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DELIVERABLE

D8.3 – SELP Impact Assessment

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Executive Summary

With the growth of digital technologies, the AI health market faces many challenges, and it is crucial that AI and robotic technologies are implemented in the healthcare system legally, ethically, and socially acceptable. To that end, the HosmartAI project has multiple tasks/deliverables dedicated to address such a wide range of issues, and the tasks/deliverables by Work Package 8 (WP8) specifically focus on social, ethical, and legal issues. The main objective of WP8 is to ensure compliance with applicable laws and regulations as well as ethical and social norms, and it aims to achieve the goal by, *inter alia*, conducting an impact assessment. The first and the second phases of the impact assessment are documented as D8.1 SELP Benchmark Report and D8.2 SELP Compliance Report respectively.

Built on the two previous tasks and deliverables, this deliverable, entitled D8.3 "SELP Impact Assessment Report, documents the activities conducted in task T8.3 SELP Impact Assessment. In the third phase, WP8 has formulated questionnaires to collect necessary information regarding all Pilot Studies and, based on the responses by Pilot partners, we have assessed and analysed each issue in the legal, ethical, and social context.

The main contributions of this document are the findings and the results of the assessment/analysis. Based on available information as of now, our findings indicate that no critical issues were identified. The key findings and assessment/analysis illuminated several critical issues, and continuing to address these issues adequately and properly throughout the period of the project will be essential to HosmartAI: (1) informed consent; (2) profiling and automated decision-making in the context of GDRP; and (3) AI technologies in the context of ethical and social issues.

(1) No informed consent procedure of each Pilot was found to be insufficient or inadequate in this first assessment/analysis conducted as part of T8.3. However, this Report also recommends each Pilot to review their informed consent procedure by referring to the elements enumerated in the relevant section. For example, reviewing if their informed consent procedure is not "bundled" meaning asking for "overall general consent to everything" is important.

(2) The profiling and automated decision-making is another issue that is critically important partly because it implicates legal compliance/risk. Findings and assessment/analysis identified AI technologies of some Pilots falls within the definition of profiling under the GDPR, thus making them subject to the relevant provisions. Also, the findings and assessment/analysis indicated that AI technologies of Pilots are least likely to trigger the provision concerning solely automated decision-making.

(3) This document also assessed/analysed the same AI technologies in the context of ethical and social issues. It provided four notable observations or analytical framework to help assess/analyse the potential risks concerning the use of AI technology. As the result, we view that risks in ethical or social context are less likely to be materialized in the forthcoming Pilot Studies.

The key issues, as well as documents, concerning informed consent and profiling will be submitted as D10.1, D10.2, and D10.3. Also, the activity/process of impact assessment/analysis will be further developed by the subsequent task and deliverable T8.4 & D8.4 “SELP Continuous Monitoring Report 1”, which will be built upon this deliverable.

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Table of Contents

Executive Summary 2
Table of Contents 5
List of Tables 6
Definitions, Acronyms and Abbreviations 7
1 Introduction 8
1.1 Project Information 8
1.2 Document Scope 10
1.3 Document Structure 10
2 Background and Preliminary Information 12
2.1 Definitions 12
2.2 Benefits and concerns 12
2.3 Task 8.3 SELP Impact Assessment 13
3 Findings and Assessment/Analysis 15
3.1 Preface 15
3.2 Baseline information 16
3.2.1 Short description of each Pilot Study 16
3.2.2 Oversight/support by ethics committee (Q. 7) and by DPO (Q. 9) 18
3.3 Medical Ethics, Medical Devices 22
3.3.1 Human Participants 22
3.3.2 Characteristics of study population and vulnerable individuals (Q. 2) 24
3.3.3 Informed consent (Q. 4, 5, and 6) 31
3.3.4 EU Medical Devices Regulation (Q. 8) 41
3.4 Data Protection/Privacy, including Profiling 43
3.4.1 Types of personal data, including sensitive personal data (Q. 10, 11) 43
3.4.2 The rights of data subject and legal basis (Q. 13 and Q. 14) 48
3.4.3 Data Controller and Data Processor (Q. 12) 50
3.4.4 Access control, anonymisation / pseudonymisation, data retention / deletion 52
3.4.5 Scale of processing of personal data (Q. 16) 59
3.4.6 Less privacy invasive means (Q. 21) 62
3.4.7 Profiling (Q. 19) and Automated Decision-Making (Q. 20) 64
3.5 AI Ethics: Ethical and Societal Issues 71

3.5.1 AI technologies involved (Q. 22) 72
3.5.2 Added or heightened risks (Q. 23) 74
3.5.3 Detection and deterrence (Q. 24) 77
3.5.4 Mitigation (Q. 25) 78
3.5.5 Assessment/Analysis 80
4 Conclusion 83
5 References 84
Appendix A Original Questionnaire 85

List of Tables

Table 1: The HosmartAI consortium. 9
Table 2: Short description of the Pilot Study (Title). 16
Table 3: Ethics Committee (Q. 7) and DPO (Q. 9). 20
Table 4: Human Participants; Estimated Sample Size. 23
Table 5: Characteristics of study population; Vulnerable groups/individuals (Q. 2). 25
Table 6: Informed Consent (Q. 4). 33
Table 7: Vulnerable individuals and consent (Q. 5). 36
Table 8: Withdrawing consent (Q. 6). 37
Table 9: Medical Devices Regulation (Q. 8). 41
Table 10: Personal Data (Q. 10) and Sensitive Personal Data (Q. 11). 44
Table 11: Rights of data subject (Q. 13) and Legal basis (Q. 14). 48
Table 12: Data Controllers and Data Processors (Q. 12). 51
Table 13: Access control (Q. 15). 53
Table 14: Anonymisation/Pseudonymisation (Q. 17). 55
Table 15: Data retention/deletion (Q. 18). 57
Table 16: Scale of processing of personal data (Q. 16). 59
Table 17: Less privacy invasive means (Q. 21). 63
Table 18: Profiling (Q. 19). 66
Table 19: Automated decision-making (Q. 20). 68
Table 20: AI technologies involved (Q. 22). 72
Table 21: Added or heightened risks (Q.23). 75
Table 22: Detection and deterrence (Q. 24). 77
Table 23: Mitigation (Q. 25). 79

Definitions, Acronyms and Abbreviations

Acronym/ Abbreviation	Title
AI	Artificial Intelligence
D	Deliverable
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
FRT	Facial Recognition Technology
GDPR	General Data Protection Regulation
ML	Machine Learning
SELP	Social, Ethical, Legal Perspective
T	Task
WP	Work Package

1 Introduction

1.1 Project Information

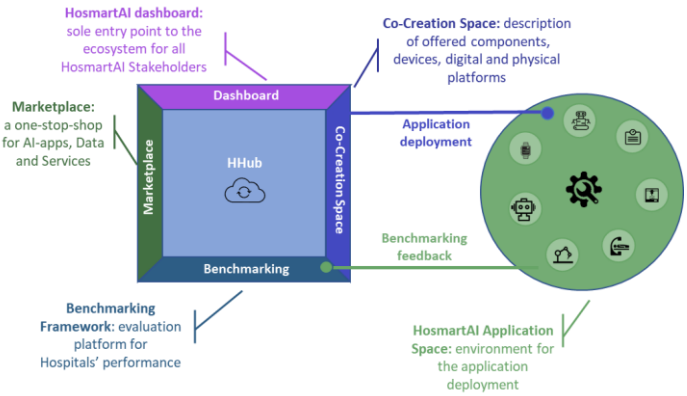
VISION

The HosmartAI vision is a strong, efficient, sustainable and resilient European **Healthcare system** benefiting from the capacities to generate impact of the technology European Stakeholders (SMEs, Research centres, Digital Hubs and Universities).

