HEALTH DATA SHARING FOR CLINICAL RESEARCH:
Designing a patient-centric approach

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TU Delft

oasys now

APPENDIX

APPENDIX A– STAKEHOLDER RESEARCH

DOCUMENTATION OF STAKEHOLDER RESEARCH

Following includes the documentation associated with stakeholder research- interview questionnaires, value redefinitions.

INTERVIEW QUESTIONNAIRE

STAKEHOLDER INTERVIEWED– PATIENT

THEME 1: GENERAL QUESTIONS
May I know a little bit of your medical condition? (You may keep details private.)
THEME 2: WITHIN THE PATIENT JOURNEY
(show picture of patient journey)
What was your diagnosis journey like?
What has been your experience with HCPs during diagnosis?
Has your HCP ever advised you to reach out to organizations outside of healthcare for guidance on your condition?
THEME 3: OTHER CONTRIBUTORS
Have you ever been enrolled in a clinical trial for your condition?
Based on what factors do you enrol in a clinical study?
At what stage in your patient journey do you register for clinical trials?
Do you have any concerns about your medical data when you register for trials?
What patient organizations are you enrolled in for your condition?
Do you stay connected to other members of the PO outside of workshops/events?
Are there any digital services you use to support your treatment? (eg: health monitoring apps/ fitbit)

STAKEHOLDER INTERVIEWED– PATIENT ORGANIZATION

THEME 1: GENERAL QUESTIONS
What patient organizations are you a member of, and how long have you been a member?
May I ask a little more about how the organization functions?
How do patients register onto your organization?
THEME 2: WITHIN THE PATIENT JOURNEY
(show picture of patient journey)
Where are the patients in their journey when they reach out to your PO? Only after diagnosis?
In what ways does your PO offer support to patients in different phases of their journey (diagnosis, testing, treatment)?
What are the challenges the PO experiences when providing support to patients?
THEME 3: OTHER CONTRIBUTORS
Does the PO have collaborations with other parties to help support your vision? (doctors for example)
What expectations do you have from these collaboration efforts?
CLINICAL RESEARCH
How does the PO impact on-going clinical research?
What are the motivations for a PO to be involved with clinical studies?
DIGITAL SERVICE
Does the PO anticipate the use of digital services in their day-to-day activities?
WRAPPING UP
What role does the PO imagine playing for their members in the future?
Is there anything I did not ask that you think might be relevant or that you want to tell?

STAKEHOLDER INTERVIEWED– CLINICAL RESEARCHER

THEME 1: GENERAL QUESTIONS
Can you briefly describe your work as a clinical

researcher?
At what pace does your clinical research usually go? Monitor timeline
How do you gather participant data?
THEME 2: PATIENT DATA AND ETHICS
Do you work with both genomic and demographic data of your participants? (When biobank/GWAS/labs)
On what conditions do you usually gain access to participant data? (eg payment/return of results offered?)
What privacy and discrimination considerations do you make while working with this data?
What responsibilities do you usually have to ensure participant consent?
Do you offer clinical research returns?
THEME 3: OTHER COLLABORATIONS
Do you also collaborate with researchers at BioNTech/pharma during your research?
With the ongoing trend of patient involvement in clinical research, have you ever collaborated with a PO for your research?
EXPERTISE QUESTIONS
Given your background in epidemiology means that you often work with population-level data, what are some of the challenges you experience?
You teach 'Genomics and Governance' as part of a master's course at Erasmus, what are your thoughts on informed consent?
WRAPPING UP
As a researcher and educator, what role do you see participatory methods of genomic research play in the future?
Is there anything I did not ask that you think might be relevant or that you want to tell?

STAKEHOLDER INTERVIEWED– CLINICAL OPERATIONALIST

PARTICIPANT RECRUITMENT
During many cohort studies, participants recruited are often expected to be involved in the study long-term. What are the risks involved?
How do you manage the risk of transient patients?
Would you say that studies are developed with a sensitivity towards the needs of patients with rare genetic diseases?
DATA REPURPOSING
Data gathering stage of clinical research is often the most time intensive.
However, do you often see opportunities for clinical data repurposing between different studies? Is that in practice?
If not, what regulatory challenges would you anticipate?
PATIENT ENGAGEMENT
Given that patient engagement in research is increasing, how would it affect the management of clinical research?
What ethical risks do you anticipate?
For patients with rare genetic diseases, would you say that collaboration with patient organizations be a good approach?
IMPLEMENTATION
Do implementations of clinical research ever go misaligned?
What do you think is the reason?
What are your thoughts on patient engagement as a means of overcoming that?
What other opportunities do you see for involvement of patients in research?
INDUSTRY
Clinical research in the pharmaceutical industry is often fast-paced.
Would you say that collaborations with pharmaceuticals drive more impactful solutions?
WRAPPING UP
As an industry expert, how do you anticipate clinical research being reformed in a time where everyone is also capable of generating their own clinical data?
Is there anything I did not ask that you think might be relevant or that you want to tell?

