MASTER THESIS

Strategic Product Design | Medisign

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TU Delft

Delft University of Technology

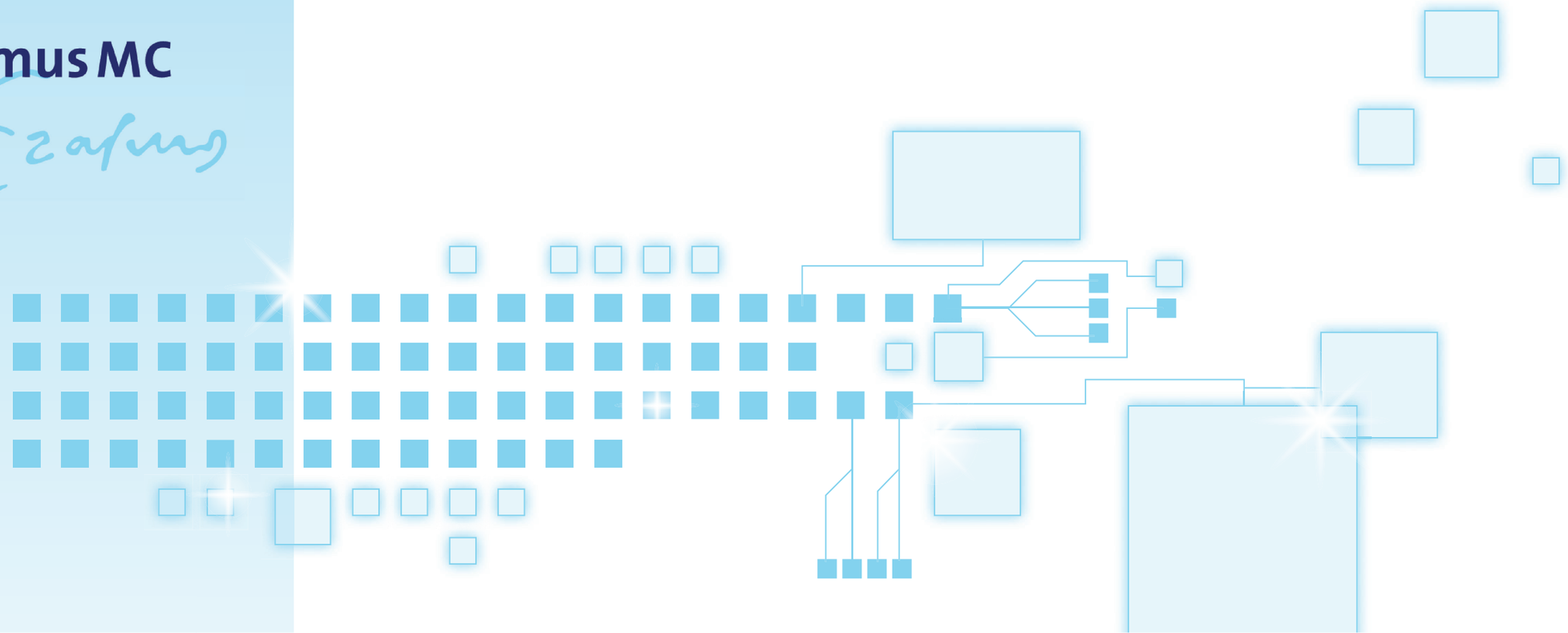
Erasmus MC

Responsible

innovation of

Artificial Intelligence

at Erasmus MC



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MSc Strategic Product Design
Medisign Specialization

Graduation Project
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Responsible Innovation of
Artificial Intelligence at Erasmus MC

Preface

Dear Reader,

I appreciate your interest for my graduation project. I am grateful that I was able to learn so much within this study which brought me to this final result of 5 years at the TU Delft. I have always enjoyed going to the IDE faculty where I first of all received a technical basis followed with a strategic approach. With a passion for improving healthcare, the medisign specialisation was a great addition. Hence, it is rewarding to apply these skills, at Erasmus MC with my graduation project, where I could engage with innovative technology and learn more about the legal context to apply both of these expertise to the medical field.

I would like to thank my supervisors for the guidance, feedback and support they gave me. Richard, thank you for your enthusiasm and overarching input of knowledge. This encouraged me to focus on the design and strive for the best end result. Hosana, thank you for your detailed constructive feedback and your positive coaching, this has improved the quality of the report and increased my enjoyment of writing. I would like to thank Greet for all the knowledge she was willing to share with me and her energetic approach with which she represented the project among others. Maud, Roëlle and Sacha, thank you for the nice working environment, it made me feel comfortable and welcomed.

I would like to thank the various participants in the study for the great conversations. Clinicians, researchers, technicians, ethicists, legal and business experts, thank you for sharing your knowledge. I have learned so much from the conversations and I hope this project represents your needs.

In addition, I am grateful for the people around me who are always there for me, with genuine interest and compassion. My boyfriend in particular who helped me in the development of the report, but also supported me mentally. Thank you for being there to supported me. Family, thank you for always being willing to help. You all have been very meaningful to me throughout my studies with the stability you offered and the empathy with which you have listened to all my stories.

I want to thank my friends. The friends from delft who are familiar with the process and always knew the right thing to say. And of course the friends from the past, where everyone has gone in different directions, which complemented my view with different perspectives.

Kind Regards,

Denise de Vries
August 2023

Abstract

In this study, the aim is to find out how Erasmus MC can properly prepare for the AI Act. An iterative design approach was utilized to explore what AI project members may experience during this regulatory process. Several factors have emerged during this experimental study, including the allocation of responsibility, the importance of education and the connection of the medical, technical and legal domains. The complexity of the problem necessitates multiple solutions, which resulted in two designs, the concept of a service system and a roadmap. The service system embodies the needs of the target group, while the roadmap offers a pragmatic guide for the organization to prepare for the changes following the legislation for AI.

Keywords

AI; AI Act; algorithm; healthcare; MDR; impact assessment; risk management; quality management system; regulations; project management; safety;

Reading guide

In a design study, the process is iterative and non-linear, often referred to as the fuzzy front end. Therefore cross-references help with the structuring of findings which ensures the coherence of the overall story line. The terms, the abbreviations and several design references are highlighted in this reading guide.

Definitions

Algorithm: An ordered set of instructions recursively applied to transform data input into processed data output, such as a mathematical solution, search engine result, descriptive statistics, or predictive text suggestions.
AI Act: the proposal by the European Commission for a new European Union regulation governing artificial intelligence systems.
Robustness: The ability of an AI system or algorithm to perform consistently well under various conditions, including unexpected or challenging situations.
Notified Body: Certification-granting entity ensuring product conformity with regulations and standards.
Sandboxes: a virtual environment in which AI applications that have not yet been approved, due to the regulatory waiting period, can run software without affecting other applications

Abbreviations

MDR: Medical Device Regulation
NB: Notified Body
AI: Artificial Intelligence
METC: Central Commission on Human Research
WMO: Medical Research Act
RMP: Risk Management Plan
CCMO: Central Commission on Human Research
IMDD: Investigational Medical Device Dossier

Heading design:

The design of the different headings can be found below:

Introduction Text

Subtitle 1

Subtitle 2

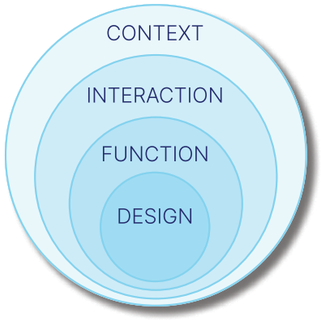
Subtitle3

Normal Text

Figure/Table

Color coding

The blue colors are to indicate which part of the process the reader is reading. Light gray is included for the general parts. Then the sections go from light blue at the beginning of the design process to darker blue. This can be seen in the sidebar as well as in the visual below showing the Vision, mission, strategy and design visual.



Core elements

To create an overview of the core elements the following parts are shown in the sidebar of the page, enabling a fast and clear overview for the reader. The following elements are shown below:

Goal
Explanation
Method
Explanation
Main insights
Explanation
Next steps
Explanation
Cluster theme
Components

References

References are used to refer to main findings, clusters and quotes. To refer to the main insights of previous chapters, the name of the finding is shown with next to this, the number of the chapter, where the main finding was gained. The same is done for the clusters. Lastly the quotes of the transcripts communicate the quote number and the participant number:

- Q: number of the sentence of the transcript
- P: number of the interviewed participant

Reference to main insight Chapter ...
Reference to a cluster Chapter ...

Quote name
This is the example of a quote which is numbered with the sentence number of the transcript: Q and the number of the participant: P
Q1 P1

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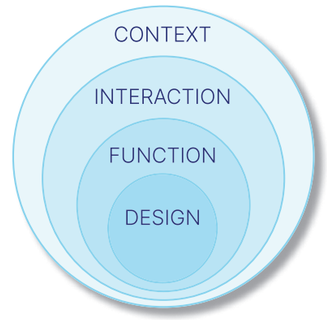
General



1. Introduction

This introduction explores the growing presence of AI in daily life, especially in healthcare, and the associated benefits and risks. It addresses challenges, emphasizes the importance of preparation for Erasmus MC, and defines the research problem, questions, and the design assignment of this study. The upcoming AI Act's strict legislation and continuous validation processes aim to ensure safe AI usage, highlighting the need for ongoing safety monitoring, transparency, and user awareness to address potential human rights impacts. The AI Act will play a pivotal role in securing the safe implementation of AI applications in healthcare and other domains.

Artificial Intelligence

Artificial intelligence (AI) has become part of our daily lives. Even in healthcare, the use of AI applications on patients' data is growing. People might not be aware of the fact that the services they use, are based on algorithms. However, these people are still providing the data to improve this intelligence. But what is this intelligence that a non-human being can provide? The definition that the European Union uses for regulation is: '*artificial intelligence system' (AI system) means a system that is designed to operate with elements of autonomy and that, based on machine and/or human-provided data and inputs, infers how to achieve a given set of objectives using machine learning and/or logic-and knowledge-based approaches, and produces system-generated outputs such as content (generative AI systems), predictions, recommendations, or decisions, influencing the environments with which that AI system interacts.*' (European Commission, 2021) The AI Act proposal's definition is complex but provides a comprehensive explanation of the involved elements. Hence, it will serve as the study's "AI" definition. This complexity with associated advantages and disadvantages will be explained further.

Benefits of AI

AI offers valuable benefits in healthcare. Through predictive analytics, it can anticipate disease progression and potential outcomes. In diagnostics, AI enhances accuracy and efficiency by analyzing medical data. It could help clinicians with analyzing photos and videos, aiding in detecting anomalies and guiding treatment decisions. Moreover, AI could enable early disease detection, leading to timely interventions and improved patient outcomes. Overall AI applications could be an additional support for healthcare professionals, driving advancements in medical care. (Slooff, 2023)

Danger of AI

Even though AI is a great innovation that offers immense possibilities, it also brings dangers. Some specific characteristics of AI makes it difficult to get a grip on the quality and safety of these applications. Firstly, it is dependent on he data accessible and integrated into the system. Therefore, data management is essential. Secondly, it is dependent on how the system is designed and how it continues to work as new data is added to make the system 'smarter'. (Janssen et al., 2020) These hazards show the importance of being aware of the risks involved in developing AI. One significant concern is the risk of discrimination, as illustrated in the 'toeslagenaffaire' in the Netherlands. This case exposed how AI systems can have biases and discriminate by only targeting certain groups, leading to social injustice. Additionally, changes in AI system operations can have unintended consequences. For instance, when the storage location of data was modified in the healthcare information exchange (HIX), the algorithm missed an essential measurement. These examples demonstrate the potential dangers of relying heavily on AI without proper testing and safeguards. Moreover, the use of AI in healthcare raises concerns about patient vulnerability. Many patients may not be aware that AI is utilized in their care, highlighting the need for transparency and user awareness.

AI Safety

The use of AI can be dangerous and can interfere with our fundamental rights as human beings. Several risks come along with the use of AI which could result in physical or mental harm to individuals. To prevent this from happening, strict legislation is needed. (Sioli & Mazzini, 2023) This is already in place for medical devices, including software. Medical software providers have to follow the Medical Devices Regulation (MDR) to get a CE certificate that enables the usage of this software in healthcare. However, this legislation is based on products that do not change in function after validation. AI is different, it is a product that can adapt to new data and thereby change its function over time, hence it is called an intelligent product. This results in a situation where the AI software might be approved based on its function now, but could harm people later. Therefore, the European AI Commission is working on a new Law: The AI Act, which includes strict rules to maintain a continuous validations process during the whole lifecycle of an AI application. To minimize the risks of AI applications, it will be required to monitor the functions (e.g. robustness, accuracy, etc.) of the AI application.

Ensuring safe AI applications

Within the AI Act, the EU AI Commission tries to combine the current regulation with the exponentially growing interest in AI usage. Within the medical sector, this means that it will be mostly in line with the MDR regulations for software applications. According to these regulations, AI software has to go through different assessments which are checked by Notifying Bodies (NB) to receive a CE mark. However, the difference between AI compared to other software is that its functioning can change over time due to its self-contained learning curve. Therefore, it is needed to ensure safety during the whole life cycle of AI applications usage. These new regulations for the AI Act are coming at the end of 2023, which shows that preparation for this law is necessary. However, some aspects of the law are not yet certain, which makes it hard for stakeholders to prepare. Thus, it is crucial to inform them about the importance of having proper documentation at the beginning of the process. Therefore preparation is needed to make sure that every stakeholder within Erasmus MC is preparing already for the law that is coming up.

Urgency of preparation

The importance of the preparation within Erasmus MC should not be underestimated. It will be mandatory to comply with the new AI Act in the future. Erasmus MC faces the risk that the AI being used now will be temporarily banned from use until they get all their regulations in order.

1. Introduction

There is also a possible scenario that new AI cannot be validated, which slows down the innovation process within Erasmus MC. Therefore, creating awareness is important (European Commission, 2021) (Sioli & Mazzini, 2023). The process of implementing AI within Erasmus MC should be streamlined and every stakeholder should be informed about the changes that will take place based on the AI Act.

Problem

The risks of the usage of algorithms for AI are especially high in healthcare when it comes to patient safety and privacy. An AI Act is currently being developed to ensure the responsible and ethical development and use of AI technology. (European Commission, 2021) Transparency of the whole development process is therefore needed to ensure that it is safe to use the algorithms for AI, but currently, there is a lack of this transparency. (Scientific Foresight Unit, 2022) There is no common storage place that enables Erasmus MC to trace the documentation. There is also a lack of guidance for AI developers within this documentation process, who often are not specialized in regulations within the healthcare sector.

This project aims to define the difficulties that AI developers face during the documentation process within the healthcare sector. The objective is to guide developers to improve the traceability and transparency of medical AI throughout its lifecycle.

Research Question

Based on the problem definition the aim is to answer the following research question:

'What can different members of an AI development team encounter during the documentation process for the regulations of the AI Act?'

Assignment

A concept of a service system combination will be designed, that will store all documentation during the development of (new) medical algorithms for AI, by guiding the AI developers to the required documentation, which will improve traceability and transparency of medical algorithms for AI throughout their lifecycle.
This service system combination will be a digital safe space for AI project members and other stakeholders within Erasmus MC. With the research, the aim is to discover the best strategy to improve the documentation process and the design will reflect the input of this research.

This strategic approach for healthcare purposes shows that the assignment fits within the Medisign specialization of the IDE masters.

In this project, the focus is on developing a visual interactive prototype of a digital safe space to show how a service system combination can be designed in such a way that the AI developer is guided in the right direction. No working product will be created, but recommendations will be made on how this overarching safe system could be developed.

Design Question

Based on the assignment the aim is to answer the following research question:

'How can a hospital develop a service system combination to give more guidance to AI developers within the regulation process of the AI Act?'.

2. General Approach

Type of research

The research in this study adopts a design research approach, using empirical data to investigate the subject. The research process follows a pattern of diverging and converging, which can be associated with the double diamond model.

The overall approach combines VIP (Vision in Product Design) and Service Design perspectives to move from a vision toward a service system combination. Throughout the study, multiple methods are used in different chapters, and an overview of these methods is provided in Figure 1, showcasing the diverse range of usage of techniques.

Data gathering

The data gathered for this study involved a combination of desk research, field research, and design research. Desk research involved collecting data from various sources such as literature, government publications, the Proposal AI Act, and newsletters related to the AI Act. Field research was conducted through interviews with relevant stakeholders, which were recorded and transcribed for analysis. Additionally, informal chats and participation in AI related lectures and congresses provided valuable insights. In line with the design research approach, data was also gathered through experimentation and observation, allowing for a holistic understanding of the subject matter.

Procedure & data analysis

During the whole study: 10 participants were interviewed 5 during the context research and 5 during interaction research. The field research data was gathered during the whole study. The experiments and observations were mainly used in the interaction and function phase. Each chapter is approached as a small experimental research, consisting in most cases of the parts: Introduction, method, results of the design method, discussion, and conclusion. At the end of each chapter the main findings were analyzed and the research/design question and sub-questions were answered.

Validity and reliability

Validity is achieved through the use of multiple ways of data collection, allowing for a comprehensive understanding of the complexity surrounding regulations of medical AI applications.

Reliability is promoted by following systematic data collection procedures and design methods, ensuring consistency. The iterative nature of design research, with its cycles of experimentation and observation, further enhances the validity and reliability of the findings. (Price & Kleinsmann, 2018)

Context

Top-down approach

3. Stakeholdermap

- Stakeholdermapping

4. Context Research

- Qualitative Research
- Partial use of Context Mapping Skills
- Partial use of VIP method

5. From Law to Action

- Ladder of Abstraction

Interaction

Bottom-up approach

6. Process mapping

- Role explanation, Inspired by:
  - Thinking hats of Edward de Bono
- Process mapping, Inspired by:
  - Journey mapping
  - Product life cycle
  - Story board

7. Case example

- Flow Chart
- Personas
- Task overview, Inspired by:
  - Agile management method
- From Research to Product. Inspired by:
  - Story board
  - Product journey

Function

8. Creative Ideation

- Analogy and metaphor
- How to
- Hits and Dots

9. Creating Components

- Qualitative research
- Content analysis

Design

10. Concept Service System

- User Interface design
- Prototype
- Design Roadmapping

11. Roadmap

- Roadmap
- Tourguide

12. Evaluation

- User Experience prototype testing
- Questionnaire
- Creative clustering

Figure 1: Approaches

CONTEXT

In the first part of this study, the context was examined with the aim of gaining as much knowledge as possible on the matter and its complexity. Later, more choices will be made within this research, slowly scoping to a specific part of the solution. Within the context research, several experts were approached to discover how Erasmus MC can prepare for the AI Act. The aim here is to find out what problems the AI project team might encounter as a result of the new legislation. Hence, both the regulations and their application within Erasmus MC were studied in depth.

CONTEXT

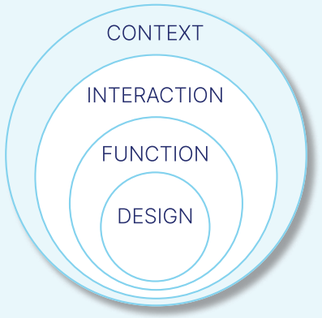
Prepare Erasmus MC for the new legislation: AI Act

Goal:

*Defining the difficulties **AI project team** will encounter during the documentation process within the healthcare sector to **prepare** them for the new legislation and to make sure that they meet the **requirements of the AI Act**.*

Focus:

Future context (AI Act requirements), past context (MDR) and other approaches



Identify the relevant stakeholders

To discover the stakeholders needed in the compliance process

Stakeholder map

Discover relevant stakeholders to approach

3. Stakeholder map

The implementation of the AI Act requires a comprehensive understanding of the stakeholders involved in ensuring compliance. This chapter presents a stakeholder map developed to answer the sub-research question: "Who will be responsible for compliance with the AI Act?" The stakeholder map aims to identify the key individuals and organizations within and outside Erasmus MC who have roles in adhering to the AI Act regulations.

Method

Goal

The primary objective was to identify the stakeholders responsible for compliance with the AI Act at Erasmus MC with the following sub-research question:

- *Who will be responsible for compliance with the AI Act?*

Data gathering

The data gathering process included desk research, analysis of the AI Act regulations, and consultations with AI experts.

Data analysis

Based on the information gathered, stakeholders were categorized in a structured onion visualization. The stakeholder identification focused on distinguishing individuals, groups and organizations responsible for compliance, both within and outside Erasmus MC.

Result

An overview of the stakeholder map can be found in figure 2. The layers of the onion model are explained in this Result section.

Final Responsibility

This layer identifies the ultimate individual or group accountable for ensuring compliance with the AI Act's regulations. Within the AI Act this person, group, organization or company is called: the AI provider.

Internal Stakeholders

Individuals within an AI project team who play a significant role in the implementation of the AI Act.

External Stakeholders

Individuals who are not part of the implementation process but do have a majer role in responsible AI innovation, e.g. the users of and AI application who are responsible for the correct usage.

External Departments

Departments inside Erasmus MC that are involved in the AI Act's implementation.

External Organizations

Other external organizations that are part of the compliance ecosystem.

Erasmus MC circle

Additionally, a separate circle shows the stakeholders specifically within Erasmus MC, further illustrating their involvement in the process.

3. Stakeholder map

Discussion

The stakeholder map presented reflects the final version at the project's completion. Throughout the research, new stakeholders emerged and were incorporated into the map.

The stakeholder map will be used to identify interesting participants for the qualitative research used in chapter 4 to get a broad perspective of the context by involving stakeholders of multiple layers.

Erasmus MC involves multiple departments in AI Act compliance, emphasizing the need for a collaborative approach and clear communication channels.

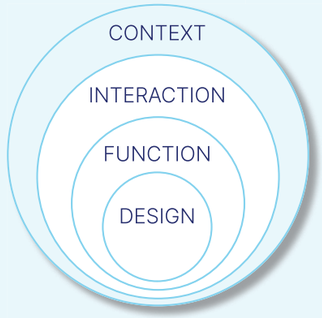
The composition of the AI project team varies based on the project's purpose and phase. Assembling multidisciplinary teams with the right expertise is crucial for successful AI project execution and compliance with the AI Act.

Limitation

While efforts were made to identify the main stakeholders, it is acknowledged that there may be other stakeholders not addressed in this research.

Conclusion

The sub research questions (*Who will be responsible for compliance with the AI Act?*) is answered with a stakeholder map. It provides a visual representation of the various individuals and organizations responsible for compliance with the AI Act at Erasmus MC. By identifying these key stakeholders, the organization can better understand the roles and responsibilities required for successful implementation of the AI Act's regulations. The stakeholder map serves as a valuable tool for fostering collaboration and ensuring effective compliance with the AI Act.



Department infrastructure Erasmus MC

Erasmus MC has a lot of expertise but these might be hard to approach

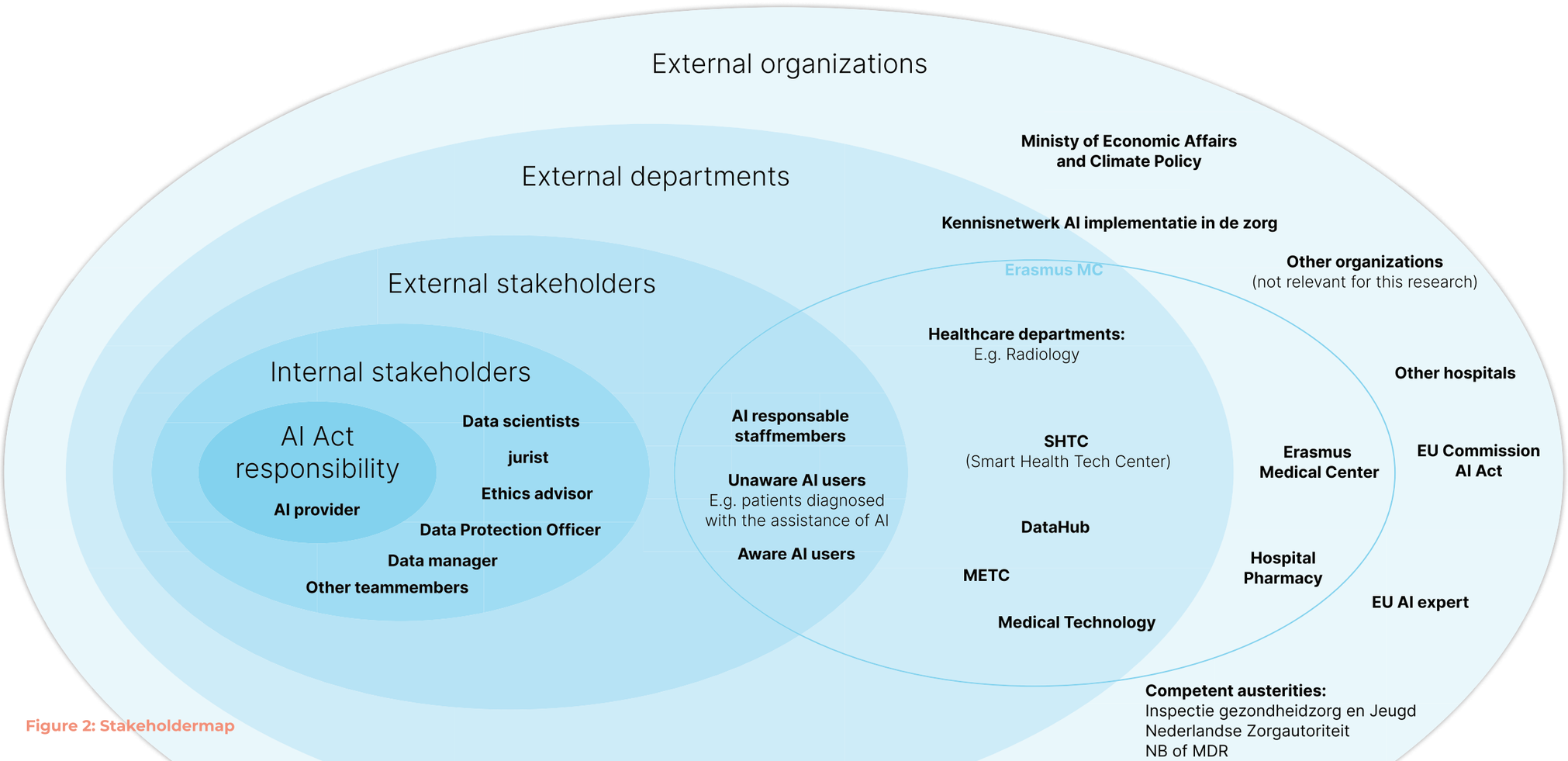
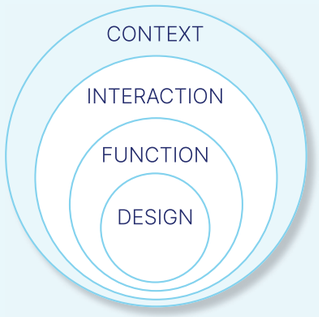


Figure 2: Stakeholdermap



Getting to know the subject

Studying the context to create a better understanding of the complexity of the problem

Discovering relevant context findings

Finding the main context findings to use as inspiration for the concept

Partial use of Context Mapping

Using statementcards and clusters

Partial use of VIP

Determine domain and time frame
Defining Context Findings

4. Context Research

To get a comprehensive perspective of what different members of an AI development team can encounter during the documentation process for the regulations of the AI Act, a qualitative study is conducted. Desk research and field research are combined to find out what will be expected in the future and how this connects to the approaches in the past. This comparison gives a better understanding of the context of the problem and the relevant findings to consider in the design process.

Method

Qualitative research is conducted in this chapter to understand opinions and experiences of the AI legislation. The data gathering aligns with this approach, where different qualitative data sources where used.

To analyze the data, multiple design methods were used or partly used.

Firstly stakeholder mapping was used to create an overview of the people involved and to find a broad range of interviewees.

In the next part, qualitative information was gathered through interviews, informal conversations and lectures and combined with desk research. The analysis of the data was inspired by a component from the Context mapping method in combination with the VIP method, where statement cards were created and clustered. (Sanders & Stappers, 2013) (Hekkert & Van, 2016)

Afterwards these findings were explained in context findings. (Hekkert & Van, 2016)

Goal

There are two main purposes of this context research. Firstly, the goal is to gain a better understanding of the subject and the complexity of the problem. Secondly, relevant contextual findings can be discovered, providing valuable insights into the background knowledge which could be helpful for the reader and could serve as inspiration for developing the concept service system.

By starting to look at the obligations and requirements of the AI Act and the approaches of others, a future vision has already been created in the shape of a law that envisions an ideal picture of a future society in which AI can be used safely. To make sure this vision connects to the context of Erasmus MC, it is needed to dive deep into the current way of working within the healthcare sector and Erasmus MC specifically, to investigate a suitable approach to this problem. This chapter provides answers to the following sub-research questions:

1. *How can AI providers meet the requirements and obligations of the future EU Regulations for AI?*
2. *How are AI providers currently adhering to the requirements of the MDR?*
3. *How is Erasmus MC currently handling the regulatory process of AI applications, made internally or externally?*
4. *How is Erasmus MC preparing for the growth of AI usage within healthcare and the requirements of the AI Act?*
5. *How are other organizations approaching this problem (preparing for the AI Act)?*

Each question will be answered in the following paragraphs in the form of contextual findings.

Data gathering

Both desk and field research are combined to explore the context of the problem. The desk research was gathered with multiple datasources and for the field research several people were approached and spoken to, which resulted in both interviews and informal information transfer.

Desk Research

As the literature on the regulation process of AI within healthcare is limited due to the novelty of the not yet existing AI Act, additional other sources are used for the desk research. Literature studies were combined with European legislation, by analyzing government publications, the proposal of the AI Act, and other relevant documents and newsletters. Other documents that communicate approaches of the problem were also analyzed to get a good overview of the complexity of the AI Act and to see how other organizations currently approach this gray area.

Field Research

To get a better understanding of the current approach of legislation within the Erasmus MC, field research was needed. Data was gathered in multiple ways. The stakeholder map of chapter 2 was created with multiple purposes. In this chapter the stakeholder map is used to approach a diverse range of participant to get a broad perspective on the matter. Firstly 5 semi-structured interviews were conducted with different stakeholders to gather in-depth insights . The interview were recorded and transcribed. Additional information was gained during the field research, informal conversations and lectures were also included in the data. This was done by writing brief summaries after the occurrences on what was told, as well as by including the notes made at these occurrences. (See table 1)

Procedure

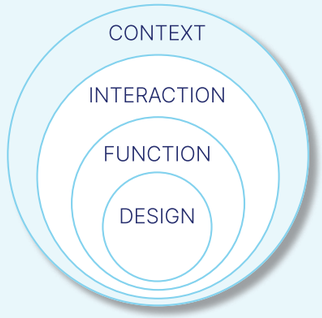
The procedure for this method started with the creation of a stakeholder map (See Chapter 2). This step ensured that key individuals and groups involved in the subject matter were identified and included in the research process.
Next, some data was gathered from the interviews, informal chats, and lectures, this data was shortly summarized. The interviews were recorded and transcribed (See Appendix 8), not literally, but capturing the valuable information shared by the participants. The quotes from the transcript were translated into statement cards and clustered, using the thematic clustering method. (Sanders & Stappers, 2013)

Data analysis

Within the overall approach, a part of context mapping and a part of the VIP method were used to explore context findings of Erasmus MC. The primary focus of the VIP approach is to identify abstract patterns. However, the objective of this research was to uncover practical strategies and and the pragmatic implementation of law requirements. To achieve this, statement cards from the Context Mapping method were employed to group the results obtained from the field research (See Appendix 1).

The results were highlighted with context findings of the VIP method, this approach can give a

4. Context Research

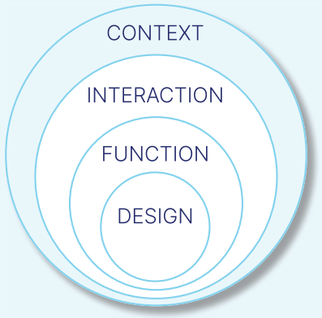


clearer story about the background knowledge that is important to the reader. Within these findings the research questions were addressed, focusing on five key context findings. These findings were selected to provide clear background knowledge to the reader. By organizing the information within these findings, the aim was to present the background knowledge in a structured and easily understandable way. Lastly, the context findings were analyzed to gather the main insights from the research.

- Interviewed
- Informally spoken
- Attended lecture

Participant	Function	Data collection		Expertise
		Audio to transcript light	*Notes*	
Participant 1	Radiologist	x	x	AI research, AI projects & AI application use
Participant 2	EU AI expert:	x	x	Data Science & European Union
Participant 3	Employee Medical Technology	x	x	Medical Devices Regulation
Participant 4	Employee METC (WMO mandatory)	x	x	Ethical research
Participant 5	University professor of Ethics	x	x	Ethical development, Policy
Participant A	Staffmember R&D office		x	Medical Technology, Legislation
Participant B&C	Employees DataHub		x	AI implementation
Participant D	Employee Quantib		x	AI application development
Participant E&F	Members of the European Commission		x	AI legislation

Table 1: Expert participants



Result - Findings Field Research

Stakeholdermap

The stakeholder map of chapter 2 was used to identify diverse participants for this qualitative research to gain a broad contextual perspectives of stakeholders in multiple layers. Most of the stakeholders were approached, but only some them contributed input to this study by providing valuable insights, these stakeholders are numbered in figure 2.1 and a summary of the input the gave is written on this page.

Interviewed

Participant 1

The interview with the radiologist was helpful to get to know the difference between the internal development of AI and purchasing AI with a CE certificate.

Participant 2

The EU AI specialist shared extensive information regarding the lack of detail in the AI Act and their efforts to translate it into actionable requirements. Additionally, he presented two examples illustrating their utilization of this approach in monitoring their current AI applications.

Participant 3

The employee of Medical Technology talked about her expertise in internal legislation and the MDR. She also explained the proposal for an AI expertise center.

Participant 4

The employee of METC talked about the approval of research, however, the AI research is not WMO mandatory and therefore it is not the expertise of her team.

Participant 5

The Ethical adviser explained why it is needed to bring ethics together with engineering and explained its preference for a Medical Ethics Commission.

Informally spoken

Participant A

A meeting with the client gave informative in-depth knowledge about the regulation and internal/external approval, which is why this is also listed under field research.

Participant B&C

Two individuals from the Datahub were open to discussions but preferred not to be recorded. They shared insights about their project and focused on creating an AI implementation funnel within Erasmus MC, which aligns significantly with this project. They suggested diving into the following question: "At which stage of the process is a medical specialist necessary, and what tasks should they be responsible for?"

Attended lecture

Participant D

Quantib gave a lecture where they talked about the 'AI in Industry challenges'. The elaborated on the situation where a data-scientist changes one line of code, which might only take one day, but creates a lot of work in the background to update all the paperwork. They also showed their deployment model where the medical specialist can approve the results of the AI application and with this feature, it automatically monitors continuously the accuracy.

Participant E&F

Lucilia en Gabrielle, members of the European Commission, spoke at the NL AI Congres. They confirmed the regulation requirements will change and they recommended preparing for the new AI Act. They kept mentioning that the commission will try to provide 'harmonized standards' if the AI Act is there, however, it is still unclear what the abstraction level of these standards will be and whether it is concrete enough to define the actions for the different stakeholders to meet de obligations. In addition, they were telling about a 'Coordinated Plan on Artificial Intelligence' of the European Union. Connecting this plan with the final design will be helpful by underlining the relevance of this project.

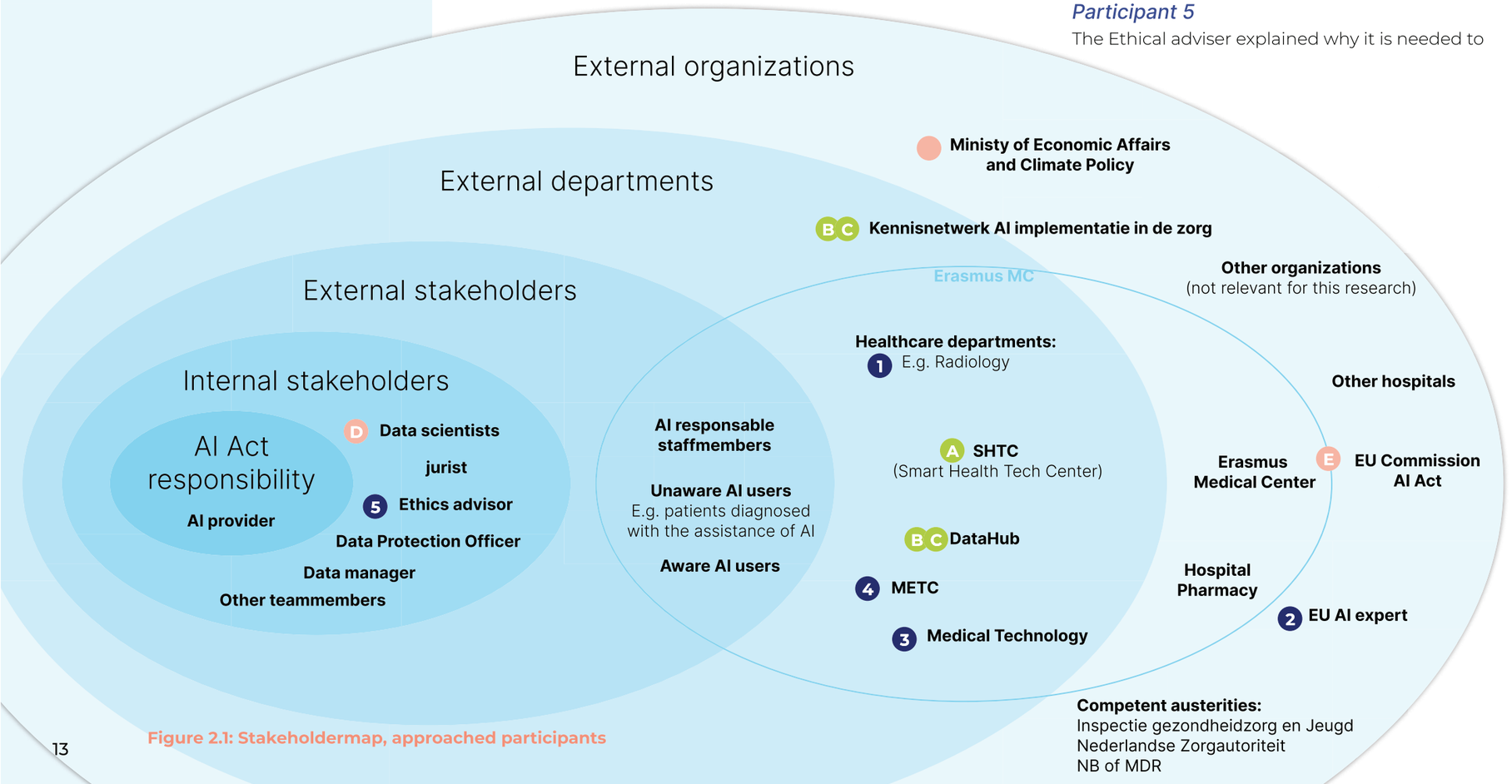


Figure 2.1: Stakeholdermap, approached participants

4. Result - Context Research

Overall, the goal is to find out how Erasmus MC can prepare for the upcoming AI Act. The context findings aim to provide insights into how different organizations, including Erasmus MC, are approaching the implementation process for AI applications. A domain is chosen to know what to focus on in the design process in combination with two time frames.

Domain and Timeframe

Domain

The concept product will be designed for the domain: regulations of Medical AI applications to help Erasmus MC envision a strategic direction into the near future when the AI Act goes into effect. This future timeframe will be based on two points in time that will be addressed in the following text. (Hekkert & Van, 2016)

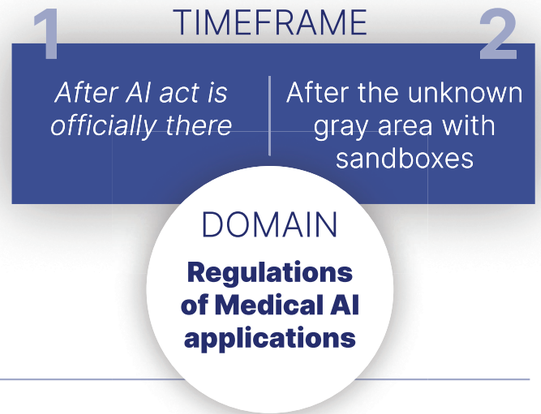
Timeframe

1: After AI Act is approved

In part 1, the recommendations based on the research will be explained to enable Erasmus MC to prepare the steps they need to take. (European Commission, 2021) (Sioli & Mazzini, 2023) This is after the AI Act is approved but when there is still a gray area with sandboxes (European Commission, 2021) (+/- 5 years) This enables multiple levels of progression in the conceptualization of a service system combination, showing the ideal situation of guidance through AI regulations. (Vermeer, 2023) (Sioli & Mazzini, 2023)

2: After the unknown gray area (+/- 5 years)

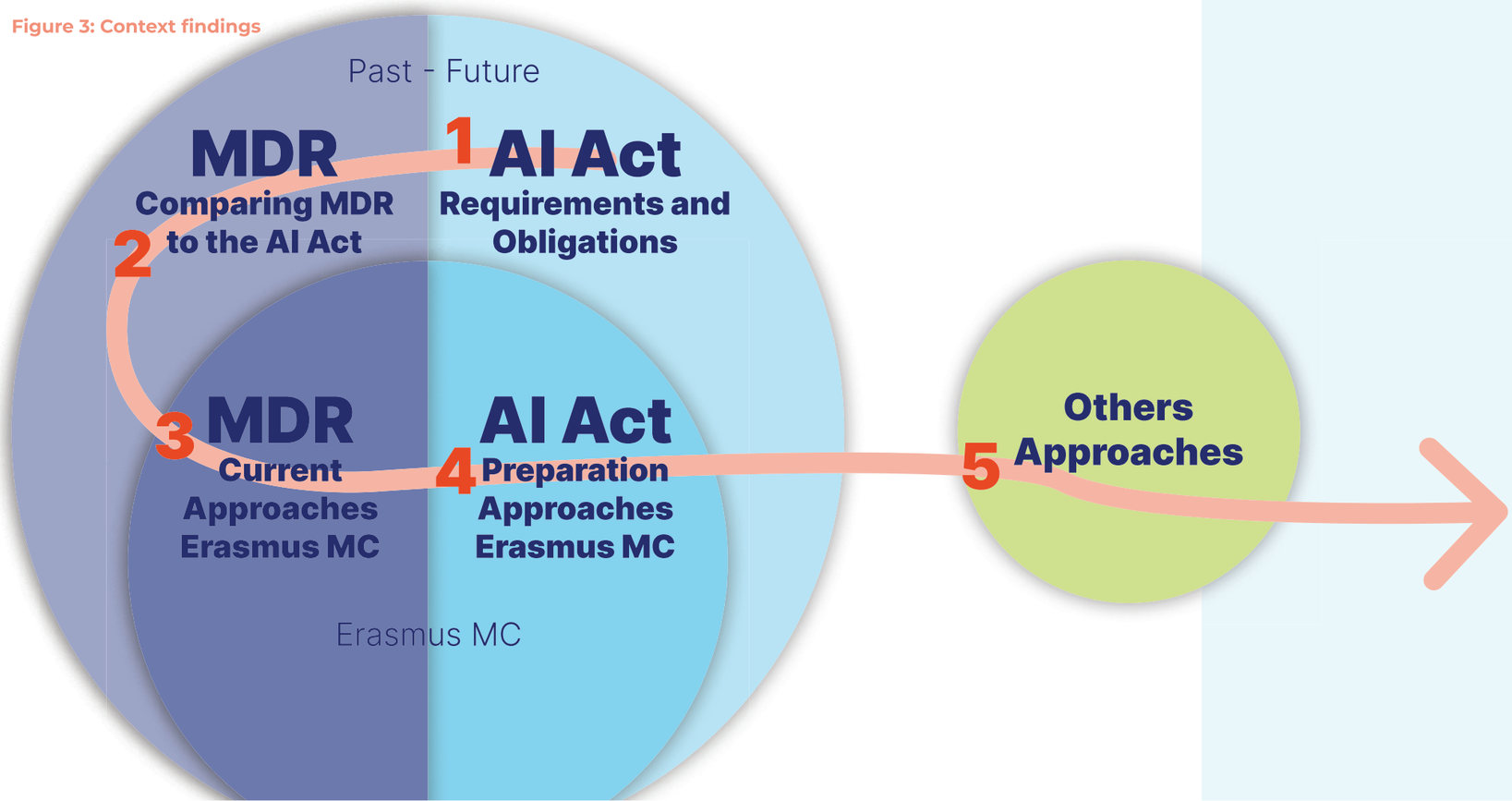
Since time is needed for people working on an AI application to comply with new legislation (retroactively), there is a gray area after a new legislation takes effect. After this unknown gray area the goal is to have a working infrastructure to implement the concept of a service system combination which works closely with other programs in this infrastructure of web 3.0. (Vermeer, 2023) (Sioli & Mazzini, 2023)



Context Findings

The context findings shown in Figure 3 discuss various aspects related to past and future approaches giving background knowledge to the reader. The first finding elaborates on the Requirements and Obligations of the proposal of the AI Act for AI providers and users. The second finding highlights the differences and similarities between the MDR and the AI Act. The other findings address the challenges of implementing the legislation by discussing different approaches. Where finding 3 explores Erasmus MC's past approaches to incorporating AI, including internal development, external purchase, and clinical validation of AI applications. Finding 4 describes Erasmus MC's future plans, such as establishing an AI expertise center. The last finding discusses the approaches of other organizations, including the municipality of Amsterdam's AI Register and a try-out solution combination in Spain.