MISSION

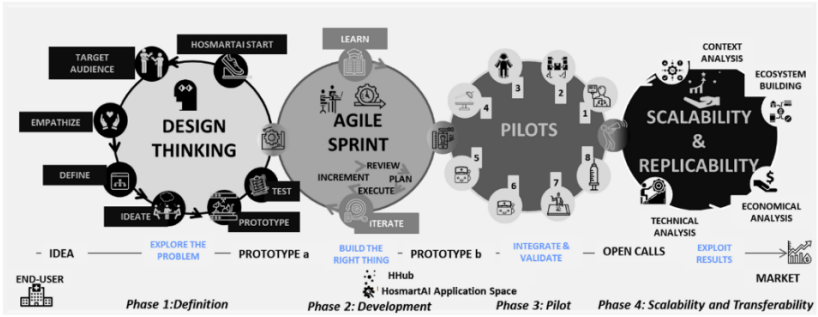
The HosmartAI mission is to guarantee the **integration** of Digital and Robot technologies in new Healthcare environments and the possibility to analyse their benefits by providing an **environment** where digital health care tool providers will be able to design and develop AI solutions as well as a space for the instantiation and deployment of AI solutions.

HosmartAI will create a common open Integration **Platform** with the necessary tools to facilitate and measure the benefits of integrating digital technologies (robotics and AI) in the healthcare system.



A central **hub** will offer multifaceted lasting functionalities (Marketplace, Co-creation space, Benchmarking) to healthcare stakeholders, combined with a collection of methods, tools and solutions to integrate and deploy AI-enabled solutions. The **Benchmarking** tool will promote the adoption in new settings, while enabling a meeting place for technology providers and end-users.

Eight Large-Scale Pilots will implement and evaluate improvements in medical diagnosis, surgical interventions, prevention and treatment of diseases, and support for rehabilitation and long-term care in several Hospital and care settings. The project will target different **medical** aspects or manifestations such as Cancer (Pilot #1, #2 and #8); Gastrointestinal (GI) disorders (Pilot #1); Cardiovascular diseases (Pilot #1, #4, #5 and #7); Thoracic Disorders (Pilot #5); Neurological diseases (Pilot #3); Elderly Care and Neuropsychological Rehabilitation (Pilot #6); Fetal Growth Restriction (FGR) and Prematurity (Pilot #1).



To ensure a user-centred approach, harmonization in the process (e.g. regarding ethical aspects, standardization, and robustness both from a technical and social and healthcare perspective), the **living lab** methodology will be employed. HosmartAI will identify the appropriate instruments (**KPI**) that measure efficiency without undermining access or quality of care. Liaison and co-operation activities with relevant stakeholders and **open calls** will enable ecosystem building and industrial clustering.

HosmartAI brings together a **consortium** of leading organizations (3 large enterprises, 8 SMEs, 5 hospitals, 4 universities, 2 research centres and 2 associations – see Table 1) along with several more committed organizations (Letters of Support provided).

Table 1: The HosmartAI consortium.

Number[1]	Name	Short name
1 (CO)	INTRASOFT INTERNATIONAL SA	**INTRA**
1.1 (TP)	INTRASOFT INTERNATIONAL SA	**INTRA-LU**
2	PHILIPS MEDICAL SYSTEMS NEDERLAND BV	**PHILIPS**
3	VIMAR SPA	**VIMAR**
4	GREEN COMMUNICATIONS SAS	**GC**
5	TELEMATIC MEDICAL APPLICATIONS EMPORIA KAI ANAPTIXI PROIONTON TILIATRIKIS MONOPROSOPIKI ETAIRIA PERIORISMENIS EYTHINIS	**TMA**
6	ECLEXYS SAGL	**EXYS**
7	F6S NETWORK IRELAND LIMITED	**F6S**
7.1 (TP)	F6S NETWORK LIMITED	**F6S-UK**
8	PHARMECONS EASY ACCESS LTD	**PhE**
9	TERAGLOBUS LATVIA SIA	**TGLV**
10	NINETY ONE GMBH	**91**
11	EIT HEALTH GERMANY GMBH	**EIT**
12	UNIVERZITETNI KLINICNI CENTER MARIBOR	**UKCM**
13	SAN CAMILLO IRCCS SRL	**IRCCS**
14	SERVICIO MADRILENO DE SALUD	**SERMAS**
14.1 (TP)	FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL UNIVERSITARIO LA PAZ	**FIBHULP**
15	CENTRE HOSPITALIER UNIVERSITAIRE DE LIEGE	**CHUL**
16	PANEPISTIMIAKO GENIKO NOSOKOMEIO THESSALONIKIS AXEPA	**AHEPA**
17	VRIJE UNIVERSITEIT BRUSSEL	**VUB**
18	ARISTOTELIO PANEPISTIMIO THESSALONIKIS	**AUTH**
19	EIDGENOESSISCHE TECHNISCHE HOCHSCHULE ZUERICH	**ETHZ**
20	UNIVERZA V MARIBORU	**UM**

[1] CO: Coordinator. TP: linked third party.

Number[1]	Name	Short name
21	INSTITUTO TECNOLÓGICO DE CASTILLA Y LEON	**ITCL**
22	FUNDACION INTRAS	**INTRAS**
23	ASSOCIATION EUROPEAN FEDERATION FORMEDICAL INFORMATICS	**EFMI**
24	FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE	**HOPE**

1.2 Document Scope

This document, deliverable "D8.3 SELP Impact Assessment Report," is the third deliverable in Work Package 8 ("WP8"). It contains the assessment and analysis of the impacts of AI technologies of 8 Lighthouse Pilots in terms of legal, ethical, and social issues.

WP8's aim is to ensure HosmartAI and all Pilots Study comply with applicable laws and regulations as well as ethical and social norms. To this end, WP8 has conducted impact assessment as Task 8.3 ("T8.3 SELP Impact Assessment"). Specifically, the impact of AI technologies in Pilots are assessed and analysed against D8.1 SELP Benchmark Report.

D8.1 "SELP Benchmark Report" summarizes the applicable frameworks and provides the regulatory landscape relevant to HosmartAI. It surveys applicable or relevant laws and regulations as well as ethical and social norms. Based on the output of D8.1, WP8 has suggested a preliminary framework for HosmartAI to comply with the applicable laws and regulations as well as relevant ethical and social norms, which is documented in the deliverable D8.2 "SELP Compliance Report".

Building upon two previous tasks and deliverables, this D8.3 "SELP Impact Assessment" report assesses and analyses each Pilot from various perspectives, namely: study protocol, including characteristics of the study population and informed consent procedure; numerous data protection issues, including issues related to the scale of processing of personal data, the profiling/automated decision-making; and AI technologies involved from the perspective of ethical and social issues.

This deliverable will be followed up with subsequent deliverables: D8.4 "SELP Continuous Monitoring Report 1" (M25[2]); and D8.5 "SELP Continuous Monitoring Report 2" (M41[3]).

1.3 Document Structure

This document is comprised of the following chapters:

Chapter 1 presents an introduction to the project and the document.

Chapter 2 provides background and preliminary information such as the detailed steps conducted as task T8.3 SELP Impact Assessment.

[2] End of January 2022.
[3] End of May 2024.

