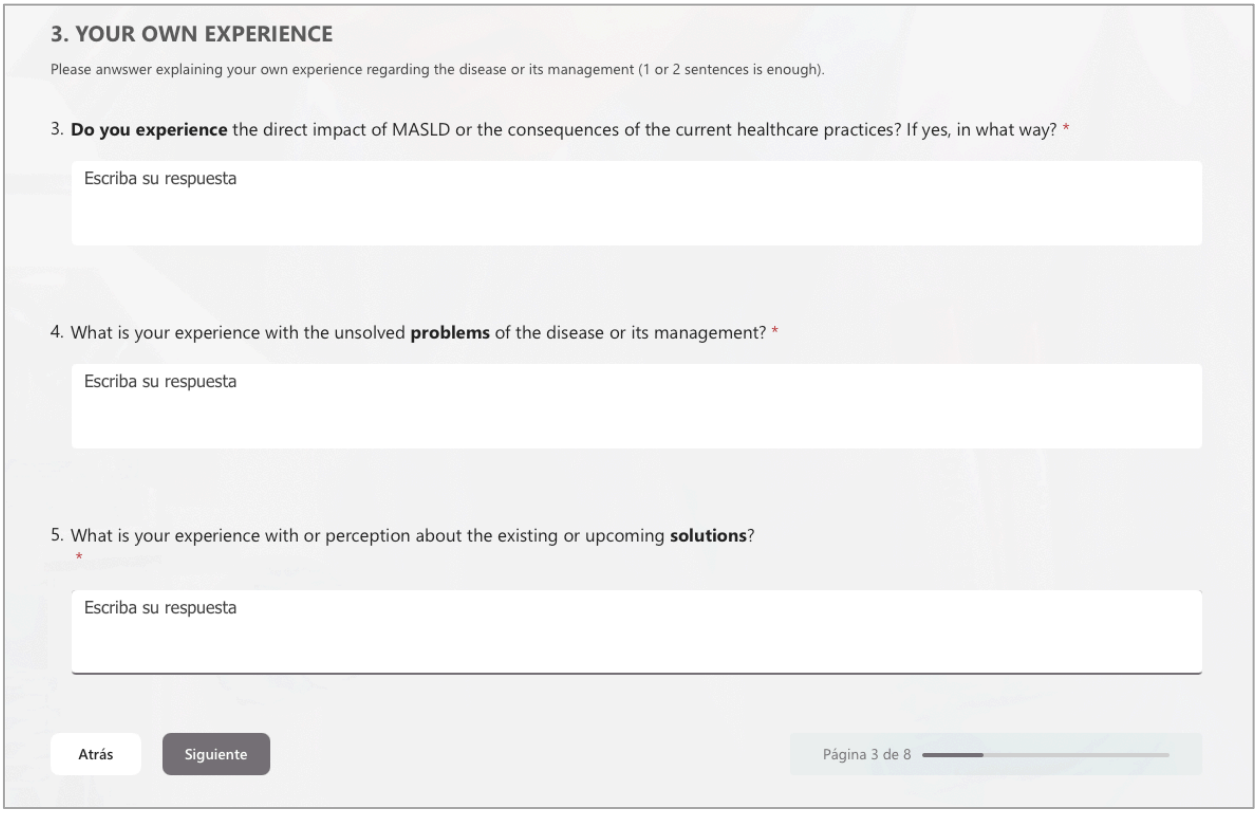

Figure 7. Screenshot of questionnaire's *section 3: Your own experience*.

The fourth section interrogates about the indirect perception of the stakeholder about the problem and potential solutions, acquired from what he/she hears from colleagues, reads from professional networks or publications, or receives in any other way from other people who have experienced it first-hand.

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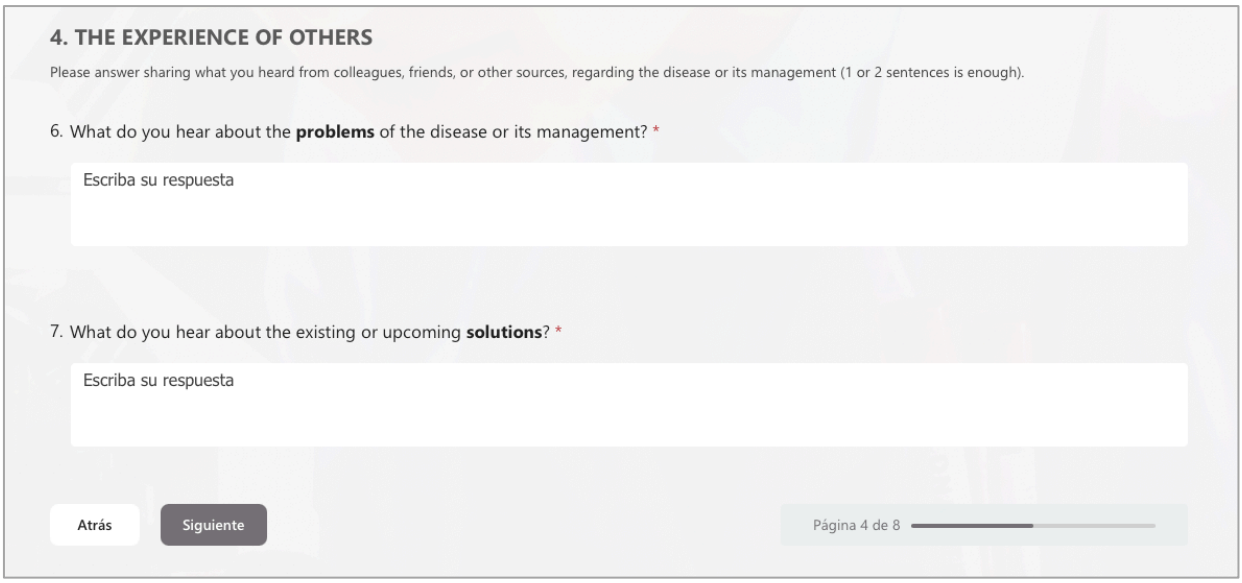

Figure 8. Screenshot of questionnaire's *section 4: The experience of others.*

Section 5 dealt with the response of the stakeholder to the challenges posed by the disease and its management: what is his/her the opinion about the current practices, what could be done to improve and what attitude could be adopted.

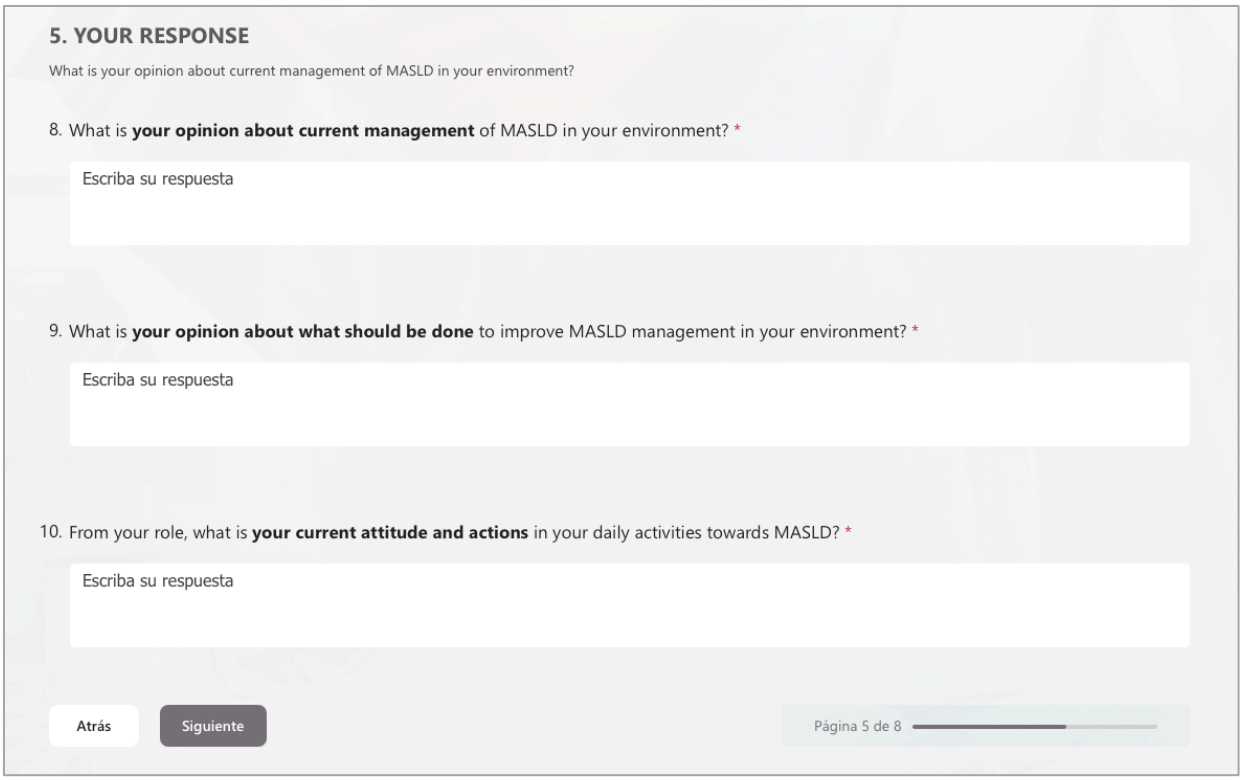

Figure 9. Screenshot of questionnaire's *section 5: Your response.*

The last section, 6, aimed to gather the information needed to fill in the gap number 7 in the Empathy Map Canvas (see Figure 2): What do they think and feel? I.e., the pains and gains of the stakeholder.