Figure 3: Context findings



Department infrastructure Erasmus MC

Erasmus MC has a lot of expertise but these might be hard to approach

Educating staff members

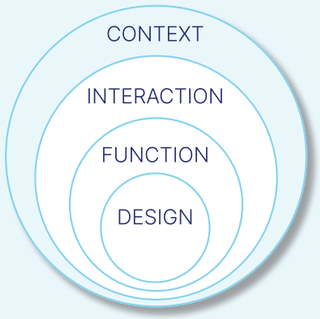
Combine expertise of technical and medical knowledge

Designate responsibility

The target group should know their responsibility

Clarify responsibility

Determine which individuals are responsible and what the need to deliver



4. Result - Legislation Context

Obligations & Regulations

AI Act

Ensuring compliance with regulations is crucial for any AI application. The proposed AI Act, expected to be finalized by the end of this year, considers the wide range of risks associated with different AI applications. While some applications pose significant risks and will be prohibited, others are considered low-risk and can continue to develop without being subject to the new regulations (e.g. AI made for logistics). However, the majority of AI applications used in the healthcare sector are likely to be classified as high-risk (e.g. AI that uses confidential information about patients), though the specific criteria for such classification are not yet defined.

Although is clear that some AI applications should be prohibited, the law remains somewhat abstract, e.g. it states that an AI system is prohibited if “the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behavior of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm;” (European Commission, 2021) As patients are often the end-users of AI applications in healthcare, and therefore particularly vulnerable, AI providers and responsible staff need to prepare for the forthcoming obligations.

Obligations

The AI Act outlines the obligations of providers and users of high-risk AI systems, as well as of other parties (e.g. obligations of importers). This list mainly consists of two components: a quality management system (QMS) that organizations can design to meet requirements, and technical documentation that must be stored within the system. The quality management system must have a strategy for regulatory compliance, technical specifications, a risk management system, and other components. However, AI requires a post-market monitoring system, which can be overwhelming for researchers new to AI development. They may struggle to understand what they must do to continue their research and development under this law. (European Commission, 2021)

Requirements

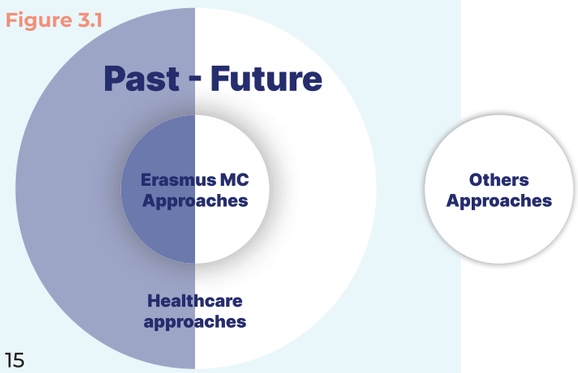
Within the obligations, there are requirements that the AI development team has to meet. One of these requirements is having a risk management system. However, the freedom given to design the quality management system and storage of technical documentation, makes it challenging to create an example or method for those who lack knowledge or experience in this area. Therefore, it is important to move from an abstract law to concrete action. For instance, a clinical expert should follow steps to manage risks starting from the abstract law to the concrete action of the AI team member. (See Chapter 4) This involves having a quality management system, a risk management system within the quality management system, and multiple steps such as systematic updating, showing possible effects, and conducting a risk-benefit analysis. All this information needs to be stored in parts of the quality management system. If even a single part of the AI code changes, a new document of risks must be created and updated to ensure it doesn't change the risk status. The difference between the obligated management system and assessments is important, as assessments are conducted at a certain point in time, while a management system requires having all documentation in place from the first to the last updated version. (European Commission, 2021)

Past Healthcare Approaches

AI Act and MDR comparison

There are multiple differences between the MDR and the AI Act. In general, the MDR focuses more on medical products, where software is one of them, and AI can be a component of the software. Within obligations, there are also differences, e.g., the consideration of bio-compatibility does not apply to software. So, it can be stated that the AI Act just explains a specific part of the MDR. (Regulation (EU) 2017/745, 2017) This is also confirmed by the participants that were interviewed in this research, most of them said that it will not change that much compared to the MDR. However, they also explain multiple problems that will arise after the implementation of the AI Act, which does indicate that it will change. These statements provided by study participants appear to be contradictory. However, due to the limited scope of the author's knowledge, it may be necessary to make certain assumptions to reconcile these conflicting perspectives. A possible explanation for this contradictory information could be that AI developers are already investigating the best way of providing quality, despite the fact that it will be necessary after the AI Act is there. This way of optimizing, based on intrinsic ethic motivation, will provide the quality that likely needs to be ensured after the introduction of the AI Act.

Figure 3.1



4. Result - Erasmus MC Context

Erasmus MC Approaches

Within Erasmus MC there are two ways in which AI can be incorporated. The AI application could originate from a study and through internal procedures be put into use by only the Erasmus MC itself. Or an AI application could be purchased by an outside provider. However, there is also a chance that an outside provider will first knock on the Erasmus MC's door for the clinical trial to be done before it is a validated product (see Figure 8 in Chapter 7). In the case of internal development, several departments are involved. First of all, the Medical Ethics Committee (METC) involved in the study. Next, the Medical Technology Department which is important in the validation of medical products, including medical software containing AI.

Research approval non-WMO METC

METC is responsible for the ethical approval of medical research. The WMO-METC normally checks if it is safe enough to test something on a patient, e.g. within the research of median. According to the METC in Eramus MC, AI does not fall under this kind of research currently and therefore does not need such approval. However, it is not yet clear whether this will fall under the WMO in the future. That is why they also have a non-WMO-METC who checks if the research is ethical in other aspects. AI is a topic that raises many ethical questions. How is patient data used, where does responsibility lie in diagnoses using AI, and how is discrimination bias dealt with? Therefore the non-WMO-METC is responsible for the approval of this research. However, this is not obligated by law yet and was set up by the initiative of the hospital itself. (Erasmus MC, n.d.)

Internal development of AI software

If research results in a need for the development of an AI Application it is possible to do this development internally. Based on the law (article 5.5 of the MDR) it is allowed to produce and use medical products validated in that particular hospital and not in another hospital. However, it is likely that if a product adds value to Erasmus MC, the provider eventually wants to introduce it to other hospitals. Therefore Erasmus MC makes sure that they follow the same requirements of the MDR, where the medical technology department supervises the developers, to enable this faster way of implementation, but on the other hand, making it ready for an NB if they want to continue. The Medical Technology department shared its template for technical documentation. There are multiple templates depending on the stage of development. This documentation aligns with the requirements for technical documentation of the MDR. Unfortunately, QA/RA was still reluctant to share a technical file of an AI application that they are currently working on with the resources they have, that are in the process of being validated internally.

External purchase of AI applications

If Erasmus MC decides to purchase a product that contains AI it should be a product that already has a CE certification. However, this certificate is not enough. There will have to be a collaboration between the users (most likely doctors) and the company since the operation of the system must be well monitored to maintain quality and have post-market surveillance in place.

Clinical validation in Erasmus MC of AI applications

After testing the feasibility and successfully conducting the pilot without patients, a validation in the clinical domain is needed. Erasmus MC could be asked to provide the staff and patient data for these clinical trials in exchange for some compensation from the company. Within these clinical trials, it is the responsibility of the company that they gather the information that they need.

→ Erasmus MC Approaches

New policy AI

Erasmus MC's policy for developing valuable AI for healthcare involves multiple strategic approaches, including a controlled and compliant process for the entire life cycle of AI, using the 'Innovative Funnel for Valuable AI in Healthcare' to guide development, validating and managing AI throughout a controlled process. (Haitjema & Nennie, 2021) Additionally, the patient is the primary focus during the development of AI application. Healthcare professionals are given a leadership role, to build trust among patients and healthcare providers. (Slooff, 2023)

AI Innovationfunnel

Erasmus MC's implementation process for the development of valuable AI for healthcare is based on the Ministry of Health, Welfare, and Sport's Innovative Funnel: named in Dutch 'Tool Handelingsruimte Waardevolle AI' (Haitjema & Nennie, 2021). This checklist is discussed further in chapter 6, figure 7. Within the policy, they acknowledge the importance of the entire life cycle of AI, including the phases of "Use & Monitoring", "Maintenance", and "Disposal", to ensure that the the use of AI applications remains safe and compliant. This is recognized as necessary by the Medical Device Regulation (MDR), and will also be required by the upcoming AI Act. Despite the focus on the whole life cycle, they do not mention the AI Act within the policy. (Slooff, 2023)

Stakeholders importance

Erasmus MC's policy for the development of valuable AI for healthcare emphasizes the importance of involving patients and clinical specialists throughout the development process as much as possible. This is achieved through various strategic approaches, e.g. focusing on the patient-centered application of AI and putting the (healthcare) professionals in the lead.

Another crucial aspect of Erasmus MC's policy is the recognition of the importance of interdisciplinary collaboration within the AI project team. The Innovative Funnel emphasizes the need for defining responsibilities and ensuring that all team members are working towards the same goal of creating safe and compliant AI solutions for healthcare. However, the policy does not specify which stakeholders should be responsible for which tasks, leaving room for flexibility and collaboration among team members. (Slooff, 2023)

Expertise centre for with data and AI

One of the key points of Erasmus MC's policy for the development of valuable AI in healthcare is the establishment of an AI expertise center. The importance of this center is also mentioned by other participants in this study. This approach also aligns with Erasmus MC's current way of working within the Medical Technology department, where they already have an expertise team to supervise other technical innovations within the hospital. (Slooff, 2023)

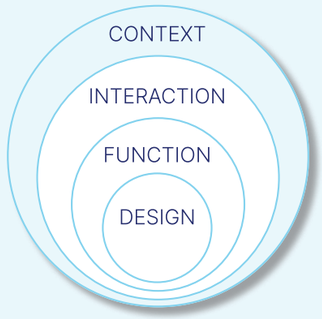
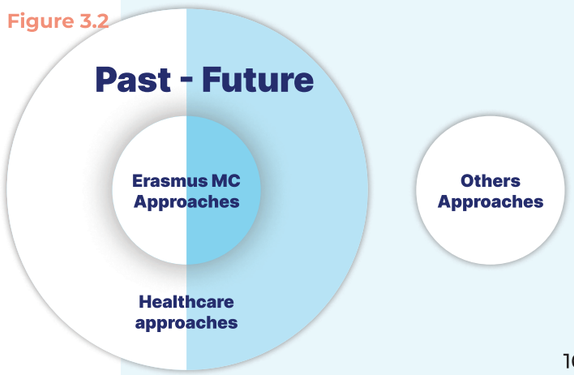
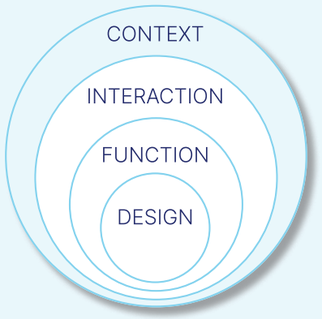


Figure 3.2





4. Result - Others approaches

→ Approaches of others

The importance of preparation is also rising in other organizations or companies. The goal of this research part is to find out how to prepare Erasmus MC for the AI Act that is coming, by looking at others' approaches as a source of inspiration. This chapter explains the approaches of different organizations within and outside the healthcare sector.

Municipality Amsterdam, AI Register

The municipality of Amsterdam recognized the importance of transparency in the use of AI within its jurisdiction. They aimed to create a system that would not only provide an overview of the AI being used but also establish a level of control by gaining knowledge of its usage. This led to the development of a register that is accessible to both users and interested parties. The register contains various elements such as the purpose of the AI, its applications, its functionality, and its contractual agreements within the municipality. The governance of the AI is also explained, including how risks are managed and what information is updated to ensure these risks remain acceptable. Responsibility is a key finding for traceability, and the register includes information on the last audit conducted. Additionally, the register provides details on bias analysis, limitations in data, and impact assessment on human rights. Overall, the municipality of Amsterdam prioritized transparency in AI usage and ensured that their register reflected this. (Yassini et al., 2022)

Try-out solution combination in Spain

The article "Artificial Intelligence in Healthcare – Applications, Risks, and Ethical Social Impacts", provides various examples to illustrate the best solution combinations for medical AI. The authors aimed to identify the risks associated with medical AI and how to manage them. They developed a framework with multiple solutions, including an AI register and an AI passport. (Figure 4) The AI register displays information about when the AI is trained and assessed, and the AI passport contains general information about the AI and details about any changes that have led to updates in paperwork and assessments. However, a register alone cannot meet the legal requirements, so they also propose a monitoring system to ensure the quality and accuracy of the AI application continuously. (Scientific Foresight Unit, 2022)

One of the authors is testing this combination of solutions in a new research project that involves developing an AI application for healthcare. The study aims to assess the sustainability and user-friendliness of this approach.

Tool Handelingsruimte waardevolle AI

The government is also aware of the challenges that AI providers face when implementing their AI applications. They recognize the gap between development and regulatory requirements for AI developers. To address this, they created a document that guides the development team throughout the stages of AI implementation. It begins with ideation, followed by exploring the context of the idea, then development, piloting, clinical trials, implementation, production, and finally, creating a valuable AI for healthcare. Although this guidance only applies to predictive and preventive AI within healthcare and does not consider triage, it provides a solid foundation to explore and connect with other findings within literature. This model explains that it is needed to follow the process stages before passing the 'gate' and being assessed to continue. This document also provides a checklist of how to comply with accountability steps. This is included in the process visualization in chapter 6. (Haitjema & Nennie, 2021)

Comparison of other approaches

By comparing these approaches: the Amsterdam register, the solutions combination of a register and a monitoring system, and the guidance of the ministry, it is remarkable that there are multiple opinions on how to deal with this validation process. For instance, the method proposed by (K. Lekadir et al, 2022) involves implementing the monitoring system at the earliest opportunity. However, in contrast, the ministry's approach only mentioned such a system in the implementation and maintenance phases to demonstrate the long-term viability of the AI application throughout its lifecycle.

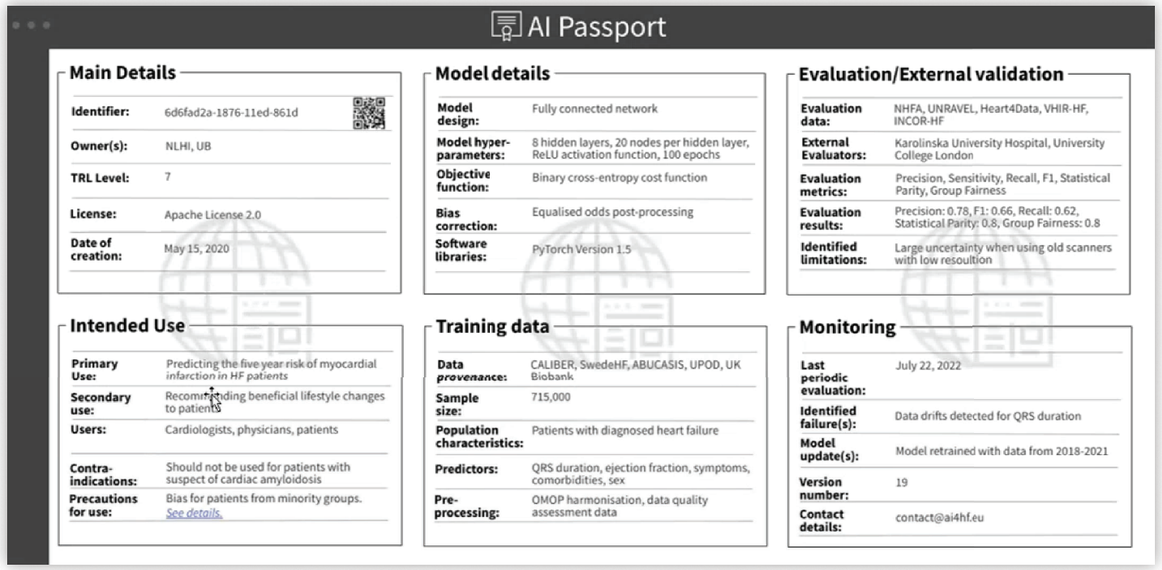
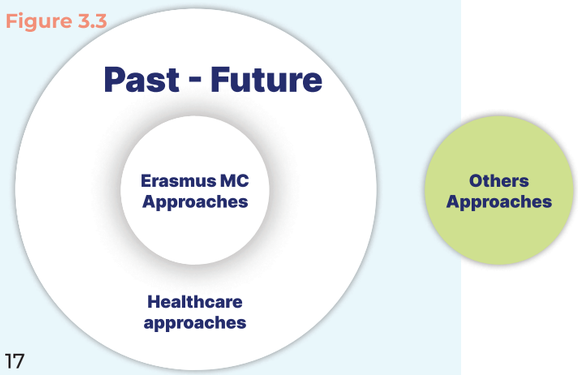


Figure 4: Context findings

Figure 3.3



4. Context Research

Discussion

With the knowledge of the context findings the purpose is to connect legal compliance procedures with Erasmus MC's operational approach to enable implementation. Clarity on required actions is crucial for successful execution.

Aligning legal procedure with Erasmus MC approach

By aligning legal compliance procedures with Erasmus MC's operational approach, the organization can integrate requirements into operations, increasing efficiency and effectiveness. This not only ensures compliance with the law but also improves overall processes. With this alignment, Erasmus MC can distinguish itself from other hospitals.

Clarify required actions

It is important to provide clear guidance on required actions, based on the policy of Erasmus MC. Instructions and personal guidance will ensure that the implementation will be understood by all stakeholders.

Defining people and responsibilities

Before this guidance can be given, it is first necessary to determine who is to be mentored and what their responsibilities are, this can vary a lot between different AI projects.

Multiple solutions are needed

Like the approach of others, Erasmus MC also needs to create multiple solutions to be able to implement all the requirements of the AI Act. Due to the time limitation of this study, choices will be made and the focus will be on the most important solutions.

Limitations

Several limitations should be considered when discussing the context of this study. First, it is important to recognize that the insights and perspectives presented in this discussion are primarily drawn from interviews with experts. While these experts have specialized knowledge, their views may present only a part of the context. Secondly, it is critical to recognize that the topic in question is relatively new and has no definitive "truth" due to ongoing research and the developing understanding concerning AI. Moreover, the author has no legal background, which could limit the research. Finally, the lack of clarity (in terms of required actions) can be caused by interviewing experts only, which may overlook practical considerations. Therefore it is recommended to broaden the scope of the study by involving various stakeholders and conducting further research.

Conclusion

The context findings contributed to the main research question: *What can different members of an AI development team encounter during the documentation process for the regulations of the AI Act?*

- They can encounter the same actions as MDR but with extra requirements, however, the specific form of those additional actions remains unclear.
- They can also encounter some guidance from Erasmus MC but it is still in the policy development phase.

The sub-research questions are answered in the context findings in the previous pages, however short conclusions of these research questions are shown below:

How are AI providers currently meet the requirements of the MDR?

- There is a lot of overlap between the MDR regulations and the AI Act, however, the difference is within the change of functioning due to the machine learning of the product.

How is Erasmus MC currently handling the regulatory process of AI applications, made in-house or externally?

- The medical technology department currently supervises technological products within Erasmus MC, including software like AI applications.

How can AI providers meet the requirements and obligations of the future EU Regulations for AI?

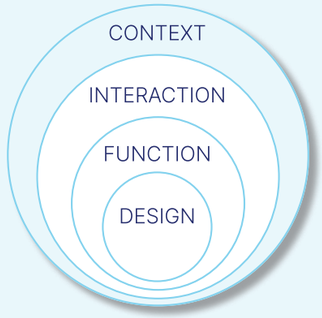
- The main obligations for AI providers are to have the technical documentation in place and create and QMS that includes multiple requirements, e.g., continuous monitoring to show persistent quality. However, there is still some uncertainty about what is going to be perceived as high risk and some uncertainty around the responsibility of assessing.

How is Erasmus MC preparing for the growth of AI usage within healthcare and the requirements of the AI Act?

- Erasmus MC is planning to create an expertise center for AI but is currently still in the phase of defining the protocols.
- The importance of a multidisciplinary team is mentioned, but the stakeholders including their roles and responsibilities are not defined yet.
- It was indicated that there is a demand for determining when a medical specialist is needed within the AI Innovation funnel process.

How are other organizations approaching this problem (preparing for the new AI Act)?

- All the approaches show the complexity of the problem
- There is a need for multiple solutions to this complex problem.
- There is a need for standardization within this process, however, to make it applicable to multiple applications it should also give some freedom in the design of these solutions to enable innovation.



Aligning AI Act requirements with Erasmus MC operation

The legal context must be translated so that it is in line with the way of working

Multiple solutions are needed

The complexity of the problem and the extensive requirements of the law cannot be solved with one solution.

Educating staff members

Combine expertise of technical and medical knowledge

Designate responsibility

The target group should know their responsibility

Clarify required actions

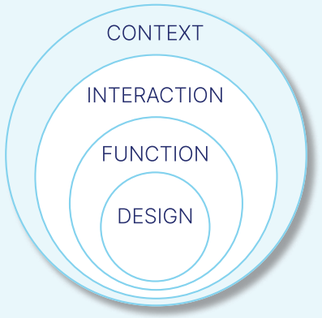
Translate abstract requirements into concrete actions

Defining people and their responsibility

Getting to know the target group

Clarify responsibility

Determine which individuals are responsible and what the need to deliver



Translate requirements to actions

The aim is to create concrete actions from the abstract requirements of the AI Act.

Inspired by the Ladder of Abstraction

A hierarchy from from abstract to concrete

5. From Law to Action

Chapter 4 shows the importance of translating the abstract AI Act into concrete actions. This chapter uses the ladder of abstraction to clarify the required actions for the stakeholders.

Method

Goal

The goal of the Ladder of Abstraction is to translate abstract requirements into concrete actions. This procedure helps to determine the appropriate level of abstraction for addressing the task at hand and it gives information about the context of the problem statement. It aims to develop a clear understanding of the vagueness of the AI Act. This includes analyzing all levels of assessments and actions. By mapping out these various dimensions and complexities of the AI Act, it becomes more transparent. This enables stakeholders to better navigate and understand the legal framework. With this method, the goal is to answer the following sub research question:

- *What levels of compliance are there for AI software in healthcare?*

Data gathering

The data for this Ladder of Abstraction is mainly gathered with field research, but the insights gathered were also exposed to experts to ask for confirmation.

During the desk research, the focus was primarily on gathering documents that already give some degree of guidance or a general overview. E.g., an overview that shows all assessments. Assessments that are already available and templates of reports, required for different innovative projects, were also considered. Existing standards for the MDR and a specific standard developed for AI in Australia were studied.

Procedure

Through comprehensive desk research, reviewing numerous articles, ministry documents, literature, and expert input, the ladder of abstraction was constructed. Since this mapping was intended to help the author understand the path from regulation to action, it was intuition based.

The Ladder technique helps to explore the means-end hierarchy. In this method, asking ‘why’ and ‘how’ are normally used to change levels. Since in this study the ladder is used to create clarity, and not to gain inspiration, it was decided to create other questions. (See right column in Figure 5.1) More options were generated by asking these questions.

Data analysis

First of all, the levels were determined and structured from the abstract law to the actions, then the levels were filled in and finally, questions were created intuitively, which could be asked to change levels.

After creating the completed overview of the Ladder of abstraction. The overview was analyzed to create a clear narrative of all steps to be taken to comply with the law. The method was used to explain the process of abstracting.

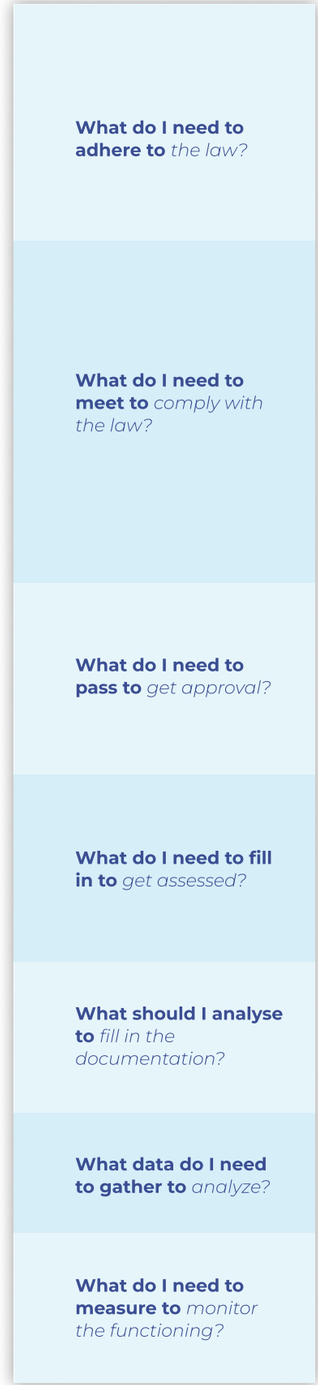


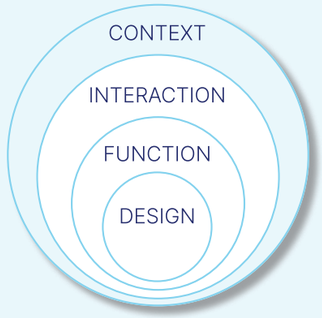
Figure 5.1: Questions, Ladder of Abstraction

5. From Law to Action

Result

From AI Act to stakeholders Actions

Stakeholders need to know how they can make sure that they comply with the law. Therefore it is needed to divide this complex part of implementation into multiple levels. (See Figure 5.2) To **comply** with the law it is essential to get approved by the confirmed authorities. It is not sure yet who the confirmed authorities will be but that is not necessary to know what requirements and obligations the stakeholders have to meet. To meet these requirements and obligations it is necessary to fill in assessments that ensure the **approval** of the AI application on different aspects, e.g., the assessment that makes sure that the impact that the algorithm has on the rights of human beings is limited. To fill in this **assessment** all documentation must be delivered to get assessed. For the **documentation**, different analyses need to be completed, e.g. a risk analysis is important to document the risk management plan. Monitoring the outcomes of the AI system is necessary to enable a person to **analyze** the data the AI is providing, and to discover changes within the outcome of the system. E.g. to show what happens if you add different data to train the AI application or in the end, if you use the AI to make sure that it's still in line with the intended use or outcome. To be able to **monitor** the outcome, it is required to measure certain results of the AI, however, the content of the **measurement** level is left out of scope.



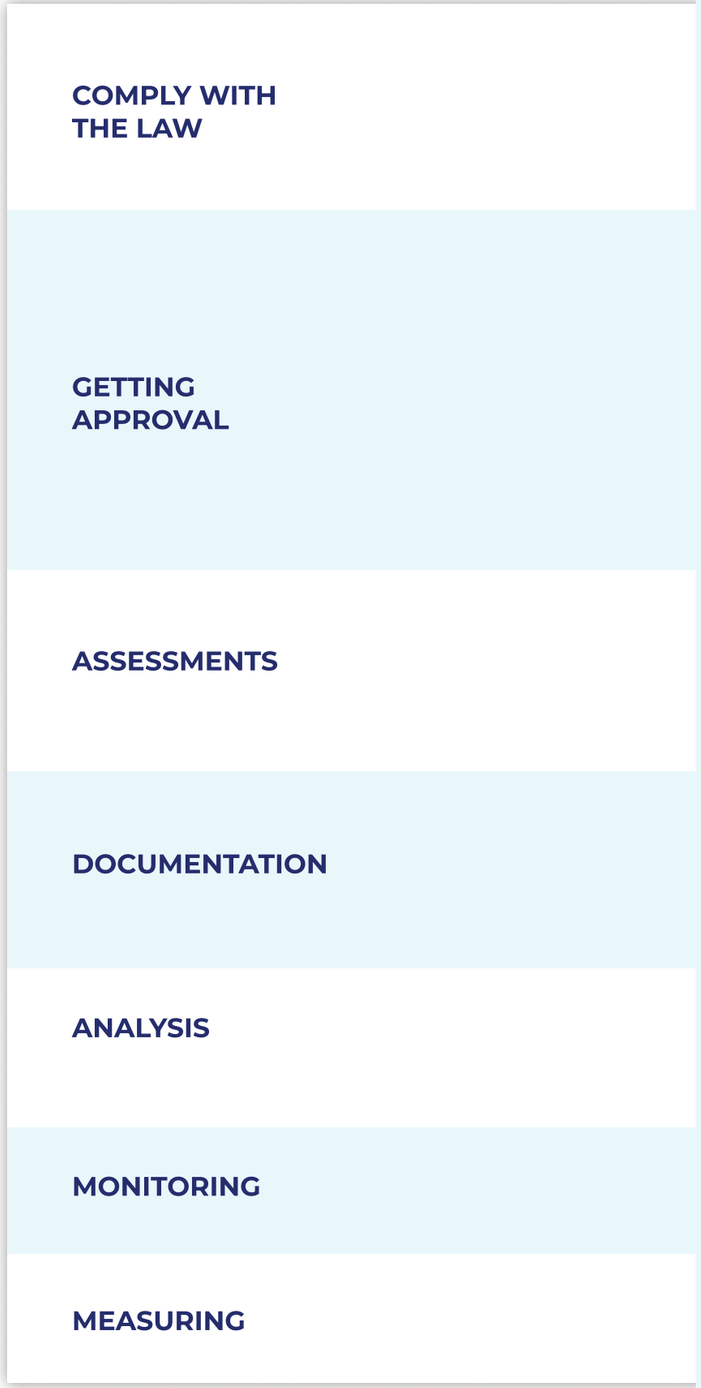
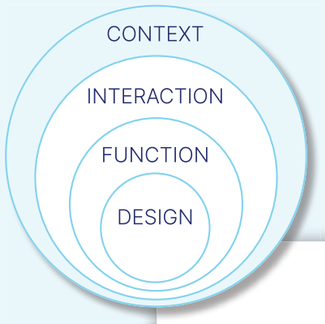


Figure 5.2: Levels, Ladder of Abstraction



5. Result - Ladder of abstraction

COMPLY WITH THE LAW	**LAW** AI Act	**What do I need to adhere to** *the law?*

GETTING APPROVAL	Obligations
	• Quality management system
	• Conformity assessment
	• Register in EU database
	• Monitoring
	  • Incident
	  • Surveillance
	  • Post-market
	• Update technical documentation
	• Update legal obligations
		What do I need to meet to *comply with the law?*

ASSESSMENTS	**AIIA** Artificial Intelligence Impact Assessment; **IAMA** Impact Assessment Mensenrechten en Algoritmes; **METC** niet-WMO plichtige Medisch Etische Toetsing; **dPIA** data Protection Impact Assessment; **Etc.** Other Impact Assessments	**What do I need to pass to** *get approval?*
DOCUMENTATION	Technical Documentation; Research Protocol; IMDD Ivestigational Medical Device Dossier; Klinische Evaluatie Rapport; Informed Consent Form; Plan (• Data management plan • Development plan • Risk management plan); Etc.	**What do I need to fill in to** *get assessed?*
ANALYSIS	**FMEA** Failure mode and effects analysis; **Impact Analysis**; **Risk analysis**; **Stakeholder analysis**; **Market analysis**; **UX/UI analysis**; **Drijfveren analyse**; **Etc.**	**What should I analyse to** *fill in the documentation?*
MONITORING	Precision; Sensitivity; Recall; Fairness; Etc.	**What data do I need to gather to** *analyze?*
MEASURING	Out of scope	**What do I need to measure to** *monitor the functioning?*

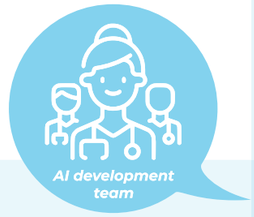


Figure 5: Ladder of Abstraction
The visual was made after studying the following sources: (European Commission, 2021) (Sioli & Mazzini, 2023) (Vermeer, 2023) (Regulation (EU) 2017/745, 2017) (Ministerie van Algemene Zaken, 2022) (Scientific Foresight Unit, 2022) (WHO guidance, 2021) (Yassini et al., 2022) (Haitjema & Nennie, 2021) (Erasmus MC, n.d.) (Janssen et al., 2020) (Bartels et al., 2022) (Gilbert et al., 2021) (Beckers et al., 2021) (Wagner et al., 2006)

5. From Law to Action

Discussion

When constructing a ladder of abstraction, several discussion points emerged that are shown below.

Unclear what levels are obligated

It was noted that the levels of obligation and requirements were unclear, which made it difficult to determine the appropriate actions to take. These were also listed interchangeably, so it cannot create a clear structure in a process.

Content of levels are not in line

It was difficult to find connections between the levels. This means that it was not always possible to make a clear link between the action that was required and under which obligation it should fall. To give an example, the links in risk management components were very clear, it is logical that the risk must be analyzed, these analyzes are then assessed and included in the risk management. However, it is not clear to the stakeholder analysis in which documents it should appear and how it is assessed.

Measuring is out of scope

A conscious decision was made to leave measuring out of scope. The measurement is essentially set by the algorithm developer's discretion. Due to limited study knowledge and significant disparity from the legal domain, the translation step remains the responsibility of the developer.

Top-down approach

The Context Research, which initially followed a top-down approach, exposed certain limitations. Although an attempt has been made to define the actions, it remains unclear who should do this, how this will work during a process, and who will use the final concept. There is a need to consider adopting a bottom-up approach. This shift is needed to identify the individuals who are responsible for taking the necessary actions and to determine the target group of the final conceptual service system. By embracing a bottom-up perspective, a more complete understanding of the roles and responsibilities within the system can be achieved, ensuring effective implementation.

Limitation

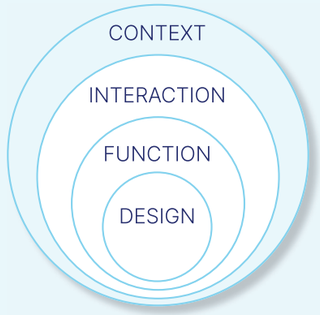
The ladder of abstraction is primarily intended for ideation purposes, and its application in the context of compliance with the law may have its constraints. Furthermore, the author's knowledge regarding how to comply with the law and the specific actions required was limited. Lastly, despite the participation of expert individuals, none were able to provide clear explanations of tasks needed to be in light with the law.

Conclusion

The ladder of abstraction serves as an asset in creating an overview from the abstract law obligations to the concrete actions to meet these requirements. The following sub research questions is answered with this visual:

What levels of compliance are there for AI software in healthcare?

- There are multiple levels of abstraction, from abstract to concrete they are listed: compliance, approval, assessment, documentation, analysis, monitoring and measurement.



Unclear what levels are obligated

The difference between a must and a helpful tool is not clear

Content of levels are not in line

It is difficult to find a connection in the content between the levels

Limitation of top-down approach

One-sided view of experts and documents

Bottom-up approach

Chapter 6-7: Interaction

Main Insights Context

CONTEXT

Department infrastructure Erasmus MC

Erasmus MC has a lot of expertise but these might be hard to approach

Educating staff members

Combine expertise of technical and medical knowledge

Designate responsibility

The target group should know their responsibility

Aligning AI Act requirements with Erasmus MC operation

The legal context must be translated so that it is in line with the way of working

Multiple solutions are needed

The complexity of the problem and the extensive requirements of the law cannot be solved with one solution.

Unclear what levels are obligated

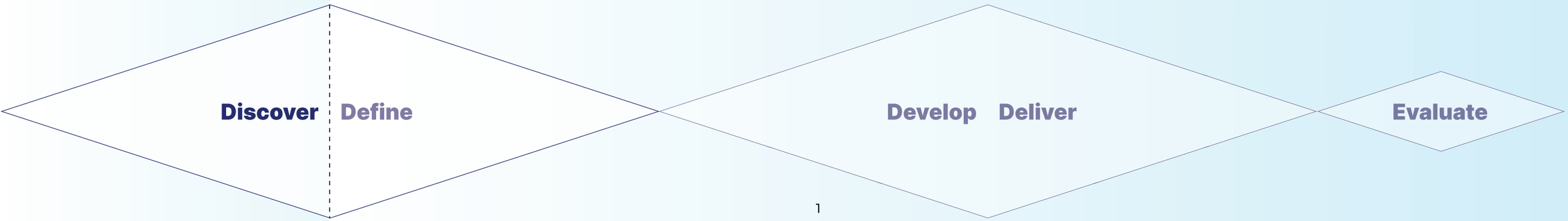
The difference between a must and a helpful tool is not clear

Content of levels are not inline

It is difficult to find a connection in the content between the levels

Limitation of top-down approach

One-sided view of experts and documents



INTERACTION

While exploring the context, gaps emerged for further research. To design a service, it is important to know more about the future interaction. In the coming section, the interaction is investigated by defining the roles, responsibilities and tasks of different future users of a service. However, during the context research it was noticed that it is not clear of which people the AI project team consists of. Hence, a number of representatives were chosen to focus on, based on assumptions made after the people spoken to during the context research and a given list from the government (Ministerie van Algemene Zaken, 2022).

CONTEXT

Prepare Erasmus MC for the new legislation: AI Act

INTERACTION

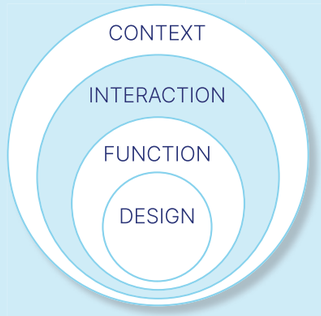
Creating clarity of the roles and responsibilities of the main stakeholders

Goal:

Defining and communicating the roles and responsibilities, of the main stakeholders within the process of AI implementation. ***When to do what is given in the processes, who, and how is unclear.***

Focus:

Focus on clinical experts, data scientist, data engineers, end-user & patient



Clarify required actions

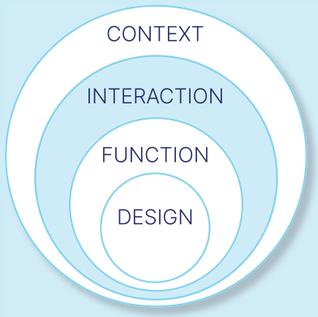
Translate abstract requirements into concrete actions

Defining people and their responsibility

Getting to know the target group

Bottom-up approach

Chapter 6-7: Interaction



Defining roles

The aim is to chose the main roles within an AI project team and define those

Connecting roles, process & AI Act

The goal is to connect the roles, process and AI Act requirements to discover what is needed when within the process

Role explanation

Inspired by: Thinking hats

Process mapping

Inspired by: Journey mapping, Product life cycle, Story board

6. Process mapping

Within this chapter, the roles of an AI development team are defined to connect this to the mapped-out process of the ministry and link this to the requirements of the AI Act. This can be seen in a process mapping visual on the following pages. The main findings of this mapping consists of two gaps. One is shown on the last page of the process map (page 33) where there is a lack of guidance during the maintenance phase. The second gap is the rarely occurring Article 12: Record Keeping. On page 34 these findings are discussed further.

Method

Goal

To link this method of process mapping to the research question: *What can different members of an AI development team encounter during the documentation process for the regulations of the AI act?* there are three important aspects to connect: the roles of *'the different members of the AI development team'*, the *'process'* and *'the regulations of the AI Act'*.

A combination of Journey mapping, product life cycle mapping, and story board is used to answer the following questions:

- *Which role is needed in which part of the process?*
- *How do these accountability steps, mapped out by the ministry, connect to the requirements of the AI Act?*

A checklist named 'Tool Handelingsruimte Waardevolle AI' of the government is used as a starting point to find out which responsibilities are needed for which part. The first important checkpoint mentioned in a checklist of the ministry is the allocation of responsibility, but there is no indication of who the individuals are of the idealistic so-called 'multidisciplinary team'. Several participants in the interview were not able to tell this either, caused by the difference between the cases. Therefore, it is important to define the roles.

Data gathering

Four different types of data were collected to link together, firstly, steps from the process were collected, secondly, key roles were determined, thirdly, the requirements articles of the AI Act proposal were collected and lastly, the hierarchy of chapter 5 was used. Page 27 shows how the data is implemented in the visual with the matching numbers below:

1. Roles, Responsibilities and Tasks

The roles were determined partly on intuition after speaking to several experts. This included another document from the ministry, which lists possible members of an AI project team. (Ministerie van Algemene Zaken, 2022) However, this document does not have health care as a starting point. Hence, a choice was made as to which roles are necessary and this was supplemented with a medical role: the clinical expert. Finally, the designation from the law has also been included in which use is made of the 'AI provider' who serves as the final responsible party.

2. Process checklist

As a starting point, a document from the ministry was used in which they offer a checklist for AI developers within healthcare. The purpose of this checklist is to prepare for requested minimum requirements and standards within laws and regulations to achieve human-centered and reliable applications. (Haitjema & Nennie, 2021) Even though the AI Act is not mentioned in this document, this is a useful starting point as this guide encourages to be ethically responsible with AI development early on, based on the MDR rules for software applications. This checklist consists of several sections (value, technology, application, accountability and ethics) where a checklist of different tasks is represented each phase of the implementation process. Since the focus in this study is on legislation, it was chosen to use only the tasks of the accountability section. (Haitjema & Nennie, 2021)

3. Articles AI Act

The AI act was revisited for an analysis of the requirements to see which steps are linked to the particular requirements needed for the legislation.

4. Ladder of Abstraction (Chapter 5)

Finally, the hierarchy of chapter 5 was used to place the steps with the matching articles on. This was done to clarify the difference of some of the steps. E.g., a risk analysis is part of the AI Act's requirement for risk management, but this is only one of its components, and therefore it is placed at the analysis level of the ladder.

Procedure

Firstly the key roles within an AI Development team were determined, (Figure 6) Secondly the 'accountability' part of the checklist was placed in the visual of the process. Thirdly the roles were placed at each step, based on assumptions made by the author, to discover what roles can be distributed to a team at different stages of the development. At last, the various articles of the AI Act are placed on the checklist of the ministry to see how this paper applies the regulations. (European Commission, 2021)

Data analysis

By analyzing the roles connected to the process of regulation, a better definition of the responsibilities and tasks can be given to the members of an AI development team in multiple cases. Afterward, one case can be chosen to divide the roles per member of the AI development team. (See Chapter 7)

Defining the key roles

Role Description

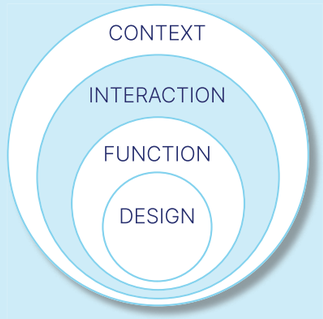
Looking back at the context research, the importance of a multidisciplinary team was mentioned, however, it was not determined which roles this team consists of. Hence the choice was made to define the roles. (See Figure 6)

Thinkers hats (Edward de Bono)

A conscious decision was made not to depict persons but hats. This method was inspired by the technique: 'thinking hats' of psychologist Edward de Bono. The reason for this choice is the difference between the roles and the persons who fill these roles. One person can fill several roles, or several people can fill one role. (See Chapter 7 Figure 11) This is why not only the role is defined, but also the persons who could fill in this role.