STAKEHOLDER INTERVIEWED– DATA SHARING PLATFORM

USER-CENTRIC
Your platform is a means of creating access to one's own health data, thereby creating agency in people's lives.
Would you say autonomy to one's own data is a part of the service you offer?
Any other?
Do you anticipate any challenges with stakeholders who would like more reliable sources of health data?
COMPENSATION
Ethical research practices always involve a proposal for returning research results, but often also include participant remuneration.
Would you say that your platform can also offer both?
What would you need from stakeholders (both) user and client to ensure that individual participants are offered fair compensation for their level of involvement in clinical research?
DATA INTEGRITY
Clinical researchers place a focus on data collection sources to ensure quality of data.
What are your risk mitigation strategies to ensure clinical grade medical data?
Do you anticipate any challenges with either user/customers regarding the same?
What responsibility will you as a service provider, be taking into consideration to ensure that integrity on your platform is maintained?
PRIVACY
A private environment often means a non-disclosed environment.
What do you think can be the consequences of that on transparency?
What risks do you anticipate for your stakeholders?
With your service, how do you anticipate the interaction between user and client?
WRAPPING UP
In the age of booming self-test DNA kits and health data generating devices, how do you see your platform empower patients in different stages of their journey towards treatment?
Is there anything I did not ask that you think might be relevant or that you want to tell?

VALUE REDEFINITIONS

ETHICAL STACK VALUES VS. REDEFINED VALUES

WELL BEING
Paying attention to the physical and mental welfare of the users and developers, designers and testers of the product.
WELL-BEING
Paying attention to factors that influence the physical and mental welfare of the patients.

DIGNITY
The feeling of control over one's own destiny that entails relationships of respect. Having a say in tracking, surveillance and control through IoT products. Ensuring that no individual or group should be adversely affected or dehumanised as a result of using or not using a product. Reflecting on the implications of connectivity in spaces and contexts users might consider as private.
DIGNITY
The feeling of control (or offering the other control) over one's own (or their) destiny that entails relationships of respect. Patients (or individuals) being able to have a say in how their own experiences should be, and exerting control within the environment and within relationships with other stakeholders that can adversely affect their own experiences.

TRANSPARENCY
Striving towards achieving clarity throughout

the technology development process about the source of materials, hardware and data that goes into the product, including communication of the source of funding for the product.
TRANSPARENCY
Striving towards achieving clarity throughout the process about the use of health data and how the implementation of the clinical research would look like.

DATA PROTECTION
Control over access to and use of private data. Making sure that users are not adversely affected by the data that is collected, processed or analysed about them- both as individuals and as groups. Giving them the control to erase or alter their data, should they wish to do so.
DATA PROTECTION
Control over, access to and use of private health data. Making sure that patients (or individuals) are not adversely affected by the health data that is collected, processed, or analyzed about them for research- both as individuals and as groups. Giving them the control to erase or alter their data, should they wish to do so as a form of consent.

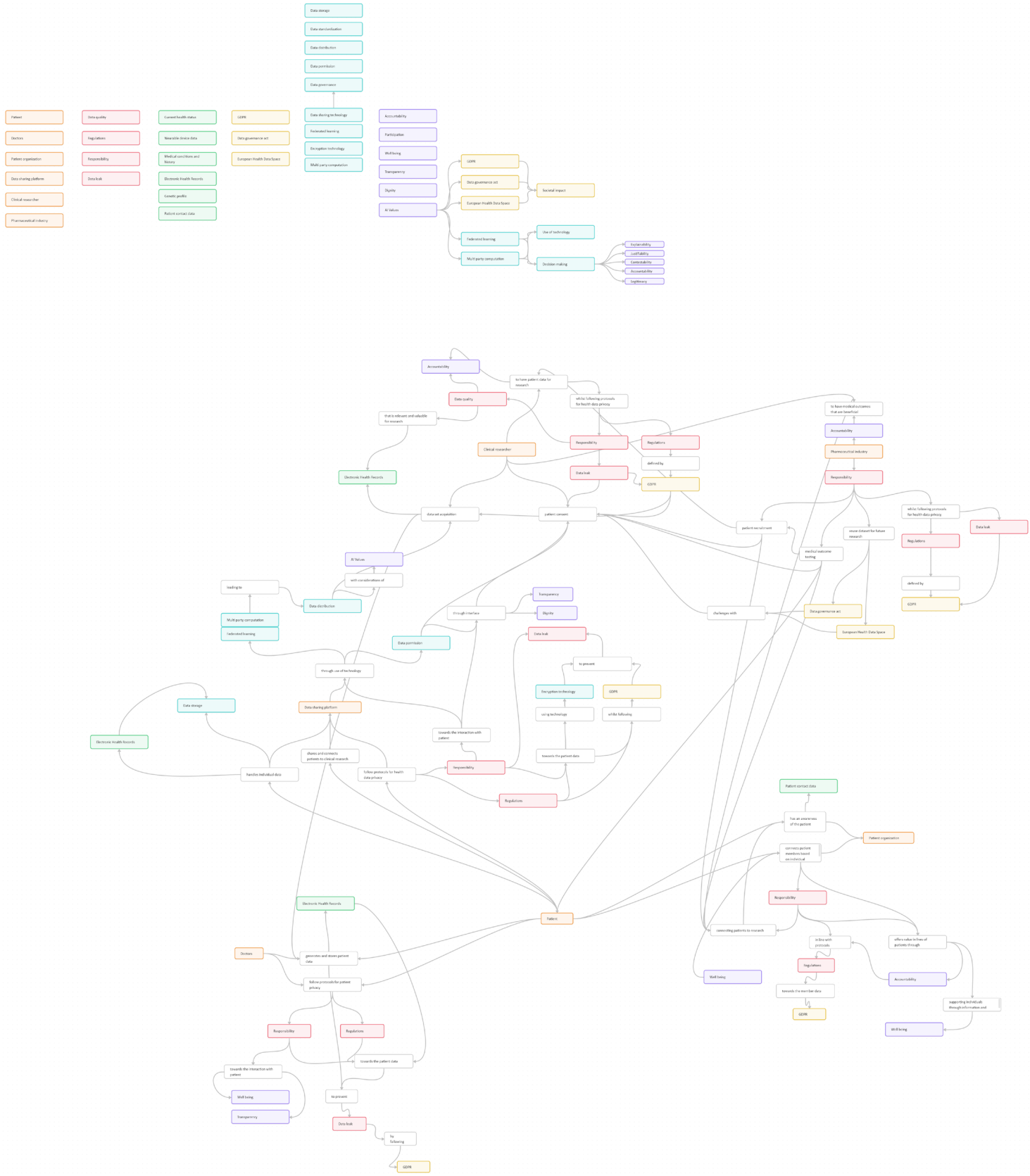
RESPONSIBILITY
Assuming duty to take care, being in charge of the decisions taken in a technology development process.
RESPONSIBILITY
Assuming duty to take care, overseeing their own individual tasks undertaken to advance the decisions taken in the clinical context.