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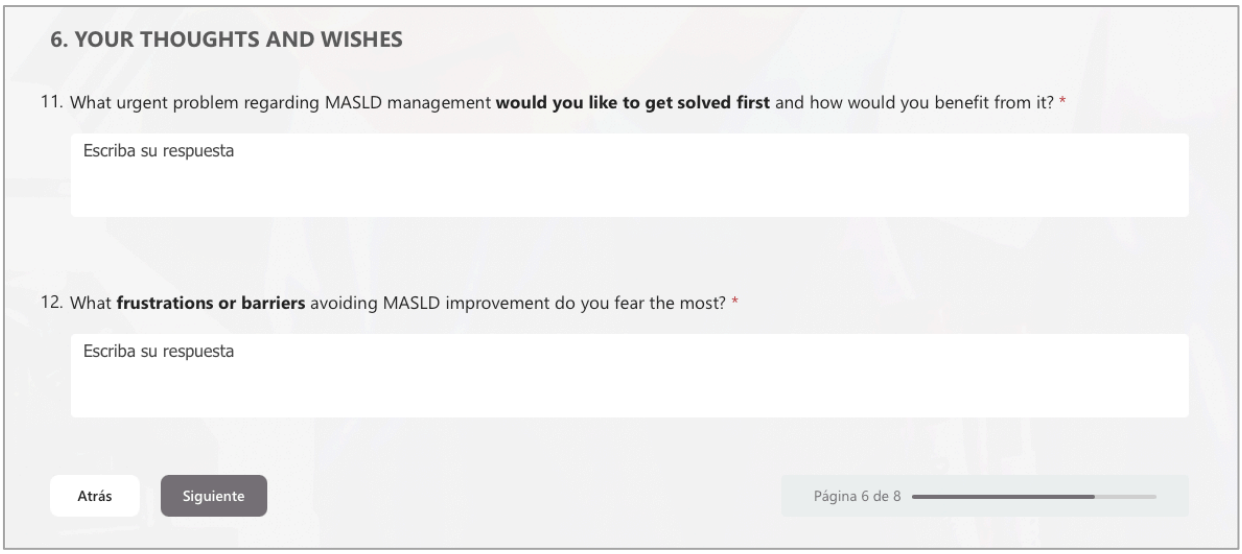

Figure 10. Screenshot of questionnaire's *section 6: Your thoughts and wishes.*

Questionnaire submission

The questionnaire was submitted to all the stakeholder groups except the patients, who will be specifically approached in future iterations, once the value proposition ideas are more mature, so they can contribute actively and effectively. In those iterations, the questionnaires will be modified in collaboration with ELPA or replaced with more suitable methods aiming to achieve a high engagement of patients.

The stakeholder groups already contacted are indicated in the table below:

Table 1. Selection of external stakeholders

Stakeholder group	Entity
Research community	Universidad de Zaragoza
	Univ. Sheffield
	Siemens Health Engineers
MedTech industry	Quibim
	Bahia Software
	GE Healthcare
Pharma / Biotech industry	BMS (USA)
	Pfizer (USA)
Healthcare services	University Hospital Pisa
	Porto University Hospital
	University Hospital of Helsinki
Regulatory bodies	DNV
Private investors / Funding bodies	Prous Research

Questionnaire analysis

Around 30% of the selected stakeholders, belonging to 4 different groups, provided a full reply to the questionnaire. Many non-respondents just apologized indicating that they are not experts in the field (although it was indicated that no technical questions were made, and their opinion could be very insightful to the project).

The completed questionnaires were analysed qualitatively, revising the responses, placing them in the corresponding fields of the Empathy Map Canvas and aggregating or summarising the information when needed. As a result, the following canvases were elaborated.

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Empathy Map Canvas

Designed for: *ARTMIs Project* | Designed by: *MATICAL Innovation* | Date: *Nov 2024* | Version: *1*

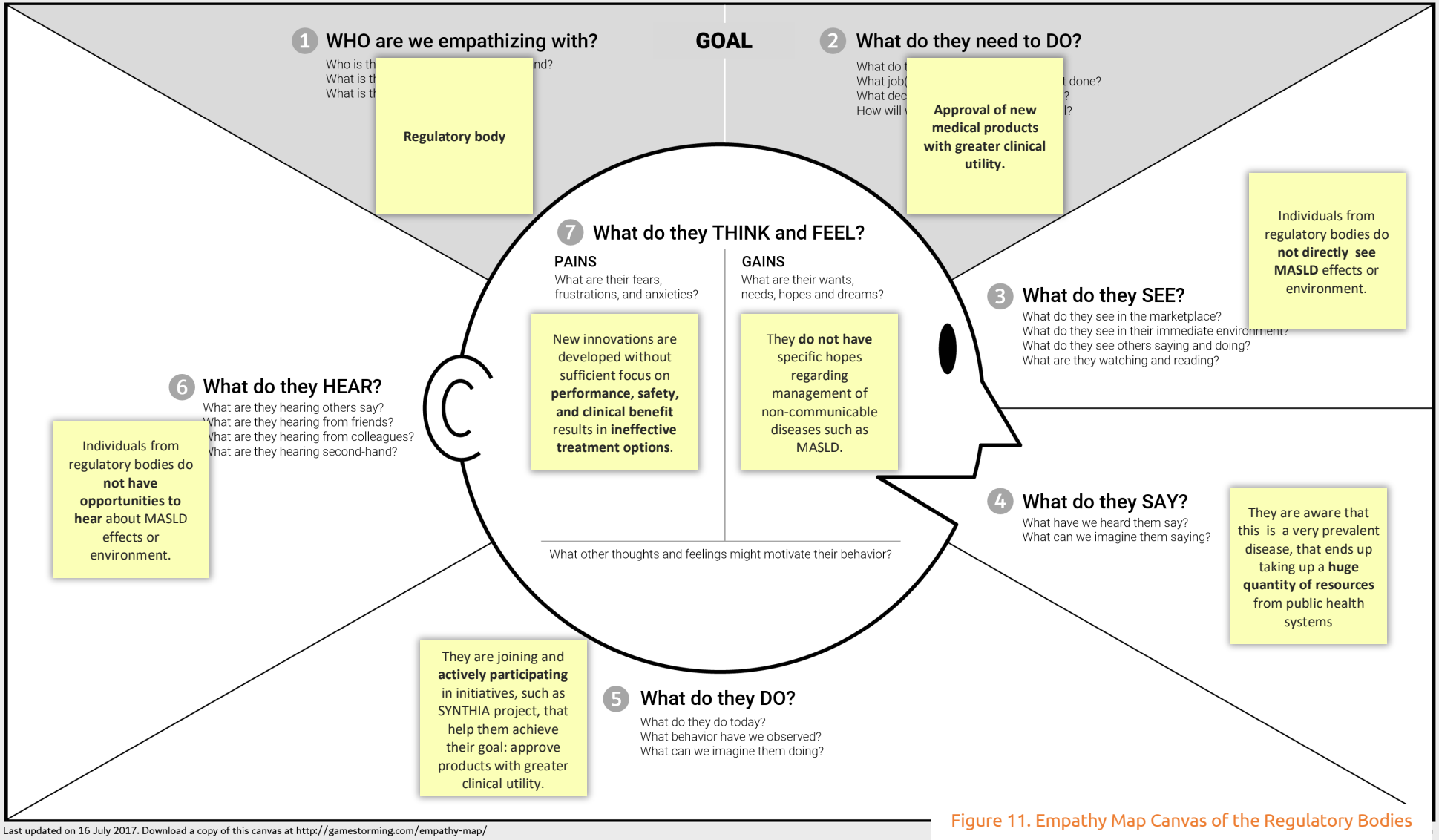

Figure 11. Empathy Map Canvas of the Regulatory Bodies

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Empathy Map Canvas

Designed for: *ARTMIs Project* | Designed by: *MATICAL Innovation* | Date: *Nov 2024* | Version: *1*

GOAL

1 WHO are we empathizing with?

Who is th… nd?
What is th…
What is th…

Medtech industry

2 What do they need to DO?

What do t…
What job(… one?
What dec…
How will …

I believe that we could develop algorithms to **better stratify patients** through IA or even contribute to the **management of these patients** through GenerativeAI

7 What do they THINK and FEEL?

PAINS
What are their fears, frustrations, and anxieties?

Medtech industry individuals are **not concerned**, frustrated or have any pains directly linked to MASLD because it is not an objective yet.

GAINS
What are their wants, needs, hopes and dreams?

Upcoming solutions such as the ones proposed by the ARTEMIS consortium (digital twins, CDSS,...) seem **promising and interesting**.

What other thoughts and feelings might motivate their behavior?

3 What do they SEE?

What do they see in the marketplace?
What do they see in their immediate environment?
What do they see others saying and doing?
What are they watching and reading?

Individuals from Medtech industry **do not experience the direct impact** of MASLD or the consequences of the current healthcare practices

6 What do they HEAR?

What are they hearing others say?
What are they hearing from friends?
What are they hearing from colleagues?
What are they hearing second-hand?

They don't hear much about MASLD and **they lack experience in the field** to know the problems that entails the disease or its management.

4 What do they SAY?

What have we heard them say?
What can we imagine them saying?