Chapter 3 provides the findings as the result of risk and impact assessment/analysis. As explained in the first section (entitled Preface), the chapter proceeds in four parts. First, the baseline information, such as descriptions of Pilot Studies are provided. In the subsequent sections, the issues are discussed in three different categories, namely (1) medical ethics, (2) data protection/privacy, including profiling, and (3) AI ethics.

Chapter 4 outlines the key findings and offers concluding remarks.

Appendix A provides the original questionnaire distributed to and filled in by the HosmartAI pilots.

2 Background and Preliminary Information

2.1 Definitions

The term “artificial intelligence,” or in abbreviated form “AI,” is widely used in society but its precise meaning is contested in both scholarly work and legal documents and we will not insist on a single definition here but instead pick out a few subtypes: Machine learning (ML), a subset of AI, has been the most popular approach of current AI healthcare applications in recent times since it allows computational systems to learn from data and improve their performance without being explicitly programmed. Deep learning, a subset of ML, employs artificial neural networks with multiple layers to identify patterns in very large datasets. Most notably, as we will see below, there are additional ethical and legal challenges in cases where ML algorithms are closer to “black boxes” (i.e., the results are very difficult for clinicians to interpret fully) [REF-01].

2.2 Benefits and concerns

The potential of AI in health is profound, given the growing volume of electronic data as well as the inherent complexity of the sector, its reliance on information to solve problems, and the variability and complexity of how disease interacts with individuals and populations. AI is a ‘general purpose’ technology that can be deployed in just about any facet or activity of the health industry, from clinical decision-making and public health to biomedical research and drug development, to health system administration and service redesign. As the COVID-19 crisis is showing, there are genuine opportunities for AI to deliver benefits for health systems, professionals and the public, making existing clinical and administrative processes more effective, efficient and equitable. In a notoriously wasteful and inefficient industry, this is a major opportunity to improve health outcomes and value for money [REF-02].

There are many opportunities also for robotic applications in healthcare, which raise the attention of regulators due to the challenges they present to existing legal frameworks and the new legal, social and ethical questions they raise. Robots and AI present many new complex challenges related to human dignity, security, privacy, safety, employment and liability, which justify a need for developing new laws and principles [REF-03].

At the same time, applications of AI in the health sector raise various concerns and anxiety [REF-02]. To list a few:

- AI in health is not yet robust: for every success story there is a cautionary tale: most AI in health is actually artificial narrow intelligence, or “weak” AI, designed to accomplish a very specific problem-solving or reasoning task, and unable to generalise outside the boundaries within which the model was trained. So incapable of versatile abstract learning.
- AI applications in health rely on machine learning methods, ranging from linear and logistic regressions, decision trees and principal component analysis to deep neural networks. They usually rely on large amounts of training data to make predictions, but

they are focused on a specific task, so they could malfunction for different datasets or populations (heavy dependence on the input data).

- A related challenge is overfitting, which occurs when an AI model learns statistical irregularities specific to the data on which it is trained.
- The large majority of machine-learning-based prediction models are based on correlation, not causation. Previous studies have identified counterintuitive associations that lead to nonsensical predictions.
- Algorithms that learn from human decisions will also learn human mistakes, biases and stereotypes.
- There is a body of evidence showing that the implementation (alert or pop-up window within electronic health record software) of health information systems can result in unintended consequences. These include alert fatigue, imposition of additional workloads for clinicians, disruption of interpersonal (including doctor-to-patient) communication styles, and generation of specific hazards that require a higher level of vigilance to detect.
- Poor health data governance means AI requires a lot of human curation: large amounts of data to train, needs a lot of human curation, data are notoriously messy, and classifications or interpretations of the underlying data can be wrong, no central repository of data readable by AI algorithm but often a large number of disconnected small data.

2.3 Task 8.3 SELP Impact Assessment

This deliverable D8.3 SELP Impact Assessment Report documents the output of T8.3 Impact Assessment and is the first risk/impact assessment report of the subsequent two deliverables (D8.4 and D8.5 SELP Continuous Monitoring Report 1 and 2). This section describes how the task T8.3 SELP Impact Assessment was conducted.

The primary objective of SELP impact assessment is to identify the risks related to social, ethical, legal issues, and to suggest the measures to mitigate the identified risks. To this end, we conducted our impact assessment/analysis consisting of the following phases:

1. Define and describe the laws and regulations as well as ethical and social norms applicable or relevant HosmartAI's Pilot Studies (documented in D8.1 SELP Benchmark Report);
2. Suggest a preliminary compliance framework for HosmartAI describing how the project seeks to comply with laws and ethical/social norms (documented in D8.2 SELP Compliance Report);
3. Conduct the follow-up research on two previous Tasks/Deliverables in light of more detailed specifications and information of each Pilot Studies (documented in deliverable "D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version" by WP5).
4. Conduct the impact assessment/analysis in HosmartAI that consists of the following steps:

a. Prepare a questionnaire addressed to all Pilot partners to obtain the necessary information regarding each Pilot Study.
b. Collect the responses of Pilot partners and clarifying by follow-up questions.
c. Assess and analyse each issue from legal, ethical, and social perspective, and where applicable provide recommendations, such as measures to mitigate the risk.

While phases 1 and 2 corresponds to the scope of T8.1 and T8.2 respectively, phases 3 and 4 are conducted as T8.3.

3 Findings and Assessment/Analysis

3.1 Preface

This chapter introduces the findings and presents an assessment/analysis. This chapter proceeds in four parts. In the first section, it will introduce a brief description of each Pilot Study and whether the Pilot Study is supervised by competent ethics committee and is supported by any department/team/personnel with regard to data protection issues. The second section will consider medical ethics issues, including Medical Devices Regulation issue. The third section will examine issues concerning data protection/privacy. Finally, the fourth section will discuss AI ethics in the context of ethics and social issues. Each section is composed of multiple sub-sections focusing on a particular topic/issue. Below provides a visual organization of this chapter:

1. Baseline information
2. Medical Ethics, Medical Devices
    a. Human Participants
    b. Characteristics of study population and vulnerable individuals
    c. Informed consent
    d. EU Medical Devices Regulation
3. Data Protection/Privacy, including Profiling
    a. Types of personal data
    b. The rights of data subject and legal basis
    c. Access control, anonymisation/pseudonymisation, data retention/deletion
    d. Scale of processing of personal data
    e. Less privacy invasive means
    f. Profiling and automated decision-making
4. AI Ethics: Ethical and Social Issues
    a. AI technologies
    b. Added or heightened risks
    c. Detection and Deterrence
    d. Mitigation

Structure of each section (or sub-section): Each sub-section, where it generally corresponds to one topic or issue, generally proceeds in four parts as structured below:

1. Issue;
2. Applicable/relevant law or ethical/social norm, how we assess/analyse the risk;
3. Responses by the Pilots or findings; and
4. Assessment/analysis.

Sources of information for the findings: Description regarding each Pilot is based on The Grant Agreement, D5.1, D6.7, each response to the Questionnaire, and follow-up questions and answers via email. The description here will be limited to the extent necessary or relevant to this Report; The more detailed specification, study design/methodology, and study protocol of each Pilot is available at D5.1 “Detailed Pilot Specification and Report on Pilot Sites

Preparation – First version". Also, more detailed specification relevant to the processing of data, including personal data, is available at D6.7 "Data Management Handling Plan – First Version".

In the tables, the response by each Pilot is written with regular fonts, while comments, supplements, or annotations by WP8 is written in *Italics*.