PARTICIPATION
Encouraging the users to take active part in the design and development of technology development, whenever possible. Engaging in a dialogue with users throughout the lifetime of a product and ensuring that their voices are heard.
PARTICIPATION
Encouraging collaboration with other stakeholders throughout the clinical research and ensuring that their involvement is deemed important.

ACCOUNTABILITY
Assuming responsibility and explaining why a decision has been taken the way it has been, if or when potential risks are identified or when adverse consequences of a decision take place.
ACCOUNTABILITY
Assuming responsibility and explaining why certain decisions (in the clinical context) are taken the way they have been, if or when potential risks are identified or when adverse consequences of a decision take place.

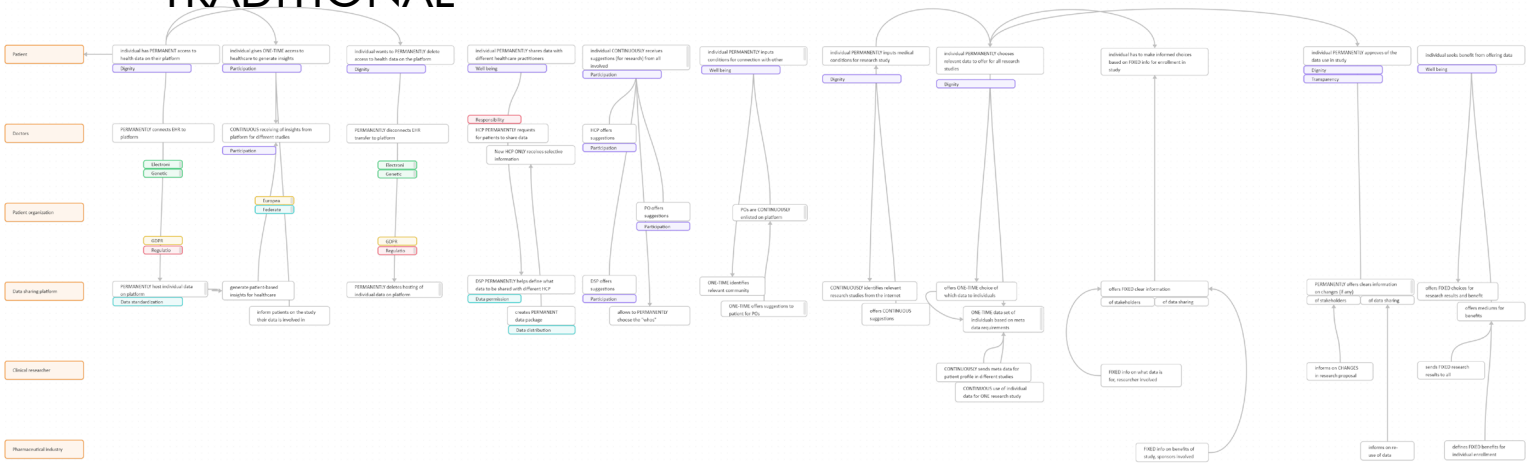
SUSTAINABILITY
Considering and accounting for the environmental impacts of sourcing materials and minerals, global production chains and end-of-life technologies. Emphasizing the materiality of technologies that are often considered as non-material (e.g., software, algorithms, cloud).
SUSTAINABILITY
Considering and accounting for the impacts of approach towards clinical research.