Medtech industry individuals **do not have yet an opinion** about the MASLD and its management.

5 What do they DO?

What do they do today?
What behavior have we observed?
What can we imagine them doing?

They are joining and **actively participating** in initiatives, such as CHAIMELEON project, that help them achieve their goal: contribute to better management of patients through IT & AI

Last updated on 16 July 2017. Download a copy of this canvas at http://gamestorming.com/empathy-map/

Figure 13. Empathy Map Canvas of the Medtech Industry

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Empathy Map Canvas

Designed for: *ARTMIs Project* | Designed by: *MATICAL Innovation* | Date: *Nov 2024* | Version: *1*

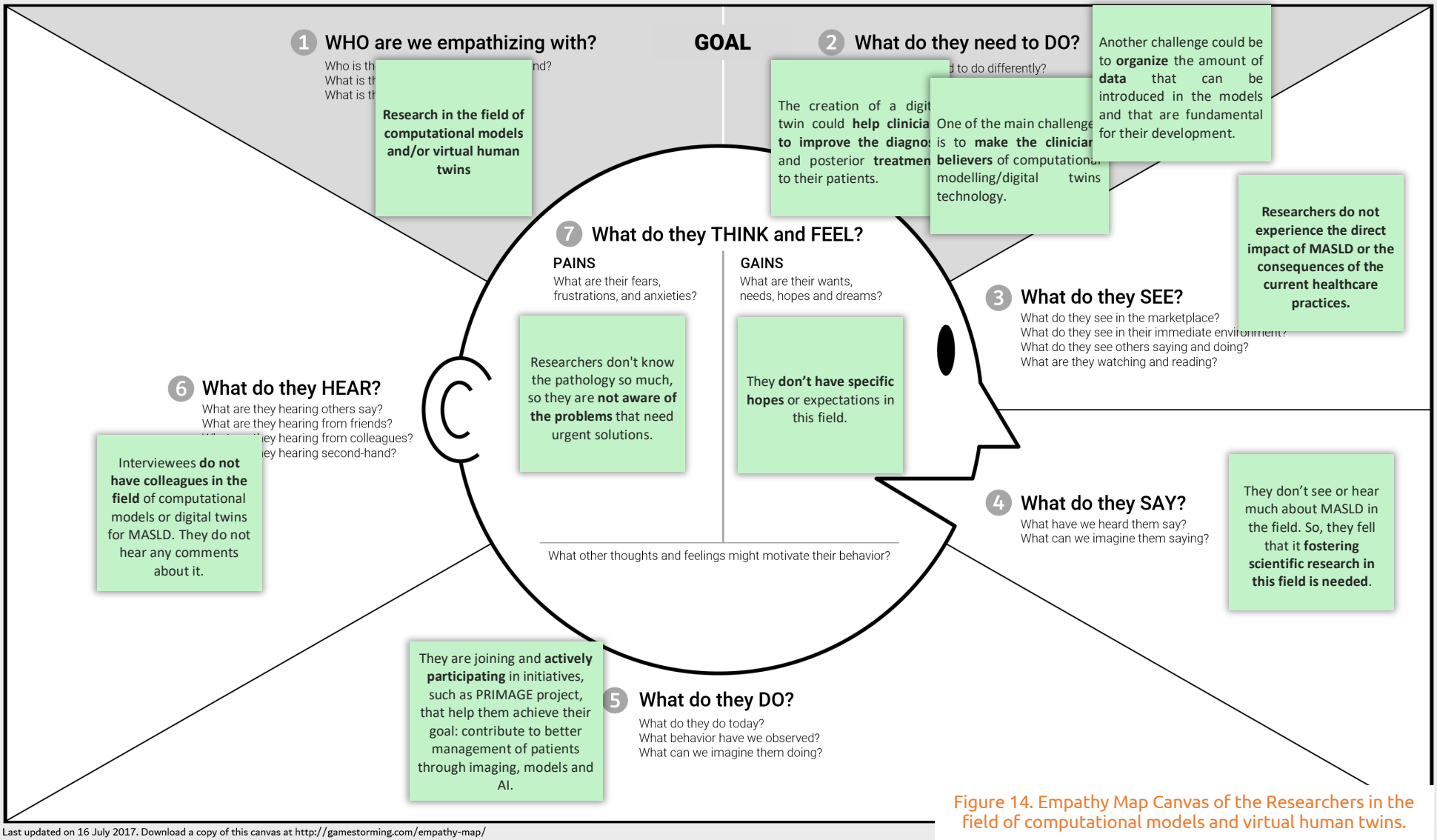

Figure 14. Empathy Map Canvas of the Researchers in the field of computational models and virtual human twins.

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Empathy Map Canvas

Designed for: *ARTMIs Project* | Designed by: *MATICAL Innovation* | Date: *Nov 2024* | Version: *1*

GOAL

Private Investor

1 WHO are we empathizing with?

Who is th… nd?
What is th…
What is th…

2 What do they need to DO?

What do…
What job… done?
What de…
How will…

They are interested in understanding the potential impact of new technologies in the market in early stages to **de-risk their decisions.**

7 What do they THINK and FEEL?

PAINS
What are their fears, frustrations, and anxieties?

The **lack of flexibility of regulatory bodies to enable new biomarkers** makes it more difficult for startups to succeed.

GAINS
What are their wants, needs, hopes and dreams?

They would like to access new knowledge to **fill the gaps in translational research**.

What other thoughts and feelings might motivate their behavior?

3 What do they SEE?

What do they see in the marketplace?
What do they see in their immediate environment?
What do they see others saying and doing?
What are they watching and reading?

Investors do not experience the direct impact of MASLD or its consequences. However, they may have evaluated related projects.

6 What do they HEAR?

What are they hearing others say?
What are they hearing from friends?
…ey hearing from colleagues?
…ey hearing second-hand?

They hear that most clinical studies fail in Phase II-III. **The selection of target patients is critical.** This could be addressed with better models and tools.

4 What do they SAY?

What have we heard them say?
What can we imagine them saying?

Startups with solutions to diseases such as MASLD have not reach the market yet.

There is a problem with genetic variability. Valid **biomarkers for patient screening are scarce**. It needs to be improved for better safety and efficacy.

5 What do they DO?

What do they do today?
What behavior have we observed?
What can we imagine them doing?

They **support new projects** contributing to validate-test new treatments beyond animal models, using high throughput methods (e.g., in-silico, virtual twins…).

Last updated on 16 July 2017. Download a copy of this canvas at http://gamestorming.com/empathy-map/

Figure 15. Empathy Map Canvas of the Private Investors.

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From the empathy maps elaborated from the questionnaires, the following insights have been obtained:

All the respondents had **very little or no awareness** of MASLD, its challenges and the impact of the disease or its management.

- The lack of awareness is a problem, as it hinders the possibility to investigate, develop new technologies and innovate in the creation of solutions that can improve the MASLD situation.
- In future iterations of the questionnaire, the questions could be wider, maybe referring to other non-communicable diseases, or formulated not as something that stakeholders should know but as ideas that the project want to source from people that may inspire the solution and could be involved in the future to some extent, or only stakeholders with some pre-existing knowledge on MASLD will be selected.
- Dissemination activities will be key to prepare the stakeholders to support or adopt the project results, as they will contribute to detect the disease and achieve a more personalized and effective management.

There seems to be a **pain related to the regulatory barriers and/or knowledge gaps** that avoid a faster improvement of treatments' performance and safety.

- Advanced models and virtual human twins are expected to address the challenge.

2.3 Questions to validate the interest of stakeholders in the solution

Once the respondent of the questionnaire provided the information required to elaborate the empathy map (needs, pains, etc.), ARTEMIS CDSS solution was briefly introduced.