Role placement on the process

The page below shows what roles are required for each accountability step of the ministry's checklist. The roles chosen are based on assumptions of the text from the checklist. E.g., a risk analysis is expected to require both a clinical specialist and a data scientist, to analyze both medical and technical risks.



Name of the role

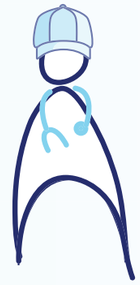
Who fulfills the role?

What are the responsibilities of the role?

Data scientist

The role of data scientist is taken by the developers of the algorithm. In the beginning, it could only be a researcher, but during development, it could grow into a team. At the end of the life cycle, it could be the case that the algorithm does not change anymore and therefore a data scientist is not needed anymore.

The data scientist analyses and interpret the data that goes into the algorithm and comes out of it. Therefore he/she needs to manage and store the data and is responsible for documenting all changes related to the algorithm.



Clinical specialist

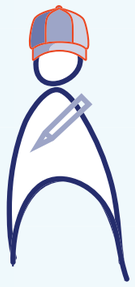
The clinical specialist is always a graduate doctor specialized in the same field as the AI application is intended for. However, he/she could either be an external party or he/she could work internally.

Firstly the clinical specialist is responsible for sharing clinical knowledge about multiple factors, e.g. user demand, intended use, risks, benefits, etc. Secondly, the clinical specialist needs to provide data, this could be monitored data of clinical decisions, but this could also be retrospective data.

Legal advisor

The person who has the role of legal advisor can also change over time. If the development starts with research within Erasmus MC, someone from the AI Expertise center might start advising, but at the end of the implementation, this role could be taken, e.g. by a consultancy.

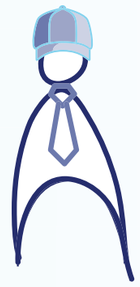
The legal advisor's main task is to inform the AI development team about the requirements of the AI Act. He/she also has the responsibility to guide the team through each phase of the implementation process and connect them to the right people.



Engineer

In most cases, the role of an R&D engineer/application engineer grows over time, where it could start with one PhD student researching and developing a prototype, and it could end with a whole team optimizing the application and its interaction.

The engineer makes the application and by doing so he/she is in charge of the interpretability of the AI and needs to provide all documentation related to the AI application. However, he/she is not responsible for delivering this documentation to get assessed.



AI Provider

Who has the role of an AI provider can change over time, firstly it could be a person (e.g. supervisor PhD student) and at the end of the cycle, it could be a company that offers AI software with a CE mark.

The AI provider is responsible for providing the AI to others, he/she does not have to come up with the requirements, but he/she needs to ensure in the end that it meets the requirements of each phase. He/she also needs to communicate the expectations to the other team members who have to deliver information.

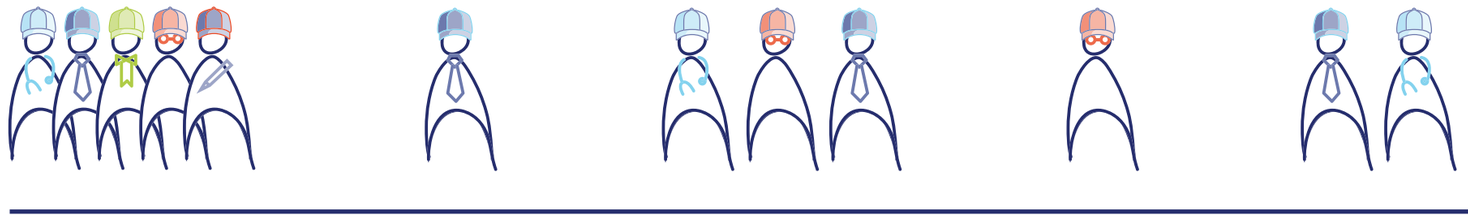
Figure 6: The key roles of an AI project team

Process

Accountability

On page, the process map begins. Several things are linked together in this mapping to find out how the ideal linear process would go, how this implements the requirements of the law, who is needed for this, and what level of abstraction in terms of action is required of these people.

1. The roles of the previous page are intuitively placed at the steps were they are probably be expected to bear some of the responsibility.
2. The Accountability part of the governments checklis report called: 'Tool Handelingsruimte Waardevolle AI' was translated to show the process steps. (Haitjema & Nennie, 2021)
3. It is analyzed how the steps related to the articles of the AI Acts requirements.
4. The levels of the ladder of abstraction are used to show how much action the steps require.



(Haitjema & Nennie, 2021)

Responsibilities

Governance with required roles and responsibilities to implement the idea has been identified, including an active strategic ambassador to build support.

Feasibility

The feasibility and conditions for responsible use were discussed and reviewed with experts in the fields of privacy, information security, ethics, legal matters and/or medical law.

Risk Scan

An initial risk scan for use of the application has been conducted; risk areas and points where a more in-depth risk analysis (e.g., PRI, FMEA or BIV) is needed have been identified.

dPIA

An initial dPIA was prepared for the exploration phase with purpose limitation and basis appropriate to the context (such as scientific research or quality improvement of care) for data processing and resulting requirements, e.g., consent. With explicit attention to privacy risks and appropriate measures (e.g., encrypted data only, data minimization).

Contractual agreements

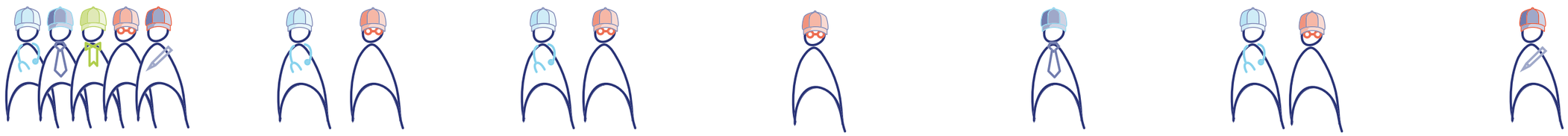
For data processing by external partners, contractual arrangements have been made regarding data protection and IP

Idea

Gate 1

	Art. 17m Art. 24-29	Art. 11	Art. 9	Art. 10	Art. 20
OBLIGATIONS					
REQUIREMENTS					
ASSESSMENTS		feasibility		dPIA	
DOCUMENTATION	Responsibility				Contracts
ANALYSIS			Risk scan		
MONITORING					
MEASURING					

Figure 7: Process map



(Haitjema & Nennie, 2021)

Liability Analysis

A liability analysis was made together with the client, experts and suppliers: what legal requirements the application must meet and how they will be met.

Risk classification

It has been determined whether the application is a medical device and if so in which risk class it falls (provisionally). The possible (self) certification process and its consequences (costs, time) have been determined.

RMP

Expanded the risk scan into a risk management plan (RMP) that established acceptance criteria for foreseeable application risks. Performed an initial risk-benefit analysis with a positive outcome.

dPIA update

The dPIA has been updated for data processing in the development phase and the purpose has been tightened. Unnecessary data have been removed from the dataset (data minimization) and the data to be used have been aggregated if possible (subsidiarity).

Determine manufacturer

It has been determined who the manufacturer is and together with legal counsel, if necessary, it has been determined that it meets any legal requirements (e.g., certified quality system such as ISO13485/ISO15189), even if the solution is used only within its own legal entity and/or there is self-certification.

Clinical evaluation plan

A draft clinical evaluation plan (depending on the risk class) has been prepared with how appropriate evidence for clinical performance is gathered based on clinical association, technical performance and clinical validation. The plan has been reviewed by an (independent) expert.

Risk classification for cybersecurity

A specific risk classification has been established for information security (e.g. according to BIV) and the infrastructure for the development phase has been set up in accordance with this classification

Exploration

Gate 2

OBLIGATIONS

REQUIREMENTS

ASSESSMENTS

DOCUMENTATION

ANALYSIS

MONITORING

MEASURING

RQ

? Art. 6 Art. 9 Art. 10 Art. 9 Art. 15

dPIA

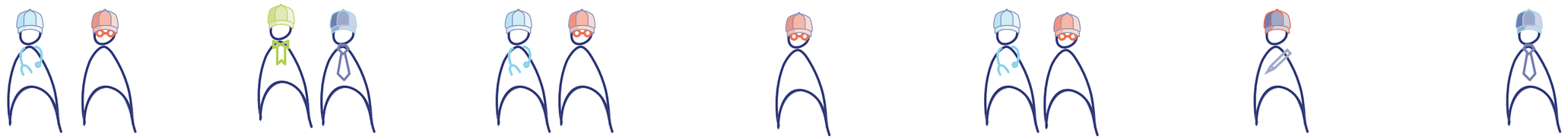
RMP

risk-benefit

CEP

Security plan

responsibility



(Haitjema & Nennie, 2021)

Final risk classification

A final risk class has been established for a medical device, with associated clinical evaluation requirements. For a purchased product, it has been determined whether the intended use is within the intended use described by the manufacturer.

CE Certification Process

A final determination has been made as to whether CE certification is necessary and how it will be met. A specific plan was prepared for the certification process and any document templates were requested from a notified body.

Risk-benefit analysis (RMP)

The risk management plan has been updated: risks have been addressed (eliminate, manage through control measures, accept) and residual risks described. A new risk-benefit analysis was performed with a positive outcome

dPIA update

The dPIA has been updated for Pilot Phase A and the purpose has been tightened. Encrypted or non-encrypted data is used as much as possible. When data is processed outside the institution and/or outside the European Economic Area, contractual arrangements have been made for data protection.

Clinical Evaluation Report

A clinical evaluation report has been prepared with a substantiated clinical association based on literature review and research from the development phase. A plan for Pilot A is in place to further substantiate technical performance.

Cybersecurity update

A specific risk classification has been established for information security (for example, according to BIV) and the infrastructure for Pilot A has been set up in accordance with this classification.

IMDD (Bundling CCMO)

A draft investigator medical device dossier (IMDD) was created by compiling documents in CCMO format:

- H1: description of problem, application and risk classification
- H2: manufacturer and manufacturing agreements
- H3: design documentation and acceptance criteria
- H5: the risk management plan (incl. risk-benefit analysis)
- H6: the clinical evaluation report
- Appendix: privacy and security reports

Develop

Gate 3

OBLIGATIONS

REQUIREMENTS

ASSESSMENTS

DOCUMENTATION

ANALYSIS

MONITORING

MEASURING

RQ

Art. 6

need CE mark?

MDR

Docum entsja blonen

Art. 9

RMP

risk-bene fit

Art. 9

Art. 10

dPIA

Art. 9

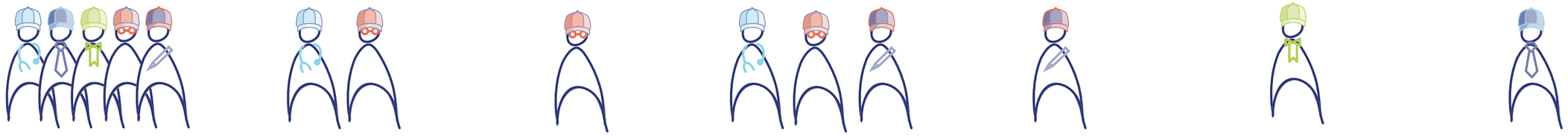
CER

Art. 15

Secur ity plan

Art. 11

CCMO → IMDD



(Haitjema & Nennie, 2021)

Governance

The governance and agreements with external suppliers and partners have been established for Pilot B (roles and responsibilities, security, delivery, preconditions, confidentiality and liability) and ensure safe and reliable use of the application.

Update RMP

The risk management plan was updated based on results from Pilot A. A new risk-benefit analysis was conducted with a positive outcome.

Update dPIA

The dPIA has been updated for study-related data use in Pilot B and the purpose has been strengthened. Purpose limitation and the legal processing basis have been established (such as scientific research with associated requirements for or exception to consent). With attention to data minimization, subsidiarity and possible data processing outside EEA.

Technical presentation

The clinical evaluation report has been updated with the technical performance (performance, explainability, reliability of outcomes including representativeness of the patient population and possible data drift) based on pilot A. There is a plan for pilot B to perform the clinical validation.

Cybersecurity

A specific risk classification was established for information security in Pilot B with guarantees of required security levels and protection (e.g., data breaches, hacking) applicable to that classification: logging, two factor authentication, access management, no direct access to the data, backups, and encryption.

METC approval

A final IMDD has been prepared and reviewed: - WMO research: approval by the METC - nWMO research review by independent party (e.g. data protection officer/ medical technology department)

Privacy Statement

A final privacy statement has been adopted for use in Pilot B.

Pilot A

Gate 4

OBLIGATIONS

REQUIREMENTS

ASSESSMENTS

DOCUMENTATION

ANALYSIS

MONITORING

MEASURING

?

Art. 9

Art. 10

Art. 13

Art. 15

Art. 11

Contr acts

RMP

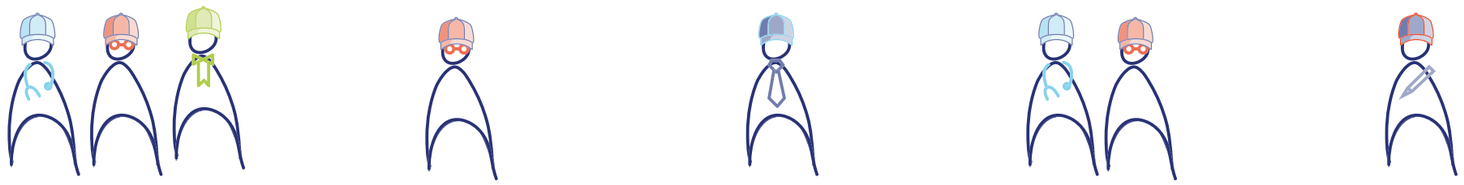
risk- bene fit

dPIA

Tech pres

Secur ity plan

nWMO -METC



(Haitjema & Nennie, 2021)

Update risk-benefit analysis

The final risk-benefit analysis was adopted incorporating the clinical evaluation report and accepting the residual risks.

Update dPIA

The dPIA has been updated for data use in training in the implementation phase. Purpose limitation and the legal basis for processing have been established (and any requirements for consent). With attention to data minimization, subsidiarity and possible data processing outside EEA.

IMDD -> product specification

The IMDD is converted into a product dossier in accordance with instructions and formats of the notified body or manufacturer in the case of risk class I/self-certification.

Clinical evaluation report

The clinical evaluation report has been updated to include the clinical association, technical performance and clinical evaluation. It has been determined that the application is safe and effective within its intended use

Cybersecurity

A specific risk classification has been established for information security for training purposes in implementation phase with assurance of required security levels and protection (e.g., data breaches, hacking) for that classification: logging, two factor authentication, access management, no direct access to the data, backups, and encryption.

Pilot B

Gate 5

OBLIGATIONS

REQUIREMENTS

ASSESSMENTS

DOCUMENTATION

ANALYSIS

MONITORING

MEASURING

Art. 9

Art. 10

Art. 11

Art. 9

Art. 15

risk-benefit

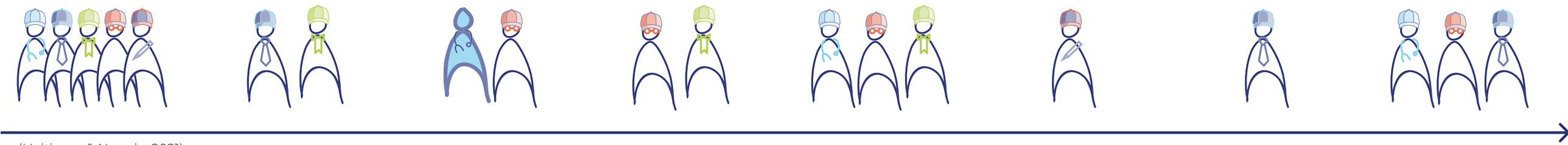
dPIA

dossier voor NB

IMDD → dossier

CEP

Security plan



(Haitjema & Nennie, 2021)

Governance

The governance and agreements with external suppliers and partners are defined for production (roles and responsibilities, security, delivery, preconditions, confidentiality, data processing and liability) and guarantee secure and reliable use of the application. Both inside and possibly outside the European Economic Area

Market Access

The application is released for market authorization or for internal use. With market approval, the application bears a CE logo, is registered in EUDAMED and carries a UDI.

Update RMP

The risk management plan has been updated with a description of how the positive benefit-risk trade-off is maintained during the production phase (indicators, monitoring of residual risks, acceptance criteria for (new) risks).

dPIA for Production

A new DPIA has been prepared for production. Purpose limitation and the legal processing basis have been established (think WBGO, quality improvement and/or (scientific) research with associated requirements for or exception to consent), as have data minimization and subsidiarity

Clinical folluw-up plan

A post-market clinical follow-up plan is in place. Depending on the risk class, based on clinical data and end-user experience (representative of practice), the clinical evaluation report should be periodically updated and reviewed by an independent body.

Cybersecurity

A specific risk classification has been established for information security for production with guarantees of required security levels and protection (e.g., data breaches, hacking) applicable to that classification: logging, two factor authentication, access management, no direct access to the data, backups, and encryption.

Privacy Statement

A final privacy statement and terms and conditions have been established for use in the production phase.

Post market surveillance plan

A post-market surveillance plan was prepared based on the post-market clinical follow-up plan and the risk management plan.

Implementation

Gate 6

OBLIGATIONS

REQUIREMENTS

ASSESSMENTS

DOCUMENTATION

ANALYSIS

MONITORING

MEASURING

NB check others

Art. 24-29

NB → CE mark

MDR

Art. 9

RMP

risks

Art. 10

dPIA produ ction

Art. 9

CER follow up plan

RQ

Art. 6&15

Secur ity MP

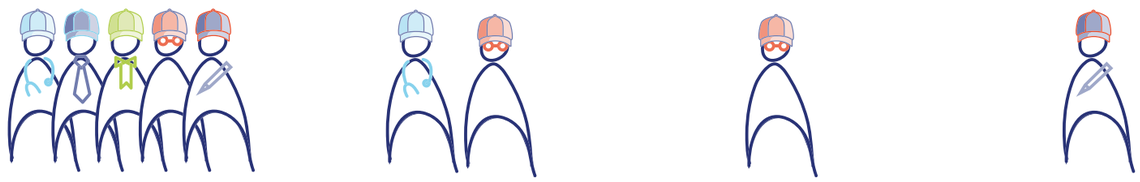
Priv acy state.

Art. 13

Art. 14

PMS plan

Contr acts



(Haitjema & Nennie, 2021)

PMS execution

The post market surveillance plan is implemented at external use:

- reporting on incidents and field safety corrective actions (at IGJ) by means of PMCF reports
- reporting of significant technical changes and updating the CE dossier if necessary (e.g. in case of change of algorithm and intended use) and the risk-benefit ratio for the benefit of the notified body.

Clinical use evaluation

Implementation of quality and risk management processes and continuous evaluation of the clinical use experience of the devices in internal use, including corrective actions.

New dPIA

A new dPIA is conducted when data processing changes (new basis, new controller, new cooperation partner, new manufacturer, etc.).

Cybersecurity

A periodic recalibration of the risk classification for information security in the production phase takes place.

Production & Maintenance

Gate 7

OBLIGATIONS

REQUIREMENTS

ASSESSMENTS

DOCUMENTATION

ANALYSIS

MONITORING

MEASURING

Art. 14

Rap. PMS plan

Art. 9

CER & RMP

Art. 10

dPIA production

Art. 15

Security

6. Processmapping

Results

A gap analysis was applied to review the result of the mapping study. Two gaps were identified during the mapping process.

Gap 1: Maintenance phase

The first gap is visible on the last page of the overview (page 33). The government checklist (Haitjema & Nennie, 2021) used to represent the accountability process is missing a section. They left out the penultimate part they mention in the beginning. Additionally the part they do cover (the maintenance phase), is moderately elaborated. Contradictory, the AI Act puts a lot of emphasis on the entire life cycles of AI applications, especially since it is so important to keep a human eye on the self-evaluating algorithm.

Gap 2: Article 12 (record keeping)

The second gap is harder to see through observation. This gap emerges after comparing the checklist with the articles in the AI Act requirements. (European Commission, 2021) Many of the items in the checklist match the articles. However, there is one article missing. This assumption is based on the limited explanation of the checklist. Article 12: Record Keeping does not stand out enough. Many analyses and assessments are mentioned, but nothing is said about a system or platform including auto-versioning of all records and intermediate drafts. Another checklist section briefly mentions system architecture, but this is often related to data storage and has less to do with record keeping of the application development itself. Additionally, this is not mentioned from the beginning of the funnel, however, it is required to keep records from the start. (Haitjema & Nennie, 2021)

Roles

The aim this chapter was to discover which roles are needed at which point in the process. Since this ranking is based on assumptions, it is difficult to analyze. It can be carefully noted that the role of the engineer is only needed later in the process according to the checklist. But this topic will be further explored in the discussion.

Discussion

Based on the results, there are two main factors to elaborate on: the limitations of the assumption-based roles and the choice of the focus, based on the gap analysis.

Limitation

Limitation of the assumption-based roles

The given roles in this chapter serve as guidelines for the dividing of tasks and organizational structure. However, it is essential to recognize that these roles are not fixed. The author's assumptions should be taken as a starting point and should be validated and refined by experts in the field. By offering flexibility in defining the roles, an AI development team itself can ensure that the defined roles match the specific project requirements, as every AI project is different.

Choice of focus

Gap 2: Implementing record keeping

In the next chapter, figure 8 shows two streams of AI development: internal and external. External development involves Erasmus MC using the AI application. Based on the AI Act, Erasmus MC has the responsibility of monitoring, following the instructions of the AI provider and therefore the responsibility of developing a monitoring system lies with the company that sells the application. Therefore it would be more valuable to focus on the other gap: the implementation of Article 12. This article refers to record keeping. However, it is important to note that this extended form of record keeping is not immediately relevant for research purposes. Nevertheless, maintaining records during the research phase has numerous benefits, such as improving transfer ability and creating opportunities for startups or industry sales. (European Commission, 2021)

Research phase

Many departments within Erasmus MC are already working to advance this process of internal development. E.g. DataHub, Medical Technology, Research Suite, METC, and others. However, these are different departments that still rely a lot on their own documentation, using Word document assessments and giving human guidance. In addition, it was also mentioned in the interviews that researchers work with the PaNaMa, a Research Management System (RMS), but this system is still very limited. Even though this offers a good storage place, it does not stimulate department cooperation. Hence, I will focus on the research phase. Chapter 7 discusses this further.

Conclusion

The main research question *'What can different members of an AI development team encounter during the documentation process for the regulations of the AI Act?'* can be answered with two insights:

1. The AI project team can encounter a lack of guidance in the maintenance phase of the project.
2. The AI project team can encounter a lack of service that enables record keeping, including the requirement of 'logging capabilities that shall enable monitoring the high-risk AI system'.

The sub-questions were answered in a visual format: The process map. In doing so, the following conclusions can be drawn from analyzing and discussing this mapping:

Which role is needed in which part of the process?

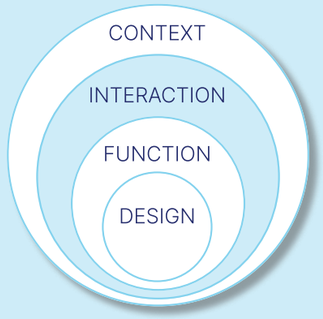
- The process of defining roles within an AI development team should involve input from experts, allowing for flexibility and adaptation based on team composition and project requirements.

How do these accountability steps, mapped out by the ministry, connect to the requirements of the AI Act?

- The implementation gap of Article 12 is addressed. By stimulating extensive record keeping during the research phase, Erasmus MC can improve knowledge transfer, enable future commercialization opportunities, and demonstrate their commitment to responsible AI development, which will contribute to the overall ethical progress of AI technology innovations.

Next steps

As mentioned in the discussion, it is important to confirm the assumptions of the roles and the process flow. Hence, the next step will be to study a case and confirm these findings. (See Chapter 7) The chapter also highlights that record-keeping improvement can be automated, keeping some degree of flexibility. The next step is to incoperate this into the service system concept (Chapter 9).



Gap 1: Little guidance after commissioning

Limited guidance in the maintenance phase of the funnel

Gap 2: Infrequent requirement: Record keeping

Checklist lacks emphasis on Article 12 (Record Keeping) requirements

Record focus

Focus on second gap: implementation of Article 12 and record keeping

Research phase focus

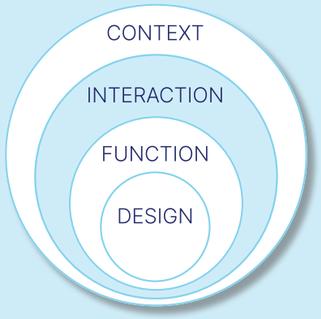
Opportunities for cooperation in documentation and systems

Case study

Confirming assumptions of the process

Record keeping focus

Improving record keeping with the Concept Service System



Confirming role assumptions

Assumptions of the roles Chapter 6
Discovering who fills in these roles

Creating personas

Discovering who fills in these roles

Connecting people and process

Discovering who is involved in the beginning of the process and how this changes over time

Flow Chart

In- and external flows of AI in Erasmus MC

Personas

Fictional characters representing user characteristics for design insights

Task overview

Connecting personas, roles and tasks
Inspired by agile management method

From Research to Product

Inspired by: story board & product journey

7. Case example

In response to Chapter 6, it is necessary to confirm the assumptions of the 'process mapping' with a case. Hence, a (partly fictionalized) case was chosen, based on multiple different case stories of interview participants, to provide a good representation of this AI development process and the AI team.

Method

Goal

The past chapter looked at what roles must be filled to meet the ideal mapped-out process. Looking back at the research question, *'What can different members of an AI development team encounter during the documentation process for the regulations of the AI act?'* it is crucial to determine the individuals who take on the roles of an AI development team in the early stages of the process.

This results in the following sub-research questions:

1. *Who can fill the roles of an AI development team?*
2. *What roles do these individuals perform during the 1st three phases of the process?*
3. *How do these individuals change during the phases of development?*

Data gathering

A PhD case was selected based on its relevance and ease of approach. This is one of the internal development cases that serves the design question by elaborating on the target group of the future service system. (See Figure 8, red line) Five participants were interviewed (See table 2) to obtain different perspectives to create one (partly fictitious) case: 1 thesis researcher and future PhD student, 2 supervising professors, and 2 regulatory experts from different AI application healthcare companies. These difference in participants give a good overview of the different individuals who have, or have had, important roles in this process. To stay in the AI theme, an AI random face generator was used for the visualization of the personas to enhance empathy. (Sashaborm, 2021)

The assumption-based roles and guidelines outlined in Chapter 6, which included a Ministry checklist were used as a reference point for defining tasks among team members of this case. (Haitjema & Nennie, 2021)

Desk research was conducted in which current employees of a start-up Quantib, which originated at Erasmus MC, were identified on the platform Linked-in, an online social networking site. To ensure the privacy of the interview participants, the company Quantib was intentionally chosen, as it is not one of the companies where the regulatory experts work.

Participant	Function	Data collection	
		Audio to transcript loose	*Quotes*
Participant 6	Business Strategist	x	x
Participant 7	Thesis Researcher AI (continuous with a PhD)	x	x
Participant 8	Clinical physicist Supervisor AI research	x	x
Participant 9	AI Quality Assurance expert of the industry	x	x
Participant 10	Neuro-physicist Supervisor AI research	x	x

Table 2: Target group participants

Procedure

First, a case was chosen, based on the flowchart in Figure 8. This flowchart was created with the input of an staff member of Erasmus MC who knows a lot about Erasmus MCs in- and external flows of technological innovation.

After the case was chosen the following visualization methods were used:

The design method 'Personas' was used, to develop a better understanding of the target audience and to discover their values and needs. Based on the information gathered in the field research, an assumptions based representative selection was made of the topics: general information, hobbies, characteristics, interest and goals. This resulted in 3 personas: a detailed description of a non-existing future user. (See Figure 9)

By connecting these personas to the roles in the process of chapter 6, an overview has been generated of the tasks from gate 1 to 3 of the process out of chapter 6. These tasks and roles are still assumption based, inspired by the Ministry's checklist, Impact Assessment, and the previous interviews with experts. (Ministerie van Algemene Zaken, 2022)(See Figure 10)

A visual representation is created of the beginning of the research phase and the last phase of the commissioning of the AI application product. This shows the reader what the roles are and how many people are filling in those roles. (See Figure 11)

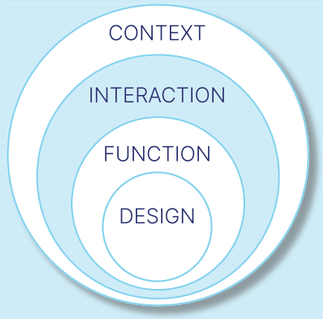
Data Analysis

Firstly the personas were analyzed to get a more consistent and shared understanding of the future users of the service system.

Then these personas with their user values, routines, skills, and social relationships were compared to the roles and associated tasks. The next step would be to see where the personas did not match well with the roles and tasks associated with them.

Finally, it was examined how the roles changed during the phase of the process. With this analysis, the differences in people and their workload becomes more clear.

7. Result - Choosing a Case



Process flowchart

Figure 8 shows a flow chart of the different in- and export flows of AI within Erasmus MC. AI can arise either from research within a hospital or from industry development. After this research phase, it can be exchanged if all documentation is properly recorded. A case was chosen in which the research starts in Erasmus MC from a PhD student. (See red line) This is the most successful way to start according to the interview participants.

The service system will focus on record keeping during the research phase where there is still much to be gained. This phase is depicted by the circled part in yellow.

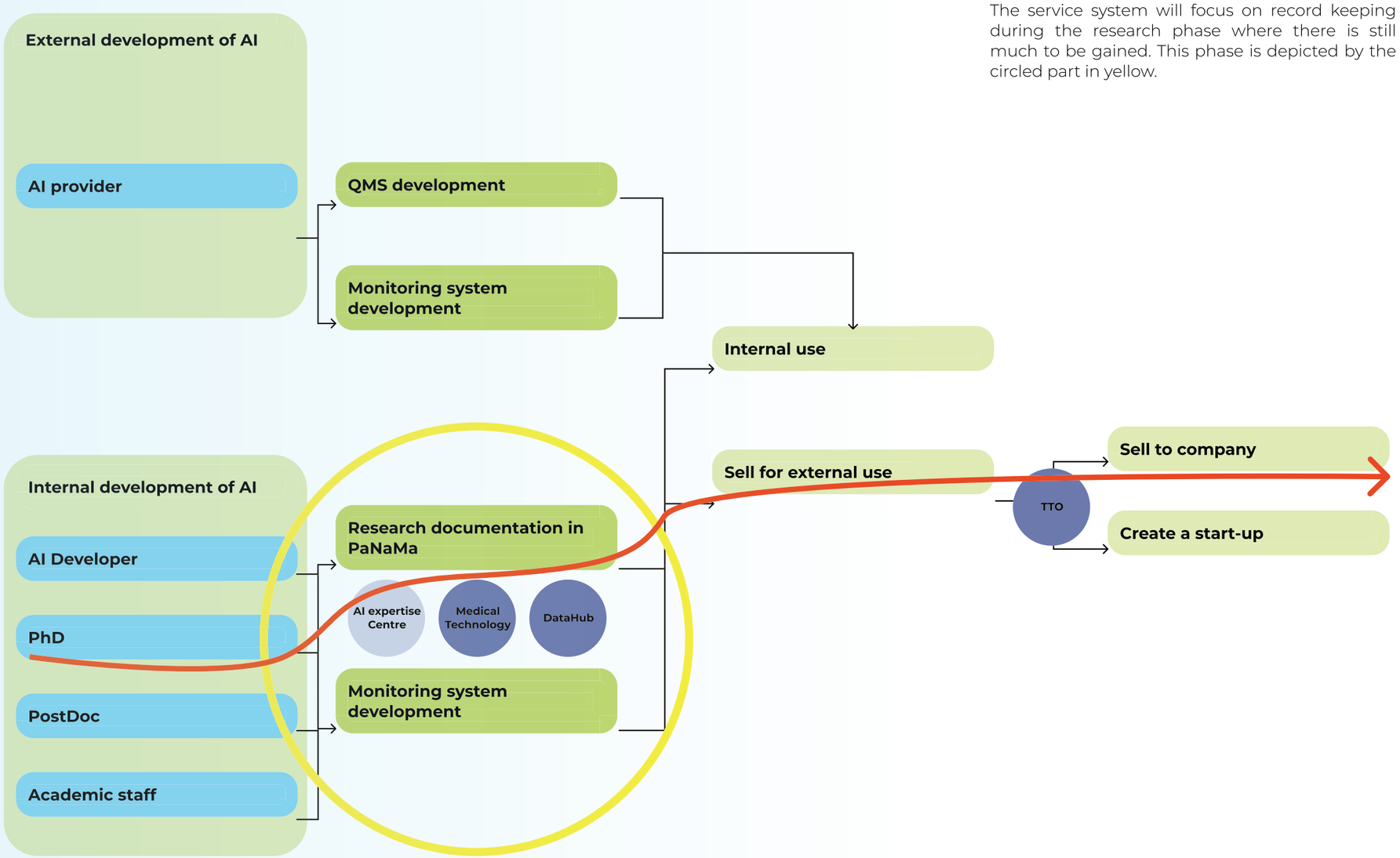
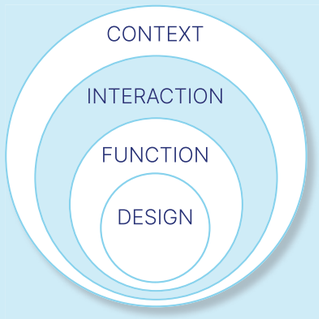


Figure 8: Process flowchart



7. Result - Personas

Personas

Below you can find 3 personas. Multiple pieces of information were collected for these personas and in doing so, this information was generalized.

First, you will find a brief description, then some general data, afterwards the personas' characteristic and personal goals. To create another slightly more empathetic picture, images showing favorite games, family, and hobbies have been added.

Personas roles and task overview

In the page below, the personas are linked with the roles they fill in the initial phase. Following this connection, the tasks they have for each part are written down.

Daan

Daan is a (PhD) student who researches the possibilities of AI for a specific problem within healthcare. He has the ambition to create value for the patient or the medical staff. He is young, eager to learn but unaware of the complexity of implementation and likes to be informed and guided.

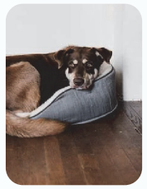
Age: 26
Education: Computer science
Job: PhD student
Family: Living together with his girlfriend

Hobbies:
- Climbing
- Gaming

Interest:
- AI and the metaverse
- Watching scifi movies

Characteristics
- Experimental
- Curious
- Analytical
- Problem-Solving

Goals
- Wants to help others by doing instead of talking
- With his holistic view he wants to change the world with the possibilities of IT
- To gain more knowledge and develop himself


Emma

Emma is a medical specialist and physicist supervising the PhD student. She has a passion for curing patients and is willing to supervise multiple studies to improve healthcare through technical innovation. She has a powerful mindset which helps her to convince different people.

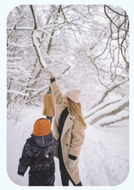
Age: 37
Education: Medicine
Job: Neurologist
Family: Family with one little girl of 3 years old

Hobbies:
- Running
- Yoga

Interest:
- Functioning of the brain
- Chemistry

Characteristics
- Precise
- Direct
- Perfectionist
- Structured
- Concerned

Goals
- Wants to help individuals
- Lives to work
- The free time that is left, she spends with her family
- To discover more of the functioning of the brain


Lennard

Lenard is representative of the (potential) AI expertise team is approachable and always willing to answer questions. He has a broad knowledge of AI development and has the right network to connect the researchers to the right experts.

Age: 42
Education: Law
Job: Quality Assurance
Family: Family with three kids

Hobbies:
- Hockey
- Reading crimes

Interest:
- History
- Ethics

Characteristics
- Critical
- Easy to talk to
- Honest
- Dominant

Goals
- Make the to do list
- Inspiring others
- Ensuring safety and honest approach of patients



Figure 9: Personas

Case 1: PhD

(PhD) student
AI research

Daan

User values: Time efficiency, easy to understand guidelines, logical to use, customization input

User routines: Using their own (laptop) and programs, having their own way of working and structuring

User skills: Conducting research and developing codes

Social relations: Closely interact with supervisor, research group and other specialist who give guidance

Supervisor / doctor/ clinical physicist

Emma

User values: Reliable system, efficient work environment, shared storage place

User routines: Familiar with documentation through research experience and protocols for doctors

User skills: Applying medicine knowledge and conducting research

Social relations: Close contact with PhD student, short connection with medical staff and department heads

AI expertise team

Lennard

User values: The expertise team is not there yet

User routines: The expertise team is not there yet

User skills: The expertise team is not there yet

Social relations: The expertise team is not there yet

Idea

Gate 1

Data Scientist

AI developer within the IT software department team, PhD student, PostDoc researcher or other academic staff

- Gathering and sharing relevant information about the algorithm improvements
- Gathering and sharing the technical risks of the idea
- Considering the best way to manage the data:
  - Storage
  - Security
  - Privacy
  - Etc.

Engineer

AI developer within the IT software department team, PhD student, PostDoc researcher or other academic staff

- Analyzing the feasibility by researching:
  - The target group (persona's)
  - The intended use (workflow)

AI Provider

AI developer within the IT software department team, supervisor of the PhD student, PostDoc researcher or other academic staff

- Managing other stakeholders
  - Making them aware of their responsibilities
- Storing information about:
  - Feasibility
  - Risks
  - Data gathering & storing
  - Contracts

Clinical Specialist

Supervisor of PhD, External advisor of clinical knowledge

- Representing demand from the medical side
- Knowing their responsibility during the whole implementation process
- Sharing their knowledge about the medical risks

Legal Advisor

External advisor of the AI expertise team

- Supervising the project by making them aware of the legal complexity
- Directing to necessary external parties and assist in drafting contracts with external parties
- State whether it is ethically acceptable

Explore

Gate 2

Data Scientist

AI developer within the IT software department team, PhD student, PostDoc researcher or other academic staff

- Gathering and sharing relevant information about the algorithm improvements
- Classify the risk
- Create a RMP
  - Including a risk-benefit analyses
  - Receiving medical advise
- Creating a medical evaluation plan
  - Evaluate technical performance
  - Receiving medical advise

Engineer

AI developer within the IT software department team, PhD student, PostDoc researcher or other academic staff

- Considering the best way to secure the application:
- (Determining value)
  - Research question
  - User stories
  - Stakeholder analysis
  - Business case
  - Market opportunities
  - User journey

AI Provider

AI developer within the IT software department team, supervisor of the PhD student, PostDoc researcher or other academic staff

- Responsible for the liabilities:
  - What legal requirements should be met and how they will be met.
- Determine manufacturer (internal developer(s))
- Manage self-certification and/or find external certification parties
- Letting the clinical evaluation plan begin reviewed by an (independent) expert.

Clinical Specialist

Supervisor of PhD, External advisor of clinical knowledge

- Being aware of the legal requirements
- Agreeing on the risk classification
- Sharing their clinical knowledge for the risk-benefit analysis in the RMP
- Helping with setting up the clinical evaluation plan

Legal Advisor

External advisor of the AI expertise team

- Supervising the AI provider by communicating:
  - End requirements and obligations
  - Complexity of the regulations
  - Importance of traceability and transparency
- Formative assess CCMO

Develop

Gate 3

Data Scientist

AI developer within the IT software department team, PhD student, PostDoc researcher or other academic staff

- Gathering and sharing and storing relevant information about the algorithm improvements
- Final classification of the risk
- Update the RMP
  - Risk have been addressed (eliminate, manage through control measures, accept)
  - Positive outcome of risk-benefit analysis
- Making a clinical evaluation report
  - Literature based study
  - Receiving medical advise or evaluation
  - A plan to evaluate technical performance in Pilot A

Engineer

AI developer within the IT software department team, PhD student, PostDoc researcher or other academic staff

- Creating a security infrastructure for pilot A based on the risk clasification
- (Preparation for first pilot)
  - Apply UX/UI research

AI Provider

AI developer within the IT software department team, supervisor of the PhD student, PostDoc researcher or other academic staff

- Start to create a IMDD
  - Bundling CCMO
  - Gathering other requirements
- Manage self-certification and/or find external certification parties
  - Getting it approved

Clinical Specialist

Supervisor of PhD, External advisor of clinical knowledge

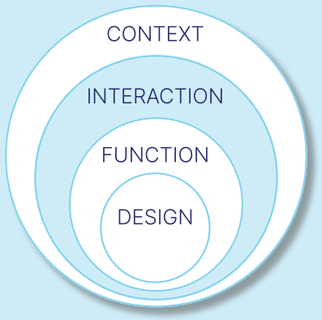
- Agreeing on the risk classification
- Sharing their clinical knowledge for the update of the risk-benefit analysis in the RMP
- Assisting or evaluating clinical evaluation report

Legal Advisor

External advisor of the AI expertise team

- Supervising the AI provider by communicating:
  - Need for self-certification or external certification
  - What to deliver
  - Where to get an CE certificate
- Formative assess IMDD

Figure 10: Tasks



7. Result - AI Research → Product

AI development team

Below is a representation of how the AI development team can change over time. The number of people and the roles they have changes, the workload also changes and is distributed accordingly.

Number of people & change of roles

As demonstrated in the visual, in the early stages there are very few people to fill multiple roles. In the process, external guidance is in high demand. This can be either overarching or specifically by small departments within Erasmus MC. In contradiction with further phases in the process where the expertise is mainly used within the company.

Workload

Even though this visual does not show how much workload difference there is, the difference in manpower does show that the workload at the beginning cannot be the same at the end. E.g. the two people at the beginning cannot document as much as the 47 people in the scale-up.

Example Quantib

Research → *Product*

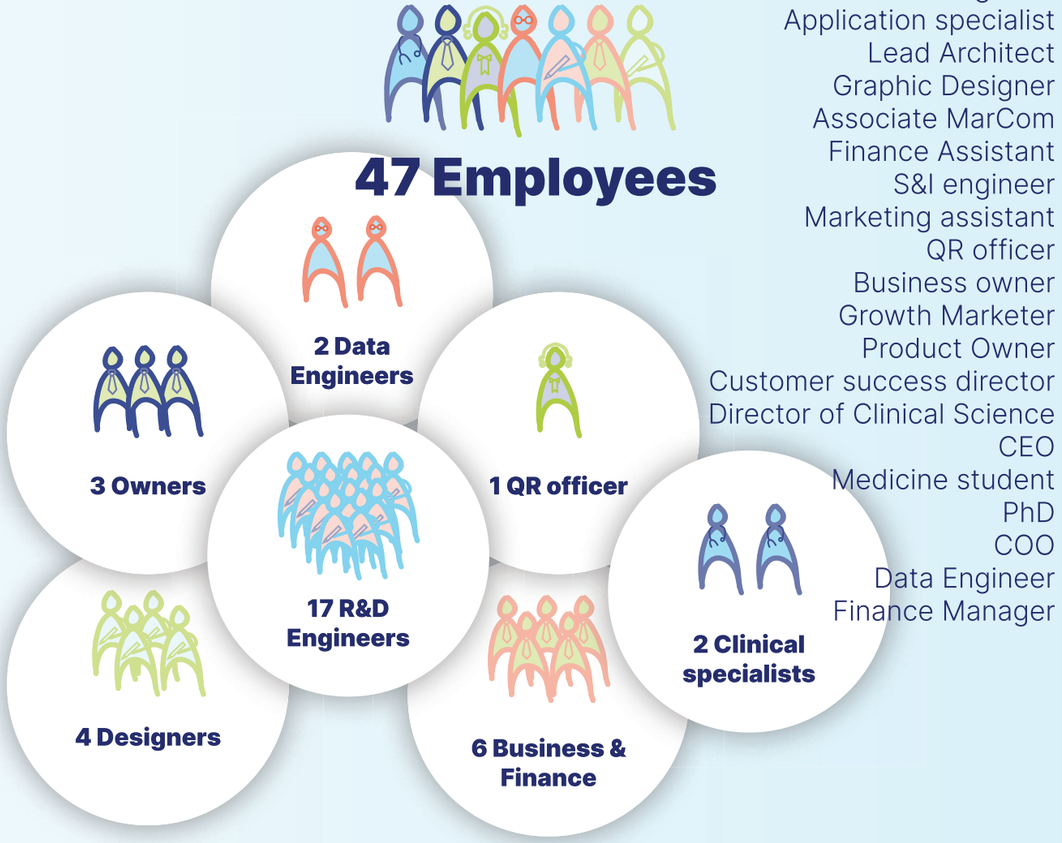


Figure 11: From AI Research to Product

7. Case example

Discussion

Several things came up while dividing the tasks among the personas. A lack of a generalist who knows something about all disciplines. The partial mismatch between the personas and the roles and the tasks they must fulfill. The personas indicate a lack of clarity regarding the required individuals as time progresses. By showing a case over time, it can also be stated that the size of the AI project team drastically increases.