Pilots: There are 8 Lighthouse Pilots in HosmartAI, which composes the Work Package 5 (WP5). Some Pilots have multiple Studies, or a Study is conducted in a separate or independent manner, such as conducted on a different site. In such cases, they are described separately, and consequently the assessment/analysis, too. Namely, Pilot 1 has four (4) studies and Pilot 5 has two (2) studies. We received 11 responses to the questionnaire: three (3) responses for Pilot 1 (where one covers two studies), two (2) responses for Pilot 5, and one (1) for each of the rest of the Pilots.

3.2 Baseline information

This section provides a baseline or fundamental information regarding each Pilot. First, it introduces the Pilot Study, and second, it provides an overview of whether each Pilot Study is supervised by the relevant ethics committee and is supported by DPO for data protection/privacy issues.

3.2.1 Short description of each Pilot Study

The table below provides a very short description of each Pilot Study with an emphasis on the technology involved. The objective is to clarify and provide a brief understanding of the Study itself as well as what and how technologies are involved in the Pilot Study, partly because the involved technology is one of the major factors that demines what risks may be implicated. The more detailed description of the technologies involved are touched in subsequent (sub-) sections entitled Profiling and Automated Decision-Making (Section 3.4.7) and AI Ethics (Section 3.5), *infra*.

Table 2: Short description of the Pilot Study (Title).

Pilot #	Short description of the Pilot Study (Title)
Pilot 1 (ECHO)	A two-phase prospective cohort study to evaluate the clinical performance and utility of an artificial intelligence-based tool for automatic estimation of left ventricular ejection fraction and global longitudinal strain in transthoracic echocardiography[4]
(VCE)	A prospective cohort study to evaluate the clinical performance and utility of an artificial intelligence-based tool for automatic detection and classification of small bowel abnormalities in capsule endoscopy[5]

[4] See D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 50.
[5] See D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 54.

Pilot #	Short description of the Pilot Study (Title)
(CCTA)	An observational study to evaluate the clinical performance of an AI-based tool for the presence of obstructive coronary artery disease (CAD) identification.[6]
(Obstetrics)	An observational study to evaluate the clinical performance of an artificial intelligence-based tool for pregnant women with symptoms of preterm labour and/or fetal growth restriction identification.[7]
Pilot 2	AI-based software for optimizing the patient satisfaction and resource utilisation by adjusting treatment (preparation) scheduling of a radiotherapy department[8]
Pilot 3	Treatment improvement with the use of innovative technologies and robotics in rehabilitation process: observational longitudinal study.[9]
Pilot 4	Robotic Magnetic Navigation.[10] Comparing the remote magnetic navigation automated with AI, in-vitro test scenarios will be created using data from multiple manual ablation procedures.[11]
Pilot 5	Evaluating the clinical impact of integrating a computerized clinical decision support system and a social robot into grand rounds and pre/post-operative care of patients with vascular and thoracic diseases and conditions[12]
	Evaluating the effects of interactive digital assistance on patient engagement and perceived quality of care of surgery patients and self-efficacy and workload of staff[13]
Pilot 6	Quasi-experimental study on detection and prevention of cognitive impairment and the presence of frailty in older adults through technologies that promotes a healthy lifestyle.[14]
Pilot 7	Smart Cathlab assistant. [15] AI-enabled solutions to support automated reporting and facilitate clinical decision process in a catheterization laboratory.[16]
Pilot 8	Prognosis of cancer patients and their response to treatment combining multi-omics data[17]

[6] See D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 58.
[7] See D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 61.
[8] See D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 63.
[9] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 66.
[10] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 69.
[11] Id.
[12] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 71.
[13] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 75.
[14] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 78.
[15] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 78.
[16] Id.
[17] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 88.

3.2.1.1 Assessment/Analysis

Pilot 1 has 4 different sub-Studies. While each scenario is different, they are all in common in the sense that all aim "to evaluate the clinical performance and utility of an artificial intelligence-based tool."

Pilot 2 will develop and test Chatbot which is "AI-based software for optimizing the patient satisfaction and resource utilisation by adjusting treatment (preparation) scheduling."

Pilot 3 seeks to improve treatment/rehabilitation process by using robotics and virtual reality technologies.

Pilot 4 will be in-vitro testing, and there will be no human participant and no data will be processed[18]. Therefore, the rest of the assessment and analysis on Pilot 4 is not included in this D8.3 SELP Impact Assessment Report. In the rest of the tables, Pilot 4 will be marked as N/A.

Pilot 5 has two Studies, each evaluating: (1) "the clinical impact of integrating a computerized clinical decision support system and a social robot into grand rounds and pre/post-operative care of patients"; and (2) "the effects of interactive digital assistance on patient engagement and perceived quality of care of surgery patients and self-efficacy and workload of staff."

Pilot 6 will conduct "[q]uasi-experimental study on detection and prevention of cognitive impairment [. . .] through technologies that promotes a healthy lifestyle" where older adults will be involved.

Pilot 7's "AI-based assistance in the cathlab will reduce the administrative burden and provide clinical decision support to optimize stenting procedures."

Pilot 8's platform offers an integrated view on the glioma patient data[19] (classifies voxels of an image into different groups (regions), to predict regions that differentiate from each other in imaging characteristics[20]).

3.2.2 Oversight/support by ethics committee (Q. 7) and by DPO (Q. 9)

The issue is whether each Pilot Study: (1) is subject to an oversight by relevant ethics committee; and (2) receives adequate compliance support by the Data Protection Officer ("DPO") of its organization on data protection and privacy related issues.

HosmartAI can be categorized as a large project which containing 8 Lighthouse Pilots, while each Pilot working in different settings (Applying AI and Robotics to different range of functions; Different medical aspects or manifestations; different healthcare settings)[21]. Considering the size and the structure of HosmartAI, WP8 and/or Ethics Committee alone to address and oversight all potential risks and issues is not only unfeasible, but also inefficient for each WP and Pilot and for the entire HosmartAI project for several reasons (e.g.,

[18] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 70.
[19] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 88.
[20] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 14.
[21] See Grant Agreement. See also D8.1 SELP Benchmark Report, pp. 14, 15.

communication overload and bottleneck; WP8 may lack medical expertise; each Pilot working autonomously with their relevant ethics committee and DPO is more efficient and effective). Therefore, we look into if each Pilot Study is supervised by ethics committee and is supported by its DPO on data protection/privacy issues in order to assess/analyse the baseline of each Pilot in terms of ethical and legal issues. If a Pilot lacks both, seeking an approval from the ethics committee and starting a conversation with DPO and legal department/team will be the first thing to do. If a Pilot is seeking or already acquired approval from the competent ethics committee and is working closely with the DPO/legal, we consider it meets the minimum requirement.

This approach (risk management or compliance framework) has multiple advantages. While one advantage is (the opposite of) the efficiency issue mentioned above, it also provides so-called "three lines of defence" in the practice of internal audit or risk management. In the context of business organization, risk controls by the management and internal control measures are considered to be the "first line of defence." Risk control elements -- such as financial control, security, risk management, quality, inspection, compliance, etc -- are considered to be the "second line of defence." Internal audit is considered to be the "third line defence," according to The Three Lines of Defense in Effective Risk Management and Control published by the Institute of Internal Auditors (IIA).[22]

In the context of HosmartAI, the term "first line of defence" would the WP5 and each Pilot with their Pilot Study Protocols in place. The "second line of defence" would be the institutional/regional/national ethics board where the Pilot seeks approval of, or it would be the data protection officer of the organization of the Pilot. The "third life of defence" would be the tasks by WP8 or the oversight by the HosmartAI Ethics Board.[23] WP8 and/or Ethics Board will focus on, among other things, SELP issues and risks as a whole.