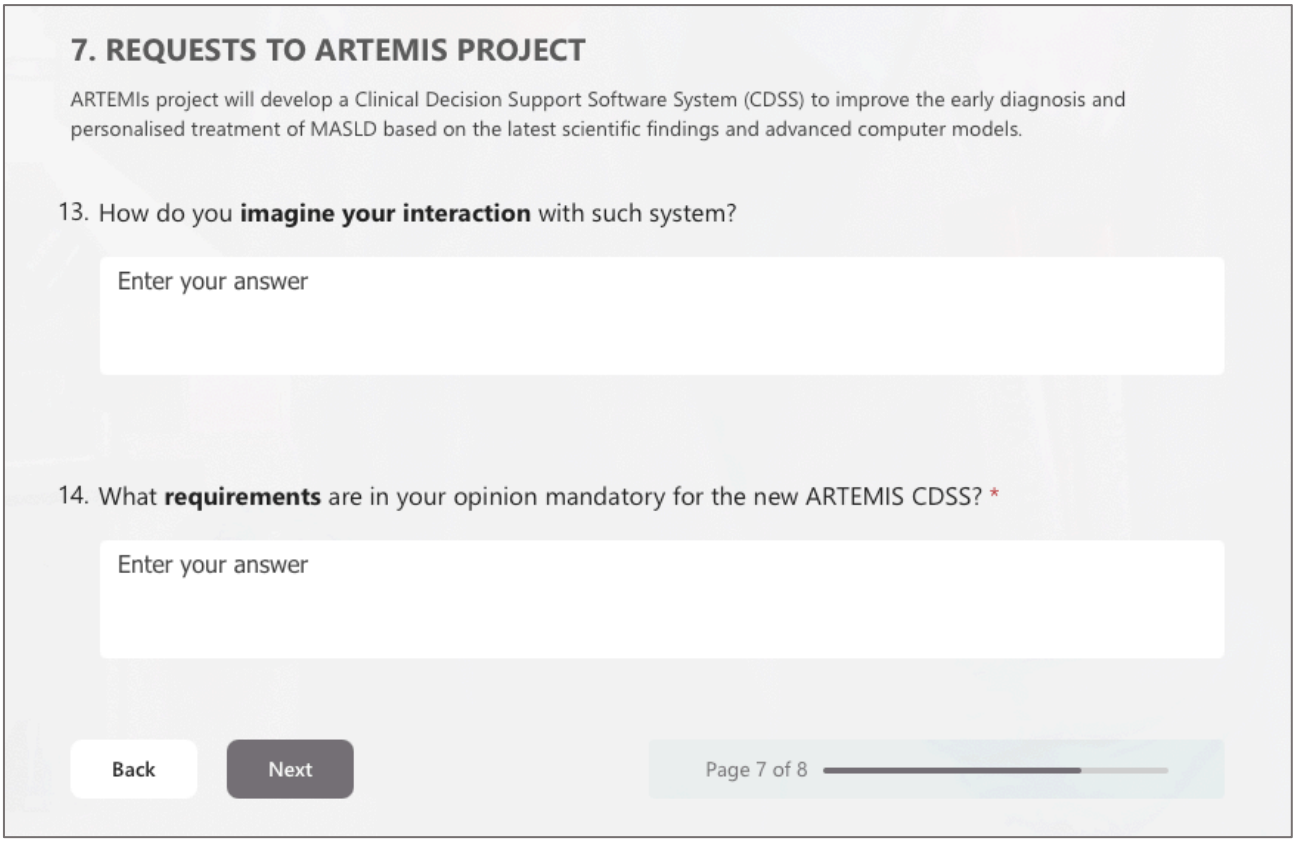

Figure 16. Screenshot of questionnaire's *section 7: Requests to ARTEMIs Project.*

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Then, two questions were formulated:

Table 2. Reply from stakeholders to question 1 in section 7.

1. How do you imagine the interaction with ARTEMIS CDSS?

The replies of each stakeholder group representative is reproduced below:

Regulatory body	*We are involved in conformity assessment of CDS, so would be part of the pre-market assessment.*
Medtech industry	*I believe that the developer will pay attention to the usability of the system, working previously with health professionals. I imagine a positive and friendly interaction*
Researchers in virtual twins	*It could be challenging but at the same time very interesting. We (the society and the health system) need to move towards this direction.*
Private investors	*An easy to-use workflow through the integration with the existing clinical software systems is a critical aspect for a successful interaction with the CDSS.*

Table 3. Reply from stakeholders to question 2 in section 7.

2. What requirements are in your opinion mandatory for the new ARTEMIS CDSS?

The replies of each stakeholder group representative are reproduced below:

Regulatory body	*From a regulatory perspective, this will be all points in MDR or IVDR, AI Act, and harmonised standards (ie., for quality management systems, risk management, and more), as relevant depending on the system and it's risk classification. MDCG is not mandatory, but guidance documents are generally relied on.*
Medtech industry	*The solution should be reliable, explainable and scalable to other clinical centres*
Researchers in virtual twins	*Good clinical data, accurate models, strong verification of the CDSS and a proper validation tool.*
Private investors	*Total integration with the clinical workflow to avoid barriers and ensure compliance (with privacy, data management rules, etc.). Integration with existing clinical data in the hospital. Bi-directional data communication to enable continuous model and algorithm improvement.*

From these additional questions, the following insights were obtained:

When asking about the hypothetical interaction with a CDSS, the answers focused on the **graphical user interface and the workflow**. No concerns or comments arose regarding the content of those interactions (e.g., to what extent will clinicians trust the results).

- The usability and integration of the CDSS seems to be considered of utmost importance for the success of the solution.
- In future iterations of the questionnaire, this question should be reformulated to gather opinions about challenges and opportunities that the CDSS could pose to different stakeholder groups.

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3 CO-CREATING THE VALUE PROPOSITION

3.1 Methodology

After learning the main stakeholders' pains, concerns, and perceptions regarding MASLD or its management, this section keeps applying the *Lean Startup* principles, which favour iterative product development, and validated learning.

This stage aims to create the value proposition in a collaborative way, based on the insights from the previous section and the expert knowledge provided by the **stakeholders within the consortium**. This group of stakeholders is the most adequate for this task, as they know the problem, and have a basic understanding about what the solution should look like.

The co-creation process consisted of an exercise in which each stakeholder, from different target groups, filled in a **questionnaire** to identify and prioritize the CDSS functionalities and features that they consider most relevant to achieve their objectives.

3.2 Questionnaire about key CDSS features

Questionnaire design for project partners

The questionnaire used Microsoft Forms application, as in the external stakeholder's version. The first section was used to introduce the form. In this case, respondents are supposed to know MASLD and there is no explanation of the disease nor the project. Only the motivation of the questionnaire is explained as well as the importance of starting the discussion about the value proposition and the exploitation of the project results.

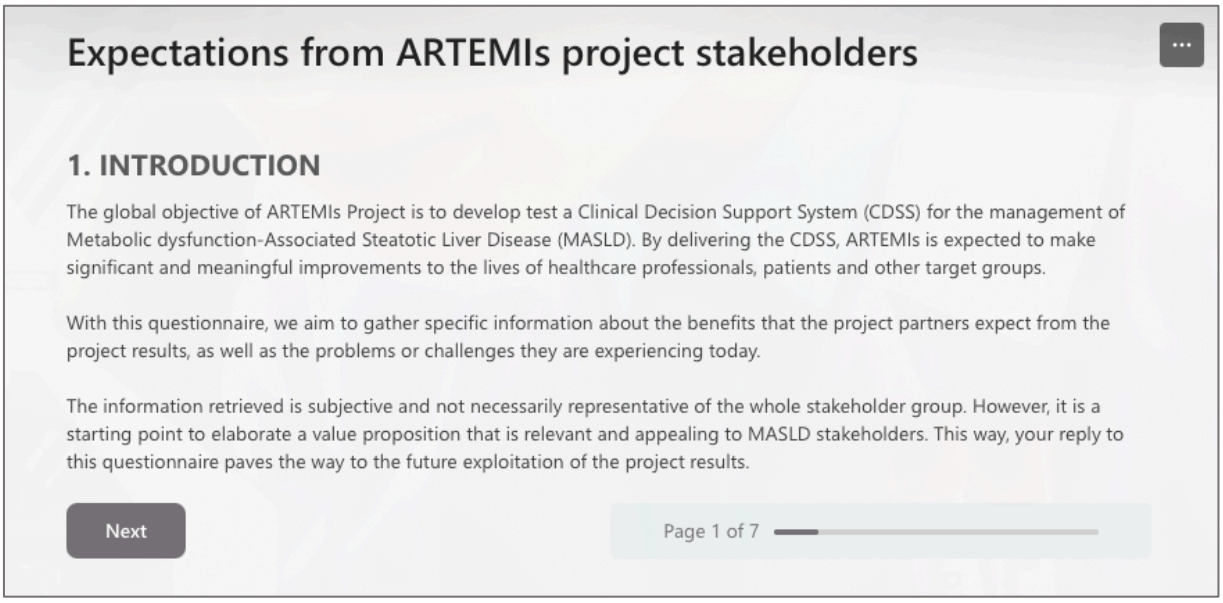

Figure 17. Screenshot of questionnaire's *section 1: Introduction*

The second section, titled "your work" aims to gather information about the stakeholder group of the respondent, his/her main professional objectives related to MASLD and the type of work or tools that they use in a day-to-day basis.