Need for overarching experts

In the PhD student's case study, there is a discrepancy between the tasks. There are the tasks closely connected to the expertise of the persona's (e.g. clinical expert tasks) and there are the tasks related to the process. Within these remaining process tasks there a lack of an overarching person that knows all the requirements of these tasks. This gap matches nicely with Erasmus MC's plans to establish an expertise center for AI. Hence, a persona representing someone from the future expertise team was also created in the visualization. For this expertise team, they must be able to zoom in to the tasks that need to be fulfilled by the team, but also that they can zoom out and match this with the requirements from the law and the assessors.

Even though the expertise team is not there yet, multiple departments are filling in this role at the moment.

Partly mismatch personas and roles

Based on the roles that had to be divided, the Doctor, supervising the PhD students is responsible for delivering the papers. However, this does not mean that the doctor also has the required technical knowledge of the research that this PhD student is conducting. In addition, it is known that Doctors already have a high workload at the moment so they cannot be expected to make this research their priority. However, this responsibility does fall on them. The PhD student is also expected to be able to take on more roles, but it may be the case that this student only has a data science background, and is less comfortable engineering.

Combined with the strict requirements of the AI Act at a later stage of development, a balance must be achieved with the expectations of the team members of the AI Development team in the research phase and the required actions following the funnel. The way to achieve this is clear personal guidance combined with a user-friendly guiding service system. (See chapter 9-11)

Inner motivation and ethical justification

Secondly, by analyzing the personas the PhD student & supervisor are likely driven by helping individuals, which could make them unaware of ethical dangers since they have good intentions. However, the documentation of ethical justification is going to be of vital importance in the future.

Limit workload doctors

By looking at the work pressure of the doctors, it is clear that supervising research is an activity in addition to a full-time job, therefore there will have to be a limit to the demand of workload placed on them.

Growing team

As expected, a clear difference can be seen in the number of people at the beginning of the research phase and the last phase of commissioning the AI application product. Hence, documentation must also increase over time.

Limitations

There are more cases where the roles are filled in by other people, However, due to the limited time of this research, one case was chosen. More cases are shown in Figure 8, but these are not discussed.

Conclusion

The results of this sub-research are related to the overarching research question: *'What can different members of an AI development team encounter during the documentation process for the regulations of the AI Act?'*

- In the case of AI PhD research, individuals may be expected to fill roles they do not want or do not have the experience for.
- This may cause a problem with the tasks that should be done. Firstly they could be unaware of the tasks, secondly, the tasks might not be clear to them, thirdly they might not be competent enough to fulfill the tasks, and finally, the tasks might take too much time next to their other work activities.

Sub-questions

In addition to the visuals that already answer the sub-questions, the sub-questions are briefly highlighted below with short conclusions:

Who can fill the roles of an AI development team?

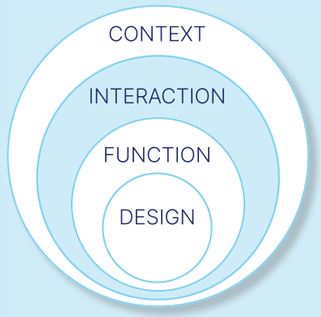
- A case is shown where the roles were filled by a PhD student and a Doctor who supervises this PhD student. The personas show an extensive generalized version of the characteristics that these persons might have.

What roles do these individuals perform during the 1st three phases of the process?

- As shown in Figure 10, the PhD student has the role of data scientist and engineer, the supervisor has the role of doctor and provider and the last role is taken by someone from the future expertise center. Even though these roles are assigned to them, it does not always suits them.

How do these individuals change during the phases of development?

- The number of individuals who are part of the AI development team changes a lot over time. It starts with two people who can ask different external people within the Erasmus MC for advice and in the maintenance phase, it could have 47 employees, of which the initial people are not always needed anymore.



Partial mismatch personas and roles

Personas might not fit the roles they are assigned to fill

Inner motivation & ethical justification

Good intentions of the AI development team can generate a negative perspective toward ethical justification

Limit workload doctor

Supervising is an addition to the fulltime job of a doctor and therefore the workload should be limited

Growing team

Documentation grows as the AI application progresses

Ideation with others in this field

Ideation to find out how to create awareness of the roles and stimulate them to take their responsibilities

Creating components

Gather the insights to create the important factors of a service system

Main Insights Interaction

CONTEXT

Department infrastructure Erasmus MC

Erasmus MC has a lot of expertise but these might be hard to approach

Educating staff members

Combine expertise of technical and medical knowledge

Designate responsibility

The target group should know their responsibility

Aligning AI Act requirements with Erasmus MC operation

The legal context must be translated so that it is in line with the way of working

Multiple solutions are needed

The complexity of the problem and the extensive requirements of the law cannot be solved with one solution.

Unclear what levels are obligated

The difference between a must and a helpful tool is not clear

Content of levels are not inline

It is difficult to find a connection in the content between the levels

Limitation of top-down approach

One-sided view of experts and documents

INTERACTION

Gap 1: Little guidance after commissioning

Limited guidance in the maintenance phase of the funnel

Gap 2: Infrequent requirement: Record keeping

Checklist lacks emphasis on Article 12 (Record Keeping) requirements

Record focus

Focus on second gap: implementation of Article 12 and record keeping

Research phase focus

Opportunities for cooperation in documentation and systems

Partial mismatch personas and roles

Personas might not fit the roles they are assigned to fill

Inner motivation & ethical justification

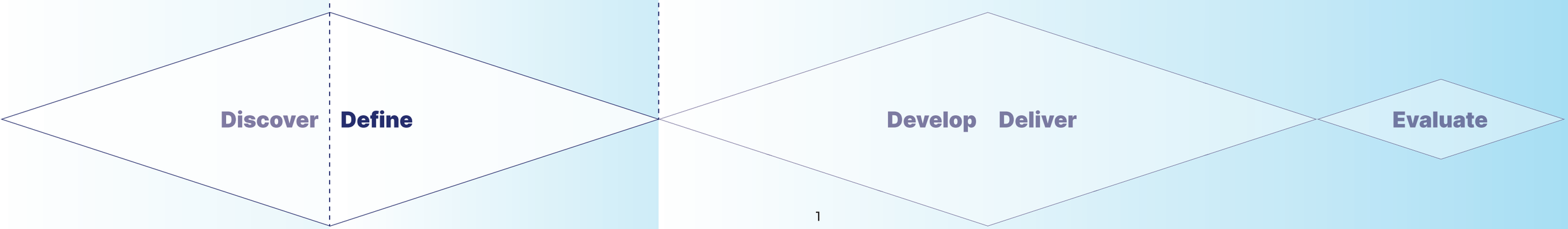
Good intentions of the AI development team can generate a negative perspective toward ethical justification

Limit workload doctor

Supervising is an addition to the fulltime job of a doctor and therefore the workload should be limited

Growing team

Documentation grows as the AI application progresses



FUNCTION

The following chapters discuss the function that the final concept should have. First, a creative session was facilitated with potential future users of the design to find out what functions they consider important. Then the main findings were collected and combined with the ideas to create an overview of the requirements and needs of the design.

CONTEXT

Prepare Erasmus MC for the new legislation: AI Act

INTERACTION

Creating clarity of the roles and responsibilities of the main stakeholders

FUNCTION

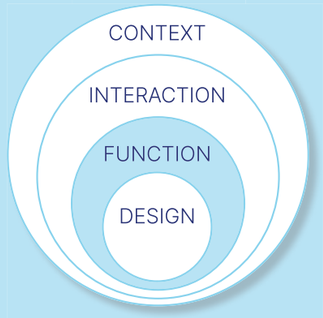
Stimulate relevant stakeholders to take their responsibility

Goal:

*Explore how the AI development team can be **stimulated to take their responsibility** by gaining inspiration through **co-creation** and generate ideas.*

Focus:

Focus on researchers within Erasmus MC and their supervisors



Record keeping focus

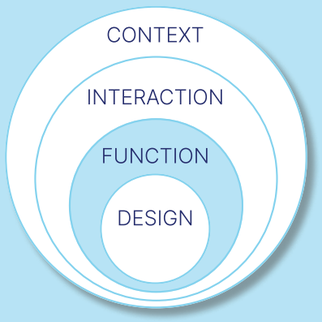
Improving record keeping with the Concept Service System

Ideation with others in this field

Ideation to find out how to create awareness of the roles and stimulate them to take their responsibilities

Creating components

Gather the insights to create the important factors of a service system



Get inspired

Co-create with (close to) target

Obtaining important design factors

Defining which factors are important to include in the Concept Service System

Analogy and metaphor

Devise an analogy or metaphor of a similar problem in another domain

How to

Step-by-step design questions starting with ‘how to’ that give instructions for creating solutions

Hits and Dots

Choosing the best ideas

8. Creative ideation session

This chapter reports the creative session that was facilitated, in which three people, of the technical medical field, were asked to come up with ideas to create awareness of the roles and responsibilities of an AI development team.

Method

Goal

The purpose of this chapter is to gain inspiration and ascertain the design needs for the final service system. Chapter 6 shows that some form of guidance is already in place, however, the implementation of this guidance still needs to be investigated. Next, Chapter 7 explained why it is so important to divide the roles within the AI development team so that it is clear what is expected of each individual.

Hence, the goal is to figure out *‘How we can create awareness of the roles and responsibilities of an AI research/development team?’*

To inspire the participants in the creative session, the following subquestions where created:

- *How could we get in contact with the AI research development team?*
- *How could we support their responsibility management?*
- *How could we educate the AI research development team about the requirements?*
- *How could we stimulate them to follow the ideal mapped out process from the beginning?*

Data gathering

Given the novelty of the topic, it was considered valuable to get input from others. However, getting the right target group of physicians, with their demanding schedules, together proved to be challenging. Therefore, a group of participants within the authors personal network was recruited. Even though they are not the specific target audience, they were all relevant to the topic to some degree, representing potential future users of the platform.

The participants consisted of:

1. A Clinical Technology student who is nearing completion of their studies at Erasmus MC and will continue with a PhD program within the same institution.
2. A PhD student at Amsterdam UMC engaged in AI research.
3. A medical student who has already attained a bachelor's degree in ‘Medical science and technology’.

To encourage inspiration and to empower them as domain experts, the design questions where asked to them in the creative session.

All the participants provided the creative input that is also the result of the sub-research. Hence, no other way of data gathering was deemed necessary.

Procedure

Multiple facilitation methods were used for the creative session. In order to get the participants in a creative mindset, comparable *analogies or metaphors* were created for the subject: roles and responsibilities. Subsequently, we looked at how these problems are solved in other domains. Then the ideation process started by answering the *How To* questions (created in advance). When the maximum level of creativity was reached and all ideas were written on post-its, *spontaneous clustering* started, including the answers to the analogies/metaphors. The clusters were named and in the end, all participants individually selected the best and most creative ideas by means of *Hits & Dots*. (Heijne & Van Der Meer, 2019) (Van Boeijen & Daalhuizen, 2010)

Table 3 shows an overview of the entire planning of the creative session, highlighting time, method use, purpose of the method, and the needed materials.

Data analysis

The generated ideas were analyzed to make connections in order to form clusters. These clusters serve as input for the design of the final service system. The individual preferences of ideas are also collected and taken into account when prioritizing features of the final design.

As all participants' native language was Dutch, the outcomes post-its of the session are also written in this language. It is difficult to maintain the same essence in the translation, so a conscious decision was made to translate only the cluster names into English.

8. Creative ideation session

Component	Time	Start	Creative facilitation	Aim & notes	Material
Introduction	5	20.20	Agenda, Rules, Code & conduct	Making clear that it's about getting inspiration, rather than having the perfect solution.	Post-its
	5	20.25	Problem explanation	Short explanation of the graduation process so far and the conclusions leading to the problem. Showing the process mapping, roles, persona's and case scenario.	Printed visuals
Problem exploration	10	20.30	Direct Analogy or Metaphor	RG come up with metaphorical situations in other domains that resemble the essence of the PaP. · Of what comparable problem does our problem remind you of? · Is there an analogy in biology/weather for our problem?	Post-its Markers Window
	10	20.40	Direct Analogy or Metaphor	Explore the domain of the direct analogy or metaphor: · How is the problem solved here? · How was the problem approached in that field?	Post-its Markers Window
	10	20.50	Break		
Idea finding	5	21.00	H2's	Letting them look at the H2 questions individual and give the space to ask questions if they do not understand it	Printed H2's Post-its Markers Window
	30	21.05	H2's	Generate answers to the H2 questions.	Printed H2's Post-its Markers Window
	10	21.35	Energizer	Sardientjes (reduced hide and seek)	
Idea defining	10	21.45	Spontaneous clustering	Letting them cluster the post-its, not only based on theme but also on feeling, approach, outcome.	
	10	21.55	Hits or Dots	Giving the RG 3 votes for the most important factor/solution and one for the most creative factor/solution	Small stickers/post-its
	10	22.05	Buffer or Finishing game		

Table 3: Creative session planning overview

Result

Figure 12 shows an overview of all the ideas created by the participants. The green post-its show the ideas that answer the design question. The blue post-its show the ideas that answer the analogies/metaphors. Both the ideas of the green and blue post-its were clustered together.

Training (Information tools)

Information tools is the largest cluster and was seen as one of the most important ways to create awareness. This cluster is very diverse and includes education as well as visual guidance or example templates

Understanding

The cluster understanding is small, but proved to be very important while choosing the best idea in the last phase of the session. Getting understanding from the users is very important to convince them of the necessity.

Co-Creation

Co-creation is important to both create a continuous feedback loop and convince the department heads. It was pointed out that trial and error is also a good way to approach this problem, which overlaps with this iterative design study.

Check-up (control)

One important cluster that has not yet emerged in the previous research chapters is the cluster 'control'. In this cluster it was mentioned that intermediate checks are needed to encourage correct usage of the organizational guidance. Although this may be forcing, it is effective and similar problems are also addressed this way.

Optimization

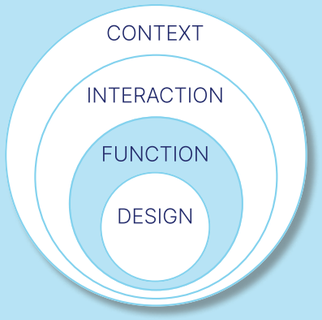
Ensuring an optimal service system also helps to encourage use. It should become easier and more user-friendly compared to current tasks.

Management

Management was an important factor in the previous chapters but is represented here only in a small cluster, which focused mainly on the individual distribution of tasks.

Reward

As a final cluster, another new factor emerged: 'Reward'. Nothing can be changed about the requirements of the AI Act, but people can be stimulated through rewarding. Several rewards that have great value, specifically for this target group, were written down as ideas.



8. Result - Clusters

Training (Information tools)

Scholing
Education program PhD
Maakt het onderdeel huidige education program
Templates voor projecten
Workshop nascholing
Workshops of lessen
Nieuwsbrief
E-learning
Onderdeel van omboarding maken
Uitleg doel & functie onboarding
ISO educatie
Specifiek op AI
Duidelijke Instructie
Duidelijke Routekaart
Duidelijke werk-omschrijving
(Beschrijving)

Optimalization

Efficientie
Weinig tijd
Geen dubbel werk
Gebruiks-vriendelijk systeem
Beginnen bij de Database

Co-Creation

Feedback geven
Evalueren
Co create met gebruikers
Begin bij de top
Trial & Error
Supervisie of cocreatie met:
Ervaren mensen die het probleem al [illegible] hebben
Betrekken in het "mappen"
Betrek de AI research development team
Overtuig de leiding
Top down approach van leiding naar PhD

Reward

Eten
Peer review game
Competitie
Data sardientjes
reverced seek and hide, find the bug and see who is last
Reproducable AI grand
Voor op je CV
Borrel uitjes
Waardering voor je werk
CPU time op het cluster
allows measurement of the processing power a single program requires
Prijs
Voor team of individueel
Reward
Spelletjes

Stand-alone post-its

Hoe zorg je ervoor dat mensen het ook willen doen?
Eigen belang

Check-up (control)

Supervisie
Dreiging
Hierarchie
Audit
Inspectie
Concequenties voor mis-management
Controles uitvoeren
Controle checkpoint
Barriere voordat je door mag

Understanding

Bouw-voorschrift
+ inspectie
Inzicht in gevolgen bij fouten
& goed gebruik
Vergelijking maken
Inzichtelijkheid dagelijkse dingen
Urgentie laten zien

Management

Taken binnen team verdelen
1 persoon de taak bedelen

Figure 12: Creative Session Results

8. 44Creative ideation session

Discussion

The creative session with the participants resulted in valuable insights into idea generation and implementation of a concept service system. This discussion section of the ideation session explains two types of ideas, different levels of abstraction, an overlap with the Erasmus MC's approach, recurring topics, and it mentions the importance of reward and control.

Two Types of Ideas

Throughout the session, two distinct types of ideas emerged: those associated with the final product service system and those concerning the implementation process. Additionally, the ideas varied in terms of level of abstraction, with some focusing on efficiency and overarching concepts, while others were more concrete, such as E-learning.

Overlap with the DataHub Project

It was interesting to note the overlap with the DataHub project, where the creative session participants also suggested the idea of implementing a barrier before proceeding further. This shared perspective highlights the importance of incorporating checkpoints or evaluative stages to ensure the viability and effectiveness of ideas before moving forward in the development process.

Management, flexibility, preparation

Several recurring topics emerged across sub-studies conducted within the overarching study. Firstly, effective management was recognized as critical in driving successful product service system development. Secondly, striking the right balance between structure and flexibility was acknowledged as important. Participants valued the guidance and clarity provided by a structured approach while also recognizing the need for flexibility to adapt to changing circumstances. Lastly, the significance of thorough preparation was consistently emphasized.

Reward and Control

Two additional aspects stood out during the creative session. The first aspect was the significance of rewards, which also stimulated the creativity among the participants. This finding underscores the potential benefits of incorporating reward and recognition mechanisms into idea generation processes. On the other hand, the session also highlighted the need for some form of control. Maintaining a level of control ensures feasibility of the quality management. The presence of assessments compared to the absence of life cycle controls shows a clear gap, giving the opportunity to develop strategies or frameworks for long term quality.

Prioritize important factors of design

During the final part of the session, the participants chose the ideas that they individually thought to be the best and most creative. These ideas were eventually placed side by side. The clusters are important parts of the final design or strategy and are therefore included in the requirements and needs in chapter 9. This will show that the concept service system must be user-friendly, the service must provide insights into the ethical and business consequences of errors and good use, and there is a preference for a reward. To implement the service system, the people will have to be part of the onboarding and a form of control will have to be developed.

Conclusion

Design Question

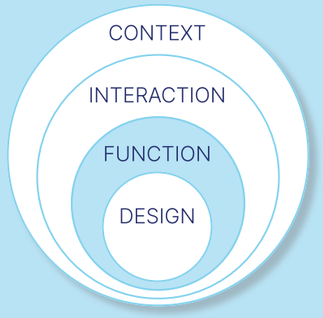
Several aspects were highlighted in the discussion that answered the main design question: *'How can a hospital develop a service system combination that gives more guidance to AI developers within the regulation process of the AI Act?'*. Providing guidance to the target audience can be done in several ways. By offering a user-friendly service, using barriers to check if it is properly implemented and rewarding the target group for proper use. In doing so, it is important to include the target group and have some degree of control over the process since they are the experts and no project is alike.

In the creative session the main questions was: *'How we can create awareness of the roles and responsibilities of an AI research/development team?*' In answering this design question it is important to create awareness by bringing the target group along through co-creation and proper education, while making it attractive to keep following the general structure of the process.

The ideas that answer the sub-questions of the creative session can be found in Figure 12. Since these supplement the main question of the session, they will not be explained further.

Follow-up steps

These insights will be included in defining the key components of the service system. Hence, the next step is to merge this input, with the interview input and the other previous discussion points to validate the components of the design.



Two types of ideas

Ideas associated with the service system
Ideas relating to the implementation

Overlap with 'gates' datahub

The idea of a barrier as a threshold overlaps with the gate structure of the datahub

Management, flexibility, preparation

Reoccurring themes from the previous chapters are reflected in the ideas

Training (Information tools)

Understanding

Co-Creation

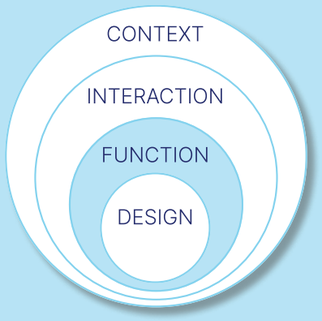
Reward

Check-up (control)

Management

Merging input to create components

Merging the main findings of this creative session, the interviews, other previous discussion points to create components of the service system



Translate findings into components

Combine the main findings of the research to create the requirements and needs for the designs

Qualitative study

Quotes were clustered of the last 5 interviews to reflect the needs of the target group

Requirements and needs list

A content analysis was done, Inspired by the method: List of Requirements

9. Creating components

In this part of the study, all the main findings were brought together to create the components of the service system and the components of a roadmap. First, the chosen requirements are highlighted from the beginning of the study. The requirements specifically chosen as important requirements for this study are highlighted in page 48. Then the needs are highlighted by linking main findings with clusters from the ideation to define clear components. The overview of the needs can be seen on page 50-51.

Method

Goal

The goal of this chapter is to gather all the information of the last chapters and translate it into requirements and needs to answer the main design question: *'How can a hospital develop a service system combination that gives more guidance to AI developers within the regulation process of the AI Act?'*

Requirements

The first focus of the requirement will be primarily on the information gained from first part of this study: the desk research combined with the context research by interviewing experts (Chapter 3-6). The goal is to reflect mandatory requirements based on the final draft of the law or in response to requests from the government.

Needs

The second focus will be on the needs of the future users and components that the service system must include to make it user-friendly and to enable future implementation of the law. The aim is to translate the main findings and ideation clusters (Chapter 6-8) into needs for a service system and a roadmap.

Data Gathering

The data for this study is collected via the findings of the previous chapters. Although no new data was collected, it is possible that new knowledge was gained in the meantime that has not yet been mentioned. This derives of the origin of the iterative design research and will be mentioned in the explanation of the requirements of need.

Requirements

Data of the first part of this research was gathered to define the requirements of the policy-making body from the top-down approach. The discussion points from chapter 3-6, including outcomes from interviews with experts, desk and field context research and assumption-based process mapping activity were synthesized to form the basis for requirements.

Needs

As mentioned earlier in the chapters, the interviews with the target group served as inspiration for several subsections of this study. The interviews from these 5 participants (P6-P10) (see Chapter 7, table 2) were loosely transcribed and the quotes were clustered (See page 49, figure 13), some of these quotes will be used later in this chapter. These quotes were clustered qualitatively which resulted in the following clusters: A complete overview of the cluster with the quotes can be found in Appendix 3.

Additionally, to understand the needs of the target group, the data of the bottom-up interaction research was gathered: the discussion points from all chapters were collected, along with interviews with representatives from the target group and the ideas generated during the creative session were also taken into account.

Team management

Change management

Flexibility

Preparation

Guidance

Limitation

Procedure & data analysis

These important code groups, quotes, discussion points and ideas were translated into requirements and needs for the concept service system.

By combining insights from all these sources, a comprehensive understanding of the requirements and needs of the target group was achieved. By creating a good overview and clear structure of requirements and needs the necessary components and features of the system can be identified.

The selected requirements from the law and government requests have been explained in a descriptive manner. For the needs part, labels are used to show in a clear way where the findings originate from. The main findings are shown in orange with only the title and the chapter they come from. The clusters from the ideation session are shown in green. A few quotes from the interviews have been chosen to highlight the importance of the need, with the number of the quote and the participant from whom it comes.

Main finding Chapter ...

Cluster Chapter ...

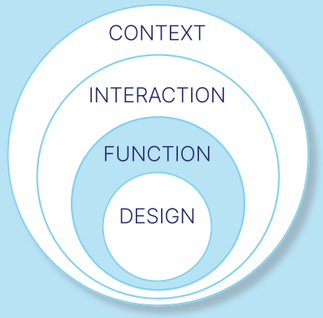
"*Quote*"

Q...
P...

Data Analysis

By analyzing the list all the requirements and the needs of the concept, the focus points where chosen in response to the intermediary conclusions of the chapter to determine whether a more developed concept could add more value to Erasmus MC. This serves as a starting point for designing the components of the concept service system and the elements of the roadmap. In the next chapters (10-11), it can be seen how these components have been translated into these designs

9. Requirements: Top-down findings



Requirements

The design requirements outlined in this chapter focus on traceability, transparency, and accountability within the project scope. By addressing these aspects with the limitations, the service system can be developed to align with the AI Act, stimulate ethical considerations, and empower healthcare professionals to make informed and safe decisions with AI technology. Additionally, further investigation into aspects beyond the project scope will be addressed for Erasmus MC to ensure the AI application's long-term effectiveness and compliance.

Requirements within project scope:

Record keeping with versioning

The service system should enable record keeping, centralizing all relevant project data and updates. Incorporating versioning mechanisms will ensure a clear history of changes made throughout the AI project, promoting transparency and ease of auditing. This requirement aligns with the AI Act, Article 12, emphasizing the importance of proper documentation.

Government assessments and storage

The service system should facilitate easy access and storage of government assessments, ensuring compliance with regulations. This will enable the project team to stay updated on regulatory requirements and streamline necessary documentation.

Stimulating Registration on the Dutch Government AI Register

To comply with the obligation to register on the Dutch government AI register since 7th July 2023, the service system should encourage the registration process for AI applications used in the hospital by facilitating configuration options with the AI register of the government.

Transparency to Patient

The design of the service system should prioritize transparency to patients regarding AI-generated decisions impacting their care. Patients should be provided with clear and understandable explanations of how AI contributes to their treatment plans, promoting trust and informed decision-making. This aligns with the AI Act, Article XX.

Stimulating Ethical Considerations

The service should incorporate mechanisms to stimulate ethical considerations within the AI project team. This can be achieved through regular human impact assessments, referencing the Framework for Responsible AI in Healthcare (FRAIA), and through encouraging ethical conversations within the AI project team to address potential biases, fairness, and social implications.

Human oversight of development

The service system should incorporate human oversight capabilities to enable interventions when necessary. This ensures that healthcare professionals can review and intervene in AI-generated decisions, maintaining patient safety and mitigating potential errors.

Out of Scope Requirements:

QMS with Monitoring:

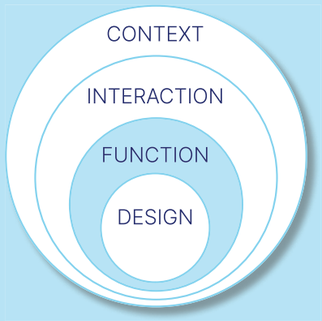
Given the limitations of time and expertise, the QMS and monitoring aspects are outside the scope of this project. However, Erasmus MC should consider investigating these aspects further to ensure ongoing quality and compliance in the AI application's deployment.

Data Privacy and Security:

While the service system should cooperate with other platforms like DRE to enhance data privacy and security, this aspect is out of the project's immediate scope.

Post-Market Surveillance and Reporting

The service system should provide a place to store post-market surveillance reports, even though conducting extensive post-market surveillance is beyond the project's current focus.



9. Result - Qualitative study

To find out the needs, several interviews were conducted. The input from these interviews has been gradually implemented in the past chapters. Here is an overview of the quotes clustered from the 5 final interview participants. An overview of these participants can be found in table 2 in an earlier chapter (7). The clusters of the quotes are shortly explained here will be used for defining the needs on the following pages. A reduced picture can be seen, the full view of these clusters can be found in Appendix 3.

Team Management

Multidisciplinary teams are crucial, integrating diverse skills for reliable applications. Developers prefer focusing on development rather than legal concerns, emphasizing the need for role and tasks assignment. Role allocation based on expertise and experience improves the accountability and software agile management encourage AI project team members to take their responsibility. Effective team management also requires collaboration and a supportive environment that promotes communication and learning across different disciplines. In addition, regular audits could ensure adherence to protocols.

Change management

Successful change management is critical when transitioning from research to product development and implementing AI applications. Flexibility in team composition and collaboration with industry partners contribute to effective change management. Effective change management can prevent innovation from being delayed due to financial considerations and compliance issues.

Flexibility

Flexibility is needed to make it possible for an AI project team to comply with regulations. This flexibility helps with facilitating collaboration, enabling different forms of data management, and giving freedom in software use to monitor the progress. There is a need for data transfer controls, collaboration with other programs to improve the transferability. In addition flexibility can stimulate ethical discussions within the AI development team to improve the validation of choices.

Preparation

Effective preparation involves proactive measures such as understanding the legal context and staying ahead of evolving regulations. Due to the limited time and other workload of the AI project team members, collaborating within Erasmus MCs departments is essential for a good preparation. Furthermore Erasmus MC could offer guidance, training, and ensuring clarity of roles and responsibilities to enable this preparation.

Guidance

There is a demand for a consulting role within the AI project team. The future Erasmus MCs expertise team should establish an overarching structure that balances flexibility. Generalists play a crucial role in bridging healthcare and technology. Besides these personal guidance there is also a need to establishing repositories, using templates, and automating documentation processes which will contribute to transparency and traceability and will help to streamline regulatory requirements.

Limitations

There is uncertainty surrounding the interpretation of the AI Act which result in a need of legal clarification within Erasmus MC. Discussions and initiatives regarding the AI Act are just starting, and additional requirements may be introduced. Therefore definitions and the required actions need to be framed appropriately even tho it may require adjustments to existing algorithms and processes. There is also a constraint for systematic support due to the limitation in the current research management systems.

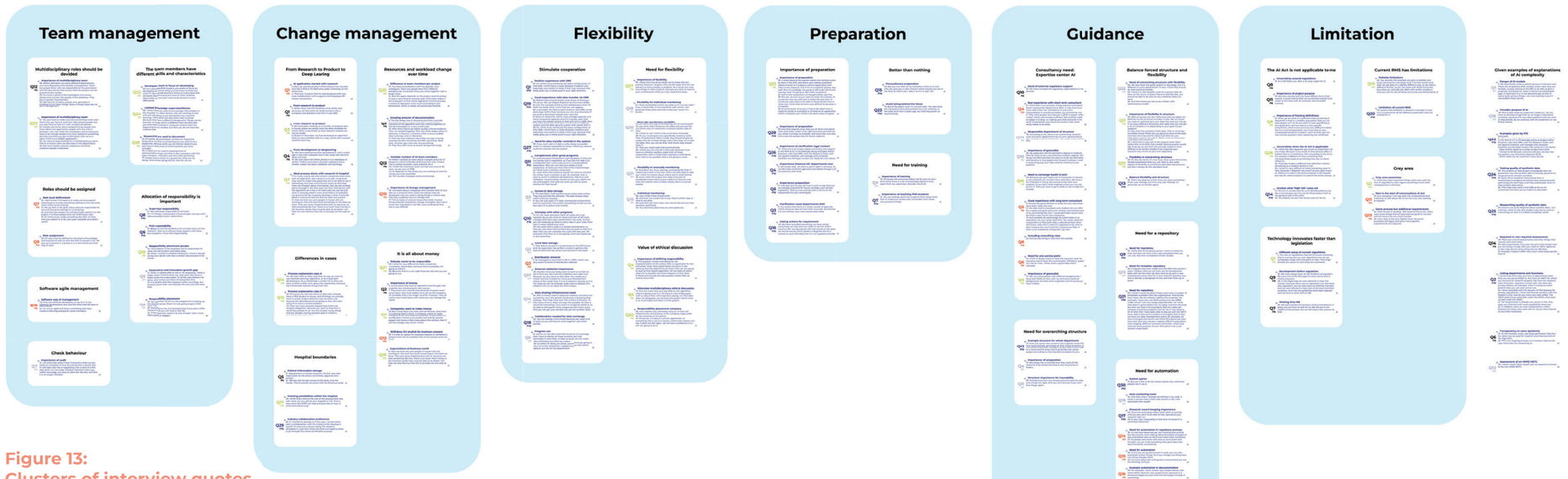
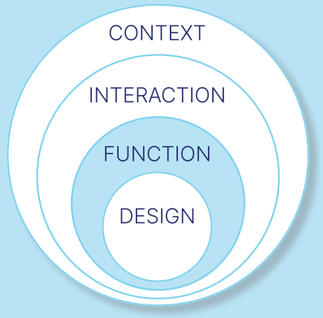


Figure 13:
Clusters of interview quotes

9. Needs: Bottom-up findings



Service System needs

This page highlights a number of headings that show what components the concept service system should have, based on the previous design research. These components will be briefly explained and the labels and quotes will show where the components come from.

Repository

The interviews revealed a demand for a repository that contains templates from other research. These examples will make it easier for researchers to fill out forms, e.g. for the METC. (See Q21P10)

> **Q21 P10** *66. I think it would be good if there were also a number of templates available from the organization. Kind of like best cases.*

In addition, this will reduce the workload of doctors by being more time-efficient.

Limit workload doctors — Chapter 7

Overarching structure

It was brought up several times that an overal structure is needed for the entire Erasmus MC, as this can provide clarity. This emerged not only in the interviews but also in the informal discussions with experts, researchers and other Erasmus MC staff. The service system should stimulate the use of such a structure. An example of this has already been set up at neurology, where a simple python script was used to organize the storage folders in the PhD students' computer in advance in order to encourage the correct way of storage. (See Q22P7)

> **Q22 P7** *64. We now have this great system in neurology, but it is different in every department. In fact, I think they should do that Erasmus broadly.*

Flexibility: Customized options

Despite the demand for an overall structure , room for flexibility is also needed.

> **Q12 P8** *29. On the one hand, it's nice if you have some kind of line thread somewhere that you can stick to, but some degree of flexibility is sometimes desirable, because you just don't always do the standard work.*

Therefore, it is important for the service system to create customizable options for users. There are multiple differences in the project: differences in department, differences in the goal of the department, differences in the goal of the research but also the differences in the team members and stakeholders during the process. Hence, it is preferable to provide guidance, but the system should not force one pattern.

Growing team — Chapter 7

(Software) Management

Management is a factor that keeps coming back several times as a discussion point in this study, due to the multiple uncertain factors within an AI project team. First, multidisciplinary knowledge is required in research, which does not always match the expertise of the team members and the size of the team. Which causes a mismatch in the roles and the people filling in those roles. (See Q18P9)

Mismatch roles & personas — Chapter 7
Growing team — Chapter 7

> **Q18 P9** *43. They are software developers, so we do it in the software development way and the thing that fits best in that culture.*

Therefore, it would be nice if a service system would provide additional clarity in the allocation of roles and tasks, so that it is clear to the team what they themselves know and where they need to bring in external expertise.

Ideation cluster: Management — Chapter 8

Automation

The demand for automation is a preferred option, even though it is not necessary, automation can help optimize the documentation process that can reduce workload. Hence it is a feature desired in the service system. An example of software that already make extensive use of automation are mentioned in Q17P9.

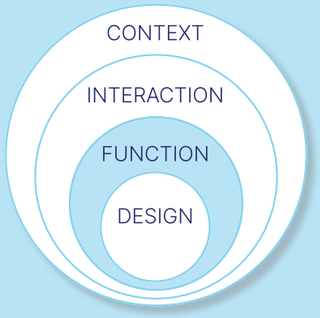
Limit workload doctors — Chapter 7
Ideation cluster: Optimization — Chapter 8

> **Q17 P9** *41. However, with the arrival of chat, GPT and the like, there are companies that already have that ready.*
> *42. On OpenRegulatory you can type a software requirements and it will really automate a lot of things in terms of documentation and that is really the next step.*

Transferability

There is so much other software that AI researchers work with so it is essential that the service system works fluidly with other software. In addition, the complexity of AI means that researchers have many more things to deal with, such as the proper exchange of data, for which software is also available. For this reason, an easy distribution channel is also preferred to make exporting data easy while maintaining security.

> **Q11 P10** *24. I also think that Erasmus should not want to reinvent the wheel. Such a solution as git, for example, that is used so much in software development, that is so well validated, I would mainly choose to train your staff in its use and support that and not come up with an extra solution for that myself.*



9. Needs: Bottom-up findings

Roadmap needs

Just like on the previous page, the needs are highlighted here, but specifically for the Roadmaps components. These are also briefly explained here and this explanation is strengthened with labels and quotes.

Long term consultancy

Beyond providing a structure in a service system, it is also important to have one central point that can provide advice to researchers. (See Q5P9)

> Q5 P9 — *9. Having the good advisors is really the core and would have been really the core.*
> *13. And certainly for technology for which there is no regulation yet, you really need that.*

This confirms the need for an expertise team, named in Erasmus MC's AI policy. (Slooff, 2023) They should be the overarching experts who can complement the roles of the AI research team, by assisting with the knowledge that the team does not possess or by referring them to the right departments within Erasmus MC.

Overarching Experts — Chapter 7

Ethical discussion

In the context of implementation, it is significant to continue stimulating ethical discussions among individuals with varying background knowledge. Through these multidisciplinary discussions, the team remains alert which helps to clarify the "gray areas" together. The quote Q5P8 demonstrates that there are disagreements regarding ethical issues, highlighting the importance of having these discussions. In addition, it stimulates the understanding of other perspectives

> Q5 P8 — *12. This can mean that you lose data to the algorithm, which is going to be in it. So there is a lot of discussion with us about that, with engineers saying, no, that data does not disappear, yes because the system learns from it, so in principle that data is in the system.*

Mismatch roles and personas — Chapter 7

Preparation

Preparation is crucial not only within the service system but also in the implementation of responsible AI research. Within the system, this translates into an overall structure in the implementation phase. Particular attention should be given to preparing for the law, even if it remains unclear. It is much wiser to proactively prepare for the unknown rather than take an avoiding approach. This implies the need to encourage the development of a well-prepared plan, with the end goal in mind, before commencing the research.

> Q5 P10 — *11. And also how do you set it up in such a way that you are already prepared for future, perhaps even stricter, legislation. That you are already safe in terms of risk assessment for your techniques.*

Training

It is evident that training is essential for facilitating successful implementation. The point of discussion raised in Chapter 7 highlights a mismatch between the roles and the individuals assigned to fulfill them. By enhancing the knowledge of team members, they can take on a broader range of tasks. Furthermore, the ideas generated during the creative session indicate that the most proposed solutions revolve around information transfer. Quote Q9P7 empathizes the need for significant improvements in effectively integrating knowledge from multiple disciplines within an AI research team.

Mismatch roles and personas — Chapter 7

Ideation cluster: Information tools — Chapter 8

> Q9 P7 — *25. Of course, this structure helps a lot for your AI, but I don't think there is a lot of knowledge about AI here, apart from my supervisor. Actually, not at all.*

Check-ups

The research indicates the need for check-ups within the AI research process. It is important to motivate individuals and ensure their adherence to requirements through effective design, it became clear that some form of control is necessary to guarantee this. Many participants in the creative session suggested to implement audits, and it was also suggested that some kind of barriers could be effective in assessing whether individuals have followed the intended process. This aligns with the guidance provided by the DataHub on incorporating checkpoints in the AI innovation funnel. Additionally, interviewees mentioned that it is rare for someone to fully comply with the correct policies and procedures, if they are even aware of these, making it an exception rather than the norm. (See Q7P7)

Ideation cluster: Control — Chapter 8

> Q7 P7 — *21. I do think that when I hear it around us that we are really an exception in how structured this is stored. But it's the idea that this is happening, this is kind of a first step alone. It's not really checked. Someone then says, within neurology you have to store this like this, but then it is no longer checked.*

Convince

To create understanding it is vital to convince the future users of the importance to meet the regulations. Creating understanding was a main topic in the creative session and even though this cluster only consisted of three ideas, one of the ideas was chosen to be the best out of all ideas. Which refers to the improvement of understanding through insight into the consequences of proper use and of errors.

Ideation cluster: Understanding — Chapter 8

Co-create

The importance of co-creation of a service system emerged during the creative session, particularly as a focal point for projects initiated by Erasmus MC. These ideas could be valuable for initiatives such as the DataHub projects and the establishment of an expertise center. Within the co-creation cluster, both top-down and bottom-up approaches were mentioned, which interestingly overlaps with the design approach adopted in this study.

Ideation cluster: Co-creation — Chapter 8

Reward

Finally, an important aspect of implementing the new regulations is the recognition and rewarding of team members who exhibit the desired behaviors. This emerged during the creative session when discussing how to incentivize individuals to perform the necessary actions to comply with legal requirements. Interestingly, there was a wide range of ideas regarding the methods of reward. Competitive examples were mentioned, as well as the allocation of CPU time in the cluster, which is highly valued by researchers engaged in AI-related work, as it enhances the time efficiency of their research.

Ideation cluster: Reward — Chapter 8

9. Creating components

Discussion

The main findings from the research had a key role in shaping the design of the two concepts. The main findings of the context research with the top-down approach helped to set important requirements for the AI system in hospitals, such as transparency, accountability, and traceability, as required by the AI Act. The main findings of the interaction research with a bottom-up approach helped to find and gather the needs of the target group. While analyzing the key insights and translating these findings into functions, a few matters emerged that will be discussed in this discussion.

Importance of Multiple Solutions: Roadmap

The research has shown that a single service system wouldn't be sufficient in addressing all the challenges of using AI in healthcare. As a result, a combination of multiple solutions has been considered, leading to the creation of a roadmap. This roadmap encompasses various aspects of AI implementation, such as technical, ethical, legal, and organizational considerations. This comprehensive approach ensures that hospitals can effectively adopt AI technology.

Design Choices and Value Addition

In the design process, the decision is made to prioritize front-end design due to the expertise in this area. The aim is to create a user-friendly interface for healthcare professionals, facilitating easy interaction with the AI application.

Additionally, the focus is on registering and record keeping to improve transparency and traceability. Monitoring the AI system, which requires AI expertise, was considered beyond the project's capabilities. Instead, efforts were directed towards enhancing the documentation and storage of research findings, ensuring that essential data is securely maintained.

Conclusion

In this conclusion, the design question is answered, showing a list of functions, emerged from the prior research. Below, the design question is repeated, followed with the requirements and needs of the two designs.

Design question

'How can a hospital develop a service system combination to give more guidance to AI developers within the regulation process of the AI Act?'.

Requirements

Based on the context research the following requirements should be reflected in the design of the service system:

- **Record keeping with versioning**
- **Government assessments and storage**
- **Stimulating registration dutch AIregister**
- **Transparency to Patient**
- **Stimulating ethical considerations**
- **Human oversight of development**

Needs

Service System Needs

Based on the interaction research, the following needs of the target group will be included in the concept of the service system:

- **Repository**
- **Overarching structure**
- **Flexibility: Customized options**
- **(Software) Management**
- **Automation**
- **Transferability**

These needs will be translated into features of the prototype.

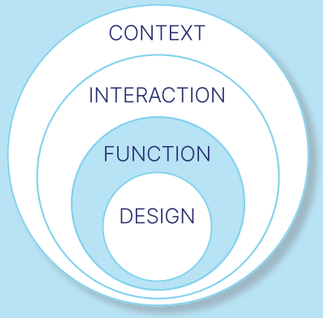
Roadmap Needs

To benefit implementation, a roadmap will be made to meet the following needs:

- **Long term consultancy**
- **Ethical discussion**
- **Preparation**
- **Training**
- **Check-ups**
- **Convince**
- **Co-create**
- **Reward**

Next steps

The next step is to develop two types of designs. First, a design of a concept service system with the user interfaces. The interaction between those interfaces will be made to give the target audience a clear picture of their demand, but also to properly represent what will be expected of them later. Secondly, a roadmap will be manifested to show clear goals and steps on how to implement the new AI legislation with Erasmus MC's approach in mind.