APPENDIX B– NETWORK MAP



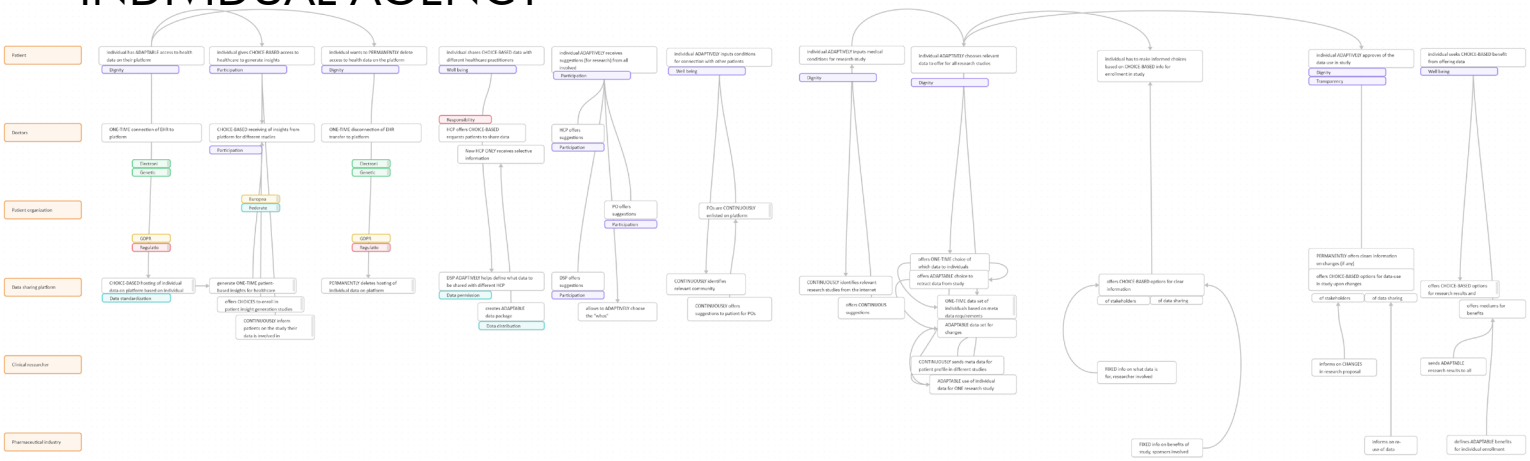
APPENDIX C– INTERACTIONS

TRADITIONAL



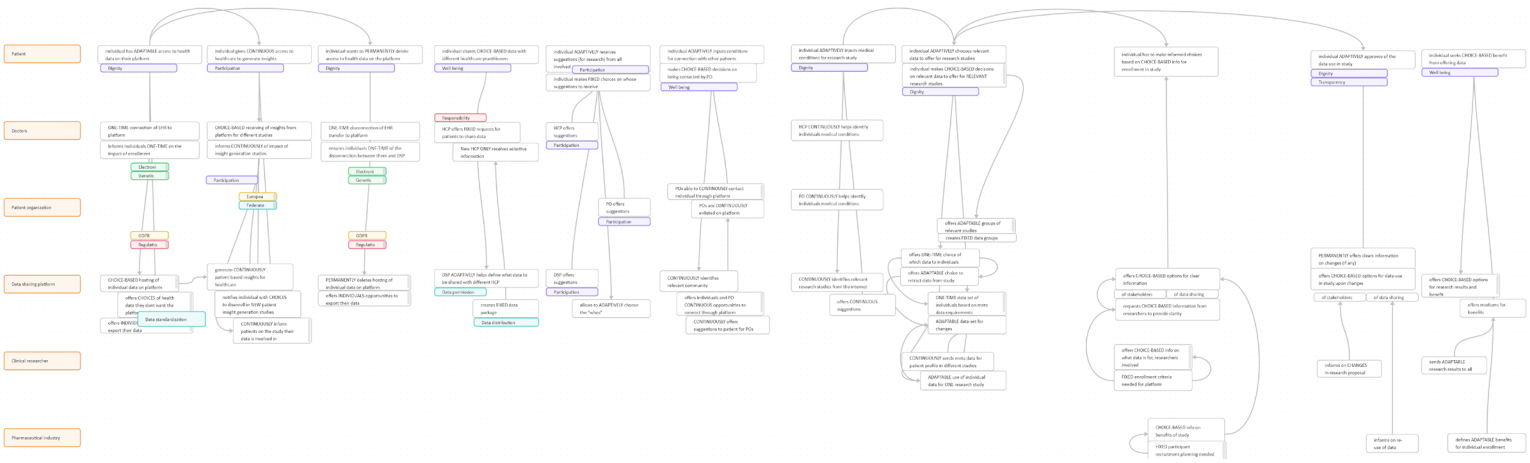
Obsidian

INDIVIDUAL AGENCY

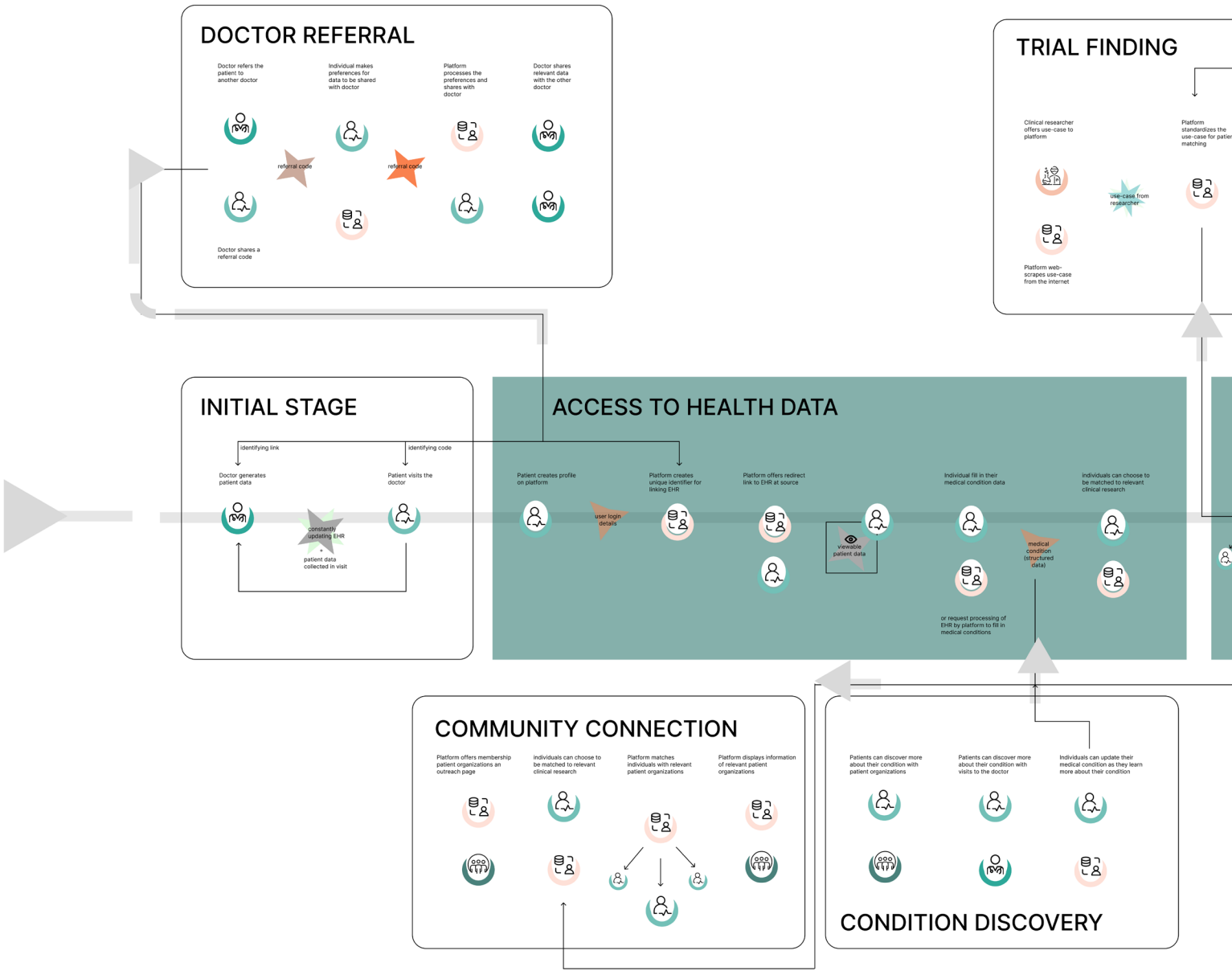


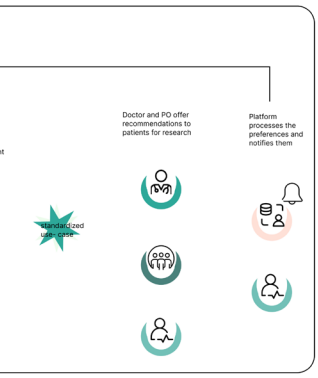
Obsidian

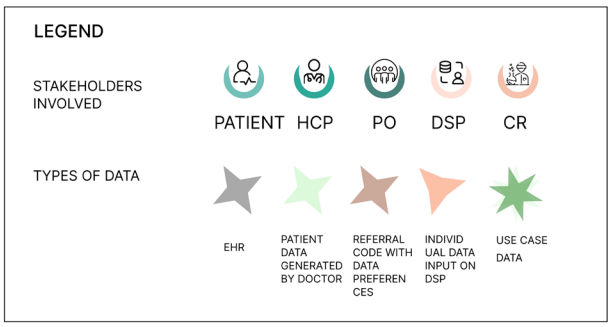
MUTUAL RESPONSIBILITY

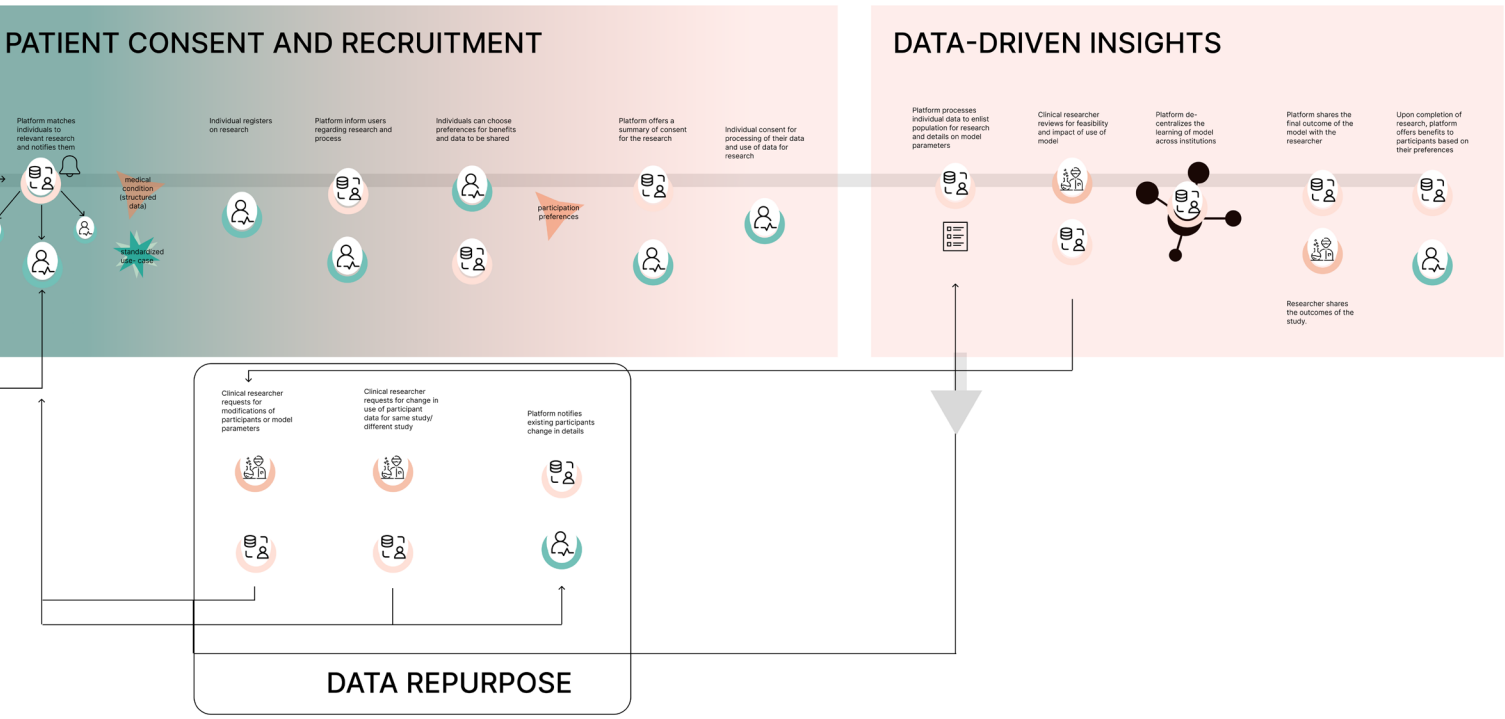


APPENDIX D– HEALTH SYSTEM FRAM




Doctor and PO offer recommendations to patients for research
Platform processes the preferences and notifies them
standardized use-case


LEGEND
STAKEHOLDERS INVOLVED
PATIENT
HCP
PO
DSP
CR
TYPES OF DATA
EHR
PATIENT DATA GENERATED BY DOCTOR
REFERRAL CODE WITH DATA PREFERENCES
INDIVIDUAL DATA INPUT ON DSP
USE CASE DATA


PATIENT CONSENT AND RECRUITMENT
Platform matches individuals to relevant research and notifies them
medical condition (structured data)
standardized use-case
Individual registers on research
Platform inform users regarding research and process
Individuals can choose preferences for benefits and data to be shared
participation preferences
Platform offers a summary of consent for the research
Individual consent for processing of their data and use of data for research
DATA-DRIVEN INSIGHTS
Platform processes individual data to enlist population for research and details on model parameters
Clinical researcher reviews for feasibility and impact of use of model
Platform de-centralizes the learning of model across institutions
Platform shares the final outcome of the model with the researcher
Researcher shares the outcomes of the study.
Upon completion of research, platform offers benefits to participants based on their preferences
Clinical researcher requests for modifications of participants or model parameters
Clinical researcher requests for change in use of participant data for same study/ different study
Platform notifies existing participants change in details
DATA REPURPOSE

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

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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: GHASIA
initials: ZH given name: ZAHRA
student number:
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: IR. HEUR, R. dept. / section:
** mentor: dept. / section:
2nd mentor:
organisation:
city: country:

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.