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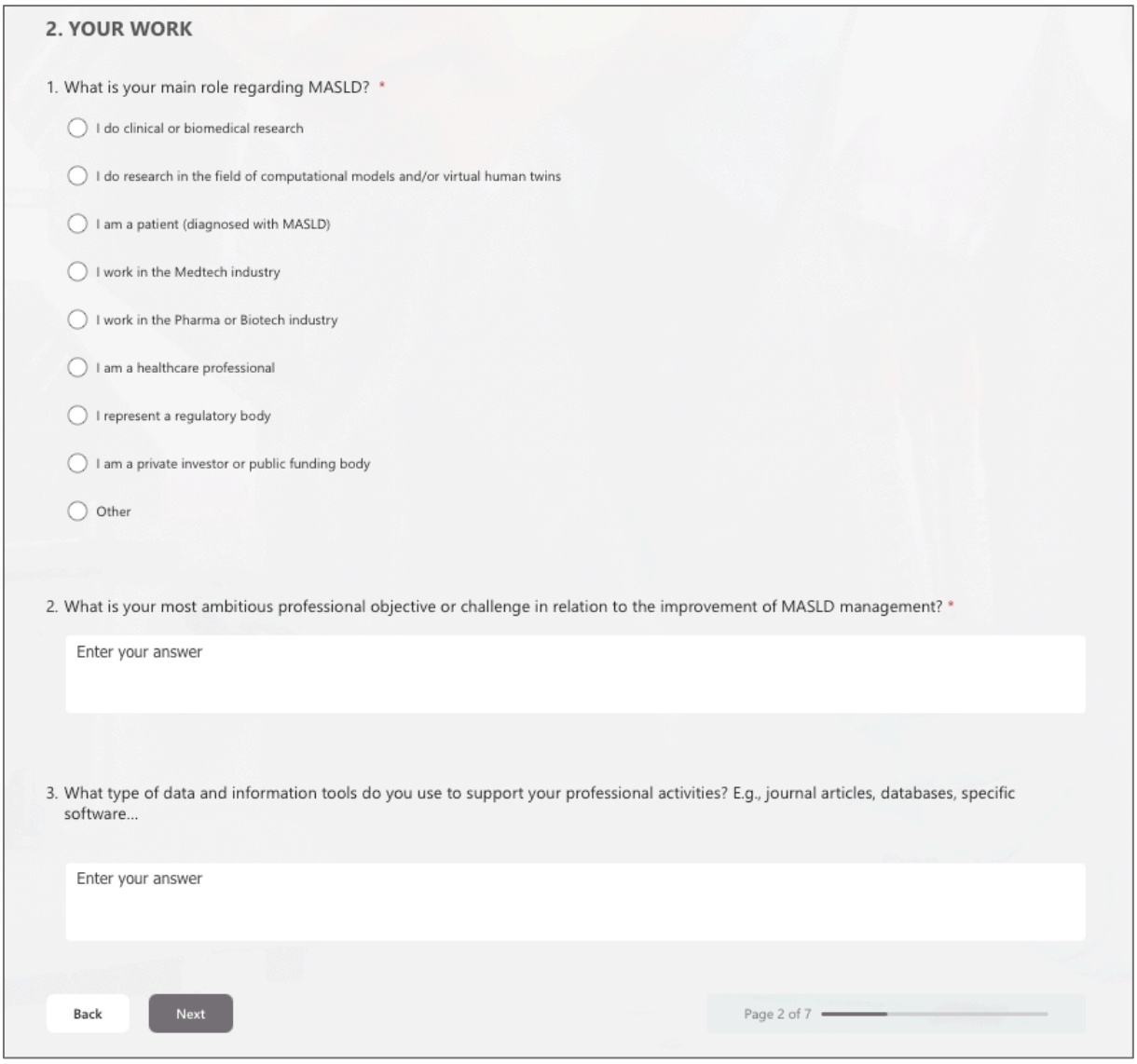

Figure 18. Screenshot of questionnaire's *section 2: Your work.*

Section 3 requests information about the limitations that the stakeholders find to improve MASLD management and, specifically, three categories are suggested (data gathering or access, data exploitation and modelling) to obtain more precise answers.

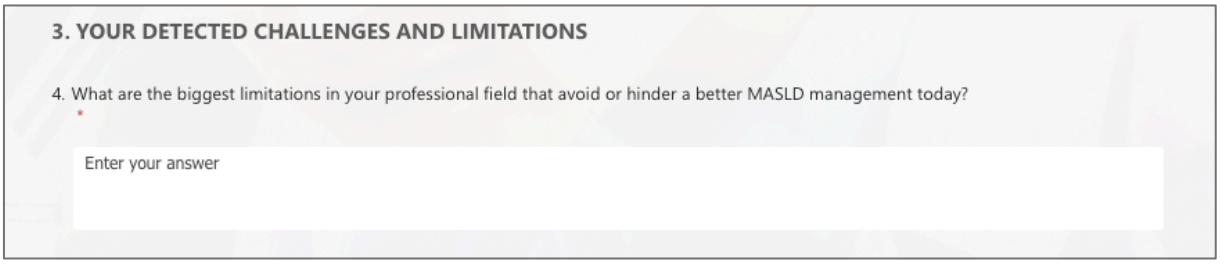

Figure 19. Screenshot of questionnaire's *section 3: Your detected challenges and limitations (1 of 2)*

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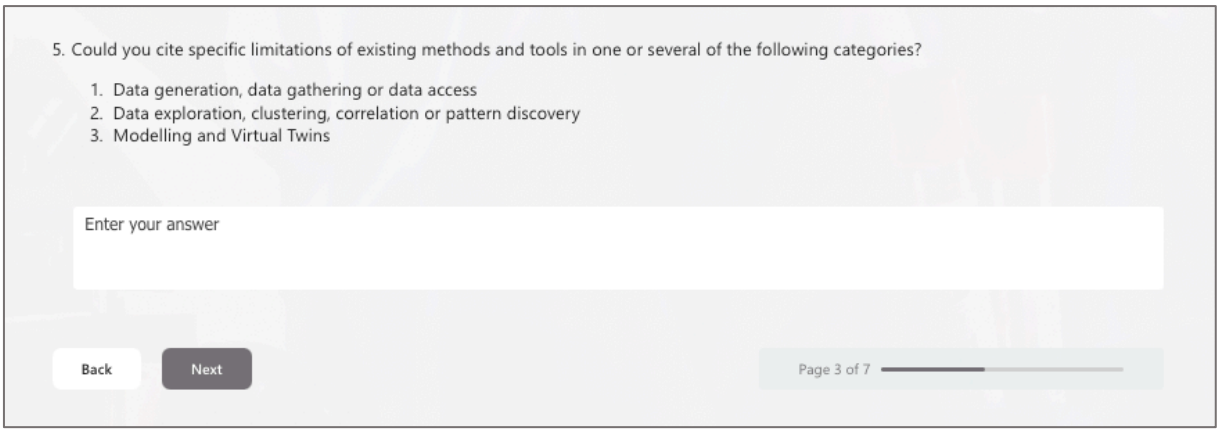

Figure 20. Screenshot of questionnaire's *section 3: Your detected challenges and limitations (2 of 2)*

The final three sections include questions about the value that the stakeholders are expecting to get from the project results.

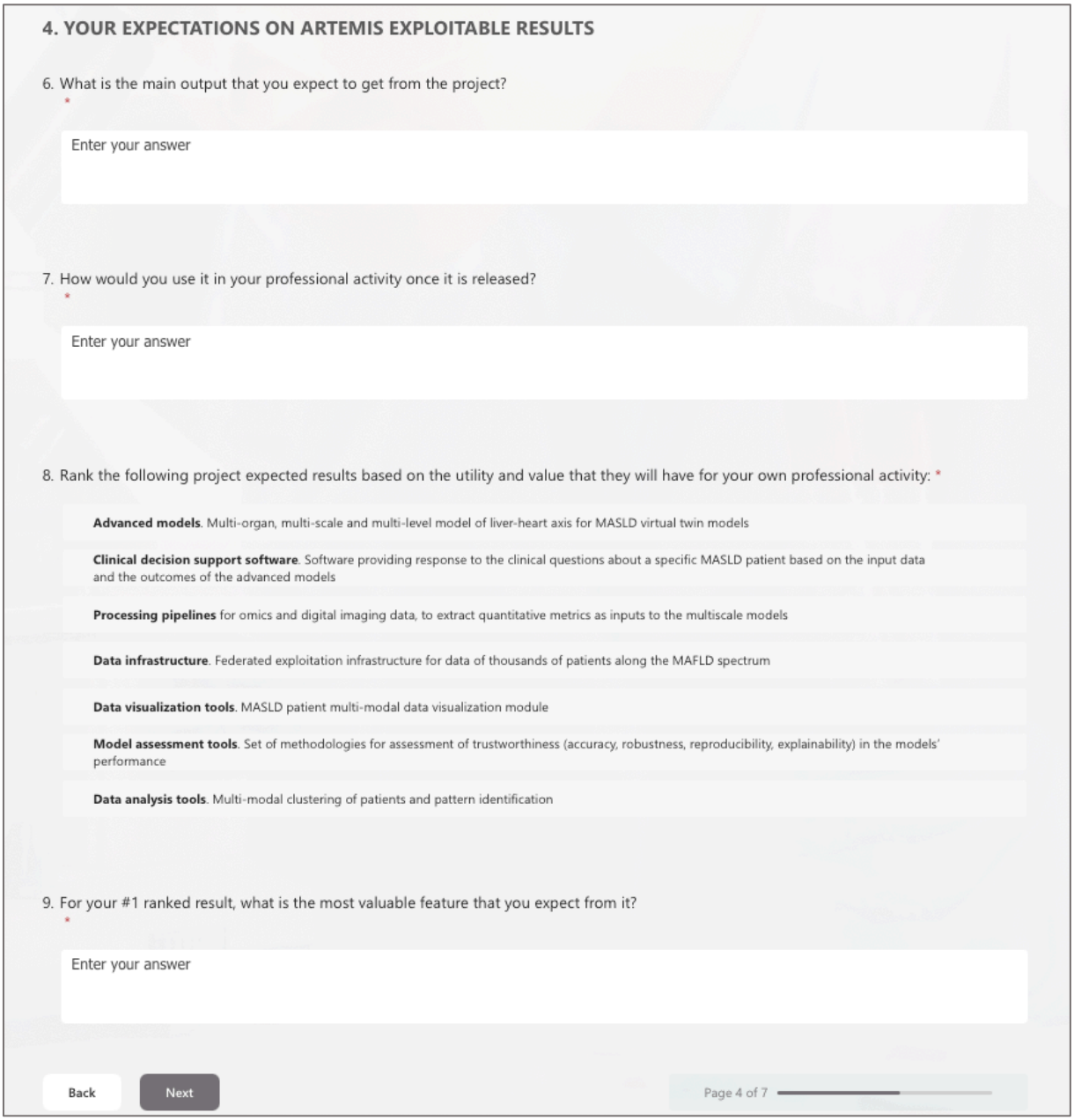

Figure 21. Screenshot of questionnaire's *section 4: your expectations on ARTEMIs exploitable results.*

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Section 4 asks the stakeholder to indicate what is the main output or result that he/she expects from the project. It also presents a list of the Key Exploitable Results (KERs) and ask the stakeholders to rank them from the most to the less important for their professional activity.