This does not mean, however, the risk and impact assessment by WP8 assumes compliance by default, without reasonable grounds. First, WP8's risk and impact assessment will look into whether each Pilot Study is properly supervised by the relevant ethics committee and receives compliance support by the DPO of its organization on data protection and privacy issues.

Second, more importantly, WP8's risk and impact assessment will look into ethical, legal, and social issues independently, especially on high-risk issues and issues for HosmartAI as a whole.

Having said that, the table below provides summarized information on whether each Pilot: (1) is seeking or acquired approval by the institutional/regional/national ethics committee, and if any, identity information; and (2) receives compliance support from its DPO and his/her team on data protection and privacy related issues.

[22] The Institute of Internal Auditors (IIA), The Three Lines of Defense in Effective Risk Management and Control.pdf (2013), https://na.theiia.org/standards-guidance/Public%20Documents/PP%20The%20Three%20Lines%20of%20Defense%20in%20Effective%20Risk%20Management%20and%20Control.pdf.

[23] Activities of the HosmartAI Ethics Board will be submitted as WP10 deliverables by Month 18. See Grant Agreement.

Table 3: Ethics Committee (Q. 7) and DPO (Q. 9).

Pilot #	Ethics Committee	Data Protection Officer
Pilot 1 (ECHO)	Research Ethics Committee of the Aristotle University of Thessaloniki (AUTH). Ktirio KE.D.E.A- 3is Septemvriou - Panepistimioupoli GR 54636 Thessaloniki, Greece E-mail: *[redacted]*[24]	Data protection officer (DPO) of AUTH. Department: Aristotle University of Thessaloniki (AUTH) E-mail: *[redacted]*[25]
(VCE)	Institutional Review Board and Administrative Council of the University General Hospital of Thessaloniki AHEPA Stilponos Kiriakidi 1, 54621, Thessaloniki, Greece[26]	Data protection officer (DPO) of the AHEPA Hospital. Department: AHEPA Hospital, e-mail: *[redacted]*[27]
(CCTA)	Research Ethics Committee of the Aristotle University of Thessaloniki (AUTH). Ktirio KE.D.E.A- 3is Septemvriou - Panepistimioupoli GR 54636 Thessaloniki, Greece E-mail: *[redacted]*[28]	Data protection officer (DPO) of AUTH. Department: Aristotle University of Thessaloniki (AUTH) E-mail: *[redacted]*[29]
(Obstetrics)	Research Ethics Committee of the Aristotle University of Thessaloniki (AUTH). Ktirio KE.D.E.A- 3is Septemvriou - Panepistimioupoli GR 54636 Thessaloniki, Greece E-mail: *[redacted]*[30]	Data protection officer (DPO) of AUTH. Department: Aristotle University of Thessaloniki (AUTH) E-mail: *[redacted]*[31]
Pilot 2	Name: Comité d'Ethique Hospitalo-Universitaire de Liège Address: 1 Avenue de l'Hôpital, 4000 Liège Contact: *[redacted]* Phone: *[redacted]*[32]	CHU de Liège has an Ethics and Data Security Committee Contact: *[redacted]* (DPO) Phone: *[redacted]* In addition: Legal Department Contact: *[redacted]* Phone: *[redacted]*[33]
Pilot 3	"Comitato Etico per la Sperimentazione Clinica della	Nucleo per la Ricerca Clinica IRCCS (IRCCS Clinical Research Unit)

[24] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p.8.
[25] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p.8.
[26] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 8.
[27] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 8.
[28] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 8.
[29] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 8.
[30] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 8.
[31] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 8.
[32] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 8.
[33] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 9.

Pilot #	Ethics Committee	Data Protection Officer
	Provincia di Venezia e dell'IRCCS San Camillo (CESC)" (Ethics Committee for Clinical Trials of the Province of Venice and IRCCS San Camillo). Azienda ULSS 3 Serenissima, Via Don F. Tosatto 147; 30174 Venezia Mestre (Italy) -Nucleo per la Ricerca Clinica IRCCS (IRCCS Clinical Research Unit) via Alberoni, 70 – 30126 Venezia Lido (VE) Tel. *[redacted]* (contact person: *[redacted]*) E-mail: *[redacted]*[34]	ensures that data protection laws are followed by the institution via Alberoni, 70 – 30126 Venezia Lido (VE) Tel. *[redacted]* E-mail: *[redacted]* Contact: *[redacted]* (DPO)[35]
Pilot 4	N/A	N/A
Pilot 5 (IM)	[36]	DPOs at both University Medical Center (UKCM) and University of Maribor (UM)[37]
(UKCM)	UKC Maribor, Ljubljanska 5, 2000 Maribor, president of the committee: associate professor *[redacted]* MD PhD[38]	DPOs at both University Medical Center (UKCM) and University of Maribor (UM)[39]
Pilot 6	Firstly, the institutional ethical committee: INTRAS FOUNDATION, with address at C/ Martín Santos Romero No1. 47016 Valladolid, Spain, *[redacted]* Finally, the regional ethical committee: CEIm Área de Salud Valladolid Este Hospital Clínico Valladolid Facultad de Medicina, Farmacología, C/ Ramón y Cajal, 7 47005 Valladolid, España *[redacted]*[40]	INTRAS entity responsible for law and regulation: *[redacted]*; From the RDi department: *[redacted]*; Hired consultancy of VIDAU ABOGADOS - *[redacted]* (DPO).[41]

[34] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 8.
[35] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 9.
[36]
[37] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 9.
[38] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 9.
[39] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 9.
[40] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 8.
[41] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 9. See also p. 25 of D6.7.

Pilot #	Ethics Committee	Data Protection Officer
Pilot 7	UZB ethische commissie onderzoek E-mail. *[redacted]* Phone. *[redacted]* Fax. *[redacted]*[42]	UZB data protection officer *[redacted]*: *[redacted]*[43]
Pilot 8	We have acquired permission of our local ethics committee at the UZ Brussels to perform this trial. Contact information: Name: Commissie medische ethiek UZ Brussel E-mail. *[redacted]* Phone. *[redacted]* Fax. *[redacted]*[44]	Data Protection Officer (DPO) VUB: - *[redacted]* UZ Brussel: - *[redacted]*[45]

3.2.2.1 Assessment/Analysis

All Pilots, including different Studies in a Pilot, answered positively: are seeking or already acquired approval from their ethics committee; and have support from its DPO or the equivalent. While not conclusive, this finding suggests all Pilots meet the minimum requirement for ethical and legal issues.

For the next steps: (1) Documents related to application file with and approved by the ethics committee will constitute evidences and will be shared with the HosmartAI Ethics Board, and the Board will review them; (2) WP8 may communicate directly with DPO/legal on technical issues, such as an explanation how the data subjects will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded, which will be submitted as a deliverable D10.2.

3.3 Medical Ethics, Medical Devices

This section will explore the following topics/issues: Human Participants, characteristics of the study population and vulnerable individuals; informed consent, including withdrawal; and EU Medical Devices Regulation.

3.3.1 Human Participants

The underlying issue is whether there will be human participants in the Pilot Study, and if so, what are their characteristics, and any vulnerable groups/individuals are anticipated (touched in the subsequent sub-section).

[42] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 8.
[43] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 8.