Multiple solutions are needed

Diverse solutions are needed for effective implementation of AI legislation

Focus: Front end & transparency

Priority in designing the interface to stimulate users to be transparent

Design Concept Service System

Designing interfaces of such a system and interactions between those interfaces

Design Roadmap

Designing a plan outlining goals and steps on a timeline to ensure implementation

- **Record keeping with versioning**
- **Government assessments and storage**
- **Stimulating registration dutch AIregister**
- **Transparency to Patient**
- **Stimulating ethical considerations**
- **Human oversight of development**
- **Repository**
- **Overarching structure**
- **Flexibility: Customized options**
- **(Software) Management**
- **Automation**
- **Transferability**
- **Long term consultancy**
- **Ethical discussion**
- **Preparation**
- **Training**
- **Check-ups**
- **Convince**
- **Co-create**
- **Reward**

Main Insights Function

CONTEXT

Department infrastructure Erasmus MC

Erasmus MC has a lot of expertise but these might be hard to approach

Educating staff members

Combine expertise of technical and medical knowledge

Designate responsibility

The target group should know their responsibility

Aligning AI Act requirements with Erasmus MC operation

The legal context must be translated so that it is in line with the way of working

Multiple solutions are needed

The complexity of the problem and the extensive requirements of the law cannot be solved with one solution.

Unclear what levels are obligated

The difference between a must and a helpful tool is not clear

Content of levels are not inline

It is difficult to find a connection in the content between the levels

Limitation of top-down approach

One-sided view of experts and documents

INTERACTION

Gap 1: Little guidance after commissioning

Limited guidance in the maintenance phase of the funnel

Gap 2: Infrequent requirement: Record keeping

Checklist lacks emphasis on Article 12 (Record Keeping) requirements

Record focus

Focus on second gap: implementation of Article 12 and record keeping

Research phase focus

Opportunities for cooperation in documentation and systems

Partial mismatch personas and roles

Personas might not fit the roles they are assigned to fill

Inner motivation & ethical justification

Good intentions of the AI development team can generate a negative perspective toward ethical justification

Limit workload doctor

Supervising is an addition to the fulltime job of a doctor and therefore the workload should be limited

Growing team

Documentation grows as the AI application progresses

FUNCTION

Management, flexibility, preparation

Reoccurring themes from the previous chapters are reflected in the ideas

Focus: Front end & transparency

Priority in designing the interface to stimulate users to be transparent

Record keeping with versioning

Government assessments and storage

Stimulating registration dutch AIregister

Transparency to Patient

Stimulating ethical considerations

Human oversight of development

Repository

Overarching structure

Flexibility: Customized options

(Software) Management

Automation

Transferability

Long term consultancy

Ethical discussion

Preparation

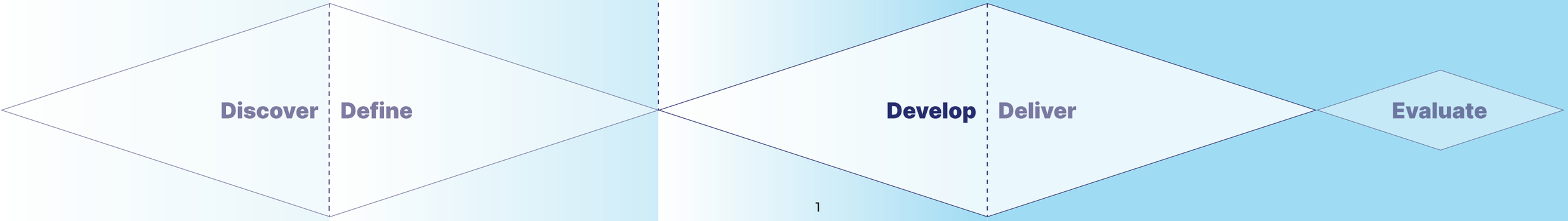
Training

Check-ups

Convince

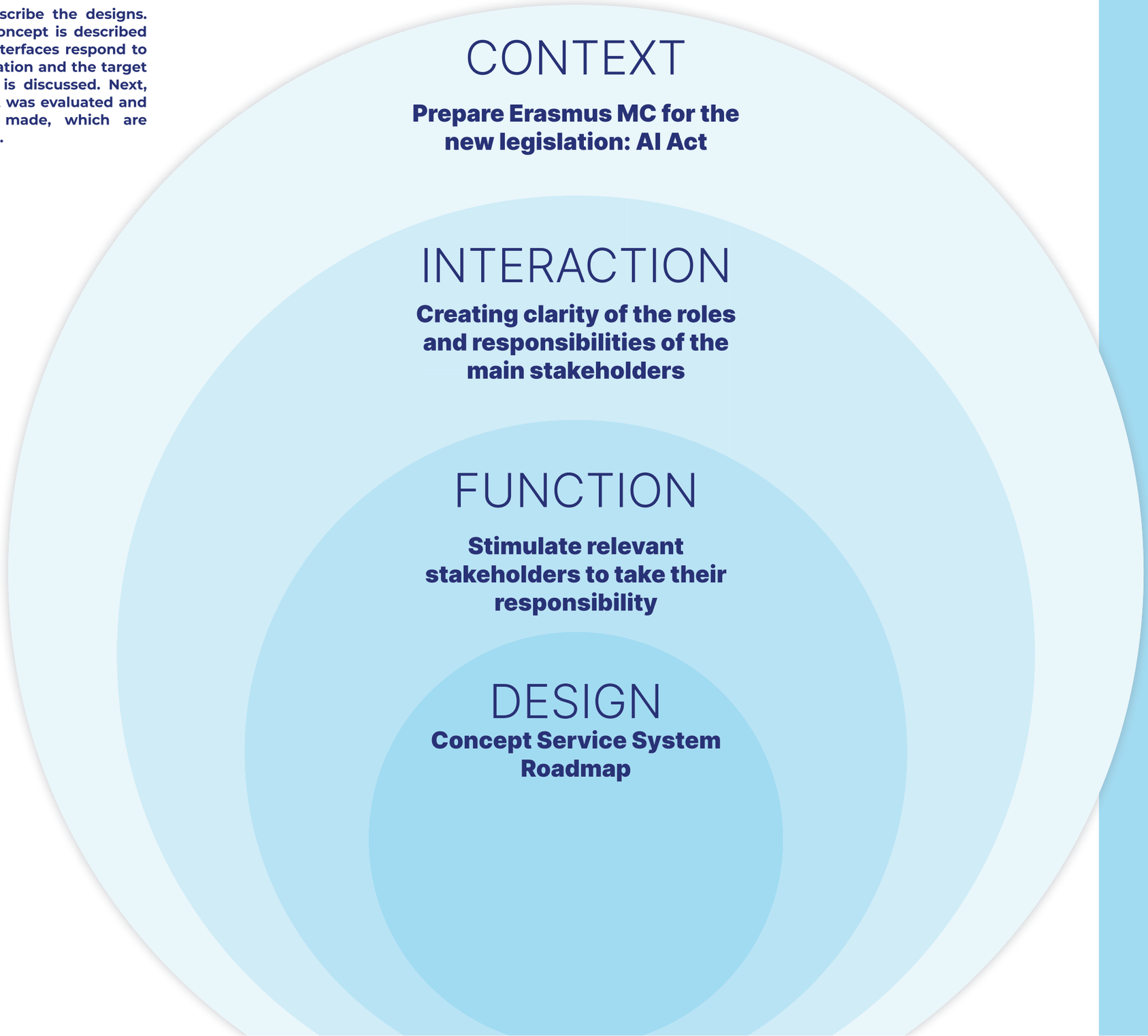
Co-create

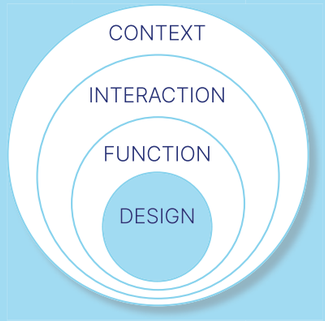
Reward



DESIGN

The following chapters describe the designs. First, the service system concept is described and it is shown how the interfaces respond to the demand of the organisation and the target group. Then the roadmap is discussed. Next, the service system concept was evaluated and some adjustments were made, which are reported in a small iteration.





Merging input to create components

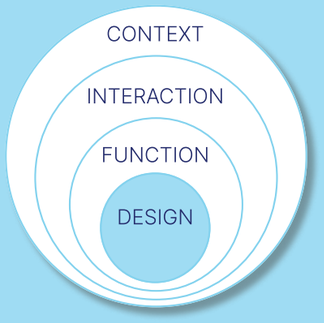
Merging the main findings of this creative session, the interviews, other previous discussion points to create components of the service system

Design Concept Service System

Designing interfaces of such a system and interactions between those interfaces

Design Roadmap

Designing a plan outlining goals and steps on a timeline to ensure implementation



Design the Concept Service System

The interfaces will be designed, based on the components of the previous chapter

User interface design

Creating user-friendly digital interaction experiences

Prototype

Early convenient modeling showcasing the design concept for evaluation

10. Concept Service System

Based on the components from chapter 9, a concept service system was created that is highlighted in this chapter. To represent this concept interactively, a prototype was made. To get access to this prototype, a link can be found on this page under the heading 'Prototype'.

Method

Goal

The purpose of this chapter is to provide a visual interpretation of the regulatory requirements and the needs of the target group. This is shown in a comprehensive front-end and a limited back-end concept. The goal is to give an answer to the main design question (*How can a hospital develop a service system combination that gives more guidance to AI developers within the regulation process of the AI Act?*) with a visual interactive representation of a service system. This question has several aspects to highlight in the design. Therefore, the main design question was split into 2 sub-design questions:

- *'How can a hospital develop a service system combination that encourage AI project team members to meet the requirements of the AI Act?*
- *'How can a hospital develop a service system combination that is easy and beneficial to use for the target group?'*

Front-end

In the front-end conceptualization, the main focus is on the usability of the components. A prototype is created to demonstrate the possibilities and advantages of a system, to inspire the governance and to create more awareness of the AI Act within Erasmus MC.

Back-end

In the back-end, attention is paid to the feasibility of implementing such a system, in order to convince Erasmus MC that a prototype of a concept can be realized with minimal resources. It shows that the difference between the fast innovation of technology and slow innovation in an organizations do not need to be a problem. The goal is to demonstrate the basic creation of a register with auto-versioning.

Data Gathering

First, the data used to create the interfaces comes from the results of Chapter 9, which serve as inspiration for the interfaces. Other systems where analyzed to see how they translated these needs, including the article of Scientific Foresight Unit (2022), the RMS of Erasmus MC: PaNaMa and the platform OpenRegulatory, mentioned as a tip of participant 9. These other approaches served as inspiration for creating the design. To get inspiration for the information that should be registered, existing templates from Erasmus MC departments METC and Medical Technology were used in combination with the inventory of 'kennisnetwerk AI implementation in healthcare'. To make the prototype look real, text was needed in the prototype representing such a similar AI project. Chat GPT was used to create fictive examples, by asking for, e.g. the title, short description, intended use of a non existing AI application in healthcare. This safes time and gives a good example of what this system will look like. Below you can see an example of some text that is generated:

Procedure

Several programs have been used to develop the front-end and the back-end prototype.

Front-end

To create the front-end interactive prototype, the program Figma was used. For each need, 1 or more interfaces were created. The house style of Erasmus MC was used for the graphic design. The needs are often abstract, therefore an overview of the interfaces has been created on the following pages which places the appropriate needs next to the interfaces.

Back-end

For the back-end prototype two microsoft programs are used: Microsoft Word and Microsoft Excel. Within the Excel document the main components where listed in a table, based on the information requested by the METC and Medical Technology. These parts of the table are linked to the current templates of a research proposal and a technical dossier to show the possibility of automation and versioning.

Result - Front end prototype

Click here or scan the QR code to view the concept of the front-end prototype.

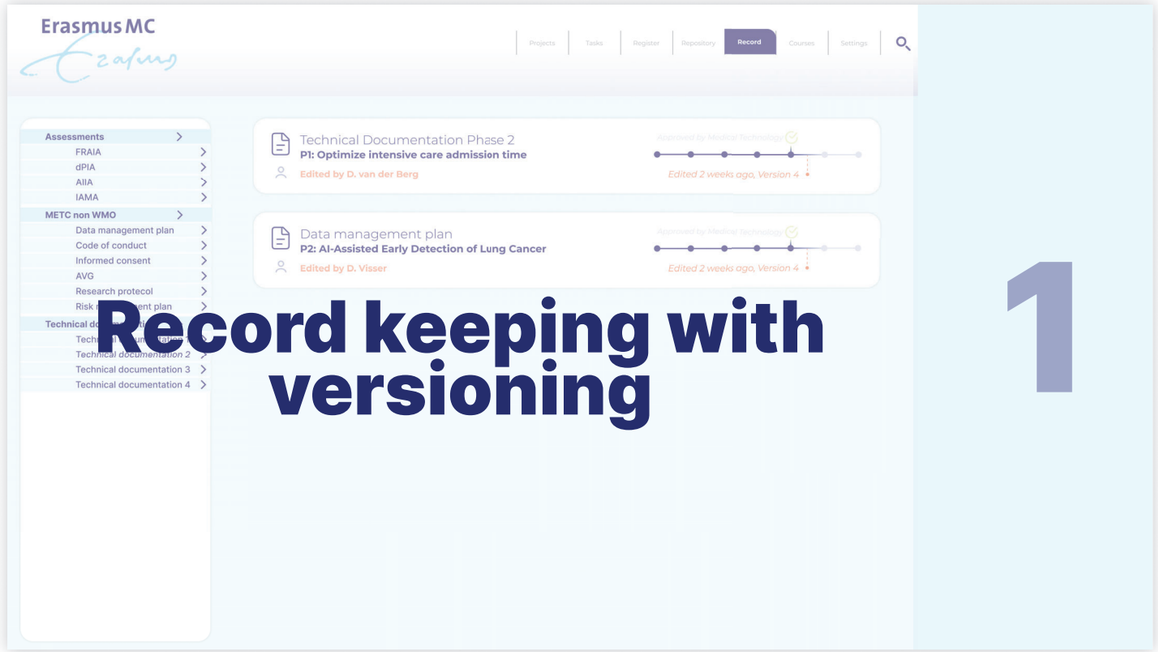
In the results section, the main requirements and needs are shown with the corresponding interfaces created for them. Below are the requirements from chapter 9 page 48, which are described in interface 1-6.

1. **Record keeping with versioning**
2. **Government assessments and storage**
3. **Stimulating registration dutch AIregister**
4. **Transparency to Patient**
5. **Stimulating ethical considerations**
6. **Human oversight of development**

Below are the needs from Chapter 9 page 50, which are described in interface 7-12.

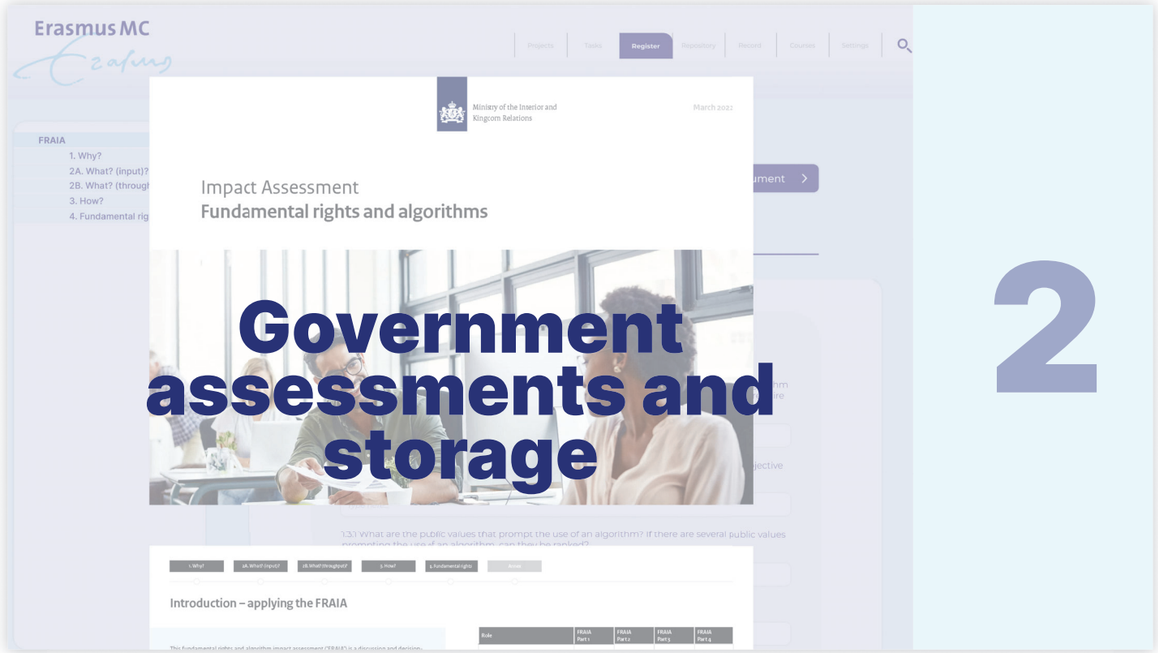
7. **Repository**
8. **Overarching structure**
9. **Flexibility: Customized options**
10. **(Software) Management**
11. **Automation**
12. **Transferability**

10. Result - Interfaces



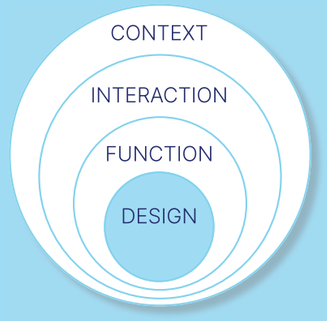
1. Record keeping with versioning

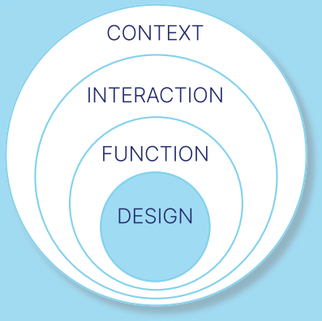
Not only could the system ideally be a repository for records, its purpose is to keep track of the versions of these records. This way, it is clear to see who added what to the record and when. You can also see this in the interface, where there is a timeline showing the named version and the person who last edited this version.



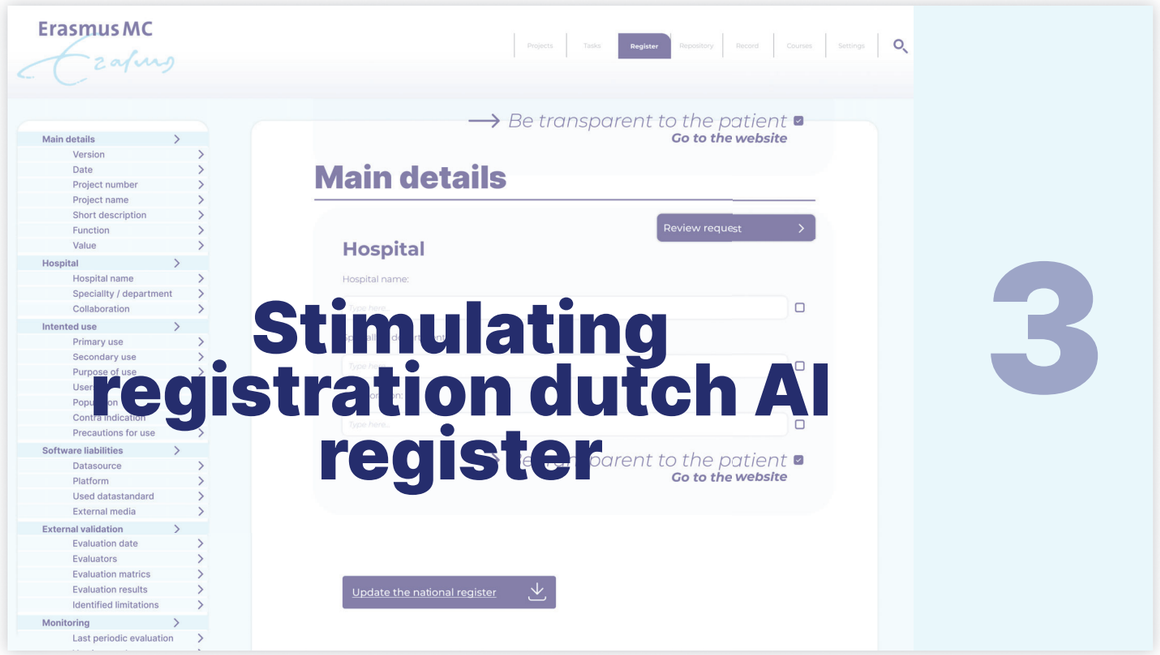
2. Government assessments and storage

Within the research phase of this study, it was discovered that many assessments are offered by the government, however, the interviews revealed that they were not always done, or not stored. Hence, you can see in this interface that it immediately encourages to start filling in these assessments. If someone starts a new project, the questions of the FRAIA (Impact Assessment Fundamental rights and algorithms) will come up immediately, so that an AI project is started responsibly from the start.



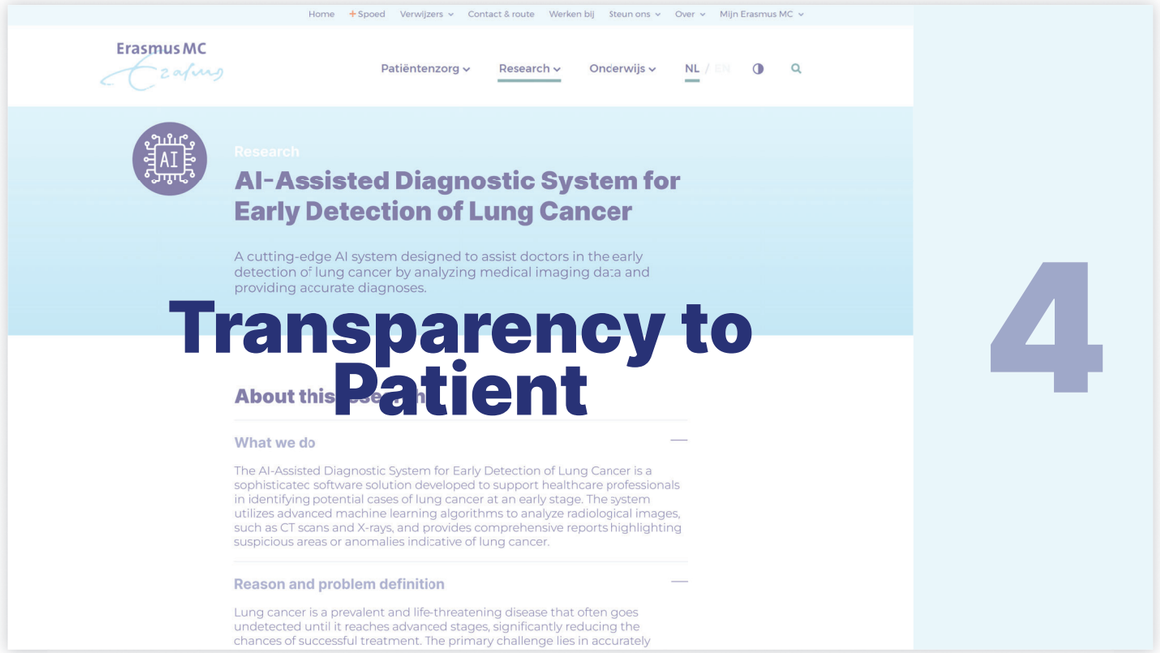


10. Result - Interfaces



3. Stimulating registration dutch AIregister

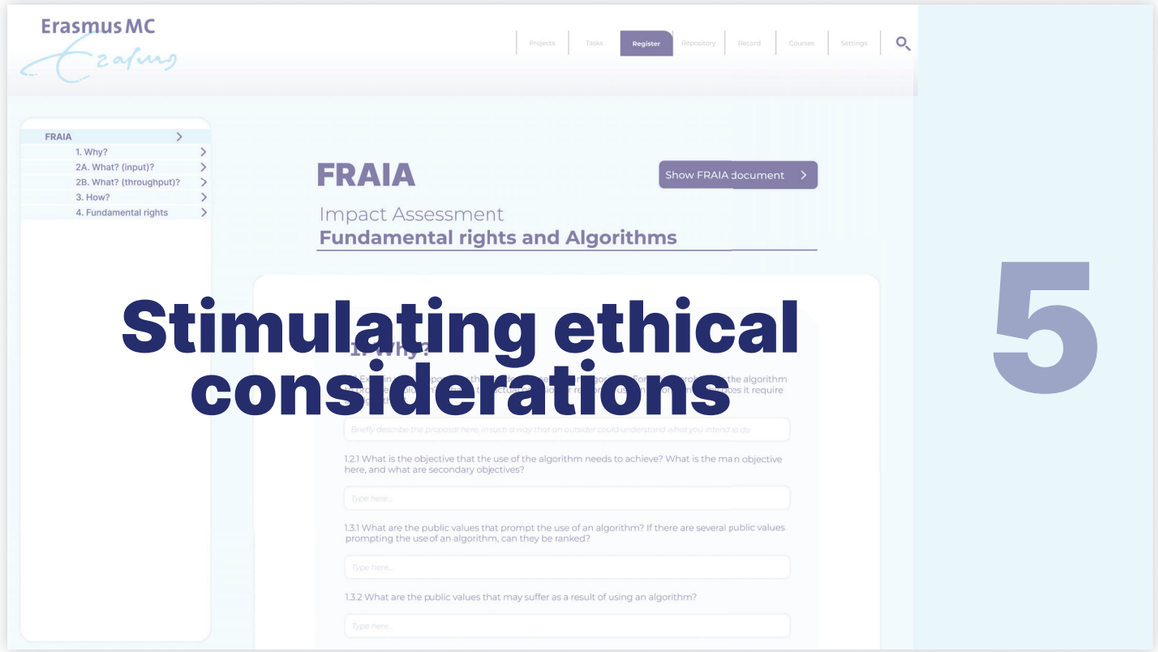
It has become a requirement to register a used AI in the government's registry. However, the button at the bottom of the interface shows that it should be made easy to do this at an early stage, by offering the possibility to automatic upload the data from this system to the governments regiser.



4. Transparency to Patient

Being transparent to the patient or user is also only necessary when the AI is put into use. Since research can already be found on the Erasmus MC website, the aim is also to offer this option earlier in this system by letting the AI project members themselves choose what they want to make public and automatically display it on the website.

10. Result - Interfaces



Stimulating ethical considerations

5

5. Stimulating ethical considerations

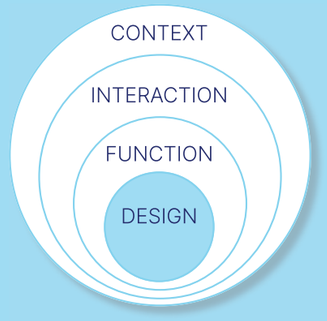
To deal etically with certain choices remains a very broad concept. One way this can be done is by making decisions with several people. Government assessments often focus on this and encourage making ethically responsible choices. Hence, as mentioned in point 2, these are encouraged from the start. In doing so, these choices and arguments will be stored in the system and there will be given the possibility to modify them.

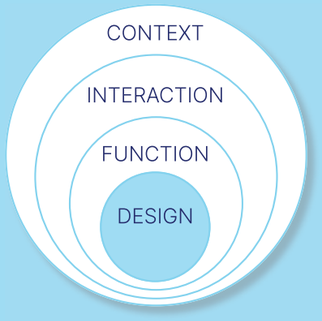
Human oversight of development

6

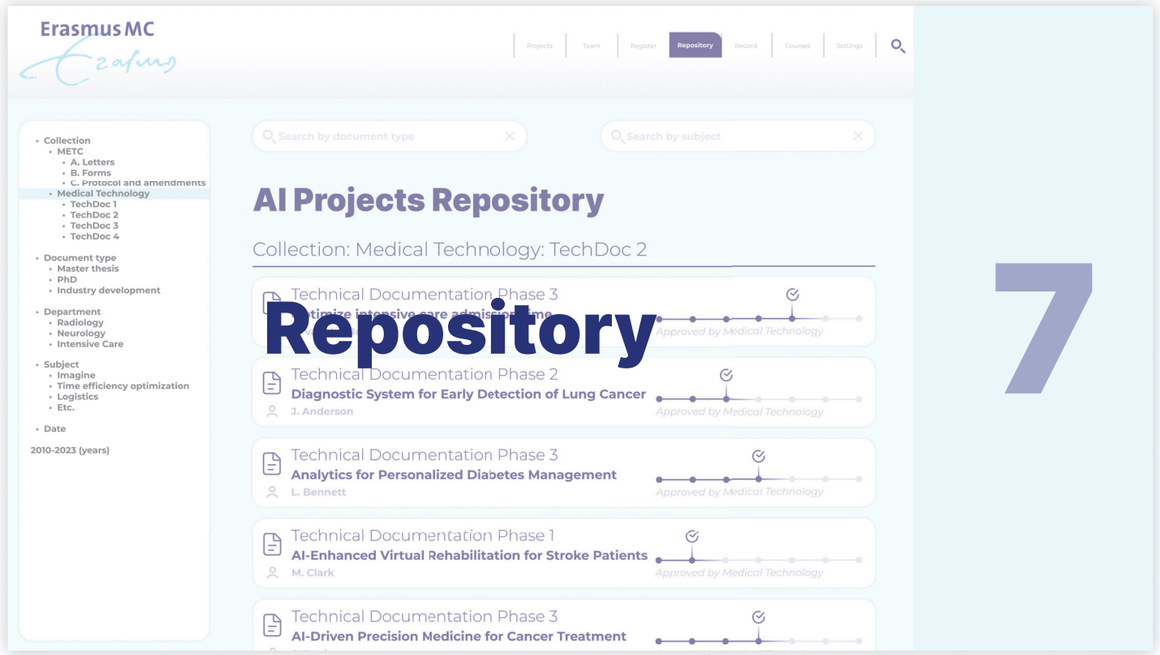
6. Human oversight of development

In doing so, there should be a clear overview of the project for each project member and external stakeholders. This should be easily understood by individuals with different backgrounds. Hence, the main screen interface shows the gates that the project has passed, which people belong to it, what records are created and what other software is used.





10. Result - Interfaces

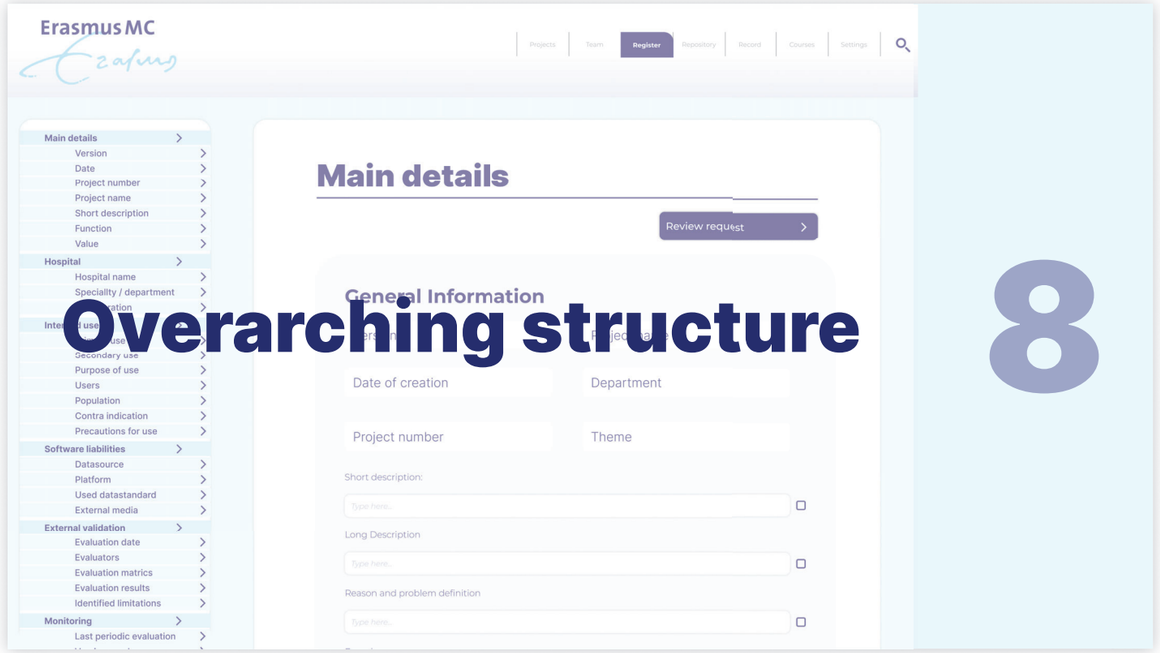


Repository

7

7. Repository

The interface shows a visual representation of a repository. This repository will consist of multiple documents from other AI projects. It will also have to be made possible to search for similar documents so that parts of the information can be taken over for new research. This will fill the demand from the target audience, asking for examples. As it is understandable that people do not want to share everything from the AI project, an option will also be offered where they can choose what to share with other Erasmus MC employees.



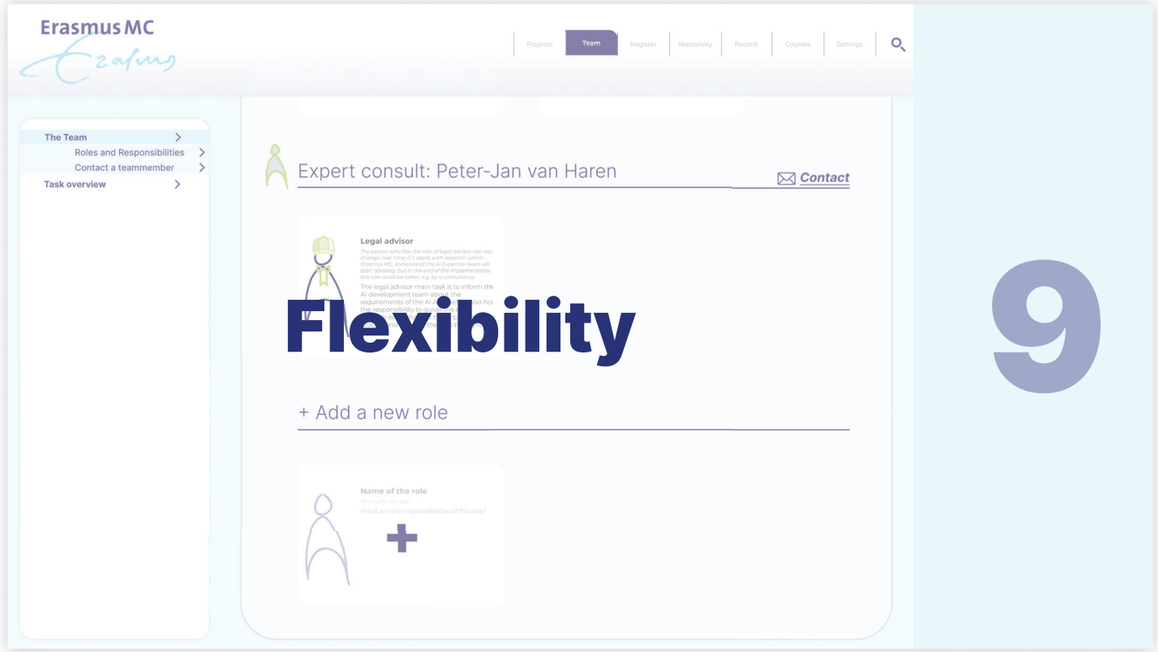
Overarching structure

8

8. Overarching structure

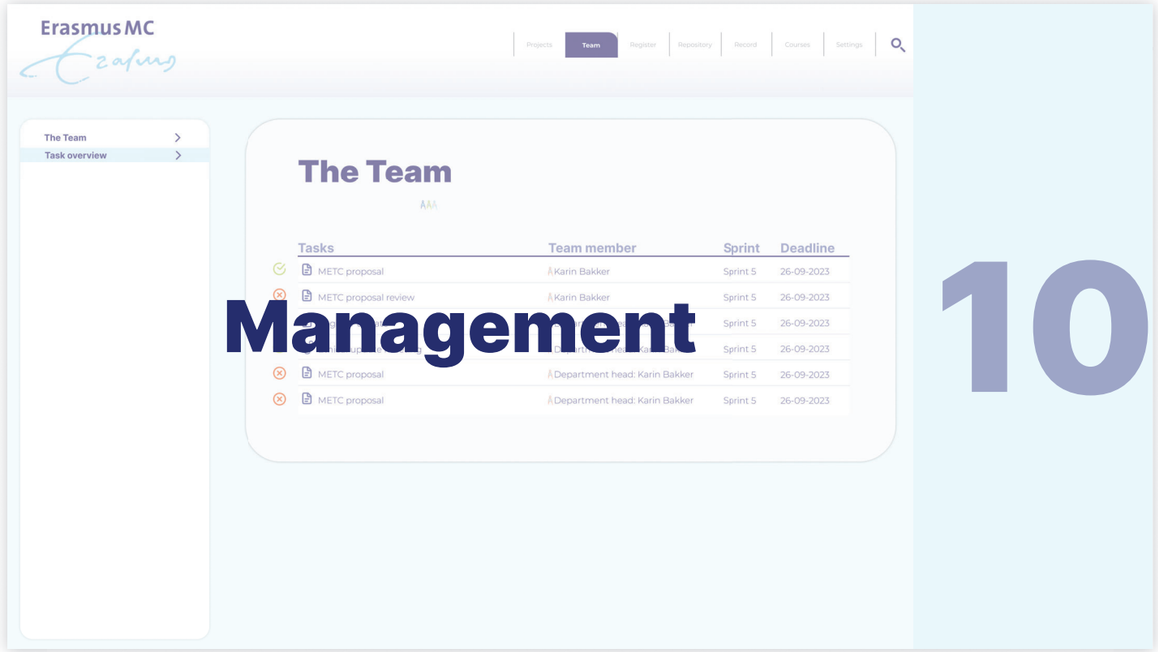
The need for an overarching structure has been translated into several components, including a register that can be seen in the interface. This is one central point where the general data of the project is stored and can be updated at any time. This information can than be requested by different departments within Erasmus MC to receive the updated information for the documentation at the right time. An overarching structure will also be offered for the organization of folders, but this will not be determined at hospital level but at department level to maintain flexibility.

10. Result - Interfaces



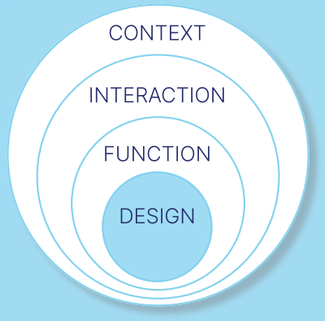
9. Flexibility: Customized options

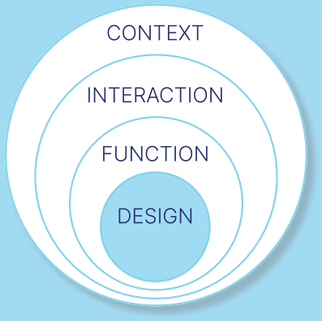
Since it has been mentioned several times that AI projects can vary al lot, there is a clear demand for flexibility. Multiple interfaces show this flexibility including this interface, showing that there is flexibility in the roles that are distributed. Roles can be added or changed. This is necessary as roles can change over time. Other flexible options have also been created. E.g. the folder structure that can be adapted by supervisors to handle the right structure for their specific project group.



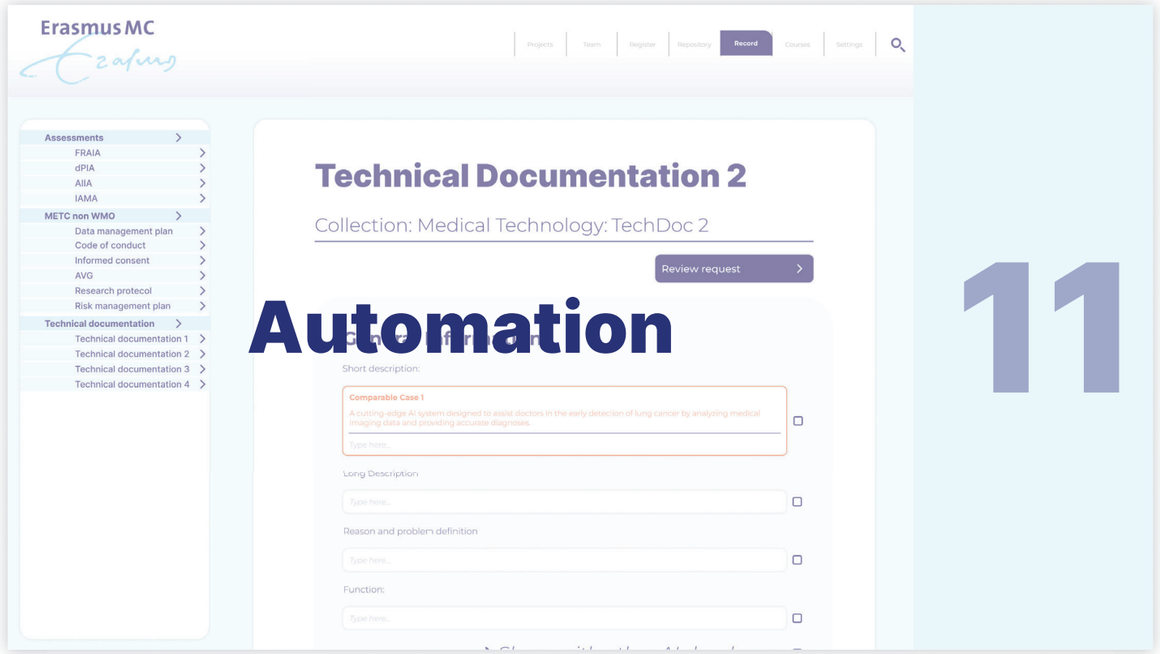
10. (Software) Management

On the left, you can see a task overview that gives an interpretation to the need for project management. The interface shows an overview of the tasks, what stage they are in, who has to fulfil them, what the deadline is and which sprint they belong to. This is a good addition to the agile(scrum) method that software developers often work with.





10. Result - Interfaces

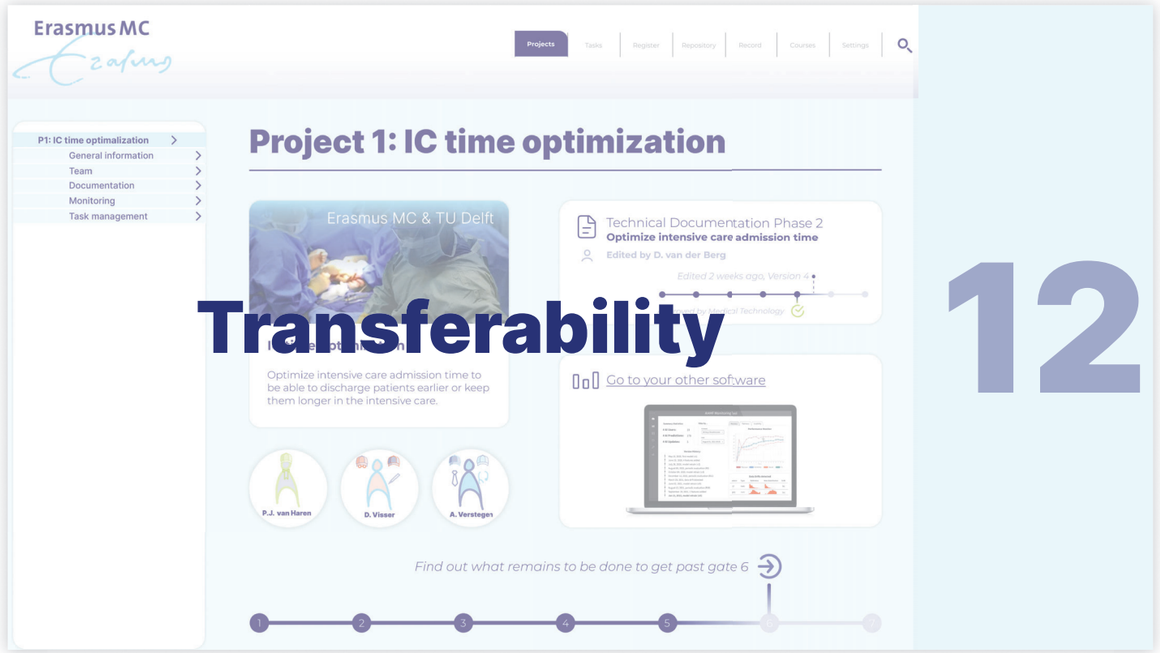


Automation

11

11. Automation

Automation is a broad definition that is also implemented in multiple ways in the concept. This interface shows one form of automation, where an AI project member can automatically see what other similar projects have written down in certain documentation. Another option is to fill in the general information directly into the documents, taken from the updated information in the overarching register. Such automatic facilities have a low-threshold but can save a lot of time for the target group that prefers to spend time on the development of the AI application.