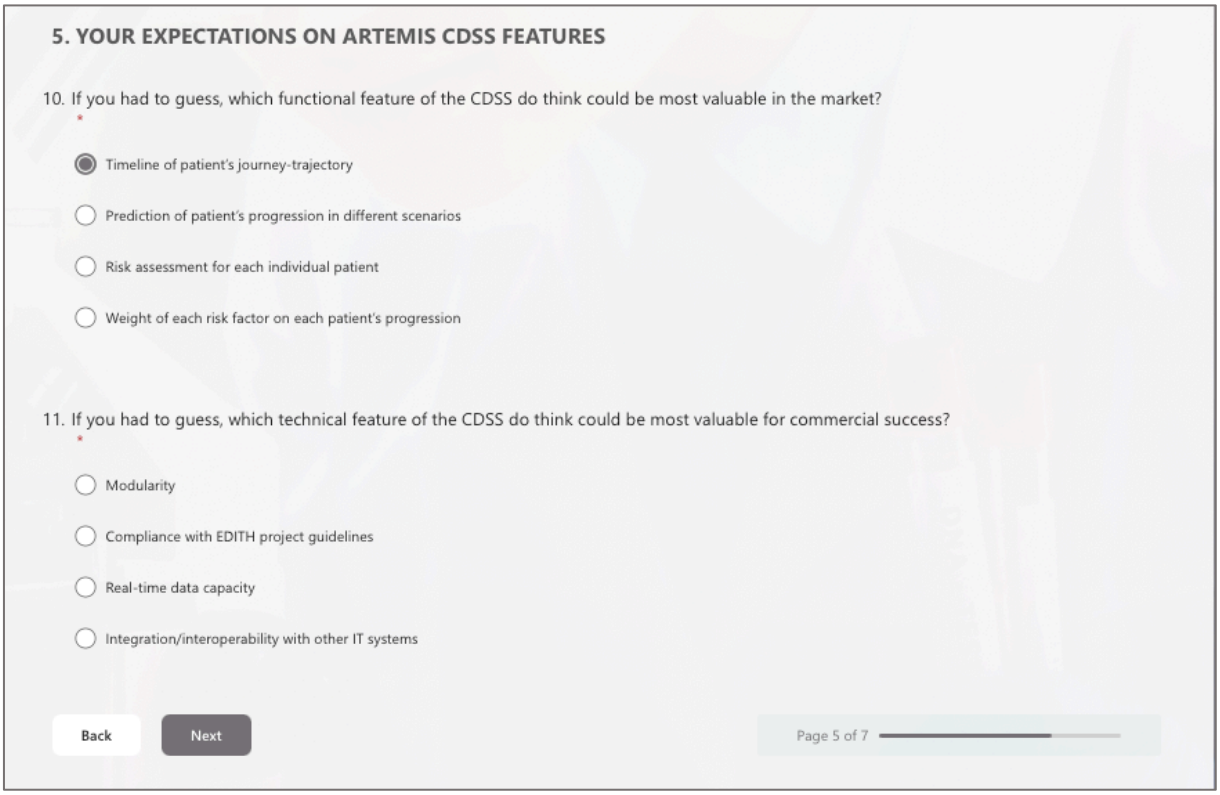

Figure 22. Screenshot of questionnaire's *section 5: Your expectations on ARTEMIs CDSS features.*

Section 5 focuses on the CDSS. Specifically, it asks the respondent to indicate the most valuable functional feature and the most valuable technical feature from a brief list.

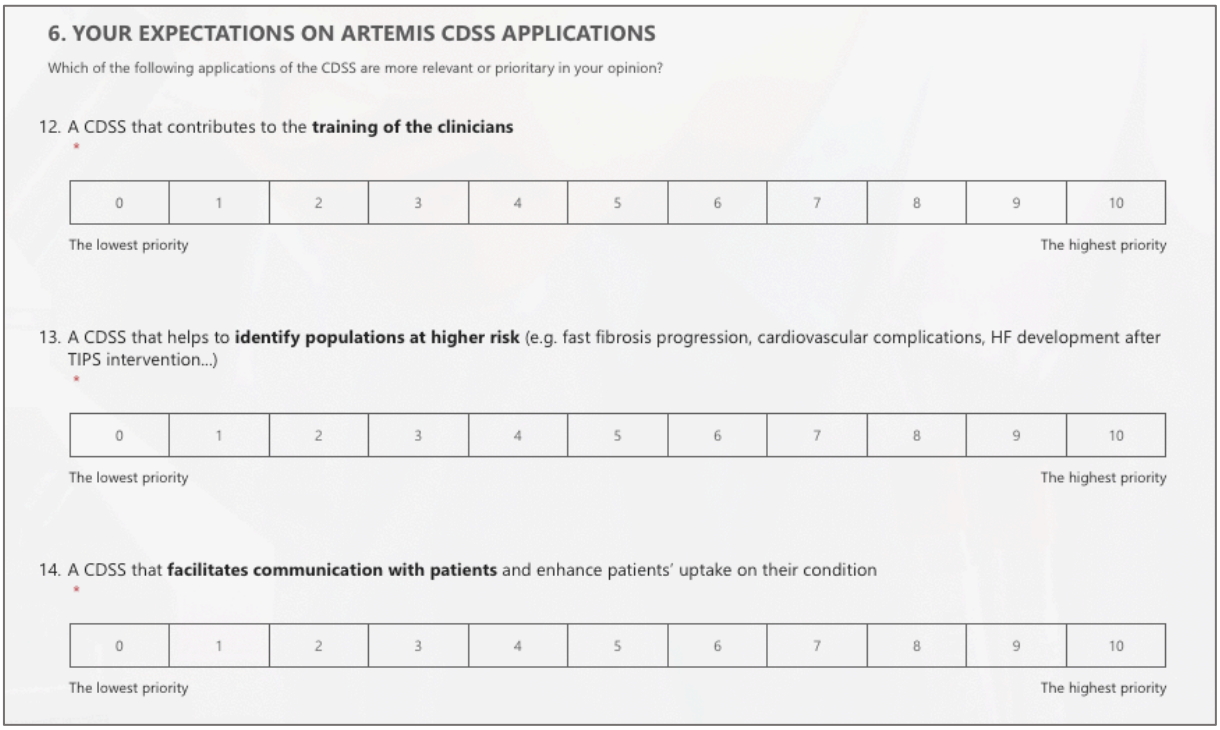

Figure 23. Screenshot of questionnaire's *section 6: Your expectations on ARTEMIs CDSS applications (1 of 2)*

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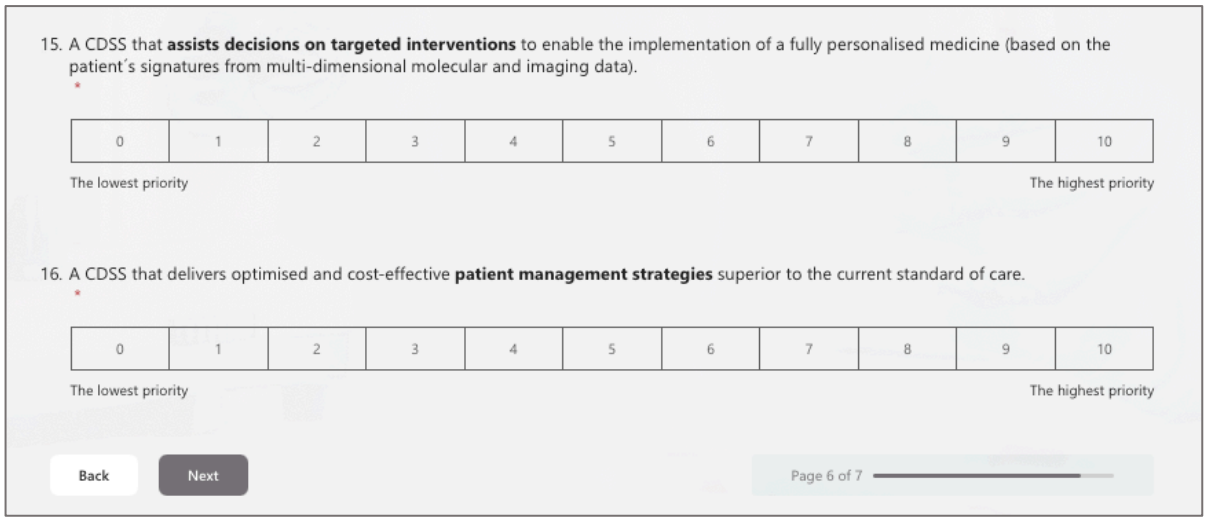

Figure 24. Screenshot of questionnaire's *section 6: Your expectations on ARTEMIs CDSS applications (2 of 2)*

Section 6 evaluates the priority given by each stakeholder to potential applications of the CDSS.