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair _____ 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 _____

Initials & Name ZH GHASIA Student number 5470102

Title of Project Leveraging the privacy needs of stakeholders in EHRs to offer an individualised solution to patients

Leveraging the privacy needs of stakeholders in EHRs to offer an individua 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 14 - 08 - 2023 12 - 01 - 2024 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, ...).

Electronic Health Records (EHRs) are increasingly used to store patient information across multiple institutions, enhancing efficiency and providing comprehensive medical records. These have the potential to improve patient care, clinical research and healthcare outcomes. (Cowie et al., 2016.)

NEED FOR OASYS NOW

To increase efficiency in medical services and to provide complete and accurate medical information, enterprises that offer expertise of maintaining the required database are growing in demand (Haas et al., 2011.) The current market involves both public medical systems (such as patient organisations and healthcare providers) and private enterprises (such as OASYS NOW) that offer services to maintain and add personal health data. OASYS NOW offers an EHR platform that allows for private storage and sharing of individual health data. This service is offered to patients (or individuals) who input their data and clinical researchers, who are interested in participant recruitment for clinical trials. Patients are recommended this platform through the healthcare practitioner or patient organisation. They enrol on the platform and input their demographic data, while mentioning their health condition. The company also offers DNA sampling test to interested individuals; the results of which are entered into the individual's profile, hereby creating access to one's own individual health data.

NEED FOR COLLABORATION BETWEEN STAKEHOLDERS

OASYS NOW anticipates a future wherein they become the central point for collecting and disclosing personal data to third parties. In such a case, collaboration amongst different stakeholders is crucial for the effective use of EHRs in clinical research. (Cowie et al., 2016.) Stakeholders of importance to OASYS NOW are patients, patient organizations, healthcare providers, academia, pharmaceutical industries, and third-party sponsors such as insurance companies.

NEED FOR PRIVACY

Despite the benefits of autonomy over one's own health data, increasing the access of personal health data to more users (or stakeholders) poses a threat to privacy even in advanced systems and research of anonymization (Li et al., 2011.) In this complex network of stakeholders, OASYS NOW may benefit from gaining an contextual awareness of both their users and their clients.

NEED FOR USER-CENTERED SOLUTION

Haas (2011) claims that patients with rare diseases (such as genetic or cardio-vascular) who are highly resourceful for the future of clinical research, are often in need of personalised focus. OASYS NOW wishes to move towards a patient-centric service wherein patients with differing needs/wants are met, and this leads the way for a personalization of their service.

REFERENCES

Cowie, M. R., Blomster, J. I., Curtis, L. H., Duclaux, S., Ford, I., Fritz, F., Goldman, S., Janmohamed, S., Kreuzer, J., Leenay, M., Michel, A., Ong, S., Pell, J. P., Southworth, M. R., Stough, W. G., Thoenes, M., Zannad, F., & Zalewski, A. A. (2016). Electronic health records to facilitate clinical research. Clinical Research in Cardiology, 106(1), 1 – 9. https://doi.org/10.1007/s00392-016-1025-6

Haas, S., Wohlgemuth, S., Echizen, I., Sonehara, N., & Müller, G. (2011). Aspects of privacy for electronic health records. International Journal of Medical Informatics, 80(2), e26 – e31. https://doi.org/10.1016/j.ijmedinf.2010.10.001

Li, F., Zou, X., Liu, P., & Chen, J. Y. (2011). New threats to health data privacy. BMC Bioinformatics, 12(S12). https://doi.org/10.1186/1471-2105-12-s12-s7

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TO PLACE YOUR IMAGE IN THIS AREA:
- **SAVE THIS DOCUMENT TO YOUR COMPUTER AND OPEN IT IN ADOBE READER**
- **CLICK AREA TO PLACE IMAGE / FIGURE**

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- **NATIVE IMAGE RATIO IS 16:10**
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image / figure 1:

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image / figure 2:

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 focus of the project is towards identifying privacy concerns amongst different stakeholders and applying it to generate a user-centered solution to EHRs. Moreover, a focus on understanding how the technology used influences the concerns of health data may lead to different implications of privacy for each stakeholder. By ensuring that OASYS NOW's mission to establish a health data storage and sharing platform is beneficial to its users, it is anticipated that the project's approach will encourage data-donation of patients through different stakeholders in a patient's user journey. Ortega presents designerly data donation as an efficient and ethical approach that encourages the active participation of users to obtain contextualised data (Ortega et al., 2021). As a designer, gaining a contextual awareness of the user's concerns with privacy can lead the way towards solutions that cater to individual differences with health data privacy.

The following issues are to be addressed in the project-

What are the concerns (both perceived and direct) of each stakeholder with invasion of privacy for health data? How does the technology used influence these concerns?

What are the consequences of these concerns together on data donation for EHRs?

How can a solution be designed considering the individual differences of patients with concerns of privacy?