Transferability

12

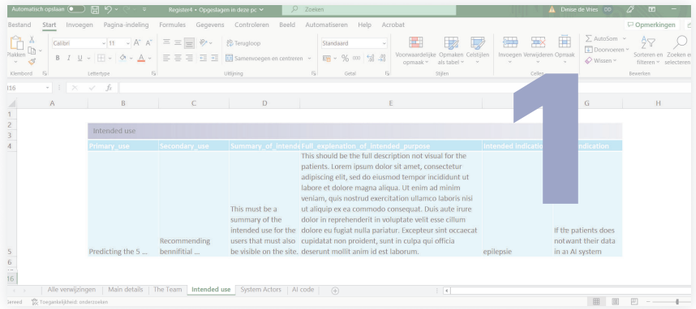
12. Transferability

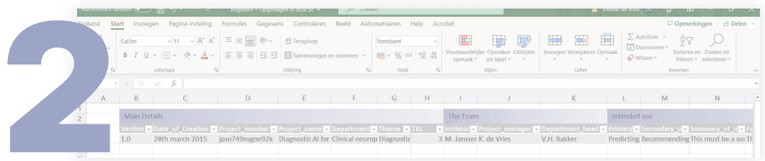
This interface shows the main screen. Since different software is already offered and used in AI projects, it is crucial that the system can exchange data properly and securely. However, it is important that experienced software experts look deeper into this connection to see how it can be done safely and to what level you want to enable tranferability. The interface therefore only shows a visualization of a button to display the importance to make this connection with other software, such as a monitor system or a code repository.

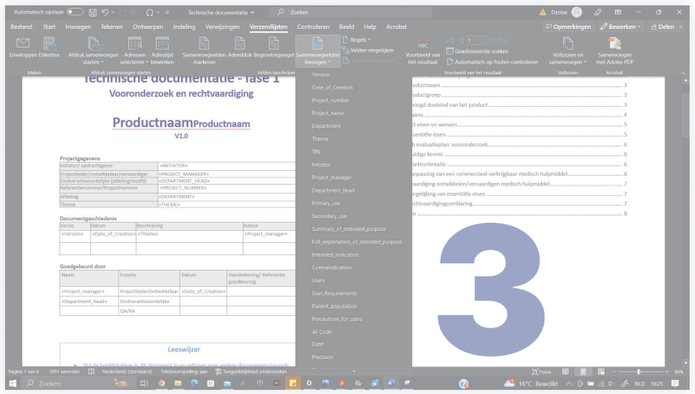
10. Concept Service System

The Prototype Back end

Below you can find some experimentation of the back end of the prototype. This is not software that has been developed, but purely some experimentation to find out how this can be realized using the current tools that Microsoft offers. There was specifically looked at the departments that use word documents for current registration and created an example of a registration system in excel to automatically update this data in the existing word documents of METC and Medical Technology departments from Erasmus MC. This demonstrates that automation is certainly possible and transparency at one central point will be beneficial for both the AI project team member and the organizational staff members of Erasmus MC.







1. Input table

In the first image, you can see one of the input table in which one can enter general data in a clearly arranged manner.

2. Register system with all data

In the second image, you see one large table that serves as a registry and automatically updates and numbers the data of all other tables by version.

3. Autofill method in word

The third image shows part of the current word document 'technical documentation' of the Medical Technology department. In this document, merge fields have been added that automatically insert the data from the register table and give the option to click through the numbers until the latest version is displayed.

Discussion

As the draft was evaluated by several people, all discussion points were collected and discussed in the evaluation chapter (12). Only a few limitations of the design process are mentioned below:

Limitations

Figma is a program that enables prototyping but it also has it's limitations. E.g. it cannot generate text boxes of other back end functions. That is why the prototype is made in such a way that it looks like it is happening in the demo, but the interactions are created just for show.

Due to the limited knowledge of automation in combination with the limited time, it was decided not to develop the back-end further, as this is much better left to software engineers who are experts in optimization.

Conclusion / Key takaways

The demonstration of the prototype show the answer to the design question '*How can a hospital develop a service system combination that gives more guidance to AI developers within the regulation process of the AI Act?*' by displaying the front-end and the back-end of a Service System for AI Researchers with some explanation.

The prototype also answers the sub design questions:
How can a hospital develop a service system combination that encourage AI project team members meet the requirements of the AI Act?

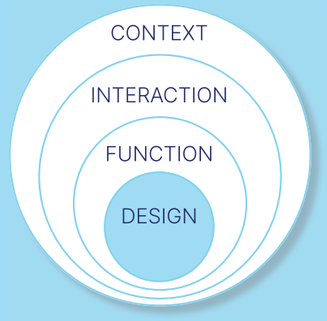
- Interfaces 1-6 show a visual representation of the implemented requirements of the AI Act.

How can a hospital develop a service system combination that is easy and beneficial to use for the target group?

- Interfaces 7-12 show a visual representation of the implemented needs of the interviewed target group and the input of the creative session with potential future users of the system.

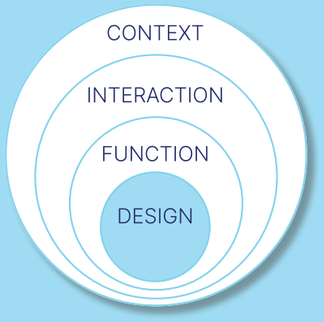
Next steps

The front end prototype will be evaluated by experts, people from the target group and people who have limited knowledge of the subject. Chapter 12 shows this evaluation



Evaluate the prototype

Test and evaluate the prototype with different stakeholders



Develop practical steps to innovate

Develop a roadmap for the organization to prepare for the AI Act

Design Roadmapping

Strategic plan outlining project's goals, tasks, and timelines

11. Roadmap

By following this design roadmap approach, the aim is to give Erasmus MC a practical guide for responsible AI innovation, helping the organization prepare for AI legislation and address the complexities of implementing AI in the hospital setting. It reflects the demand of the target audience and provides a structured plan for the organization to meet this demand.

Method

Goal

The goal is to develop a design roadmap for responsible AI innovation within Erasmus MC, focusing on actionable steps to prepare for the new AI legislation. With the roadmap the aim is to address the complexity of the problem by providing a clear overview of the multiple solutions required to ensure responsible innovation of AI within Erasmus MC. The goal is also to reflect the needs expressed by multiple stakeholders, including employees within Erasmus MC who are part of an AI project team. By addressing their needs the right assistance can be given through various internal channels within the organization. Since the main design question: '*How can a hospital develop a service system combination that gives more guidance to AI developers within the regulation process of the AI Act?*' is more focused on a system, sub design questions are created:

- *How can a hospital encourage AI developers to meet the requirements of the AI Act?*
- *How can a hospital give more guidance to AI developers within the regulation process of the AI Act?*

Data Gathering

Data for the roadmap was gathered in two ways.

First, the x-axis data involved the roadmap phases, linked to the time frame established in Chapter 4, with an additional time frame included.

Second, for the y-axis, the findings and insights gathered in this study were combined and presented in a need overview (see Chapter 9), which served as the foundation for the components in the design roadmap. This need overview, identified critical requirements and areas of focus.

Procedure

The roadmap was created by filling in the X-axis and Y-axis with the relevant information mentioned in the data gathering. To fill in the steps of the roadmap, assumptions were made based on the knowledge gained during the study and the author's intuition to create a comprehensive and useful roadmap for guiding the project. The steps were devided into three types: researching, realizing and validating steps.

Roadmap

Results - Roadmap

The results of the roadmap can be divided into three different parts. The X-axis showing the different phases, the y-axis showing the different components and the placement of the specific tasks on these axes. On this page, more information is given about the chosen axes by explaining where they come from within this research. The tasks can be found on the next page as part of the roadmap, these tasks are color coded into: Researching, realizing and validation tasks, what can be seen in a small legend at the top right of the roadmap.

Phases (X-as elements)

At the beginning of this study, the timeframes for which design will be done were determined (see chapter 4 page 14). These timeframes are also included in the roadmap. The first phase is called the **awareness** phase, which is the period after the adoption of the AI Act during which various stakeholders should slowly start to understand what is expected of them as a result of the new legislation. The standards will be developed at European level. During this time there will be given more clarity. The second phase is called the **action** phase, which will most likely be in the so-called 'gray area'. During this time, various tools (e.g. sandboxes) will be offered to help AI project members to comply with the legislation. The third phase is called the **implementation** phase. This phase will be further into the future when the AI environment in Europe will be further developed with different infrastructures that will facilitate the AI development process.

AWARENESS
Approved AI Act

ACTION
Gray Area

IMPLEMENTATION
Safe AI Infrastructure

Components (Y-as elements)

By linking the past findings of chapter 9 to the components of the roadmap, organizations like Erasmus MC can better understand how to implement responsible AI research and achieve successful outcomes.

The main components resulted of this research are listed at the right and reflected in the elements of the roadmap showed below:

- **Long term consultancy** — Chapter 9
- **Ethical discussion** — Chapter 9
- **Preparation** — Chapter 9
- **Training** — Chapter 9
- **Check-ups** — Chapter 9
- **Convince** — Chapter 9
- **Co-create** — Chapter 9
- **Reward** — Chapter 9

Components

People

- AI project team (bottom-up approach): This reflects the *"Convince"* and *"Reward"* component to encourage team members for following responsible AI practices.
- Erasmus organization (Top-down approach): This reflects the *"Convince"* component by promote awareness and convince the organization of responsible AI practices across the organization.
- Ethical discussion (Encourage self-management): Multidisciplinary *"Ethical discussions"* foster self-management and understanding.

Organization

- Educate (Offering training by providing courses): Training aligns with the *"Educate"* component for successful AI implementation.
- Consult (AI expertise team): *"Long-term consultancy"* with expert advisors correspond to the need of the target group for process support.
- Check-ups (auditing cycle): Audits ensure compliance, corresponding to the *"Check-ups"* component.

Technology

- Co-create (with users and organization): *"Co-creation"* benefits projects initiated by Erasmus MC.
- Software development (creating a working system): Good project *"Preparation"* can be realized with software development to *"Convince"* and stimulate the right actions taken by the AI project team.
- Guide (ensure good project preparation): Emphasis on preparation corresponds to the *"Preparation"* and *"Training"* components.

Elements

People

AI project team
Bottom-up approach

Erasmus organization
Top-down approach

Ethical discussion
Encourage self-management

Organization

Educate
Offering training by providing courses

Consult
AI Expertise team

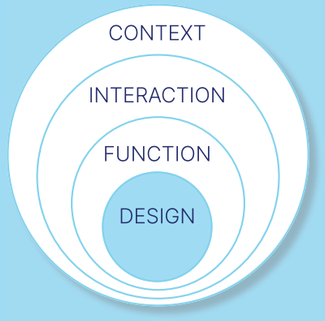
Check-ups
Auditing cycle

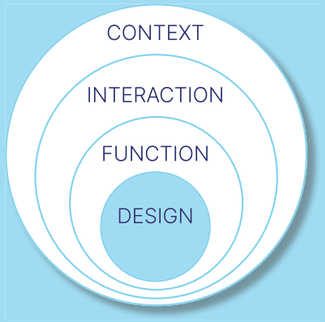
Technology

Co-create
With users and organization

Software development
Creating a working system

Guide
Ensure good project preparation

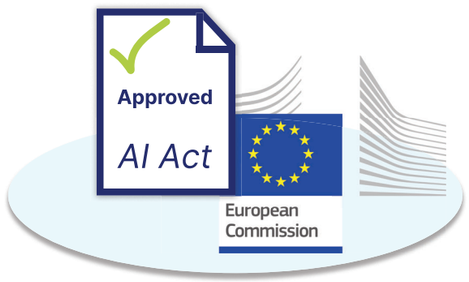




Roadmap

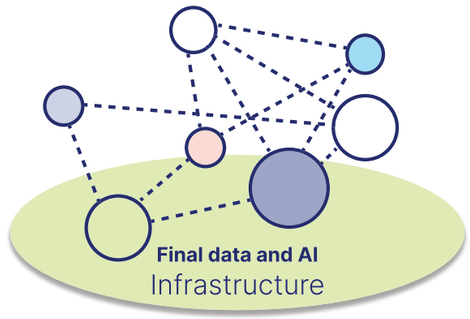
Researching
Realizing
Validating

AWARENESS
Now — **Approved AI Act** — 2 years



ACTION
2 years — **Gray Area** — 4 years

IMPLEMENTATION
4 years — **Safe AI Infrastructure** — 6 years



People

AI project team
Bottom-up approach

- Inform organization on the needs of the AI expertise team
- Testing concept system
- Inform organization on the needs of the AI-ethics lab
- Start using the system
- Provide feedback of the system
- Updating the organization on technical innovations and system use
- Provide feedback of the training

Erasmus organization
Top-down approach

- Keeping updated about the creation of standards for the AI Act
- Testing concept system
- Set up register project
- Validate feasibility
- Collect every AI used in Erasmus MC
- Start using the system
- Validate feasibility
- Keep updated about other systems of the infrastructure
- Improving the system and making register data available for everybody

Ethical discussion
Encourage self-management

- Qualitative research to discover how to complement the AI-ethics lab
- Gather a few AI project teams for an ethics meeting
- Create Erasmus MC ethical guidelines
- Compare with the legislation
- Design a cardgame with some ethical questions
- Keep evaluating and improving the AI ethics lab
- Evaluate the guidance and ethical conversation stimulation

Organization

Educate
Offering training by providing courses

- Research of other trainings
- Develop technical training for clinicians & researchers
- Develop medical training for technical staff
- Start with the training
- Validate importance and improve training
- Improve training purpose

Consult
AI Expertise team

- Gather information of AI systems that are used within EMC
- Get expertise of the subject
- Qualitative research to discover how to set up the AI expertise team
- Start using the system
- Support with implementing the system
- Give expertise and guidance
- Gather feedback of the system and training and improve them
- Keep updated with innovation changes & new requirements

Check-ups
Auditing cycle

- Gather information of AI research within EMC
- Develop Audit structure
- Validate audit structure and improve
- Find out how to stimulate the right behavior instead of forcing
- Develop Reward structure

Technology

Co-create
With users and organization

- Facilitate a co-creation session with target group and organization
- Create awareness of tasks & responsibilities
- Validate system functions and components
- Test system by deciding roles
- Gather management preference
- Improve system with innovative new options
- Evaluate new options
- Improve system with e.g. agile options

Software development
Creating a working system

- Validate front-end
- Develop system with basic components
- Validate back-end
- Gather retrospective templates
- Keep updating the system based on the standards
- Gather feedback and improve
- Connect to other systems
- Improve infrastructure
- Develop Auto-takeover templates
- Develop AI Auto-generate input templates

Guide
Ensure good project preparation

- Create tour guide through Erasmus MC departments
- Create intuitively UI to follow the right pattern
- Update tour guide (e.g. with AI expertise center and AI ethics lab)
- Gather behavior feedback with system evaluation
- Update tour guide (e.g. with support of other organizations)

Roadmap

Discussion

In this discussion, the main points arising from the analysis of the roadmap are discussed, focusing on the approach needed for the roadmap steps to be successful implemented. It will briefly look at the limitations and make recommendations on how to further develop this roadmap and prepare for the AI Act.

Main findings

Linking ethical, legal and technological domains

One of the important findings while analyzing the roadmap was the demand for linking ethical, legal, and technological domains in AI implementation. These themes remain big in meeting AI Act requirements and the languages of these disciplines are not always in lign. Therefore, efforts should be made to keep encouraging interaction between these domains.

Collaboration among various departments

The findings shown in the roadmap reveal broadly diverse solution, which cannot be carried by one department, indicating the importance of collaboration among various departments, including the AI expertise center, Medical Technology, METC, AI ethics lab, legal experts, Educational departments, and IT departments, to realize the steps successfully.

Flexible experimental approach

Since this roadmap shows a future perspective, it is important to note that no experts have full experience in this area yet, due to the newness of the AI Act. Therefore it requires a flexible and experimental approach of all the stakeholders, to adapt quickly.

Limitations

The main limitation is the time constraint, leading to potential incomplete data for the roadmap. Limited participants in the research may have reduced diverse perspectives, and the author's biases could have influenced the questions. Additionally, the roadmap's reliance on assumptions about the future leads to uncertainties in the future accuracy of the roadmap content.

Recommendations

The following recommendations were made to enhance the effectiveness of the design roadmap:

Expertise center as a starting point

It is recommended for the AI expertise center to use the roadmap as a basis to set up initiatives that effectively address the needs of the target audience.

Involvement of IT expertise

As this is a one-man research conducted by a designer, it is strongly recommended to involve IT experts in the development of the roadmap. In order for the steps to be well aligned with practical needs. The IT expertise will also ensure better technical guidance.

Continuous evaluation and adaptation

Since the roadmap is a plan for the distant future, it is recommended to regularly update the roadmap to effectively respond to changing circumstances. Especially with the uncertainty surrounding legislation and rapidly changing technology development.

Larger and diverse participant group

The involvement of a lager and diverse group of participants will enrich insights and foster a holistic approach to AI ethics and regulation.

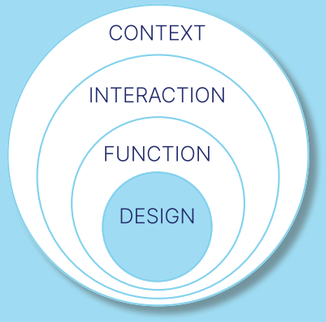
Conclusion

As already mentioned in the method section, the main design question does not quite match the roadmap approach. Hence, only the sub-design questions are briefly answered below:

How can a hospital encourage AI developers to meet the requirements of the AI Act?

- By developing different services, AI project members will be encouraged to adapt their behaviour to the requirements of the law. These services include long-term guidance of an in-house consultancy, check-ups, better education or a service system that encourages proper data storage.
- By using all the services in the process, they will be more likely to interact with experienced people who can steer them in the right direction.

How can a hospital give more guidance to AI developers within the regulation process of the AI Act?



Linking ethical, legal and technological domains

Generalists who know a bit about all in combination of experts in these domains is necessary

Need: collaboration among departments

To bridge the gap of these domains, collaboration is needed

Flexible experimental approach

The novelty of this topic requires an experimental iterative approach to tackle the problem

Expertise center as a starting point

They can apply the insights from the roadmap

Involvement of IT expertise

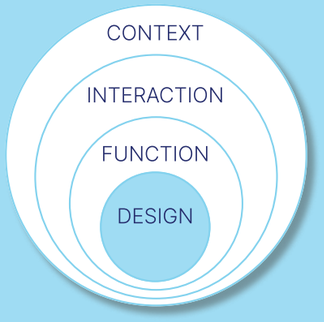
The limited expertise within this study calls for the involvement of IT experts

Continuous evaluation and adaption

The future perspective of the roadmap is based on expectations and will have to be adjusted over time

Larger and diverse participant group

A more valid qualitative study requires multiple participants



Discover users experience

To find out how the concept gives guidance, is perceived as encouraging and if the stakeholders see the benefit

User Experience prototype testing

Test UI prototypes for improvement

Questionnaire

Evaluate UX/UI through questions and statements

Creative clustering of feedback notes

Qualitative approach grouping feedback notes for iteration insights

12. Evaluation

This evaluation chapter shows how the concept was tested and how feedback was collected. A conscious decision was made to collect feedback only on the concept service system and not on the roadmap due to time constraints. Testing was done with a broad diversity of stakeholders. They first explored the prototype, then gave verbal feedback and were asked to fill in a questionnaire afterwards. The feedback was taken into account in the final iteration of the concept and in the recommendations.

Method

Goal

The aim of the evaluation is to discover areas for improvement. In doing so, it is important to find out how the concept gives guidance, if the concept is perceived as encouraging and if the stakeholders see the benefit in using the system. To find out about there experience, sub-questions were created:

- *How do the future users experience the concept of the service system?*
- *How could the service system be improved?*

Data Gathering

Both quantitative and qualitative data was collected, combining ratings and feedback to obtain a comprehensive understanding of the concept's strengths and areas for improvement. The structured survey format ensured consistency in data collection, while the open-ended questions provided valuable insights into participants' perspectives and creative ideas for the next iteration phase of the concept.

Participants

A total of 14 participants were selected for the evaluation process, ensuring representation from various relevant fields. Out of the 14 participants, 9 responded to the survey, providing valuable insights on the concept's performance. Participants were asked to anonymously provide information about their expertise, and they had the option to fill in multiple areas. An overview of the types of evaluators can be found in Figure 14.

Data collection

The survey included statements (See Figure 15) related to the concept, rated on a scale from 1 (strongly disagree) to 5 (strongly agree). An open inspiration question about the encouragement was also included to gather qualitative feedback (question 16), and an open-ended question at the end allowed participants to provide additional thoughts and suggestions. The survey reflects the factors of the previous research questions: encouragement, benefit or use and guidance.

In addition to the survey outcome, detailed notes were collected during the evaluation sessions with the participants. These notes documented their verbal feedback, expressions, and any other relevant observations made during the evaluation process.

Procedure

The user test began with an introduction to the concept. Participants had the choice to start with a guided demo or explore the interfaces independently. Those who chose for the second option followed a 'test script' (see Appendix 6), evaluating specific aspects of the concept's components and interfaces. They were asked to provide real-time verbal feedback during the test. After the test, participants had the change to talk about their experience, providing them with the opportunity to share their feedback. Some points of improvement and valuable insights were documented on notes, capturing their thoughts and suggestions. Later, some notes and the comments from the survey were transcribed into quotes to create consistency in the feedback and enabled the clustering of information.

Later, participants received a Google form to provide structured quantitative feedback.

Data analysis

Closed questions were analyzed in graphics made by the google form and conclusions are drawn based on these findings. In addition the notes were rewritten in 'quote sentences' and clustered, including last open question of the survey. After the clustering, conclusions are drawn and the feedback was included in the iteration.

Results

An overview of the results of the questionnaire can be found in Appendix 4. The clusters of the qualitative feedback can be found in Appendix 5.

While analyzing the results of the questionnaire, a few points emerged that will be further highlighted in the discussion. The overall score of the statements was high, meaning that they generally agree with the statements and are a positive about the prototype. It can also be seen that question 7 had the highest score which means they see a lot of benefit in the repository. Question 11 asked about the balance between structure and flexibility and was answered very dividedly. Question 12 the lowest rated question which means it did not necessarily make people more ethically aware.

The qualitative data is clustered in 3 main themes: Improvement tips, Positive Tops and Recommendations, that will be discussed on the next page, and can be found in Appendix 5.

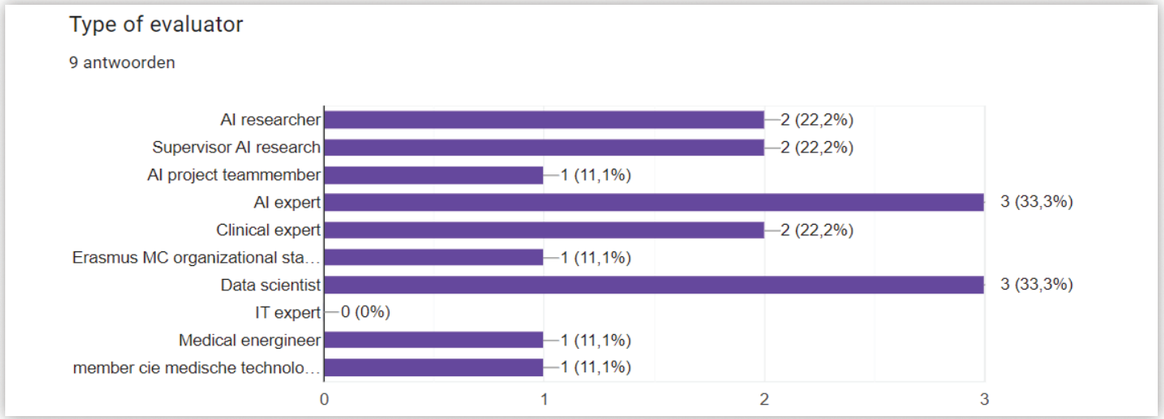


Figure 14: Type of evaluators

Evaluation

- Type of evaluator
1. I like using the interface of this service system.
2. I believe that the service system would help me to better prepare for the AI legislation.
3. I believe that the service system has all the functions and capabilities that I expect it to have.
4. I found the various functions in the system well integrated.
5. The information in the interfaces is effective in helping me complete the tasks and scenarios.
6. It was easy to learn to use the service system.
7. I see the benefit of having a repository, where you can look up similar documents from other projects.
8. I see the benefit of automation through automatically filling in the required documents based on the data in the register.
9. I see the benefit of automation through automatically displaying others' completed questions from similar documents and projects.
10. I see the benefit of transfarability through enabling data exchange with the government register and other systems.
11. The user research resulted in both a demand for a clear leading structure and a demand for flexibility to customize. How did you experience the system?
12. This service system evaluation has made me more aware of the ethical responsibilities involved in an AI project.
13. I believe this service system will contribute to the guidance that the AI expertise team will provide.
14. I understand that the regulations of the AI Act will require more action and I am convinced that such a service system could help to meet these requirements.
15. I would not mind if this registration were made mandatory and its use monitored.
16. Which kind of reward would encourage you to put more effort into the documentation?
17. Overall, I am satisfied with the service system.
18. I recognize the added value of the system and I would recommend it to be realized.
19. If this service system were to be realized, I would you like to be part of the co-creation?
20. If this service system were to be realized, I would recommend it to AI project members.

- If you have any additional recommendations or other feedback, please mention below:

Figure 15: Survey statements and questions

Discussion

This discussion will first elaborate on the results of the survey, followed by the clusters of the qualitative feedback results.

Overall Agreement:

Most participants show positive feelings about the prototype. They generally agree with the statements, which is a good sign that the prototype meets their expectations.

Significance of Repository

Question 7 received the highest scores. This means participants see the repository as very valuable. This is not the most evolutionary idea, however, it shows that it is the most essential feature.

Balancing Structure and Flexibility

Question 11 had mixed answers. This shows that people have different thoughts about how the prototype balances structure and flexibility. It is important to understand these different views for making improvements. One of the reasons could be the differences in participants. For instance, clinical experts often mentioned that they wanted more guidance, while people with a technical background wanted more flexibility in this iterative process.

Ethical Awareness

This suggests the prototype might not be making people more aware about ethics. Improving this aspect can make the prototype more aligned with ethical considerations.

Improvement Tips

These tips for improvement are divided into three clusters: tips following the actions that needed to be done, tips that have already been implemented and tips that can still be implemented in the user interface. Below you can see a quote where it was recommended to offer a video tutorial or manual. Hence, a tutorial video was also created for inclusion in the final presentation of this study.

Q7 “*I would recommend making a video explaining the concept.*”

The iteration chapter (13) discusses the specific tips for the user interfaces that are implemented after the evaluation.

Positive Tops

Many positive things were also mentioned as positive feedback, below a quote is shown from a clinical specialist:

Q22 “*These innitiatives should be there to make it clearer to us clinical specialists what is expected of us.*”

Recommendations

There were also many recommendations beyond the scope of this project. Below is an example of one such recommendation.

Q35 “*To make it consistent, a back-end infrastructure should be created.*”

In the general discussion (Chapter 14) these recommendations are discussed.

Limitation

There are several limitations within this evaluation study. For instance, the statements in the questionnaire could be too guiding, as most are positive statements. There could also be a difference in the experience of the participants who were given a demo or who tested the prototype themselves. There are limitations to collecting notes as feedback. Within the iteration from notes to quotes, the notes could be misinterpreted and the notes written down could also be a biased selection.

Conclusion / Key takaways

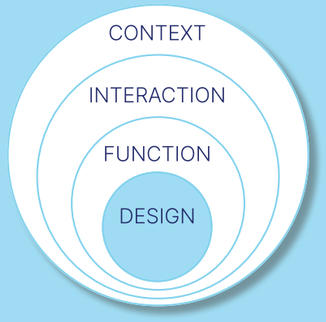
This chapter shows how the concept is perceived. The sub questions are answered below:

How do the future users experience the concept of the service system?

- Overall they have a positive experience after testing the concept which can be seen in the agreement of the statements.

How could the service system be improved?

- Some User Interfaces can be improved, shown in Chapter 13, the other possibilities for service improvement can be found in the recommendation part of the general discussion (Chapter 14).



Overall agreement with the statements

Which shows that the participants got a positive experience of the prototype test

Significance of Repository

Showing examples of others documentation is experienced as the most beneficial component

Balancing Structure and Flexibility

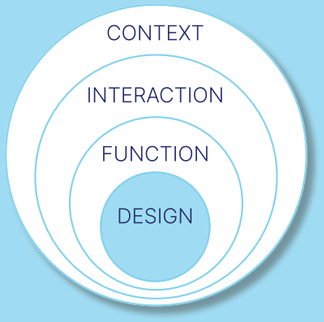
Diverse perceived experience in the structure and the flexibility offered

No increase of ethical awareness

The results do not show the concept contributing to the ethical awareness of the target group

Implementing improvement tips

The tips concerning the user interfaces are adapted in a small iteration section



Applying feedback of the evaluation

In design interfaces

One iteration of Concept Service System

Repeating and refining the features to improve the design

13. Iteration

Following the recommendation for the user interface, a few more adjustments were made to the concept shown in this iteration chapter. The interface visualization shows how this feedback was incorporated. The quotes based on the notes made during the evaluation are included in the explanation.

1. Show the project name

Since it was not clear in all interface which project one was in, it was recommended that this be noted with it in a way to avoid confusion.

Q15 "*I would show in a way which project you are working on when you click on the other parts.*"

2. Help button

It was sometimes not clear to participants what was expected of them, which is why a help button is always good to offer, in addition to an instruction manual.

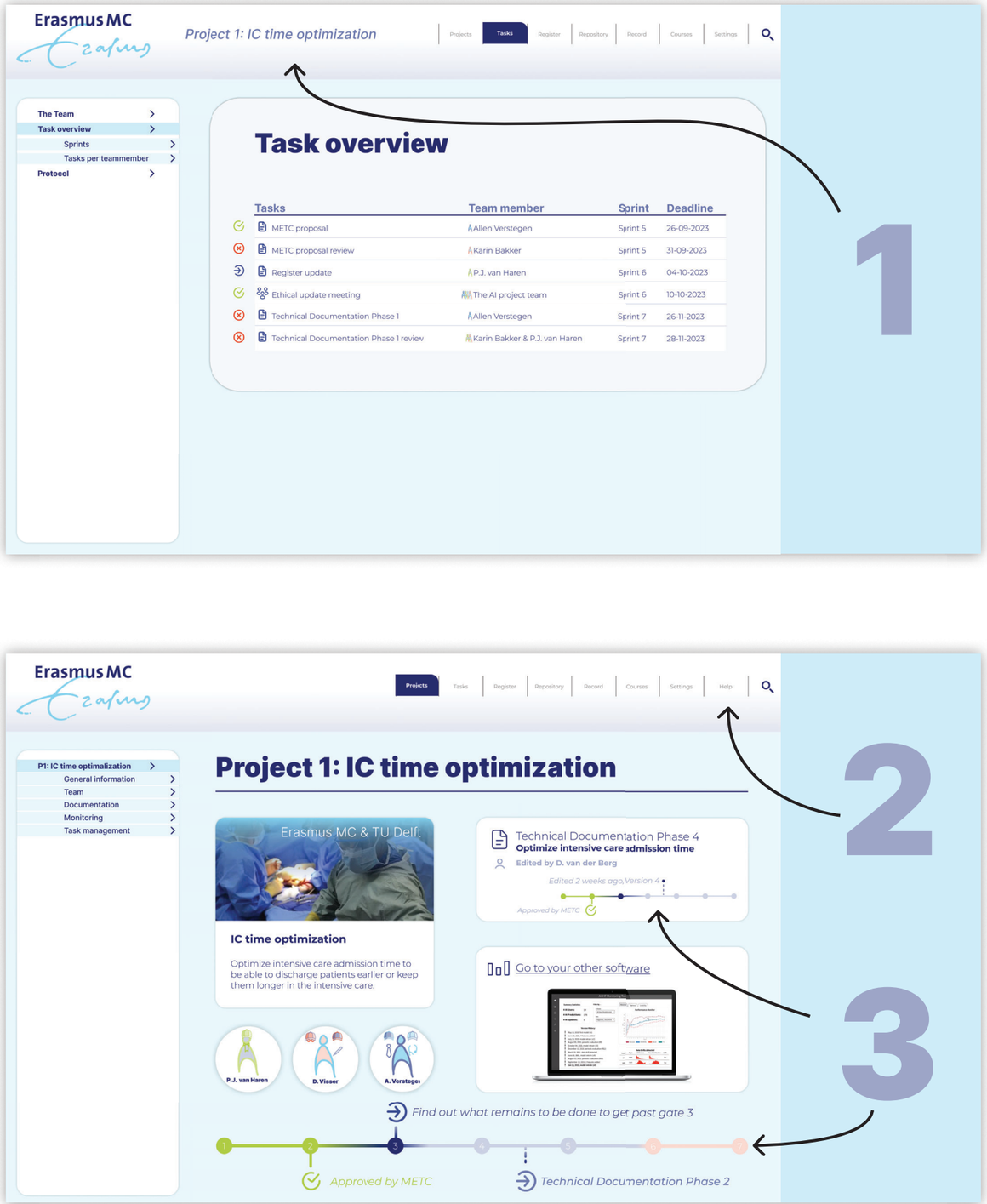
Q18 "*A general 'help' option that provides additional explanation could be a good addition.*"

3. Flexibility within the gates

Multiple evaluators have told us they want more flexibility within the first few gates as it could be the case that you are busy with the documentation of a 4th gate while also having to go through validation in the 2nd gate. However, the last two gates remain mandatory: the implementation and maintenance phase of the AI application.

Q23 "*It would be nice if there were options to go back and forth in the process. Through soft go's in the interim and hard go's at implementation.*"

Q26 "*It would be nice if you are flexible in getting to the gates allowing you to work in different gates at the same time.*"

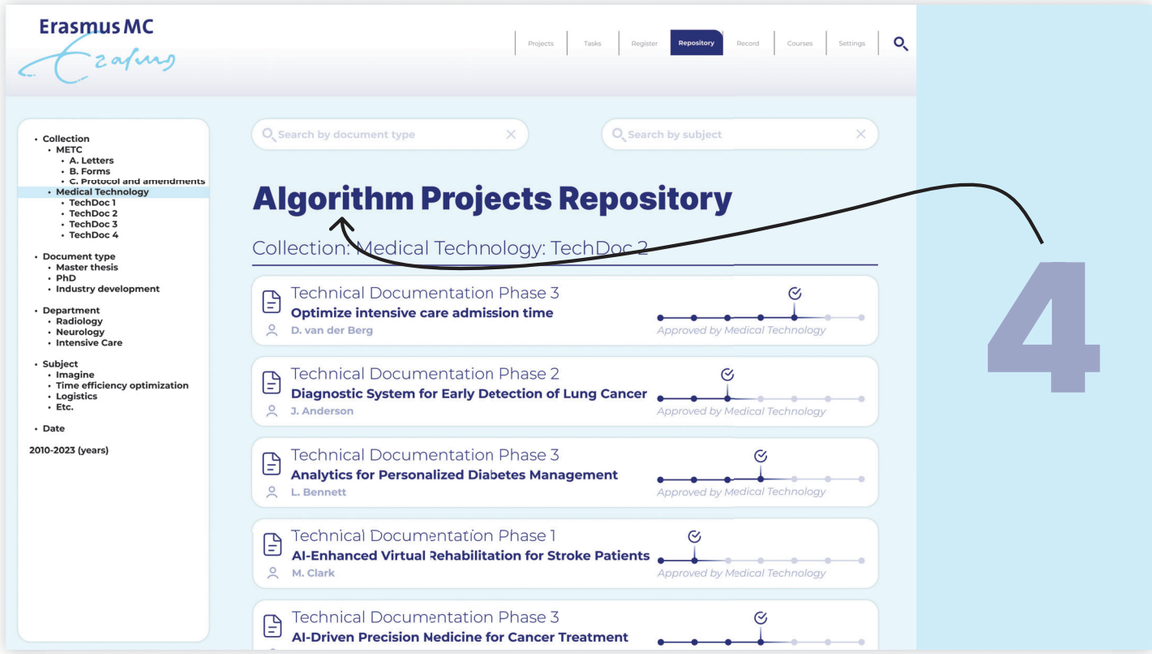


Iteration

4. Algorithm instead of AI

A small tip was to change AI to algorithm, as AI development always starts with creating an algorithm on retrospective data, with this change more people will feel compelled to make use of this system.

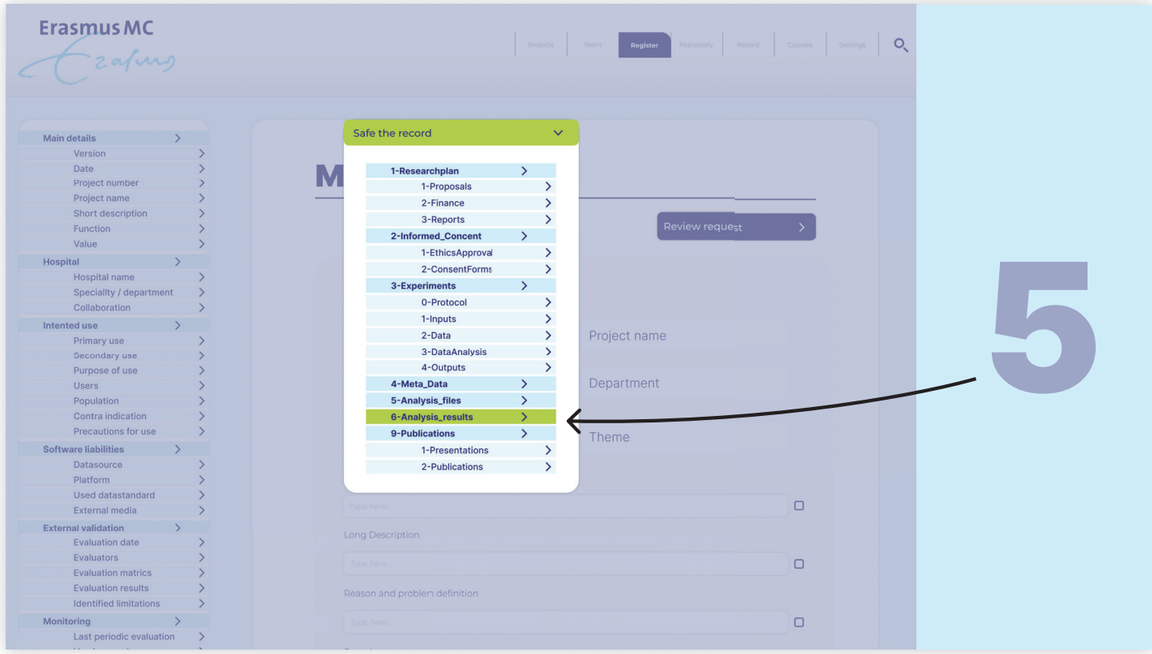
Q21 *"I would recommend changing AI to algorithm, since algorithm research and applications need to take this into account as well."*



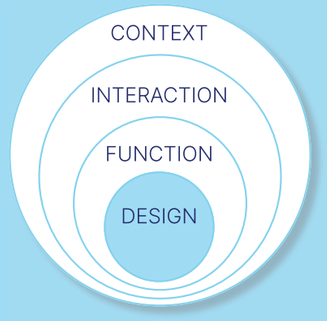
5. Automatic safe in correct folder

It was already taken into account that the structure should be encouraged by the department heads, but it was well noted that this could be done better by saving documents automatically in the right folder to avoid errors.

Q17 *"When someone submits the document it should automatically be saved in the correct folder to avoid errors."*



The iteration chapter only consists of implementing the feedback from the evaluation chapter (12), hence it has no method, discussion or conclusion part.



Main Insights Design

CONTEXT

Department infrastructure Erasmus MC

Erasmus MC has a lot of expertise but these might be hard to approach

Educating staff members

Combine expertise of technical and medical knowledge

Designate responsibility

The target group should know their responsibility

Aligning AI Act requirements with Erasmus MC operation

The legal context must be translated so that it is in line with the way of working

Multiple solutions are needed

The complexity of the problem and the extensive requirements of the law cannot be solved with one solution.

Unclear what levels are obligated

The difference between a must and a helpful tool is not clear

Content of levels are not inline

It is difficult to find a connection in the content between the levels

Limitation of top-down approach

One-sided view of experts and documents

INTERACTION

Gap 1: Little guidance after commissioning

Limited guidance in the maintenance phase of the funnel

Gap 2: Infrequent requirement: Record keeping

Checklist lacks emphasis on Article 12 (Record Keeping) requirements

Record focus

Focus on second gap: implementation of Article 12 and record keeping

Research phase focus

Opportunities for cooperation in documentation and systems

Partial mismatch personas and roles

Personas might not fit the roles they are assigned to fill

Inner motivation & ethical justification

Good intentions of the AI development team can generate a negative perspective toward ethical justification

Limit workload doctor

Supervising is an addition to the fulltime job of a doctor and therefore the workload should be limited

Growing team

Documentation grows as the AI application progresses

FUNCTION

Management, flexibility, preparation

Reoccurring themes from the previous chapters are reflected in the ideas

Focus: Front end & transparency

Priority in designing the interface to stimulate users to be transparent

Record keeping with versioning

Government assessments and storage

Stimulating registration dutch AIregister

Transparency to Patient

Stimulating ethical considerations

Human oversight of development

Repository

Overarching structure

Flexibility: Customized options

(Software) Management

Automation

Transferability

Long term consultancy

Ethical discussion

Preparation

Training

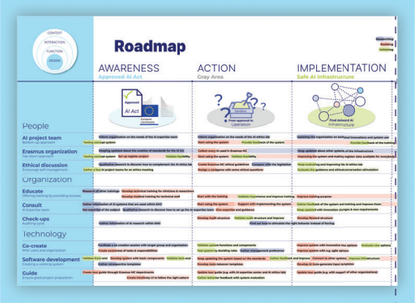
Check-ups

Convince

Co-create

Reward

DESIGN



Need: collaboration among departments

To bridge the gap of these domains, collaboration is needed

Flexible experimental approach

The novelty of this topic requires an experimental iterative approach to tackle the problem

Expertise center as a starting point

They can apply the insights from the roadmap

EVALUATE

Overall agreement with the statements

Which shows that the participants got a positive experience of the prototype test

Significance of Repository

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Mentioned by the board of directors, but internal development could give an advantage as a Technical UMC

Need for experts

Overarching generalists are needed to bridge the gap between the domains, combined with the need for legal, technical, IT and medical experts

Users understanding

Examples enhance compliance understanding of the AI Act legislation

Discover | **Define** | **Develop** | **Deliver** | **Evaluate**

Responsible Innovation of AI

at Erasmus MC

In this study, the aim is to find out how Erasmus MC can properly prepare for the AI Act.

An **iterative design approach** was utilized to explore what **AI project members** may experience during this regulatory process. Several factors have emerged during this experimental study, including the *allocation of responsibility*, the *importance of education* and the *connection of the medical, technical and legal domains*.