Questionnaire submission

The questionnaire was internally submitted, as a first iteration, to a selection of partners of ARTEMIs project:

Table 4. Selection of stakeholders belonging to the project consortium

Stakeholder group	Entity
Regulatory bodies	Betthera
MedTech industry	BC Platforms
Healthcare services	JUH

3.3 Questionnaire analysis and value proposition creation

The questionnaire provides qualitative information that helps understand the challenges, needs or pains of the stakeholder, as well as the gains or factors that would increase the likelihood of the stakeholder adopting a value proposition. This information is complementary to the questionnaire submitted to the external stakeholders.

The first section asked about the objectives. At this regard, the MedTech industry member and the healthcare professional are aligned, indicating that their aim is to improve different aspects of **patient management**. The regulatory body representative plays a support role in the implementation of the software tools.

Regarding the limitations, many of them refer to the difficulties of an **interdisciplinary approach** that involves integrating several tools, data sources, etc.

The solution that these stakeholders expect from the project are aligned to some extent (e.g., data visualization tools are demanded) but differs notably in other aspects (e.g., the importance of federated data infrastructure varies significantly from one stakeholder to another) as will be seen in the following sector.

The qualitative analysis has been done by mapping the answers in a **Value Proposition Canvas** for each stakeholder group, which is useful to categorize and visualize the ideas, especially the coherence of fit between what is demanded and what is offered.

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The Value Proposition Canvas for the MedTech Industry

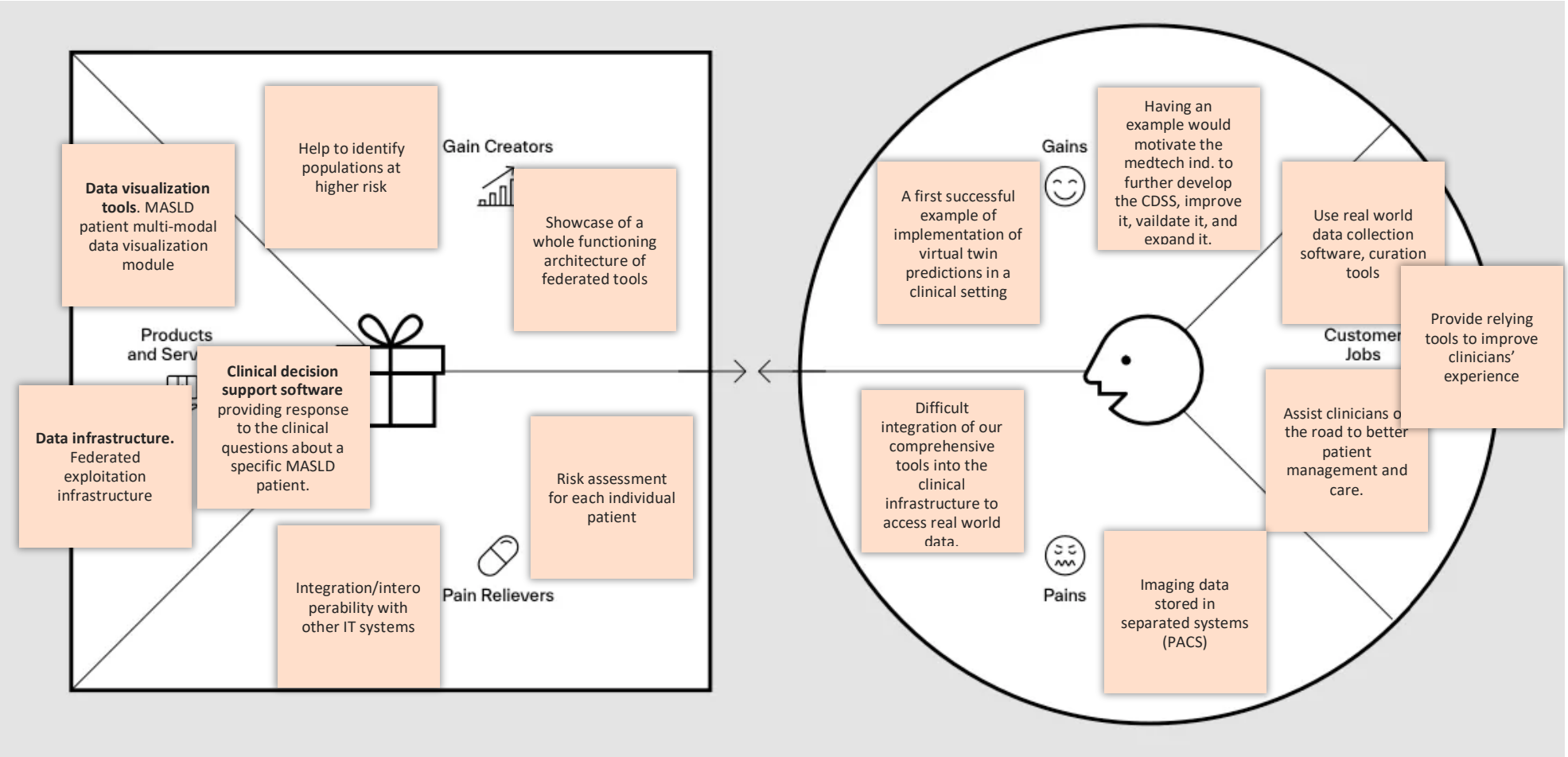

Figure 25. Value proposition canvas for the MedTech industry.

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The Value Proposition Canvas for Regulatory bodies

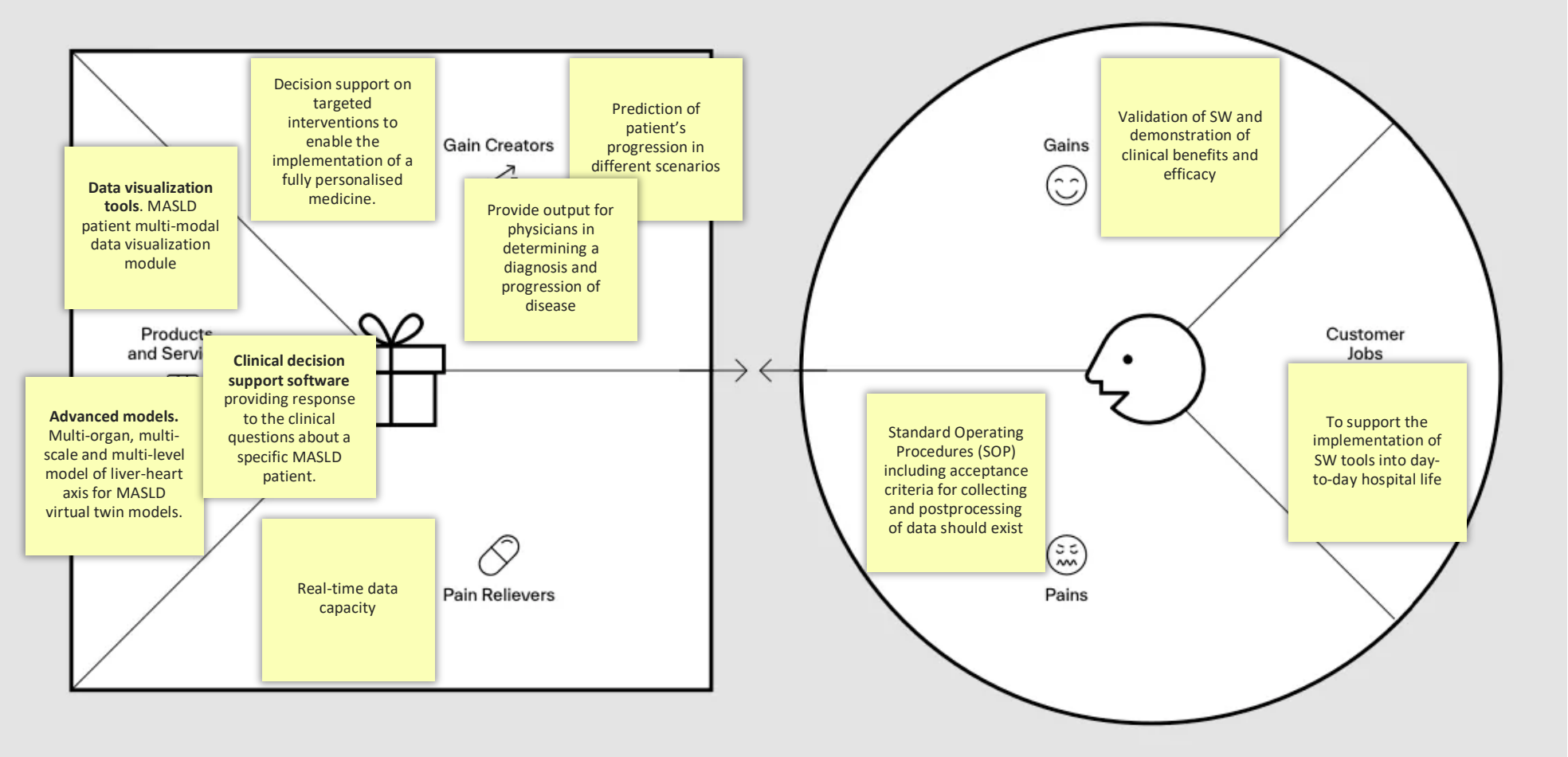

Figure 26. Value proposition canvas for regulatory bodies.