[44] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 8.
[45]

Simply, if there are no human participants, then the risks and issues related to individuals are likely to be smaller.[46] If there are human participants, associated risks and issues need to be addressed. However, whether or not there will be human participants is not determinative when assessing or analysing the risk; it is one of the many factors to consider.

The table below provides summarized information of: (1) whether human participants are anticipated in the Study, and (2) the estimated sample size, if any.

Table 4: Human Participants; Estimated Sample Size.

Pilot #	Human Participants; Estimated Sample Size
Pilot 1 (ECHO)	• 120 subjects for collection of echocardiograms • 15 cardiologists in three groups according to their echocardiography experience (low, medium, high) • 3 experienced cardiologists that will provide the reference measurements and diagnoses[47][48]
(VCE)	• 80 subjects for collection of CE videos • 20 gastroenterologists in two groups according to their CE experience [non-experienced (NXP), experienced (XP)] • 3 expert gastroenterologists that will provide the ground truth abnormalities and the reference diagnoses[49]
(CCTA)	• ~1.000 subjects (training and evaluation). • (to be defined) expert cardiologists and (to be defined) expert radiologists that will provide the ground truth.[50]
(Obstetrics)	• ~1.000 subjects (training and evaluation). • expert obstetricians will provide the ground truth.[51]
Pilot 2	• 40 patients for a feasibility study[52]
Pilot 3	• 80 patients.[53] Adult people affected by neurological diseases (i.e., Stroke, Parkinson's Disease or Multiple Sclerosis, or other).[54]
Pilot 4	N/A (in-vitro)[55]
Pilot 5 (IM)	• In this study, 100 patients treated for Vascular Diseases will be enrolled in the study. • In this study, 100 patients treated for Thoracic Diseases will be enrolled.[56]

[46] See generally D8.1 SELP Benchmark Report.
[47] See D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 53.
[48] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 5.
[49] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 57.
[50] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 60.
[51] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 63.
[52] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 65.
[53] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 68.
[54] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 5.
[55] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 70. Also, the Response by Pilot 4 to the D8.3 IA Questionnaire indicates the same, p. 5 (stating "No human participant for pilot 4.2 at ETH Zurich.").
[56] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 74.

Pilot #	Human Participants; Estimated Sample Size
(UKCM)	• Originally: plan to recruit 73-163 patients (37-82 per ward) and at least 34 nursing and physiotherapeutic employees (17 per ward).[57]
Pilot 6	• Sample of 180 participants, older adults that comply with the established inclusion and exclusion criteria (see the corresponding section) and healthcare professionals. • The participants of the control group (CG) will be placed on a waiting list to use the device if they are interested, at the end of the intervention. Sample size: 25. • The experimental group (EG) will be formed by different subgroups: ○ GE_1: Participants attending INTRAS Foundation´s Memory Clinic. Sample size: 25 ○ GE_2: Participants who participate in active ageing workshops. Sample size: 90 ○ GE_3: Older adults who support the device at home. Sample size: 30 ○ GE_4: Healthcare professionals. Sample size: 20[58]
Pilot 7	• Around 6000 patients data, but the final number to be confirmed in the function of manpower resources and funding. • If CA annotation will be done only by UZB physician and with available funding, the final number of patients will be dramatically reduced.[59]
Pilot 8	• All relevant clinical and personal information starting from inclusion in the study until death will be collected.[60]

3.3.1.1 Assessment/Analysis

The notion of "Human Participants" does not always mean "patients" in HosmartAI; It can also be healthcare providers, medical professionals/staff, and the like (e.g., 4 Studies in Pilot 1). As noted earlier, there are no human participants in Pilot 4. Importantly, the estimated sample size or the detailed scale of participants is subject to change.

3.3.2 Characteristics of study population and vulnerable individuals (Q. 2)

Whether Pilot Study involves vulnerable groups/individuals is relevant for two purposes: (1) medical research ethics; and informed consent. Regarding the former, the issue is whether the research study has sufficient justification(s). On this issue, ethical instruments, such as the Declaration of Helsinki,[61] provides a guidance. Specifically, paragraph 20 of the Declaration of Helsinki stipulates that "[m]edical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from

[57] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 78.
[58] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 83.
[59] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 11.
[60] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 11.
[61] Para 19 and 20 of the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

the knowledge, practices or interventions that result from the research." Thus, we look into: (1) if the Pilot Study cannot be carried out in a non-vulnerable group; and (2) the group involved may benefit from the fruit of the Pilot Study. Regarding the latter, the issue is discussed in the subsequent sub-section.

The table below provides summarized information of: (1) characteristics of study population; and (2) whether Pilot Study anticipates vulnerable groups/individuals as participants.

Table 5: Characteristics of study population; Vulnerable groups/individuals (Q. 2).

Pilot #	Characteristics of study population; Vulnerable groups/individuals (Q. 2)
Pilot 1 (ECHO)	For subjects involved in **echocardiogram** collection: **Inclusion criteria**: • Female or male, 18 years of age or older • Subject must be in sinus rhythm during the examination **Exclusion criteria**: • Presence of atrial fibrillation • Presence of sinus or other tachycardia (heart rate > 100 bpm) • Presence of pacing rhythm • Subject has complex congenital heart disease • Subject has myocardial hypertrophy • There is need for contrasting agent to improve echocardiographic resolution • Subject is incapable of providing full consent[62]
	Vulnerable groups/individuals • ***Yes,*** *in the following way*: "Vulnerable individuals may exist among the subjects referred for ECHO. Such individuals are likely to have cardiac conditions that render them vulnerable"[63] • ***No,*** *however,* ***for the purpose of informed consent***: "Individuals incapable of providing full consent will not be included in the study."[64]
(VCE)	For subjects that will undergo **capsule endoscopy**: **Inclusion criteria**: • Female or male, 18 years of age or older **Exclusion criteria**: • Subject has small bowel stricture • Subject has obstructive symptoms • Subject has altered GI tract anatomy after surgical procedure • Subject has severe comorbidities that would prevent surgical management should this be necessary

[62] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 53.
[63] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 5.
[64] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 7.

Pilot #	Characteristics of study population; Vulnerable groups/individuals (Q. 2)
	• Subject is incapable of providing full consent[65]
	Vulnerable groups/individuals • ***Yes**, in the following way*: "Vulnerable individuals may exist among the subjects referred for VCE. Such individuals are likely to have small bowel conditions that render them vulnerable"[66] • ***No**, however, **for the purpose of informed consent***: "Individuals incapable of providing full consent will not be included in the study."[67]
(CCTA)	**Inclusion criteria**: • Patients with acute coronary syndromes and possible abnormalities in the partial movement of the wall. • Patients with heart failure. • Age ≥ 18 years. **Exclusion criteria**: • Patients who refuse to give written consent to participate in the study.[68]
	Vulnerable groups/individuals • ***Yes**, in the following way*: "Vulnerable individuals may exist among the subjects in both medical scenarios (CCTA, Obstetrics). Such individuals are likely to have cardiac conditions or complications in pregnancy respectively, that render them as vulnerable."[69] • ***No**, however, **for the purpose of informed consent***: "Individuals incapable of providing full consent will not be included in the studies."[70]
(Obstetrics)	**Inclusion criteria**: • Pregnant women with symptoms of preterm labour. • Pregnant women with symptoms of FGR. • Age ≥ 18 years. **Exclusion criteria**: • Women who refuse to give written consent to participate in the study.[71]
	Vulnerable groups/individuals

[65] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 57.
[66] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 5.
[67] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 7.
[68] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 60.
[69] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 6.
[70] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 7.
[71] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 62.