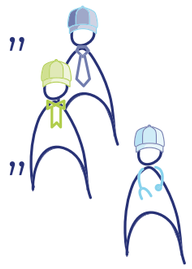
Allocation of responsibility

Importance of education

Connection of medical, technical and legal domains

Q1 *"Shouldn't this be established across the entire UMC (University Medical Center)?"*

Q2 *"The aim of Eramus MC is to become Technical UMC in 2028, with such a system you can get ahead of other UMCs and they can use it later."*



Q22 *"These innitiatives should be there to make it clearer to us clinical specialists what is expected of us."*

The aim was to get answers to the following questions:

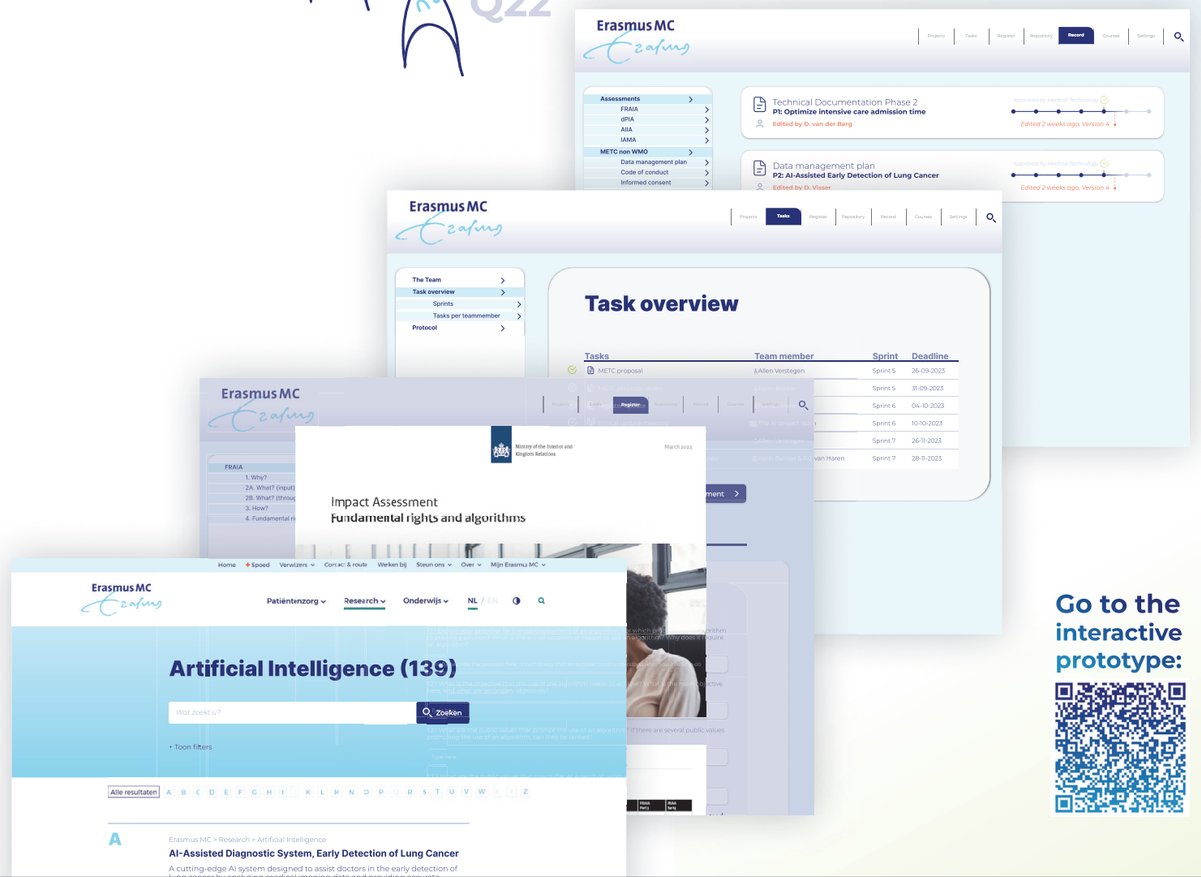
Research Question

'What can different members of an AI development team encounter during the documentation process for the regulations of the AI Act?'

Design Question

'How can a hospital develop a service system combination to give more guidance to AI developers within the regulation process of the AI Act?'.

The complexity of the problem necessitates multiple solutions, which resulted in two designs, the **concept of a service system** and a **roadmap**. The service system embodies the needs of the target group, while the roadmap offers a pragmatic guide for the organization to prepare for the changes following AI Act legislation.



Go to the interactive prototype:

Denise de Vries
Responsible innovation of Artificial Intelligence
25-08-2023
Strategic Product Design (Medisign)

Committee Prof. dr. ir. Goossens, R.H.M. (Chair)
MSc. Morales Ornelas, H.C.(Mentor)
Ms. drs. Vink, M. (Company Mentor)

Company Erasmus MC

Faculty of Industrial Design Engineering

Delft University of Technology

14. General Discussion

Several small discussion points are mentioned in each chapter. This discussion summarises the findings of the entire project, including limitations of this entire project and recommendations for future research or concept development.

General

Problem

Erasmus MC has the obligation to prepare for the AI legislation. The first problem faced in this study was was the lack of a clear understanding of the specific actions the organization should take to meet the requirements of the AI Act.

The second problem, however, is that people of the AI project teams do not have clear instructions on exactly what to do to follow these rules since there is not enough useful guidance available.

Solution

This confusing situation highlights the urgent need for a clear plan to assist both the organization and the AI project members. The support of the organization is done with a structured plan (roadmap), showing the organization the steps to prepare for the AI Act.

The ambition of the concept service system is to help AI project members to better understand the requirements of the AI Act and encourage them to follow the legislation.

Questions

In this discussion, the research question and the design question are answered in a more abstract overarching manner. There is also an overview of all the sub-questions of both the research, design and evaluation chapters (See figures 16-18)

Research Question

Based on the problem definition the aim is to answer the following research question:

'What can different members of an AI development team encounter during the documentation process for the regulations of the AI Act?'

AI project team members can expect a lot of documentation due to the new AI regulations. Several specific topics that will be expected based on the requirements of the law are discussed in the chapters. However, if you look at the main research question from a more abstract point of view, members of an AI project team can mainly expect lack of clarity and an iterative (non-linear) process where mistakes will be made. There is a chance that stakeholders who do not have a technical or legal background will receive guidance, training and support from Erasmus MC.

Sub research questions

- *Who will be responsible for compliance with the AI Act?*
- *What can different members of an AI development team encounter during the documentation process for the regulations of the AI Act?*
- *How are AI providers currently meet the requirements of the MDR?*
- *How is Erasmus MC currently handling the regulatory process of AI applications, made in-house or externally?*
- *How can AI providers meet the requirement and obligations of the future EU Regulations for AI?*
- *How is Erasmus MC preparing for the growth of AI usage within healthcare and the requirements of the AI Act?*
- *How are other organizations approaching this problem (preparing for the new AI Act)?*
- *What levels of compliance are there for AI software in healthcare?*
- *Which role is needed in which part of the process?*
- *How do these accountability steps, mapped out by the ministry, connect to the requirements of the AI Act?*
- *Who can fill the roles of an AI development team?*
- *What roles do these individuals perform during the 1st three phases of the process?*
- *How do these individuals change during the phases of development?*

Figure 16: Sub research questions

Design Question

Based on the assignment the aim is to answer the following research question:

'How can a hospital develop a service system combination to give more guidance to AI developers within the regulation process of the AI Act?'.

The design question was answered in the form of a prototype. Nevertheless, it became evident quite rapidly that this design question did not address the complete issue. Several solutions are needed beyond just providing guidance in the form of a system. Besides a service system, human guiding services should be offered, ethical issues will arise, education will have to be adapted and, in the distant future, data infrastructure changes will have to be anticipated.

Sub-design questions

- *How we can create awareness of the roles and responsibilities of an AI research/development team?*
  - *How could we get in contact with the AI research development team?*
  - *How could we support their responsibility management?*
  - *How could we educate the AI research development team about the requirements?*
  - *How could we stimulate them to follow the ideal mapped out process from the beginning?*
- *How can a hospital develop a service system combination that let AI project team members meet the requirements of the AI Act?*
- *How can a hospital develop a service system combination that is easy and beneficial to use for the target group?*
- *How can a hospital encourage AI developers to meet the requirements of the AI Act?*
- *How can a hospital give more guidance to AI developers within the regulation process of the AI Act?*

Figure 17: Sub design questions

Evaluation questions

- *How do the future users experience the concept of the service system?*
- *How could the service system be improved?*

Figure 18: Evaluation questions

14. General Discussion

Interpretations

A number of interpretations were made of the main discussion points by looking back at the resources reviewed in this study and linking these to the findings.

Multiple solutions

This finding is in line with the paper (Scientific Foresight Unit, 2022) which mentions the need for multiple solutions. This is also a conclusion of this applied research, which is reflected in the Roadmap mentioning multiple action points to create an overarching solution.

Importance of eduation

A recurring theme is the importance of education, which was a major focus of the desk research and was repeated in every part of this research, as the issue is relatively new and the evaluation makes it obvious that continuous education is needed. However, there is still a great deal of ambiguity around the issue, leading to the challenge of what to teach.

Responsibility

Another recurring theme is individual responsibility. The question of "who is responsible" was central to this study. Mainly because this question cannot be answered by different experts, which leads to an ethical challenge for a project team itself.

Bridging the disciplines

It has been suggested in the literature that an expert with knowledge of different disciplines can help in the search for responsibility and bridge this gap. (Sensakovic & Mahesh, 2019) This also came back as a demand from the target group, resulting in the recommendation of a long-term constancy role within the EMC.

Overlap with QMS

The design of the service system overlaps with the functions that a quality management system (QMS) is legally required to have. The importance of a QMS has already been mentioned in the literature, but such a system is not used in the hospitals in the Netherlands. (Wagner et al., 2006) This research confirms the importance of a hospital's QMS for improving internal and external traceability and transparency, but more importantly it encourages staff to work according to protocol and legal requirements and it supports predictability.

Choice of tools

Desk research has shown that many people are working on this issue and would like to give more structure to the target group, but this research also shows that, for someone new to this area, it is not clear what is needed and which tools should be chosen. Choices need to be made within Erasmus MC to make it clearer to the target group which tools to follow.

Balance structure and flexibility

A pattern was observed in this study showing a opposing demands for structure on the one hand and flexibility on the other. Finding a balance between these two values remains a challenge. This could also be seen in the evaluation, where the experiences were very different.

Process optimalization as a reward

It was noticed during this study that people are aware that documenting is not pleasant to do and cannot be made more fun. Hence, the thoughts from the target group were more towards imposing rather than encouraging through reward, which contradicts with the design approach. This resulted in the best-appointed form of reward: facilitating the documentation process.

Implications

The aim of this study is to activate governance in Erasmus MC's organisation so that they are prepared for the actions required for the new legislation, giving them an edge over other hospitals in terms of technical innovation.

This study gives a good picture of the analysis and shows what a hospital needs to add. In addition, it not only provides research findings and inspiration for policy, it goes a step further and shows a plan on how to achieve this future perspective. With the target group research, it reflects the demand of the AI project team members and shows what they need from the organization, this perspective is valuable to bridge the gap between the organization and their staff.

Practical implications

Roadmap

The roadmap designed in this research can be used to design the architecture of the AI Expertise Centre.

Concept Service System

The concept service system designed in this study can be used as a starting point to develop a support system for the stakeholders of an AI project and eventually for more purposes, resulting in an overarching QMS for the entire hospital.

Unexpected outcomes

No overarching QMS in the hospital

Throughout this study, there remained a surprise that some kind of QMS system was not yet being used in such a large organisation. This resulted in the decision to take a step back to improve the current situation first (but with the future vision in mind). Hence, several features in the system are accessible on a low level.

Responsibility

Another unexpected finding was that throughout this project, no one could answer the question the individual responsibility placement since it does not work that way. Realizing that the goal is to be able to track and document everything in order to place responsibility on several people rather than one person. In addition, the need to take responsibility is only there when something goes wrong that could result in a claim for the hospital.

Ongoing ethic debate

The ethics around AI and the new legislation are a hot topic, but this remains a new subject where opinions remain divided, resulting in a limitation of expert knowledge in this area. The most updated experts were the ones following the latest changes, but even for these experts, ethical dilemmas remain unclear.

14. General Discussion

Suggestion: Value for all UMCs

Mentioned by the board of directors, but internal development could give an advantage as a Technical UMC

Need for experts

Overarching generalists are needed to bridge the gap between the domains, combined with the need for legal, technical, IT and medical experts

Users understanding

Examples enhance compliance understanding of the AI Act legislation

Limitations

Limited knowledge in IT, AI and legislation due to a design background necessitated an initial focus on familiarisation with the subject in the early stages of the project. This led to different interpretations.

Time constraints further limited the number of interviews and other field research. Had there been more time, it would have been insightful to conduct interviews with individuals from the research suite, the IT department and legal experts.

In addition, minor limitations were identified within the sub-research sections of this study.

Recommendations

It is recommended to further develop such a system with a centralized approach, involving different specialists who can both guarantee the development and provide clear legislative guidelines for AI in healthcare.

Value for all UMC's

It is recommended by the evaluation participants to establish a centralized and comprehensive system UMC wide to exploit the potential benefits of AI and technical advancements. However, the implementation internal development of such a system can position Erasmus MC as a technical forerunner. This relevance was also mentioned during the evaluation of the concept which can be seen in the quotes below:

> *"Shouldn't this be established across the entire UMC (University Medical Center)?"*

> *"The aim of Eramus MC is to become Technical UMC in 2028, with such a system you can get ahead of other UMCs and they can use it later."*

Need for experts

For the successful implementation of the system, it is essential to involve specialists in the design and further development. In order to deploy the system, it must be tightly connected to data storage and it must have a back-end infrastructure. In addition, clarity in legislation, especially with regard to AI-related rules and standards, would be beneficial to provide more clarity and to guide clinical specialists.

Users understanding

It is advised to offer additional information about the complexity of the unattractive process to highlight the advantages of implementing such a system. Providing users with information about the underlying legislation and standards by showing examples of how the system simplifies the process, will not only ensure correct form submissions but also enhance users' understanding of compliance requirements.

Personal Reflection

During this journey, I successfully achieved my goal of gaining a deeper understanding of healthcare and technology regulations. Furthermore, my objective to streamline the documentation process and making it less burden, has shown promising results in the evaluation, if such a system is to be realized. Working with the hospital environment has taught me a lot, and I am proud to have learned from the expertise of many professionals who have guided me in navigating my role as an intern.

15. General Conclusion

The aim was to find out what an AI project team could encounter during the compliance process for the regulations of the AI Act, in order to eventually provide guidance in this process. Through qualitative and quantitative design research, it was discovered that an AI project team can encounter more documentation and workload. In addition, the AI Act creates uncertainty among clinicians and technicians about the legal requirements and individual responsibilities. This addresses the need for guidance and support that should encourage the target group to meet the requirements of the AI Act.

Resulting in two designs: the concept of a service system, showing how a hospital can develop a quality system that provides more guidance to an AI project team, which answers the original design question. This concept was complemented with a roadmap that responds to the implementation of this guidance to facilitate a practical guide to prepare for the compliance with the AI Act. To execute these designs properly, multidisciplinary expertise is required complimentary to this project.

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Van Boeijen, A., & Daalhuizen, J. (2010). Delft Design Guide. https://repository.tudelft.nl/assets/uuid:b00f2758-4beb-4f9c-9dc6-f27e9e7ecc7d/Delft_Design_Guide.pdf

Methods, tools, theories not located within design books

Onion Stakeholder map (Edward Freeman)

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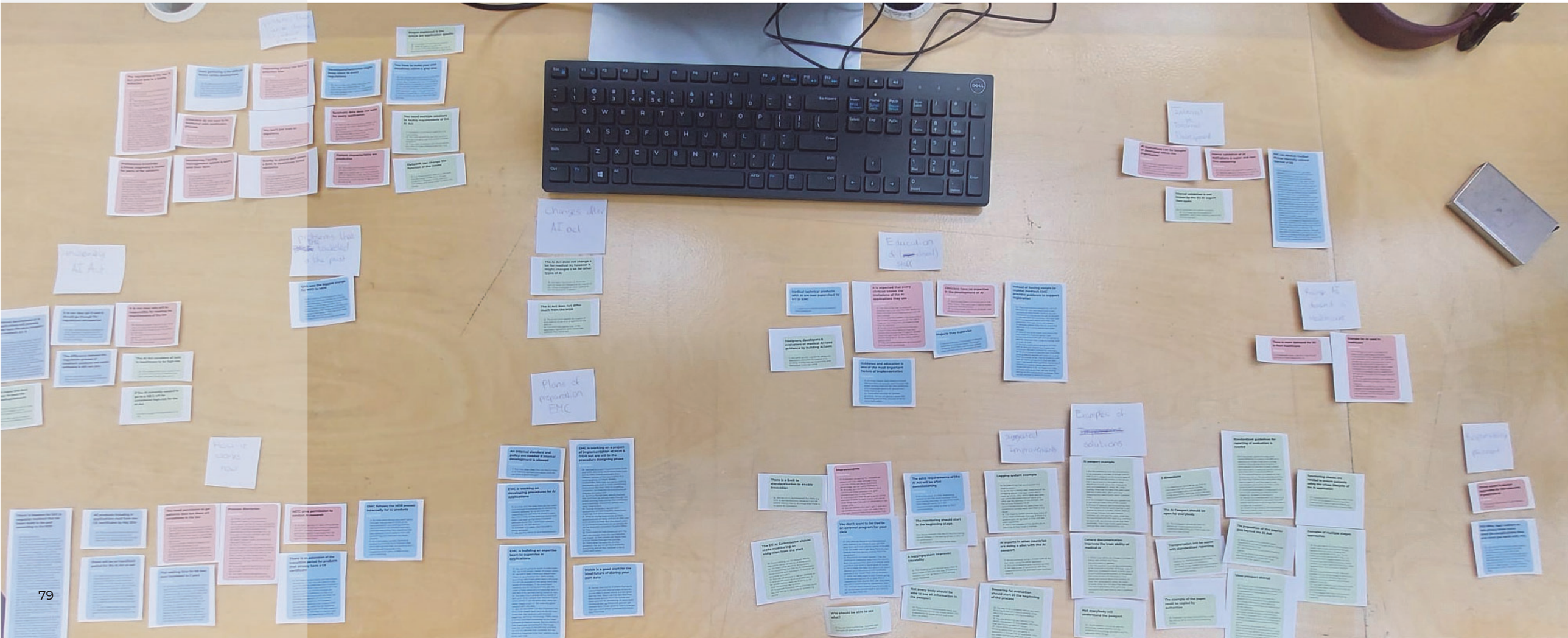
Thinking hats (Edward de Bono)

Appendix 1 - Clusters Experts

This appendix shows the physical clustering of the first part of the study, where experts were interviewed and statementcards were created from the quotes of these experts. Then these statementcards were clustered, the next page shows the cluster names with some findings.



Appendix 1 - Clusters Experts

Context Mapping

In figure below a cluster session is shown, where quotes were analyzed provided by the first five interviewees. The quotes were translated into statement cards and organized into clusters to facilitate understanding. Three concrete factors, related to the needs of the target group, will shortly be explained, and the other statements are integrated with the findings in the next pages.

Infrastructure of multiple departments

There are many departments with expertise in Erasmus MC, but due to the size of the organization it can be difficult to approach.

Education of staff members is needed

The gap between technical knowledge and medical knowledge is still very large according to the insights, hence education is a very important factor.

The responsibility must be designated

Even though this is a small cluster, the responsibilities must be designated, but before this can be done it must first be clear what these responsibilities are.

Context factor findings

The purpose of this interview study was to get to know the subject, which is also reflected in the clusters. The context findings are explained by combining desk and field research to provide background knowledge for the reader. On the next page, five context themes are explained in detail.

Department infrastructure Erasmus MC

Erasmus MC has a lot of expertise but these might be hard to approach

Educating staff members

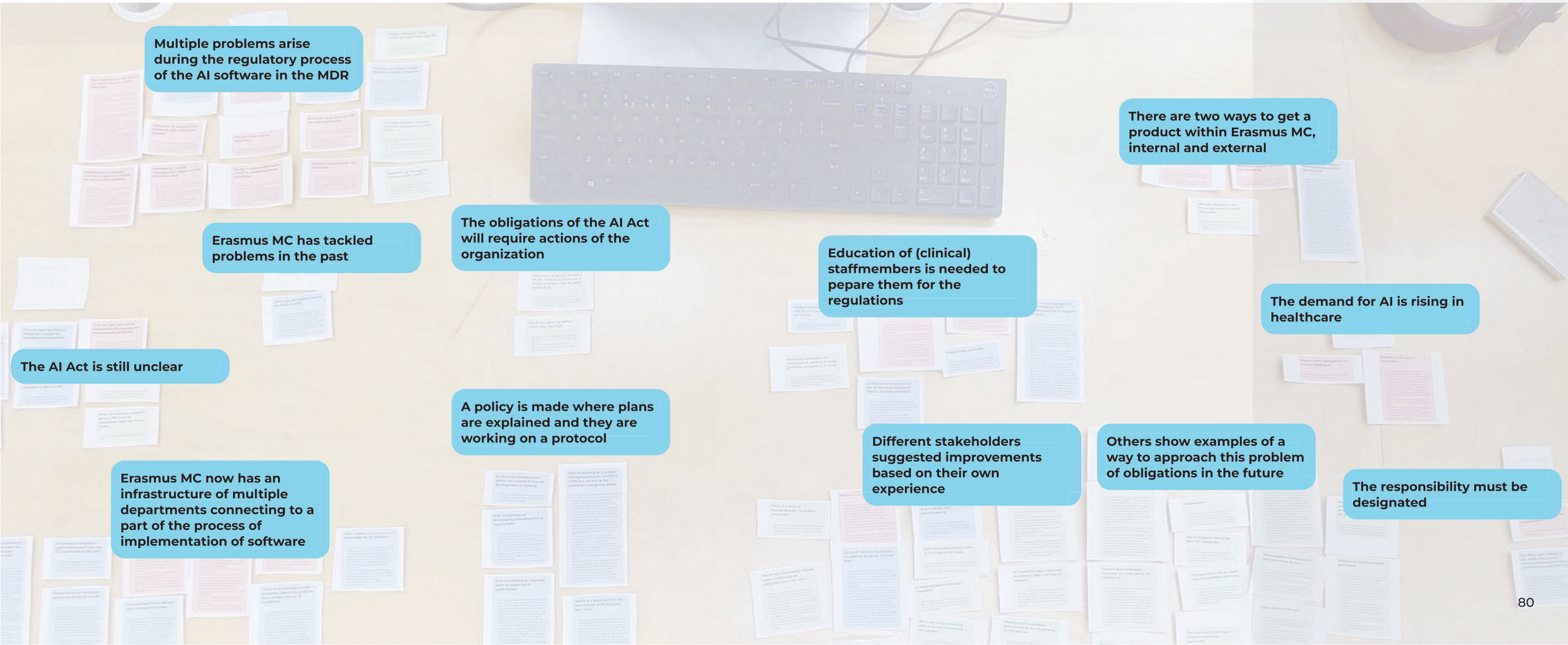
Combine expertise of technical and medical knowledge

Designate responsibility

The target group should know their responsibility

Clarify responsibility

Determine which individuals are responsible and what the need to deliver



Appendix 2 - Creative Session

Below is the physical version the creative cluster session with the digital post-its copied. The next page shows the post-its that received the most votes. The orange stickers represent the best idea, the blue ones the most original.

Appendix 2 - Creative Session

Appendix 3.1 - Clusters targetgroup

On the next page are the normal-sized clusters of the last 5 interview quotes mentioned in page 49, with the last being a stand-alone group of sample quotes.

Multidisciplinary roles should be devided

Q12 P6

Importance of multidisciplinary team

38. Within Skinvision you have different departments, you have Regulatory and Quality management. There are people there who are responsible for the permission and the documents that ensure that the product can be placed on the market.
39. You have a panel of dermatologists who review photos and monitor the quality of the database. They give a quality characteristic.
40. We have an AI team, people who specialize in building AI and other things. Many of these tasks also lie with management.

Q23 P8

Importance of multidisciplinary team

61. You just have to make sure that something works well, that's why you have to look at it with several people, but you also have to look at it with multiple disciplines.
62. People who know about programming, people who know about the application, people who are a bit in between, who can make the translation and so there just have to be enough people who have looked at something like that and then you get confirmation that we as a team think it is a reliable application.
69. You have to keep looking for a multidisciplinary team, that is of course what we also have in the department.
70. We have medics, doctors, engineers, technical medicine people in between.

Check behaviour

Q7 P7

Importance of audit

21. I do think that when I hear it around us that we are really an exception in how structured this is stored. But it's the idea that this is happening, this is kind of a first step alone. It's not really checked. Someone then says, within neurology you have to store this like this, but then it is no longer checked.

The team members have different skills and characteristics

Q22 P8

Developers want to focus on developing

60. As a developer/PhD student, you prefer to focus on developing the whole thing and not want to think, but what if I have turned around a minus or a plus here and someone dies. Of course you have to think carefully about that, but you don't want to be thrown in court afterwards.

Q24 P8

Limited knowledge supervisor/doctor

68. I think that if you look at the average PhD student in the hospital, it is often doctors who are working on this who are also going to put themselves into machine learning. I think there are also some risks involved, because they have a different background. Things can be learned, of course, but it is different from the fact that you have been involved in computer science from the beginning of your studies, but then you do not have the medical side.

Q26 P8

Researcher are used to document

75. Of course, documentation remains an important thing there, but that is something you are used to as a researcher, because when you do clinical research you also have to keep track of which patients you have included.
76. In itself, you are used to keeping track of administrative things and that is also necessary with this type of project. It shouldn't just be a little pythoning.
77. People have to think at a good time: what are we doing, what are we doing this for, how far we are.

Team management

Appendix 3.1 - Clusters targetgroup

Roles should be assigned

Q7 P9

Role level definement

16. I don't know if the goal is to really come to explicit individuals or to have everything defined at the role level, that's what we do anyway.
17. We say first in the QMS, these roles are responsible for this and everyone belongs to a role group.
18. And then per project we will also make explicit, for this project it is these people who can fulfill those roles.
19. So I think if you make something like that, at least how you explain it so far, yes super valuable and useful.

Q9 P9

Role assignment

23. All roles must be defined on the basis of knowledge and experience and we also link that to people's CVs. We just put everyone in a group or in a role where we think they fit best.

Software agile management

Q18 P9

Software way of management

43. They are software developers, so we do it in the software development way and the thing that fits best in that culture.
44. It's scrum agile and that's something that does involve a learning process for some members.

Allocation of responsibility is important

Q8 P10

Supervisor responsibility

6. I feel ultimately responsible at all levels.
14. I'm already a reasonable micromanager, but you can't take every step of your researchers.

Q6 P10

PhD responsibility

12. Below me are the students who actually carry out the research. I also try to discuss these aspects with them, but in practice I have that responsibility.

Q19 P8

Responsibility placement people

54. The professor is the employer and is responsible for what the PhD student ultimately does.
55. When it comes to medical treatment, I think it should always be a doctor who has a certain care process in his hands.

Q5 P7

Governance and innovation growth gap

14. When I'm doing edits to this or I'm analyzing, I have a folder where I have to store my code and I also have a folder where my output goes. So all the calculations I've done, what comes out that's all stored like that.
15. It is the idea that this happens within neurology, but practice shows that I am actually the only one who does that.

Q8 P7

Responsibility placement

22. My supervisor. So he is a neurologist and is setting up his research group. Since I'm only going to get a PhD after this.
23. According to me, it is standard that if you start a PhD research that you will receive that file.
24. If the supervisor doesn't do this himself, I don't think that's going to happen.

Appendix 3.2 - Clusters targetgroup

From Research to Product to Deep Learing

AI application started with research
Q1 P9
3. Start-up was the product of the thesis of our founder, who did a PhD at TU Delft and Leiden University at the same time.
4. That was 1 product that he had designed with very close collaboration with surgeons that displayed 3D motion simulations.

From research to product
Q1 P6
4. When there was first evidence of its safety and accuracy, at that point we really turned it into a company and started it and then it was CEO.

From research to product
Q3 P8
5. We have been working on a number of projects here in-house where we simply have the data available for which METC is permitted, so that research-related use can be made.
6. Based on that data, we had developed an algorithm that we were satisfied with in a way, which also involved machine learning.

From development to deeplearing
Q4 P6
18. We have experienced that development, until 4 years ago it was only ruebased now it has really only become deep learning.
19. We now have 4/5 million photos in our database of which 1 million have been clinically validated and a smaller subset has been validated with paralogy.

Ideal process starts with research in hospital
Q7 P8
17. In it you mainly see that certain companies that come with an algorithm, who come to us to test, or because they want to check how good they are to be able to use it themselves, but that a lot of errors come up that they have not thought about themselves, that we can already pierce through in the first case, but then that device with the algorithm on it has a CE mark and can just be sold when it actually doesn't work and millions of subsidies are given to let the company develop it when it actually doesn't work at all and we find out after one patient.
51. Now we have our own people in-house who are working on this and have built something on the data we have. That was never implemented with us, because we had something like this, 'there is so much more money in the business world, they must be able to do better', but then we now find out that this is actually not the case at all.

Resources and workload change over time

Difference in team members per project
Q25 P8
73. You have consultations with the postdoc, your colleagues. There are people here from different backgrounds. At certain times you come together with a larger team.
74. But this again depends on the project and the phase, it's just a very dinamic process and I think that makes it the tricky part of that whole legislation and the process. It wants to approach it too much according to one framework, which is simply not practically feasible.

Growing amount of documentation
Q3 P6
9. The first phase was in Romania and then a private dermatology clinic was involved. He compared the outcome of the algorithm with the clinical judgment of the dermatologist on a very small scale.
10. Then there had to be higher-quality clinical evidence. Then we worked together with one of the larger clinics in Germany, in Munich. A German clinic is more credible than a private clinic in Romania.
11. Then the first evidence came that we were moving towards the 80% sensitivity and 80% specificity. Back then, 10 years ago, that was very promising.
12. Only then did I come to board, during that study.

Variable number of AI team members
Q13 P6
43. When I started we were about 5 people and a lot of people in a kind of flexible shell around it who, if there was a certain question, were asked to do it.
44. I think the maximum team we had was once at 30 men, we are now at 17/18.
45. So depends on the phase you are working on and the money you have available.
46. The number of people varies enormously.

Importance of change management
Q10 P9
26. I've heard about companies that monitor their AI, but also on a personal level, that's not always easy for developers who are used to doing things a certain way, that they suddenly have to change that.
27. This is really an external issue that really involves hiring external companies: change managers. But I don't know how that goes in real life, I just understand that this is very difficult.

Appendix 3.2 - Clusters targetgroup

Differences in cases

Process explanation case A

Q14 P8

44. We start with an idea, and then we say, we want to use machine learning, algorithm, AI on it and start developing it. Or a scholarship is written for it, then you have to think a little more about the application, because the scholarship requires things from you.

Process explanation case B

Q15 P8

45. Of course you can also have an idea here, already have a PhD student in-house. And thinking, we actually have a certain project direction and we think now, because the developments are going so fast, let's start using AI to solve a certain problem.
46. Then you have actually skipped that entire risk analysis altogether, because you want to look first, is anything possible at all. You are already trying things and are already moving towards 'pilot A' which is actually partly exploration.

Hospital boundaries

Patient information storage

Q5 P6

21. Requirement of clinical research, Munich was fully responsible for the ethics committee, approval and privacy.
22. We also did not get access to this data, only the results. That is exactly the same with the Erasmus study.

Framing possibilities within the hospital

Q17 P8

50. I think that's kind of the size of the playing field now, with what can you still do as a hospital or not. That is also where the SHTC can help and give tips on how or what and where to go.

Industry collaboration preference

Q29 P10

86. If I wanted to develop it in this way, I would rather seek a collaboration with the industry than develop it myself. I'm also just a doctor doing the research alongside it, I just don't have the time and opportunities to go through the whole certification process.

It is all about money

Nobody wants to be responsible

Q21 P8

58. I think it's very difficult to make companies completely responsible, because they're probably not going to want it.
59. Because that is a very high financial risk that you are going to run.

Importance of money

Q2 P6

6. At one point they had an algorithm and thought, this could be very interesting for skin cancer.
7. They have won awards and attracted investors and I know them, they have asked me to set up the company.
47. Scalable, that's the magic word for investors. They all want a very small team with which you can change the world.

Companies want to make money

Q9 P8

23. But I think that's the case with all devices, that there is a playing field in them, a company wants to make money and are convinced of a process. All you need is a certification. If there is no control over this by several people who know a little more about the content, then it will not change very much, I think.

Withdraw EU market for business reasons

Q12 P9

33. It is also an option for business reasons to withdraw a product from the EU market if the AI Act proves to be too strict.

Expectations of business world

Q18 P8

51. Now we have our own people in-house who are working on this and have built something on the data we have. That was never implemented with us, because we had something like this, 'there is so much more money in the business world, they must be able to do better', but then we now find out that this is actually not the case at all.

Change management

Appendix 3.3 - Clusters targetgroup

Stimulate cooperation

Positive experience with DRE
Q1 P10
63. So I think if you reimburse the basic configuration of that DRE, I think that's a really fantastic initiative and especially very explicit to keep it that way, because that really gives you a whole push in your right direction.

Good experience with data transfer via DRE
Q19 P10
55. Patient data should simply never leave an Erasmus MC server. We use Digital Research Environment (DRE) for this The example of this is that collaborators from TU Delft can easily enter it and that you use logging.
58. In principle, the PhD student works in that DRE, so the data stays within that, because you can only download if you send a download request and I see that.
61. Every AI researcher wants more storage capacity and more computing capacity and if it is simply clear that you have the easiest access to that with such a DRE, then it actually becomes automatic to also use the logging system and the data security system that comes with it.
63. So I think if you reimburse the basic configuration of that DRE, I think that's a really fantastic initiative and especially very explicit to keep it that way, because that really gives you a whole push in your right direction.

Need for data transfer controls in the system
Q27 P10
59. If you work with a V disk or other freely accessible write, it is almost impossible to check. I think you have to build the controls into the system.

Complement other great programs
Q11 P10
23. Look the great thing about a git repository is that you can locally such a repository, so if you tell me code is so confidential that I can't even put it in a closed github respository, then you can also just create a local respository, at least you have that of the trackchanges. So I think such a solution works best.
24. I also think that erasmus should not want to reinvent the wheel. Such a solution as git, for example, that is used so much in software development, that is so well validated, I would mainly choose to train your staff in its use and support that and not come up with an extra solution for that myself.

Access to data storage
Q3 P7
8. The bed fabric itself cannot access these dates either. They only provide the software. The data always stays within erasmus anyway.
9. You can only open it in their commercial environment and my supervisor has written something so that we can also open it in python and matlab.

Interplay with other programs
Q10 P10
19. For the code operation itself, all codes are in git repositories, so you have an exact overview of all track changes that have been performed in the code. So that you can basically go back to every step in your code, from how it's been edited over time.
20. You work with a code in a certain environment, so that you also save that environment yourself, so that at a later time you can compare the code with last year, for example, and show as a changelog what has happened in the meantime.

Local data storage
Q2 P7
5. That data is stored, it is somewhere on the KNF server and my supervisor has written a script in python that sells all that from the server and converts it into data.

Distribution channel
Q2 P9
5. He managed to send that in 3D in a PDF, which was very useful in terms of distribution channel.

External validation importance
Q17 P7
48. Another thing we really want to work on is that we don't have any real external validation sets right now. Because we now have so little data. You create your model and this is based on more your development phase of the model than it is (it is research anyway so it is not used yet, but we actually really want a dataset of a children's ICU or an adult ICU from Leiden.

Data sharing infrastructure need
Q14 P7
34. EEG is mainly used to diagnose epilepsy and there are sometimes very rare genetic syndromes underlying that epilepsy. Then they have seen this 2 times in 10 years. To then draw AI on it, that's actually not possible. So then it would be interesting, if you want to recognize patterns, to be able to distinguish those subgroups from each other, that you can get your sample size up with syntetic data.

Collaboration needed for data exchange
Q18 P10
54. You are already a bit limited because you need a lot of data, so you will have to work together with other parties.

Program use
Q6 P7
19. And so it's the idea with that structure of neurology that I have to deliver all those versions, but that ultimately in that folder of data analysis are the codes that ultimately provided my output.
20. So when I'm done, you know, you're obviously going to try a lot in the meantime, I happen to save that within github, but not for the department.

Appendix 3.3 - Clusters targetgroup

Flexibility

Value of ethical discussion

Importance of defining responsibility
Q4 P8
8. The question is (also interesting for the implementation to the clinic): Who is responsible for this and when. How many black boxes can be in it, the training that the algorithms all need. That you are going to look at train-based algorithm. On the basis of which data this is possible and what happens to that data.
9. Those are actually the big question marks that we mainly encounter.

Stimulate multidisciplinary ethical discussion
Q5 P8
12. This can mean that you lose data to the algorithm, which is going to be in it. So there is a lot of discussion with us about that, with engineers saying, no, that data does not disappear, yes because the system learns from it, so in principle that data is in the system.

Responsibility placement company
Q20 P8
56. And whether you ultimately have an AI that will influence the care process, is the company responsible for the outcome or the doctor.
57. Of course, it is about a certain application of something and a use of a means, where still a doctor can say, it does not feel right, I do not have confidence in it, I am not going to do it.

Need for flexibility

Importance of flexibility
Q27 P8
78. I think care should be taken not to make this too pushed, frequent, analysis with certain steps that are not relevant to some studies or projects. As a result, you may miss things in other projects, because you have to stick to such a framework while you may need extra steps.

Flexibility for individual monitoring
Q18 P7
51. I have automated it all in my code, so if I run my code 1 time, it stores files in the meantime with which I can generate those plots and that is also just 1 push of a button.

Manually monitoring posibility
Q20 P7
Do you think that if Erasmus MC offers this service? Do you think every AI researcher could put his/her data in this?
55. I think so, but I think it has to be done manually.
56. Or you could agree very specifically, erasmus-wide that, if researchers make a code, they should all give as output the list of these things, every time they run it with the date, then you can do that. And where they should store it.
57. Then you could read that automatically.
58. I think you can only do it that way, because if you have to combine random codes from all these researchers with a model that is going to understand that, that is not possible, that is not going to work.

Flexibility in manually monitoring
Q21 P7
61. And there are, if you develop something like that, if researchers want a new size, that's not that hard to add, but I think it's mainly about where and in what format.
62. If you want the output of a code to be just an excelsheet where there is just a date in a Column and then the colloms next to these values, then it must be doable.

Individual monitoring
Q15 P7
36. I just make those simple plots.
38. And then my model has to say, they're either okay or they're not okay.
39. And then you have sizes, how accurrrate are you how sensitive, specitivity.
40. You also have plots that you then generate

Appendix 3.4 - Clusters targetgroup

Importance of preparation

Q13 P8

Importance of preparation

36. A while back at the session where the ministry came by here in the EMC and there were indeed questions asked of when is it indeed a clinical application and when is the research. And if it's in a research phase, they said, then it's probably not going to fall under the AI Act anyway, then it's going to fall under exceptions.
37. Half of the researchers all thought pfoee was fine.
38. But yes, as soon as you want to enter the market, of course you end up with such a whole file and then of course you also have to be able to demonstrate how or what, but I think that remains very difficult to develop in a hospital.
39. At some point, of course, it has to be taken from a research phase to a product or at least to an application within a hospital, yes I think it all seems easy on paper.

Q28 P10

Importance of preparation

29. And that requires once that you sit down and agree with each other, what is the right structure and how do you make it as easy as possible, and once that runs then this is just the easiest way for future research.

Q26 P10

Importance of clarification legal context

74. There are a lot of grey slopes and areas, the support in the field of ICT is increasingly being arranged within Erasmus, with that DRE, with the Research Suite, with the Square initiative, with storage and computer facilities, but the legal context can really be a lot clearer.

Q4 P10

Importance Erasmus MC departments tour

9. We simply said, 'we want to get it right in all areas. So we did a tour of all the agencies and talked through a lot of scenarios with them.

Q5 P10

Importance preparation

11. And also how do you set it up in such a way that you are already prepared for future, perhaps even stricter, legislation. That you are already safe in terms of risk assessment for your techniques.

Q3 P10

Clarification need departments EMC

8. You notice that there is a whole variety of agencies within Erasmus that all have their own task. Sometimes it is not entirely clear who exactly does what.

Q16 P10

Listing actions for requirement

46. We have recorded everything, we have tested everything, we only store our data on service within erasmus MC, we log exactly who has access to the data, we record exactly which patient categories the AI is trained on, but ultimately the AI is not applied clinically.

Preparation

Appendix 3.4 - Clusters targetgroup

Better than nothing

Q15 P10

Precautionary preparation

45. But you can hear all my hesitation, there is no one who can give you a clear answer where exactly you are in the field, so that's why I take it as if it is high risk.

Q23 P10

Avoid being behind the times

75. But at European level it is not yet clear. You also have the impression that policymakers are now working on the state of AI from 5 years ago, but that has grown so exponentially.

Need for training

Q9 P7

Importance of training

25. Of course, this structure helps a lot for your AI, but I don't think there is a lot of knowledge about AI here, apart from my supervisor. Actually, not at all.

Q7 P10

Importance of teaching PhD students

13. You can already teach the students from those tricks, how to make your system less vulnerable, from those very practical things.

Appendix 3.5 - Clusters targetgroup

Consultancy need: Expertise center AI

Need of external regulatory support
Q10 P6
33. We have included the regulatory organizations in the process.

Bad experience with short term consultant
Q4 P9
8. I think that in our process, hiring external consultants hasn't necessarily helped more often, it may have hurt more often than not. Confidence in one's own interpretation is sometimes better, but sometimes not.
11. They were people who had put a QMS on paper within 2 days, which was broadly sufficient. But putting a QMS on paper in 2 days, vs making sure that everyone in the team understands why there are certain rules, what really needs to be done.

Responsible department of structure
Q23 P7
70. According to me, there is an overarching research suite and each department has its own representative, but my supervisor knows better. You really need to talk to him.

Importance of generalist
Q10 P7
26. My supervisor did the bachelor's degree in medicine, then he went to do a neuroscience master's degree, then he got his PhD and then he went on to do his internships and became a neurologist and his goal is always, I want a research group, but I also want to continue to see patients.

Need to converge health & tech
Q16 P8
49. Because you just need a lot of manpower to develop a very extensive AI, we don't have that here. We have a lot of people in-house, but everyone has their own projects, so you don't have engineers that you can just put on it. Then you have to go to Delft or call in help from outside.

Good experience with long term consultant
Q5 P9
9. Having the good advisors is really the core and would have been really the core.
12. We later had a consultant who walked into our office for a week and gave advice for months and trained some of us, something like that I would definitely recommend, but that is also much more expensive.
13. And certainly for technology for which there is no regulation yet, you really need that. You really need that cooperation so that both sides understand each other and know, okay this is what it's supposed to be, that we don't impose too much and don't impose too little. If there is an imbalance, things don't go well.

Including consulting roles
Q8 P9
21. And we also bring in rolls from the outside.

Need for one central point
Q6 P9
15. I think it always helps to have the overview clear for everyone and to have the central point. Whatever system you use for that, I think, that's a good idea, that's valuable.

Importance of generalist
Q6 P8
14. We now have people with different backgrounds, I have both fields of view with my technical medicine background, we have some engineers and of course you have medics.

Balance forced structure and flexibility

Need of overarching structure with flexibility
Q22 P7
64. We now have this great system in neurology, but it is different in every department. In fact, I think they should do that erasmus broadly.
65. I think it is also feasible. Look at a system that we have on the neuro, it doesn't have to look like this, you should be able to do that on any, whatever data you have.
66. And then there just has to be a folder with 'performance model'.