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The Value Proposition Canvas for Healthcare services

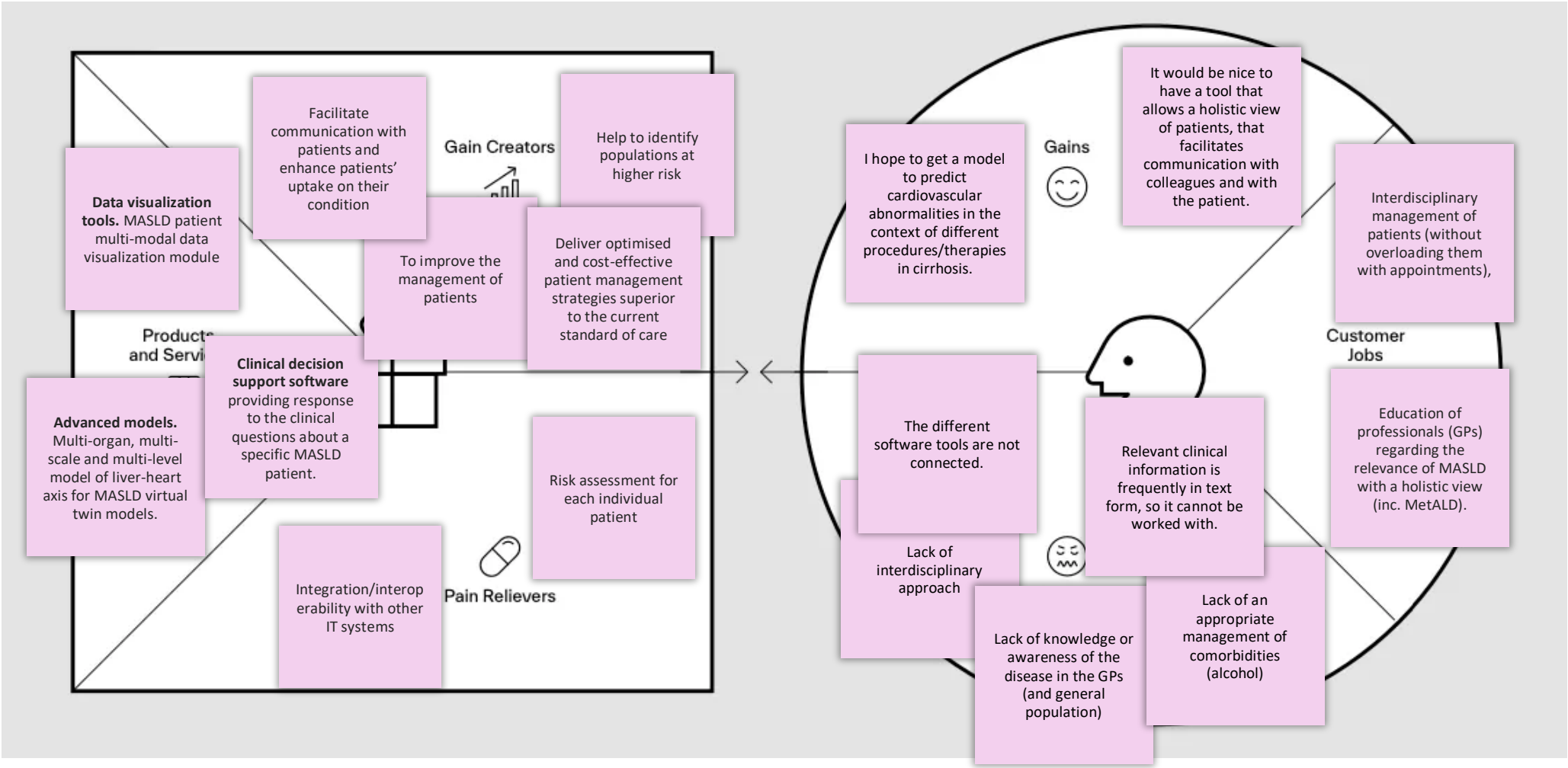

Figure 27. Value proposition canvas for the healthcare services sector.

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3.4 Questionnaire analysis and development of the value proposition

In addition to the qualitative assessment, the questionnaire design also incorporated quantitative data that can be very useful to rank or prioritize the features, functionalities or modules that make up the value proposition.

Questionnaire analysis – Ranking of the Key Exploitable Results

The expected results of ARTEMIs were ranked by the consulted stakeholders based on the utility and value that they expected for their professional activity, being **1 the most** and 7 the less valuable result. The ratings are presented in the table below:

Key Exploitable Result (KER)	Medtech	Regulatory	Healthcare
Processing pipelines for omics and digital imaging data, to extract quantitative metrics as inputs to the multiscale models.	5	6	5
Data analysis tools. Multi-modal clustering of patients and pattern identification.	4	5	4
Data visualization tools. MASLD patient multi-modal data visualization module.	3	3	3
Clinical decision support software. Software providing response to the clinical questions about a specific MASLD patient based on the input data and the outcomes of the advanced models.	2	1	1
Advanced models. Multi-organ, multi-scale and multi-level model of liver-heart axis for MASLD virtual twin models.	6	2	2
Data infrastructure. Federated exploitation infrastructure for data of thousands of patients along the MAFLD spectrum.	1	4	7
Model assessment tools. Set of methodologies for assessment of trustworthiness (accuracy, robustness, reproducibility, explainability) in the models' performance.	7	7	6

Table 5. Ranking of ARTEMIs' Key Exploitable Results for each stakeholder.

The CDSS is clearly the most valuable result for these stakeholders.

The advanced models are key for regulatory and healthcare professionals, but not for MedTech, who gives the highest rank to the federated data infrastructure unlike the other two stakeholders.

These insights indicate that the project has several results that could be highly appreciated in the market. Therefore, it is necessary to understand the motivations of the potential customers and use them in the design of the value proposition and the corresponding products or services.

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Questionnaire analysis - Functional and non-functional features of the CDSS

Section 5 of the questionnaire was focused on the CDSS. Firstly, the respondents chose the functional feature that, in their opinion, would be most valuable in the market (for users). The results are shown below:

Functional feature	Medtech	Regulatory	Healthcare
Timeline of patient's journey-trajectory			
Prediction of patient's progression in different scenarios		X	
Risk assessment for each individual patient	X		X
Weight of each risk factor on each patient's progression			

Table 6. Most valuable functional features

Secondly, they chose the non-functional (technical) feature considered as the most critical for the CDSS commercial success.

Technical feature	Medtech	Regulatory	Healthcare
Modularity			
Compliance with EDITH project guidelines			
Real-time data capacity		X	
Integration/interoperability with other IT systems	X		X

Table 7. Most valuable technical feature.

Although the sample size is not representative, this method can be used to orient future developments and/or the product design and marketing.

Questionnaire analysis – Applications of the CDSS

Section 6 of the questionnaire evaluated the priority given by each stakeholder to potential applications of the CDSS (the higher the number, the more priority is given to the application).

Application of the CDSS	Medtech	Regulatory	Healthcare
A CDSS that contributes to the training of the clinicians.	6	7	7
A CDSS that helps to identify populations at higher risk (e.g. fast fibrosis progression, cardiovascular complications, HF development after TIPS intervention...)	10	9	10

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A CDSS that facilitates communication with patients and enhance patients' uptake on their condition	7	5	10
A CDSS that assists decisions on targeted interventions to enable the implementation of a fully personalised medicine (based on the patient´s signatures from multi-dimensional molecular and imaging data.	8	10	7
A CDSS that delivers optimised and cost-effective patient management strategies superior to the current standard of care.	8	7	9

Table 8. Priority level of the potential CDSS applications.

The type of information gathered in this section (quantitative priority level) and in the previous one, can be used to build the "product backlog", which is a prioritized list of the functionalities that the CDSS product should contain. This is based on agile methodologies, which are widespread in software development and entrepreneurship programmes.

Although building the CDSS product backlog is a highly technical task that involves a comprehensive and multi-domain analysis of use cases (which is done in WP2 and WP7), this version is based on the use of questionnaires and interviews and intended to identify those functionalities that are top-of-mind and constitute the essence of the value proposition for each stakeholder group.

The ratings obtained show that the opinion of the stakeholders participating in the questionnaire is that the CDSS should prioritize its application as **1)** a tool to support the identification of populations at higher risk, followed by **2)** assist the decisions on targeted interventions towards personalised medicine and **3)** the delivery of cost-effective patient management strategies.

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4 CONCLUSION

This deliverable contains a description of the consultation activities (questionnaires and interviews) carried out with representatives of various stakeholder groups, both internal and external to the Project. These activities have made it possible to gather first-hand information about the expectations and needs of the different stakeholder groups, and to initiate a **co-creation of the value proposition** for the CDSS, through the identification and prioritization of the product features.

5 FUTURE WORK

This report contains the methodology and the questionnaires that can be used anytime during the project lifecycle and beyond to gather the opinion of the stakeholders and analyse the problem-solution fit or the product-market fit. i.e., to determine whether the value proposition satisfies needs of potential users in the market. Therefore, this report only contains a first iteration of the process.

As described in D9.1, after the elaboration of the value proposition, other business-oriented activities will follow, starting with the market analysis and the business model formulation.

Figure 28. Main steps of the Exploitation Strategy development

In January 2025, Task 9.1 will shift its focus to the IPR management, supporting Technology Transfer Offices in the exploitation of IP, while Task 9.2 and Task 9.3 kick-off to start elaborating the exploitation plan for the project results and defining the sustainability of the data exploitation strategy. All three tasks run until the end of the project (month 48).

By the end of the project, a complete strategic cycle will be completed to facilitate the future commercial exploitation of ARTEMIs project results.

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