Pilot #	Characteristics of study population; Vulnerable groups/individuals (Q. 2)
	• ***Yes**, in the following way*: "Vulnerable individuals may exist among the subjects in both medical scenarios (CCTA, Obstetrics). Such individuals are likely to have cardiac conditions or complications in pregnancy respectively, that render them as vulnerable."[72] • ***No**, however, **for the purpose of informed consent***: "Individuals incapable of providing full consent will not be included in the studies."[73]
Pilot 2	(40 patients, ≥18 and ≤75 years at the moment of recruitment; male and females, no sex distribution, **Inclusion Criteria** • Patients suffering from either bone metastasis, breast or lung tumor needing among others a radiation therapy • Patients must belong to the internal CHU de Liège emergency categories: IIa, IIb, III and IV* o *Category IIa: first consultation and simulation on the same day and start of treatment within 2 to 3 days o *Category IIb: simulation within 3 to 5 days after the first consultation and treat 1-3 days after the simulation. o *Category III simulation within 5 to 8 after the first consultation and treatment within 8 days after the simulation. o *Category IV simulation within 7 to 10 after the first consultation and treatment within 14 days after the simulation • ≥18 and ≤75 years at the moment of recruitment; • Life expectancy of more than 6 months according to the clinicians' opinion; • Ability to understand the study instructions and sign the informed consent form • Patient owning a smartphone • Sufficient level of technology literacy enabling the patient to manage mobile terminals and a Chatbot on smartphone • Patient having a good internet connection in his/her home or on smartphone • Good adherence to Chatbot solutions **Exclusion Criteria** • Any patient without bone metastases or a primary tumor outside the breast or lung • Internal CHU de Liège emergency category I * o *Category I: 1st consultation, simulation and treatment the same day

[72] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 6.
[73] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 7.

Pilot #	Characteristics of study population; Vulnerable groups/individuals (Q. 2)
	• <18 and >75 years at the moment of recruitment • Short life expectancy (< 6 months) according to clinicians' opinion • Patient with cognitive decline preventing him/her to understand the study information and sign the informed consent form • Patient with low digital literacy • Patient without internet connection • Patient who does not adhere to the Chatbot solution • Current participation in other clinical studies[74]
	Vulnerable groups/individuals • ***Yes**, in the following way*: "Cancer patients fall under the definition of vulnerable individuals because they are suffering from a serious illness."[75] • ***No**, however, **for the purpose of informed consent***: "Although cancer patients are considered vulnerable individuals, only those with sufficient cognitive skills to understand the study and manage a Chatbot will be enrolled."[76]
Pilot 3	**Inclusion Criteria** Adult people affected by neurological diseases (i.e. Stroke, Parkinson's Disease or Multiple Sclerosis, or other). **Exclusion Criteria** All patients affected by the following comorbidities will be excluded from the study: • Non-stabilized fractures; • Diagnosis of major depression; • Severe deficits in visual acuity and acoustic perception; • Dementia; • Epilepsy not pharmacologically controlled; • Ideomotor apraxia; • Neglect; • Severe impairment of verbal comprehension[77]
	Vulnerable groups/individuals • ***Yes**, in the following way*: "there will be people affected by the aforementioned pathologies *[i.e., pathologies stated in the inclusion criteria]* and they are therefore considered as vulnerable individuals."[78]

[74] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 64.
[75] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 6.
[76] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 7.
[77] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 68.
[78] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 7.

Pilot #	Characteristics of study population; Vulnerable groups/individuals (Q. 2)
Pilot 4	N/A (in-vitro)[79]
Pilot 5 (IM)	**Inclusion Criteria** In total 200 patients admitted to Abdominal Surgery and Thoracic Surgery Ward for an elective (non-emergency) procedure. **Exclusion criteria**: • emergency patients, • patients without consent, • patients already randomized on either abdominal or thoracic surgery ward in Study 1 (no-double enrolment), • patients with Abbreviated MentalSU Test score 6 or lower, • patients with special needs or appointed guardians, • patients allocated to an intensive step-down unit and/or regimen are excluded.[80]
	Vulnerable groups/individuals • ***No for the informed consent purpose***: "If the individual cannot not, legally or otherwise sign the letter of consent, the individual cannot be required"[81]
(UKCM)	**Inclusion Criteria** • The patient sample will consist of patients admitted to Abdominal Surgery and Thoracic Surgery wards for an elective (non-emergency) procedure. • The staff sample will be composed of nursing and physiotherapy staff working on either the Abdominal Surgery or the Thoracic Surgery ward. Again, only employees aged 18 years or above, who have signed a consent form, will be invited to participate in the study.[82]
	Vulnerable groups/individuals • ***No for the purpose of informed consent***: "If the individual cannot not, legally or otherwise sign the letter of consent, the individual cannot be required" • The elderly patients might feel compelled to participate in the study or might sign the consent letter without reading it due to relative vision impairment. • In cases where the informed consent would be questionable, we will treat it as an exclusion criterion.[83]

[79] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 70.
[80] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 74.
[81] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 8.
[82] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 77.
[83] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 8.

Pilot #	Characteristics of study population; Vulnerable groups/individuals (Q. 2)
Pilot 6	**Older adults (N=145)** **Inclusion criteria**: • ≥ 60 years. • MMSE(≥23y≤30). • Being able to understand and consent to participate in the study. • Sign to consent for the participation and management of the data of the study (the transfer of the data to a database of open access is an option and it does not imply the exclusion of the study). • Having expressed their desire to have some support related to: a) using technologies, b) mood, c) cognitive stimulation. **Exclusion criteria**: • Sensorial difficulty that hinders the use of the device. • Having psychiatric conditions or neurologic problems that incapacitate the person to participate in the study. **Professionals (N=20)** • **Inclusion criteria**: Being a qualified social and healthcare professional to participate in the study. • **Exclusion criteria**: Have reported any interest conflict with the technology used.[84]
	Vulnerable groups/individuals • ***Yes,*** *including* ***for the purpose of informed consent***: "older adults are the vulnerable group of Pilot 6, seeing that the inclusion criteria (2) requires older adults with mild cognitive deficits (MMSE ≥ 23 and ≤ 30)."[85]
Pilot 7	**Inclusion criteria**: • All patient entering the cath lab for a coronary angiogram **Exclusion criteria**: • < 18 y o patient • ACS complicated by cardiogenic shock or cardiac arrest[86]
	Vulnerable groups/individuals • "No"[87]
Pilot 8	**Inclusion criteria**

[84] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 83.
[85] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 6.
[86] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 87.
[87] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 6.

Pilot #	Characteristics of study population; Vulnerable groups/individuals (Q. 2)
	Patients must meet all of the following recruitment criteria to be eligible for enrolment into the trial: • Diagnosis of high grade glioma (grade III or IV according to 2016 WHO classification, eligible for resection. • The patient or his/her legal representative must be able to understand the planned study procedure after receiving a detailed verbal explanation, after which they had the chance to ask any remaining questions. • No contraindication for evaluation by MRI. • Baseline MRI is performed maximum 1 week before initiation of treatment. • Current clinical status does not prevent the patient from undergoing the standard • treatment for the abovementioned condition(s); standard inclusion and exclusion • criteria for surgery in general will apply. • The patient or his/her legal representative signed and dated the informed consent (IC) document indicating that the patient (or legal representative) has been in- formed of all the pertinent aspects of the trial prior to enrolment. **Exclusion Criteria** • Patients not amenable for safe surgical resection of the HGG. • Patients not giving IC to enter the study. • Patients who do not meet the inclusion criteria.[88]
	Vulnerable groups/individuals • Vulnerable individuals may exist among the subjects. Such individuals are likely to have cardiac conditions or other health issues, that render them as vulnerable for undergoing surgery and chemotherapy. However, the primary objective of the study, is to evaluate the clinical performance of the AI-based diagnostic tools to be developed, mandates the inclusion of groups that are representative of the population encountered in regular clinical neuro-oncological practice. Vulnerable groups may benefit indirectly from the research results, in case the tools are proven to be effective.[89]

3.3.3 Informed consent (Q. 4, 5, and 6)

The central issue is whether the informed consent procedure in each Pilot is adequate.