Importance of flexibility in structure
Q11 P8
26. Well, of course, you can make sure that we adapt our behavior to the structure to make it clear. But of course you want to optimize your own data flow and you can go in so many different directions with data that you will get a lot of variation in it, depending on your goal of your research.
27. Also with the provision of the data. That is, of course, incredibly broad. What are you going to store of the data and how and why and for what and what are you ultimately going to do with it. That's going to determine a lot about the structure.
28. I think that is also one of the reasons and I often notice this in the EMC that certain fixed structures would like to be set up, but that this actually makes it more difficult to do certain studies if you organize your research very much on your own objectives.

Flexibility in overarching structure
Q12 P8
29. On the one hand, it's nice if you have some kind of line thread somewhere that you can stick to, but some degree of flexibility is sometimes desirable, because you just don't always do the standard work.

Balance flexibility and structure
Q13 P10
36. That's the balance all the time, you want something that's user-friendly, but if it's very user-friendly, it's generally not as flexible again.

Appendix 3.5 - Clusters targetgroup

Need for overarching structure

Example structure for whole department
Q12 P10
27. Sure, but we've now turned it into a python script that now automatically generates all that whole structure. So the moment you start a project, all you have to do is type in a name and hit enter and it generates the whole project according to that standard template for you.

Importance of preparation
Q4 P7
12. Neurology has a word file how they want all the research to be stored and that is very structured in folders.

Structure importance for traceability
Q11 P7
28. And because he's very structured and wants to make sure things are right, and you can't be sure if you can't find things again.

Need for a repository

Need for repository
Q9 P10
16. I think that as the group grows I want to outsource that, but then we have a few clear templates that you can use. Also from completed similar studies.

Need for template repository
Q13 P7
30. A request was once made from the KNF, this counts 5 years I believe, that we can then use all retrospective data with the fact that we then have to do such a new annonement every time for a new research question, but that is literally a paragraph of text and then they say is good.

Need for repository
Q21 P10
66. I think it would be good if there were also a number of templates available from the organization. Kind of like best cases. We are already making this ourselves. For example, I have one, not WMO protecol at the MREC, under which I can now hang subprotecollen. So I once described in great detail how we apply machine learning, but then we have a lot of projects that are really just variants of previous projects. And for me it now saves a lot of time that I have been able to discuss with the METC once, that is how such a project is arranged, that is how we have our data management plans, for example, we have arranged permission and those 10 projects per year that start that only choose a slightly different population and a slightly different outcome parameter, where else with the same process, we can then place it as a sub variant underneath.

Need for automation

Easiest option
Q30 P10
31. But yes it has to be the easiest option hey, otherwise people won't use it.

Auto versioning need
Q19 P7
52. And then when I change something in my code, it saves a version that it then calls version 2. But I did automate that myself.

Research record keeping importance
Q17 P10
48. Since the techniques follow each other so quickly, and you also want to be able to fully reproduce your research later on.
49. In any case, traceability in this form of research is extremely important.

Need for automation in regulatory process
Q14 P9
36. It's not that advanced yet, but creating and writing the documents, we're talking about hundreds of pages of documentation and we don't even have class 3 products.
37. So people were done with that at some point and thought, we can write something that generates that documentation consistently.

Need for automation
Q15 P9
38. And if you set up documents in code, you can also automate certain things. So if you change one thing here, one thing changes there.
40. It's more about the writing that is automated, but not the thinking work yet.

Example automation in documentation
Q16 P9
39. For example, I have written very simple checks with which PDFs check for very stupid errors, because in a thousand pages you just miss that one page is empty or something.

Automation in QMS
Q17 P9
41. However, with the arrival of chat, GPD and the like, there are companies that already have that ready.
42. On OpenRegulatory you can type a software requirements and it will really automate a lot of things in terms of documentation and that is really the next step.

Guidance

Appendix 3.6 - Clusters targetgroup

The AI Act is not applicable to me

Uncertainty around regulations
Q8 P6
31. AI is still fairly new. Skin is an easy organ for AI.

Importance of project purpose
Q11 P6
37. We then started with the most difficult form of skin cancer, it could well be that we would have looked much wider at this time and, for example, also included eczema.

Importance of framing definitions
Q8 P8
21. When do we think it is sufficient that something is detected? Is that in a healthy population that you can pick people out? Or do you want to look specifically at the application and we look at a very specific arrhythmia, which turns out to be very difficult to detect. Not in a normal population, but if you look at very complicated patients, it doesn't work on that, but that was not the question when obtaining the certificate.

Uncertainty when the AI Act is applicable
Q28 P8
31. I think this also depends very much on what kind of AI you make. Because if you make AI that directly affects a patient flow or a treatment, then according to the AI act, it is already a different AI than something that retrospectively looks at something that has no direct influence.
32. That also makes a difference by definition whether something is a medical device or not.
34. I think it's very difficult to make something clear for that, because it depends very much on your goal of your AI. Where it is used in the entire process in the hospital, but also for what purpose it is used in the entire process.

Unclear what 'high risk' cases are
Q14 P10
41. The AI is a certain tool for us to identify patterns, just like a microscope, but it is not the final product that we are going to use in the clinic.
43. Yes indeed, we train the doctor and not the AI.

Current RMS has limitations

PaNaMa limitations
Q10 P8
25. Yes, actually the example you give is already very good, because for neurology such a format would work well, we use data in a slightly different way, so we need a different format, so you can work with fixed structures, but what you actually see often with certain studies is that you cannot use all those structures yourself properly.

Limitation of current RMS
Q20 P10
65. Systems like PaNaMa or Research manager is also very cumbersome all the different protecollen that are needed for it.

Grey area

Gray area awareness
Q2 P8
3. I think the most important thing is still, even with the new AI regulations, how vague everything is and what consequences it will have.

Now is the start of conversations AI Act
Q11 P9
31. As a company, I can say that the conversations and initiatives to talk about the AI Act are only now starting to happen.

Same process but additional requirements
Q13 P9
34. With the bit of reading I did myself of the AI Act, there were some things that at least seemed good to me and will not have to be too much trouble.
35. If you look at the very highest level, the same processes still apply and some more specific requirements are required.

Appendix 3.6

Technology innovates faster than legislation

Different setup of current algorithms
Q1 P8
2. The new AI regulations that are of course something that is coming, but our own algorithms are not yet completely made with that point of view. That might already be a point to take away for evaluation.

Development before regulation
Q9 P6
32. We have always been at the forefront of regulation. We were one of the first apps to come online and do clinical research.
48. In the beginning we were allowed to enter the market, because there was no regulation yet, then there was regulation, but we were seen as relatively harmless and we were allowed to take care of the documentation ourselves. And now the guidelines have been adjusted and we have to work with an NB.

Waiting time NB
Q7 P6
28. We have started the process, all documentation is in place, but we have to wait for an NB. We are in the middle of the process, but we still have a few years to do that.

Limitation

Given examples of explanations of AI complexity

Danger of AI models
Q1 P7
3. We specifically chose a patient group in intensive care. These are all patients after cardiac arrest. Here they are already visually looking at the EEG to be able to give a prognoze and based on what a clinical neurofisiologist says, a treatment is or is not discontinued, so that is about quite serious things. I am now looking to see if I can predict those results.

Consider purpose of AI
Q16 P7
46. That is also what my supervisor insists on, I do not want to develop things that we no longer understand ourselves, because it is now about patients and we want to help decide, do we continue with the treatment or not. Pretty intense.

Examples given by P10
Q22 P10
Examples:
74. There are a lot of grey slopes and areas, the support in the field of ICT is increasingly being arranged within Erasmus, with that DRE, with the Research Suite, with the Square initiative, with storage and computer facilities, but the legal context can really be a lot clearer.
- Date of birth dates by number of days from birth
- Trained at 60-80 years old and a 20 year old also has the pattern, you should be skeptical (21.51)
- Which data can be used from entry (34.40)

Testing quality of synthetic data
Q24 P10
80. The student on that project investigates how we guarantee how this syntetic data is actually equal to our measurements of brain activities.
81. Some of our students come purely from a mathematics background and are only concerned with optimizing the technique and they could easily work on that syntetic data alone.
82. Then they only work in the DRE as far as I'm concerned, but then you've made it a step safer.

Required vs non required assessments
Q14 P6
49. There are a lot of assessments and other things that overlap with each other.
50. Most importantly, if you are not yet in the market and you are doing a study, then you need an METC approval. In fact, they do the same thing that an NB does.
51. Actually, it doesn't differ that much what those parties look at.

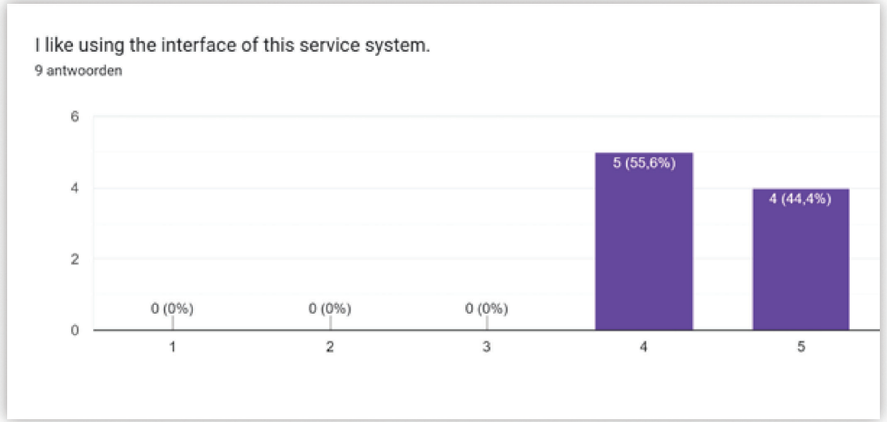
Listing departments and functions
Q2 P10
7. At the end of the day, you have a department head that you are accountable to. You have an METC for which you account for research projects. We have the research suite here that I regularly consult with. You have the privacy officers, for example, when it comes to which patient data you can and cannot use.
10. I have consulted with the lawyers of PKO (bureau for privacy regulations). I have had several contacts with the research suite, how do you store your data safely. The METC determines what falls under the WMO, what does not fall under the WMO.
51. The reseachsuite is already very active in this, they keep you informed with what possibilities there are.
52. In addition, there are also collaborations within Erasmus for those who work with AI. So you have Square AI and other initiatives.

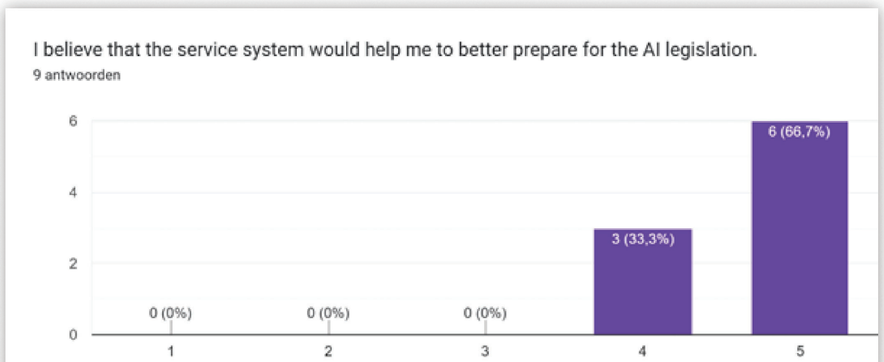
Transparency to users (patients)
Q6 P6
25. At the moment, every user gives permission that his / her data may be used for research and improvement of the algorithm.
26. This is an ongoing process, so it remains clear to the user what they are consenting to.

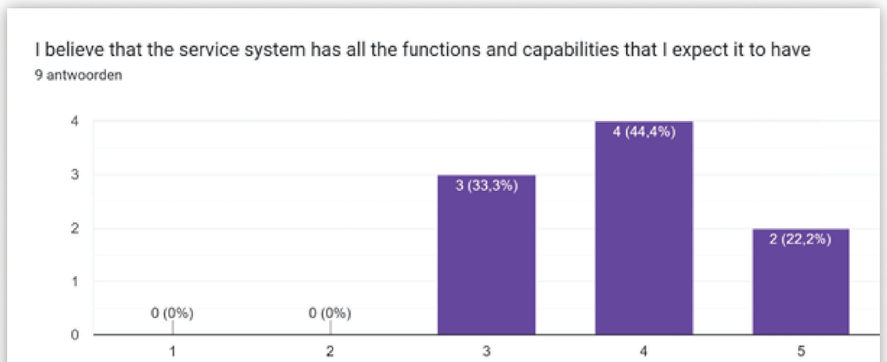
Assessment of on-WMO METC
Q12 P7
29. I haven't been there myself, but my research is known to the non-WMO METC.

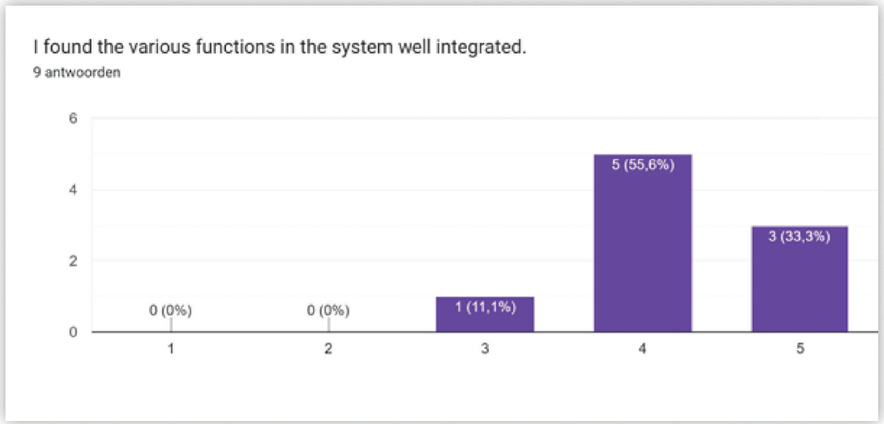
Appendix 4 - Survey Results

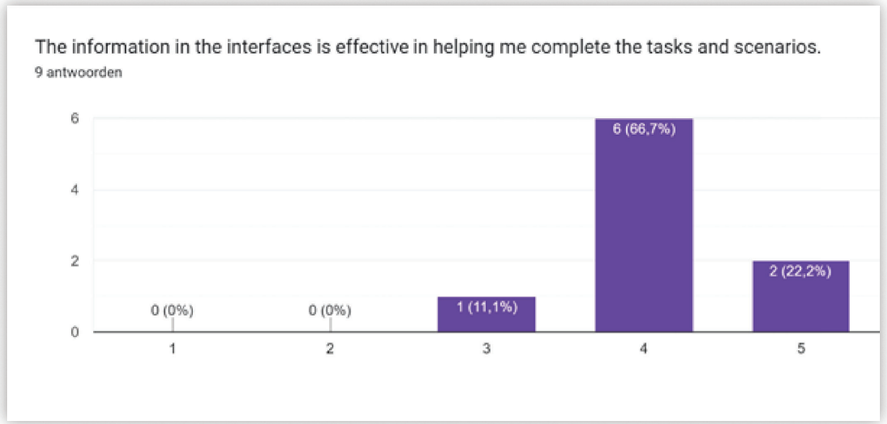
This appendix contains the responses to the evaluation questionnaire. Google forms was used as an online questionnaire that generated these plots as an outcome.







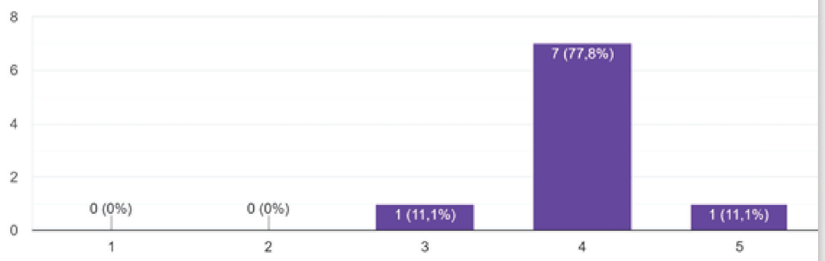




Appendix 4 - Survey Results

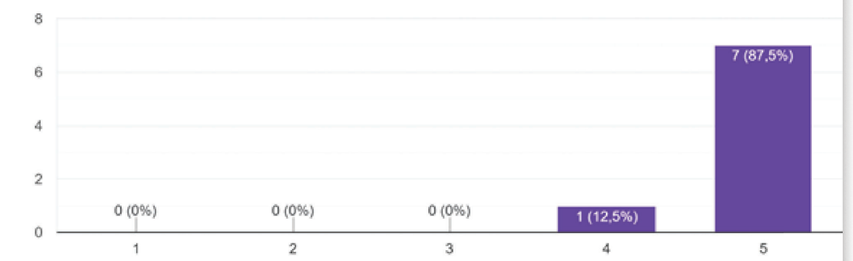
It was easy to learn to use the service system

9 antwoorden



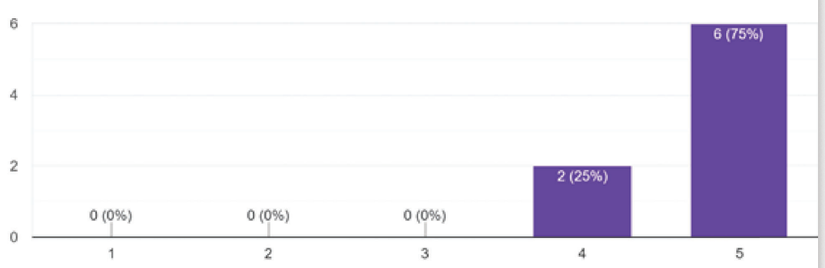
I see the benefit of having a repository, where you can look up similar documents from other projects.

8 antwoorden



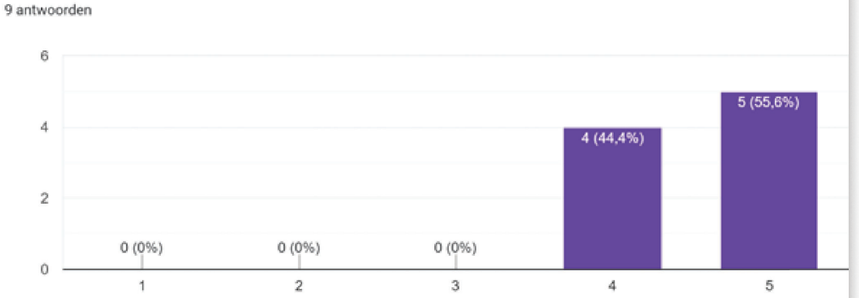
I see the benefit of automation through automatically filling in the required documents based on the data in the register.

8 antwoorden



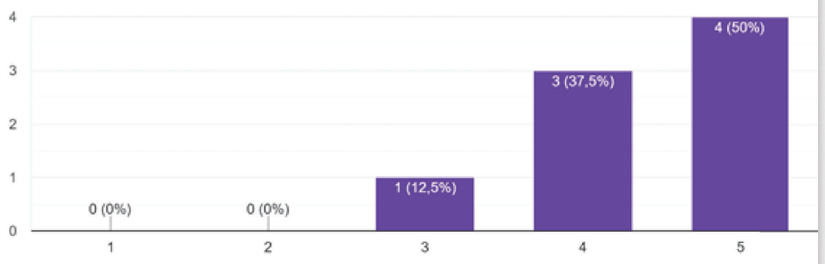
I see the benefit of automation through automatically displaying others' completed questions from similar documents and projects.

9 antwoorden



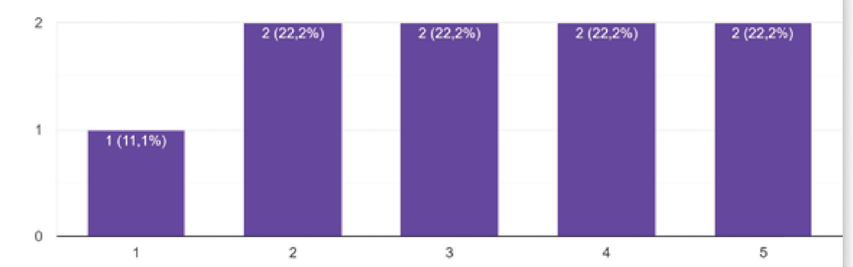
I see the benefit of transfarability through enabling data exchange with the government register and other systems.

8 antwoorden



The user research resulted in both a demand for a clear leading structure and a demand for flexibility to customize. How did you experience the system?

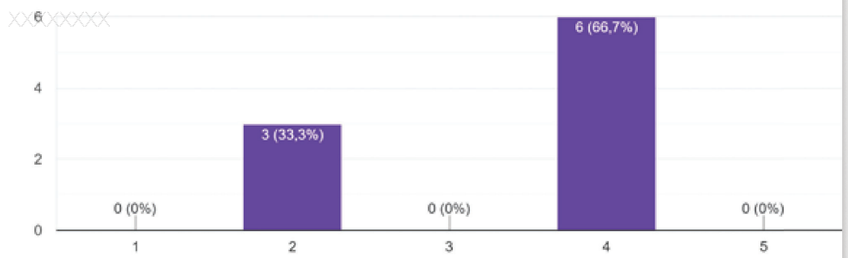
9 antwoorden



Appendix 4 - Survey Results

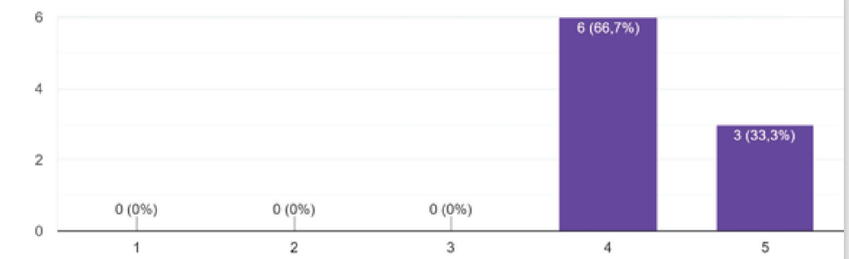
This service system evaluation has made me more aware of the ethical responsibilities involved in an AI project.

9 antwoorden



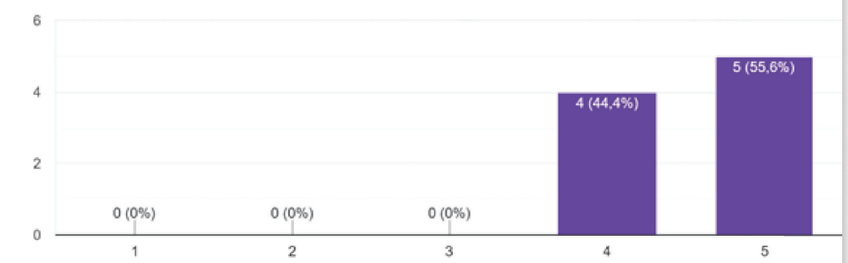
I believe this service system will contribute to the guidance that the AI expertise team will provide.

9 antwoorden



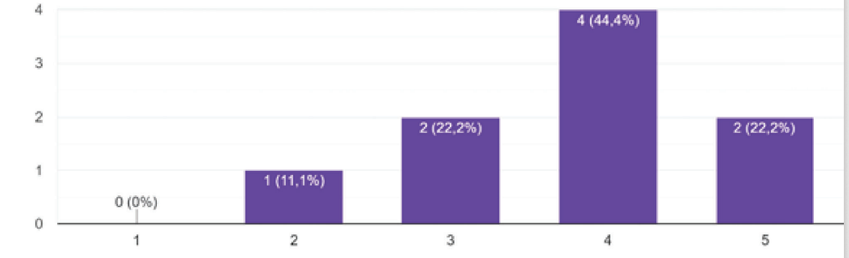
I understand that the regulations of the AI Act will require more action and I am convinced that such a service system could help to meet these requirements.

9 antwoorden



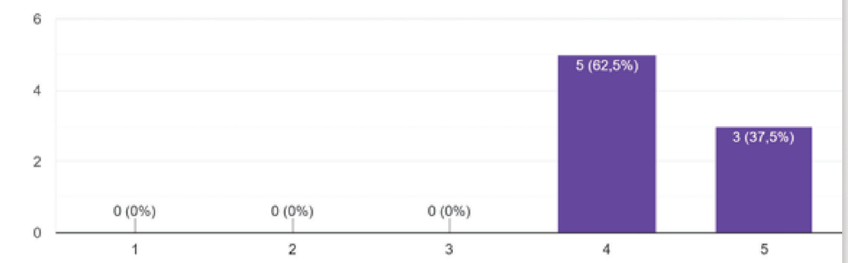
I would not mind if this registration were made mandatory and its use monitored.

9 antwoorden



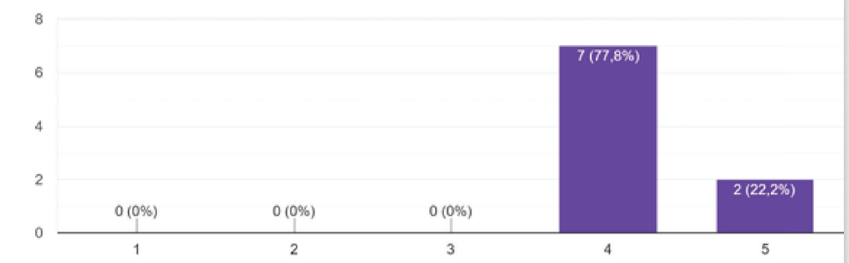
Overall, I am satisfied with the service system.

8 antwoorden



I recognize the added value of the system and I would recommend it to be realized.

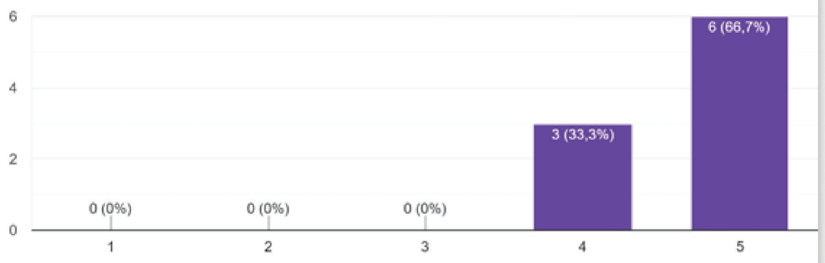
9 antwoorden



Appendix 4 - Survey Results

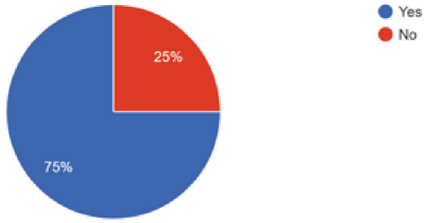
If this service system were to be realized, I would recommend it to AI project members.

9 antwoorden



If this service system were to be realized, I would you like to be part of the co-creation?

8 antwoorden



Which kind of reward would encourage you to put more effort into the documentation?

7 antwoorden

- a beautifull page on the website or promo via linkedin for my project
- Dat de toepassing merkbaar sneller tot een implementatie overgaat
- That's a difficult question. The main issue I can see with putting effort into this is a conflict of the interest. When as PI I am more interested in finalizing as fast as possible the project and paper, to publish it, then spending time on internal documentation. So, there should be some rewarding system implemented for such motivation.
- Eigen belang
- To be reprimanded when documentation is not provided
- If you cannot continue unless your document has been reviewed
- Financial reward (eg to invest in new assays/biomarkers/equipment - research focussed, not own pocket)

If you have any additional recommendations or other feedback, please mention below:

4 antwoorden

- thanks for making this system!
- Sommige vragen kon ik niet volledig beantwoorden omdat ik alleen een demo gezien heb en niet er actief zelf mee heb zitten werken
- Een uitgebreide handleiding van de sevice system zou een fijne toevoeging zijn. Hiermee kan je de zelfredzaamheid van de members verhogen & zijn alle handelingen en stappen makkelijk terug te lezen. Het zou goed zijn om in de handleiding nogmaals het nut te benoemen van de service system.
- Emphasis on the added benefit to users. They need to work according to legislation with or without this system. Therefore, resistance to using the system will only make things more difficult for the user.

  In addition, a lot of information for the underlying legislation and standards would be beneficial for users. This would get users to not only submit the forms, but also to know which standard they are fulfilling by filling in the form.

Appendix 5 - Clusters Evaluation

The notes collected during the evaluations were translated into quotes and these quotes were then clustered. Clusters of the evaluation notes can be found on this and the next page.

Improvement Tips

Already implemented

Q3 "I recommend testing it with many different stakeholders."

Q4 "The questions from the Fundamental Rights and Algorithms Impact Assessment must be asked before you start a project in the first place."

Q6 "In team management, you want to find the tasks easier than the roles. People generally know the roles."

Q12 "The link to GitHub is not a link to a monitor device. This should be worded differently or taken out, otherwise it gives the wrong impression to people. For example, it could be called "code repository."

Manual/video

Q7 "I would recommend making a video explaining the concept."

Q36 "I would recommend including a manual explaining the processes."

Q37 "I would explain how tedious the processes and systems can be now and how it supports in this in order to get more people to join in using them."

Q39 "An extensive manual of the service system would be a nice addition. This allows you to increase the self-reliance of the members & all actions and steps are easy to read back."

Q40 "It would be good to mention the usefulness of the service system again in the manual."

Q41 "Emphasis on the added benefit to users. They need to work according to legislation with or without this system. Therefore, resistance to using the system will only make things more difficult for the user."

UI

Q15 "I would show in a way which project you are working on when you click on the other parts."

Q17 "When someone submits the document it should automatically be saved in the correct folder to avoid errors."

Q18 "A general 'help' option that provides additional explanation could be a good addition."

Q21 "I would recommend changing AI to algorithm, since algorithm research and applications need to take this into account as well."

Q23 "It would be nice if there were options to go back and forth in the process. Through soft go's in the interim and hard go's at implementation."

Q26 "It would be nice if you are flexible in getting to the gates allowing you to work in different gates at the same time."

Appendix 5 - Clusters Evaluation

Positive Tops

Q5 "Good that it was made right in the style of Erasmus MC. This looks professional."

Q9 "PaNaMa cannot be used for everything, hence an umbrella system would be better."

Q14 "The Project page provides a clear overview of the components."

Q16 "It would be very helpfull if we could share these documents within Erasmus MC."

Q20 "Good that you draw attention to accountability. The Board is responsible, then the department head, then the supervisor and then the PhD student. Arguing and reporting this is very important."

Q22 "These innitiatives should be there to make it clearer to us clinical specialists what is expected of us."

Q28 "It is always good to share knowledge and be transparent to patients."

Q30 "Examples are always good to demonstrate."

Q31 "If such a service system were facilitated it already gives a lot of support and guidance."

Q32 "An overview of the whole process is already great to have."

Q33 "Thanks for making this system!"

Q38

Further Recommendations (out of this projects scope)

Q1 "Shouldn't this be established across the entire UMC (University Medical Center)?"

Q2 "You want to become Technical UMC in 2028, with such a system you can get ahead of other UMCs and they can take over later."

Q8 "This would be useful for many more use cases."

Q10 "It would be nice if that kind of system could be implemented in the near future."

Q13 "Specialists are needed to develop this further."

Q19 "Some AI research does fall under WMO duty at the METC. Perhaps that is why more sections of the METC could be added."

Q25 "The risk of a timeline is that you force yourself to think this way, but it doesn't work that way in real life."

Q27 "The development of such a system should be centralized."

Q29 "Clarity of the legislation would be nice since the MDR is also still very messy."

Q34 "To make it reproducible, it must be connected to data storage. Therefore, I recommend working with anDREa and other similar platforms."

Q35 "To make it consistent, a back-end infrastructure should be created."

Q42 "In addition, a lot of information for the underlying legislation and standards would be beneficial for users. This would get users to not only submit the forms, but also to know which standard they are fulfilling by filling in the form."

Appendix 6 - Test Script

Evaluation Concept Service
System graduation project

Graduation project SPD Denise de Vries

In order for Erasmus MC to be well prepared for the AI Act, a concept of a service system has been developed which aims to help the members of an AI project team meet the requirements of this new regulation. With this form, the goal is to find out the experience of the future users of such a service system.

1. You are the supervisor of the AI research: Log-in
2. Add a new project
3. Get more information about the FRAIA
4. Submit FRAIA
5. Connect to your monitoring software
6. Register the main components:
    a. Click on ‘date of creation’
    b. Click on keybord ‘V’ and than on enter
    c. Click on the ‘type here textboxes
7. Chose the components you want to show on the website (first 3)
8. Go to the website
9. Click on an example research case to look at the example
10. Go back to the system
11. Update the register information with the national register
12. Go back to the system
13. Go to project 1: You want to manage the team
14. See the task overview
15. Get the overview of the team members and their roles and responsibilities
16. Manage the structure of your PhD students by editing the protocol
17. Go to project 1:
18. Look for comparable documents in the Repository: a PhD research on the Intensive Care working on time efficiency optimization
19. Add both cases as comparable templates
20. You want to fill in the Technical Documentation phase 2. Let the general information automatically be filled in.
21. Fill in the additional questions (click on keybord ‘right’ and ‘left’ to change the comparable answers)
22. Request a review of the legal advisor.
23. Log out
24. You are the legal advisor:
25. Log in
26. Wait
27. Review record
28. Submit and safe record

Appendix 7 - Project Brief

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT

Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name: de Vries
initials: D given name: Denise
student number: 4539095
street & no.:
zipcode & city:
country:
phone:
email:

Your master programme (only select the options that apply to you):

IDE master(s): ( ) IPD ( ) DfI (★) SPD
2nd non-IDE master:
individual programme: (give date of approval)
honours programme: ( ) Honours Programme Master
specialisation / annotation: (★) Medisign
( ) Tech. in Sustainable Design
( ) Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: Richard Goossens dept. / section: AED
** mentor: Hosana Morales Ornelas dept. / section: IoT
2nd mentor: Margrietha H. (Greet) Vink
organisation: Erasmus MC
city: Rotterdam country: Netherlands

comments (optional)

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

Procedural Checks - IDE Master Graduation

APPROVAL PROJECT BRIEF
To be filled in by the chair of the supervisory team.

chair Richard Goossens date - - signature

CHECK STUDY PROGRESS
To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair.
The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: _____ EC

Of which, taking the conditional requirements into account, can be part of the exam programme _____ EC

List of electives obtained before the third semester without approval of the BoE

★ YES all 1st year master courses passed

NO missing 1st year master courses are:

name date - - signature

FORMAL APPROVAL GRADUATION PROJECT
To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **.
Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: APPROVED NOT APPROVED

Procedure: APPROVED NOT APPROVED

comments

name date - - signature

Personal Project Brief - IDE Master Graduation

Improve traceability and transparency of medical AI throughout their life — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 06 - 03 - 2023 31 - 08 - 2023 end date

INTRODUCTION **
Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Due to the older growing population and the current and future shortcomings of healthcare staff, more care is needed, but there are less specialized people available to give this care. (World Health Organization: WHO, 2022) Artificial Intelligence (AI) will be one of the technologies to fill this gap in the future. AI is already being used in various areas of medical care, e.g. for diagnosis and prediction-based diagnosis or to support clinicians to provide more personalized care. (WHO guidance, 2021) The European Union are working on regulations that make the use of algorithms for AI safe, but this will also slow down the process of implementing AI in healthcare. Therefore, it is very valuable to streamline all the processes of regulation and corresponding documentation so no more time is lost than necessary.

There are multiple stakeholders with different background who have to work together to eventually enable the usage of these AI applications in hospitals. An AI developers need to work closely with AI responsable staffmember, clinicians, patients, social scientists, healthcare managers and AI regulators. (Scientific Foresight Unit, 2022) The interaction with patients means that the AI developers need to ensure that the algorithms for AI aligns with all the regulations. Which means that the algorithms for AI should be approved on all aspects: technical (e.g. safe system enginering) , medical (e.g. risk management) and ethical/social (e.g. data security). (Figure 1)

An AI Act is currently being developed to ensure safety, but there is no clear overview of the requirements yet. Even though some AI applications are currently allowed to be used, they must still comply with the regulations retroactively after the AI Act is finished. Therefore, it is likely that AI developers will not have the proper documentation ready on time. This will result in a situation where they are sent back and forth to meet all the requirements for ex-post enforcement. Erasmus MC sees a great opportunity to faster this process by guiding the AI developers to be transparent with the right documentation from the start. It is expected that this guidance will clarify the evaluation process of medical algorithms for AI. (Figure 2) (Scientific Foresight Unit, 2022)

Ethics and governance of artificial intelligence for health: WHO guidance. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Scientific Foresight Unit. (2022). Artificial intelligence in healthcare Applications, risks, and ethical and societal impacts. European Parliamentary Research Service. doi: 10.2861/568473

World Health Organization: WHO. (2022, October 1). Ageing and health. https://www.who.int/News-Room/Fact-Sheets/Detail/Ageing-and-Health

space available for images / figures on next page

introduction (continued): space for images

Fig. 1.3.1 The IDE domain

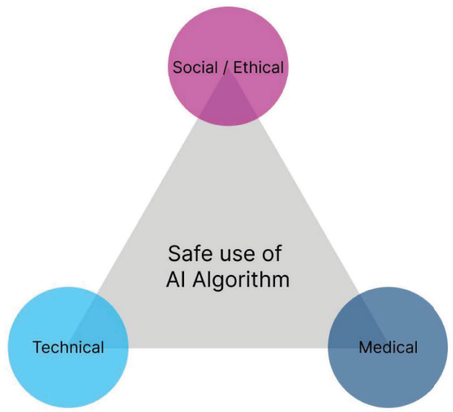


image / figure 1: The triangle for a safe use of algorithms for AI

Figure 12 – Example of a multi-stage approach for medical AI evaluation

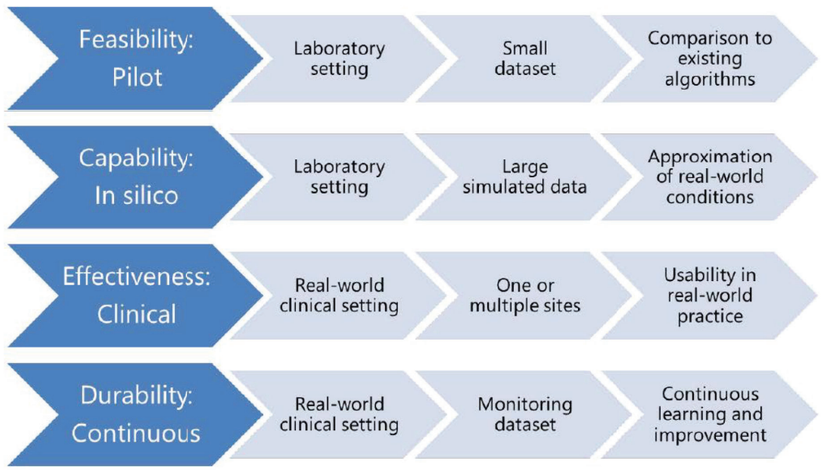


image / figure 2: Medical AI evaluation approach (Scientific Foresight Unit, 2022)

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

The risks of the usage of algorithms for AI are especially high in healthcare when it comes to patient safety and privacy. An AI Act is currently being developed that include an Impact assessment to test human rights and other important impacts of the use of these algorithms. (Ministerie van Algemene Zaken, 2022) Transparency of the whole development process is therefore needed to ensure that it is safe to use the algorithms for AI, but currently there is a lack of this transparency. (Scientific Foresight Unit, 2022) There is no common storage place that enables you to trace the documentation. There is also a lack of guidance for AI developers within this documentation process, who often are not specialized in regulations within the healthcare sector.

In this project I will define the difficulties AI developers face during the documentation process within the healthcare sector and I aim to guide them through this process to improve traceability and transparency of medical AI throughout their lifecycle.

Ministerie van Algemene Zaken. (2022, December 21). AI Impact Assessment. Rapport | Rijksoverheid.nl. https://www.rijksoverheid.nl/onderwerpen/rijksoverheid/documenten/rapporten/2022/11/30/ai-impact-assessment-ministerie-van-infrastructuur-en-waterstaat

Scientific Foresight Unit. (2022). Artificial intelligence in healthcare Applications, risks, and ethical and societal impacts. European Parliamentary Research Service. doi: 10.2861/568473

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

Design a service system combination, that will store all documentation during the development of (new) medical algorithms for AI, by guiding the AI developers to the required documentation, which will improve traceability and transparency of medical algorithms for AI throughout their lifecycle.

This service system combination will be a digital safe space (e.g. passport or wallet). With the research I aim to discover the best strategy to improve the documentation process and I will base my design on this strategy.

This strategic approach for healthcare purposes shows that the assignment fits within the medisign specialization.

In this project, the focus is on the visual prototype of a digital safe space to show how a service system combination can be designed in such a way that the AI developer is guided in the right direction. No working product will be created, but recommendations will be made on how this overarching safe system could be developed.

Research question:
- What can AI developers encounter during the documentation process for the regulations of the AI act?

Design question:
- How can a hospital develop a service system combination to give more guidance to AI developers within the regulation process of the AI Act?

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 6 - 3 - 2023 31 - 8 - 2023 end date

			For more details about the workload, look at the other planning.																								
Week number			10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
Project week			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
Research	Discover	**Literature research** AI in healthcare																										
		Interviews Medical AI developers Valorisation specialist Etc.																										
		Observations Impact centre AI used in healthcare context																										
	Define	**Findings** Statement cards of interviews Gathering main other findings																										
		Clustering																										
		Defining focus points Define where guidance is needed Define where transparency is needed Define where traceability is needed																										
Design	Develop	**Ideation (Co-creations sessions)** How to make medical AI traceable & transparent and how to simplify this documentation process																										
		Conceptualisation Creating 'digital safe space' for AI Creating 'guidance'																										
		Testing (Co-creation) Testing concept and adjust																										
	Deliver	**Finalizing design** Adjusting concept																										
		Finalizing report																										
		Finalizing presentation																										

Above you can find the planning of my graduation project. I am currently working as a student assistant and therefore I plan to spend 35 hours a week on average on my graduation. Which means that the duration of my project will be 24 weeks. In total this will make the requirement of 35*24=840 hours (100 full-time days, 30 EC). I also chose to have a vacation (table: green filling) during the summer break. I realise that the availability of chair and mentors are limited during the summer break and this is the reason that I planned my graduation at the end of august. I will also try to be as flexible as possible during this period.

You can find the important dates (table: orange filling) where everyone must be present below:
- 6 March: Kick-off (Day 1)
- 4 May: Midterm Evaluation (Day 40)
- 13 July: Green light (Day 80)
- between 24-31 August: Graduation (Day 100)

I divided my project into a research and a design parts where I plan to spend more time on the design part. Within these parts you can find four phases, the double diamond: discover, define, develop and deliver. I will try to finish the research part (discover and define phase) before the mid-term. During the greenlight meeting I plan to have already tested some concepts (develop phase) which will ensure that I still have enough time to finalize these concepts (deliver phase). The components within these phases are explained in the schedule above.

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

My interest in healthcare has always been there. The extra value you are able to offer within the healthcare sector is fulfilling. As a strategic designer I also am interested in complex systems and problems, and my aim is to visualize the structure in this complexity. Especially in healthcare the problems that are occurring are becoming more and more complex caused by the aging population in combination with the rising cost and a lack of medical specialists in healthcare. Therefore this is the sector where I would like to add value.

I will link healthcare with technology so that some processes in the current healthcare system can be digitized, which will make sure that the professionals can continue to do what they are already good at: the treatment of the patients. With the overall goal of reducing the workload for healthcare personnel.

During the master's program at SPD, I discovered the importance of the implementation process of technology. My drive to solve problems expressed itself more and more to the way that I search where in the development process of innovation I can exert the most influence.

Within this project I want to challenge myself to not only work with a solution oriented perspective, but also with a result-oriented perspective by focussing on a design that will improve the implementation of algorithms for AI.

I specifically chose a totally different sector for my graduation project to learn about the environment of a hospital and the complexity of all the regulations. I will challenge myself to be assertive and show another discipline the value that strategic design can offer.

During my master I joined the Medisign board where I learned a lot from the other members but also trained my organizing skills as an event manager and a Chair. I would like to show my organizing competences by facilitating co-creation sessions and take the lead in my own graduation project.

I want to improve my knowledge of AI in healthcare and the regulations for not only algorithms for AI but also other technologies within healthcare. With this knowledge I hope to become more aware of the limitations within healthcare, so I can eventually use my background for interdisciplinary communication within my career.

Within this project I am planning to experiment more with system-design or process-design by focussing on the guidance of the documentation process within the development of AI and I aim to make this process less of a burden for AI developers.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.