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.

Develop a user-centered solution for OASYS NOW, which focuses on assessing privacy concerns related to health data among diverse stakeholders, whilst integrating the impact of technology facilitating health data storage and sharing in the Dutch environment.

To accomplish the objective, research activities such as exploring impact of privacy on individual stakeholders, researching factors that influence stakeholders, and investigating the individual patient differences with health data privacy will be carried out. An integrated approach that involves understanding the technology to store and share health data from a designer's perspective, will help incorporate how this data is used and transfered between stakeholders. Moreover, designerly data donation practices are to be incorporated such that the individuals who enrol onto OASYS NOW's service are also able to learn more about their own attitudes towards health data.

This thesis creates an opportunity for integrating technology and stakeholders to design a feasible solution that ensures the company's mission to promote privacy, further shaping the way towards individualised solutions in e-health. Within the IPD framework, it is foreseen that prototypes of the solution will be made based on the company's current interests. Though the solution may result in non-tangible concepts and solutions, IPD methods of prototyping concepts in a tangible manner to test and validate will ensure the feasibility, viability and desirability of the solution.

During this project, a lean approach will be carried out such that with every new fundamental learning, an iteration is developed that can further be tested to generate feedback.

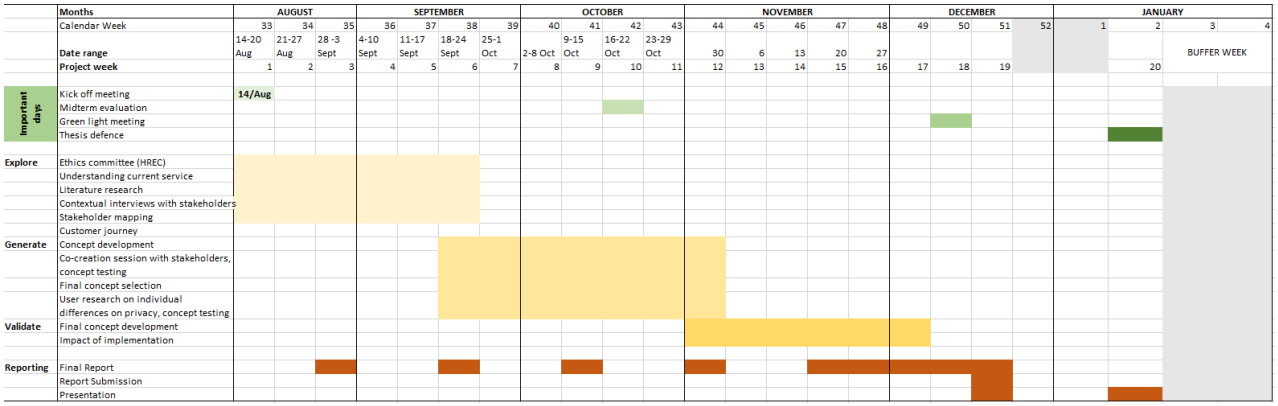
Initials & Name ZH GHASIA Student number

Title of Project Leveraging the privacy needs of stakeholders in EHRs to offer an individualised solution to patients

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 14 - 8 - 2023 — 12 - 1 - 2024 end date



The project plan's aim is to promote collaboration, iteration and testing. Accordingly, the work is to be divided under three phases; that of exploration, generation and validation.

1. Explore (6-7 weeks):
With a focus on research and research synthesis, literature and user research with stakeholders will be carried out to understand concerns of privacy that need to be prioritized for a collaborative solution. This phase will also focus on understanding the implementation of technology on health data privacy. Resulting from the research, a first ideation of solution concepts will be generated.

2. Generate (7-8 weeks):
This phase will be initiated with testing the solution concepts with patients. Patient differences with privacy will be determined, leading to further adaptation of initial ideas that are presented and tested with relevant stakeholders. A final choice between the solutions will be made based on it's impact on the company's current interests.

3. Validate (6-8 weeks):
Final solution will be further elaborated with features of personalisation that can be added based on the user research carried out. This solution will be prototyped in a tangible manner, with which enhance the testing of solution with different stakeholders. In the final three weeks the report will be optimised and the graduation presentation will get prepared.

Initials & Name ZH GHASIA Student number

Title of Project Leveraging the privacy needs of stakeholders in EHRs to offer an individualised solution to patients

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.

The motivation for this project comes from my interest in exploring the innovation opportunities that data can offer in healthcare. This is the domain I want to continue working in, which is why developing competencies is a crucial aspect of my project. Given that the USP of OASYS NOW is a privacy-informed platform for electronic health records, collaborating with them on this project is an exciting way to better understand the systemic concerns in privacy of health data. I will be testing competencies of my experience with developing personalised and user-centered solutions, whilst bringing a tangible approach to testing a non-tangible solution. Learning opportunities are endless and possibly better to be reflected upon during the course of the project.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

Initials & Name ZH GHASIA Student number

Title of Project Leveraging the privacy needs of stakeholders in EHRs to offer an individualised solution to patients