[88] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 7.
[89] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 6.

Informed consent is fundamental to both medical practice as well as scientific research. Both are built upon the notion of principle of autonomy, and the concept of informed consent is the cornerstone of autonomy. It is not only essential from the legal point of view (i.e., Article 7 GDPR), but also from the viewpoint of ethics. A number of documents or instruments emphasizes the importance of informed consent.[90] In the subsequent sub-sections, we address the issues surrounding informed consent, including withdrawing from once given consent.

In assessment/analysis, the following elements, inter alia, are factored in:

1. Conditions for consent required by the GDPR (freely given, specific, informed, and unambiguous under Article 7 GDPR; explicit consent in relation to Article 9 GDPR and Article 22 GDPR);[91]
2. Conditions required by the Oviedo Convention and the Oviedo Additional Protocol;[92]
3. Additional consideration for participation of elder individuals;[93]
4. Additional considerations for those who are unable to provide valid consent, if applicable;[94]
5. Whether there will be sufficient time to contemplate, opportunities to ask questions;
6. Whether participants can withdraw consent at any time, with or without giving any reason, and without any negative consequences;
7. Whether withdrawing consent is as easy and simple as giving consent, at minimum;[95]
8. Whether personal data already processed for the purpose of HosmartAI will be deleted retroactively.

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[90] See e.g., Nuremberg Code; Declaration of Helsinki; International Ethical Guidelines for Health-Related Research Involving Humans; Good Clinical Practice; Handbook for Good Clinical Research Practice; International Covenant on Civil and Political Rights; Universal Declaration on Bioethics and Human Rights; or Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.

[91] See generally EDPB, Guidelines 05/2020 on consent under Regulation 2016/679 (2020), https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_202005_consent_en.pdf [hereinafter *Guidelines on Consent*].

[92] E.g., "expressly, specifically and is documented" under Article 16(v) Oviedo Convention; "adequate information in a comprehensible form" including the nature, extent, duration of the study, risks and benefits of participation, the handling of personal data and compensation in case of damage" under Article 13; "no research on a person may be carried out . . . without the informed, free, express, specific and documented consent of the person" and that "such consent may be freely withdrawn by the person at any phase of the research" under Article 14.

[93] While the consent requirements for older individuals are no different from those for general population (see GA, Annex 1, Part B, p. 102.), it is worth considering the inherent risks (e.g., confined setting where they may feel less freedom to refuse participation or assumed that giving consent will be rewarded).

[94] See Council of Europe, Recommendation No. R(99)4 of the Committee of Ministers of the Member States on Principles Concerning the Legal Protection of Incapable Adults, Part I, para. 1 (23 February 1999), https://search.coe.int/cm/Pages/result_details.aspx?ObjectID=09000016805e303c. See also The Declaration of Helsinki, the Oviedo Convention and its Additional Protocol.

[95] Although they are in a different context, consider the CNIL's action on cookie against Google and the FTC's Enforcement Policy Statement Regarding Negative Option Marketing, https://www.ftc.gov/system/files/documents/public_statements/1598063/negative_option_policy_statement-10-22-2021-tobureau.pdf.

The assessment/analysis is comprehensive or holistic, meaning a particular element does not determine the outcome and these elements are viewed in totality, as a whole.

3.3.3.1 Informed Consent (Q. 4)

The table below provides a summarized description of the informed consent procedure by each Pilot.

Table 6: Informed Consent (Q. 4).

Pilot #	Informed Consent (Q. 4)
Pilot 1 (ECHO)	Each prospective participant must provide written consent with full knowledge of the procedures involved. Informed consents, approved by the Research Ethics Committee and in accordance with regulatory guidelines, must be fully explained by the investigator or member of the study staff including the study aims, methods, benefits and risks, and signed by the subject before enrolment into the study. Prospective participants will be informed that study participation is voluntary and that they may withdraw at any time. The subjects will be told that choosing against participation will not affect the care received for treatment, in the case of data collection subjects, and their residency or work, in the case of clinicians. The prospective participant will be given sufficient time to read the study information and consent and ask any questions. Once the informed consent is signed, the participant will be given a copy of the document. Signed consent documents will be stored separately from other study records, in a locked cabinet with limited access, located at the research coordinator's office in the Hospital premises.[96]
(VCE)	Each prospective participant must provide written consent with full knowledge of the procedures involved. Informed consents, approved by the Research Ethics Committee and in accordance with regulatory guidelines, must be fully explained by the investigator or member of the study staff including the study aims, methods, benefits and risks, and signed by the subject before enrolment into the study. Prospective participants will be informed that study participation is voluntary and that they may withdraw at any time. The subjects will be told that choosing against participation will not affect the care received for treatment, in the case of data collection subjects, and their residency or work, in the case of clinicians. The prospective participant will be given sufficient time to read the study information and consent and ask any questions. Once the informed consent is signed, the participant will be given a copy of the document. Signed consent documents will be stored separately from other study records, in a locked cabinet with limited access, located at the research coordinator's office in the Hospital premises.[97]
(CCTA)	Each prospective participant must provide written consent with full knowledge of the procedures involved. Informed consents, approved by the
(Obstetrics)	

[96] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p.6.
[97] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 6.

Pilot #	Informed Consent (Q. 4)
	Research Ethics Committee and in accordance with regulatory guidelines, must be fully explained by the investigator or member of the study staff including the study aims, methods, benefits and risks, and signed by the subject before enrolment into the studies. Prospective participants will be informed that study participation is voluntary and that they may withdraw at any time. The subjects will be told that choosing against participation will not affect the care received for treatment, in the case of data collection subjects, and their residency or work, in the case of clinicians. The prospective participant will be given sufficient time to read the study information and consent and ask any questions. Once the informed consent is signed, the participant will be given a copy of the document. Signed consent documents will be stored separately from other study records, in a locked cabinet with limited access, located at the research coordinator's office in the hospital premises.[98]
Pilot 2	1) The radiotherapists or the project manager will explain the project to the patient during his/her first visit. We will ask the patient a few questions orally to ensure that he/she understood the project and its objectives. Patients will have time to read the informed consent and ask any questions before giving their consent 2) The explanations on the anonymization method are detailed in the patient consent. However, they will again be explained orally to the patients to assure them that their sensitive data will be processed in accordance with Belgian and European laws. Patients will be informed that a DPO in the hospital guarantees data protection and that a mediator is at their disposal for any complaint. We will provide the name, phone number and email address of these two professionals. In addition, if the patient believes that his/her study data are being used in violation of applicable data protection laws, he/she will informed to send a complaint at *[redacted]*[99]
Pilot 3	(1) Healthcare professionals (Physiotherapists) or the project manager will explain the project to the patient during his/her hospitalization. We will ask the patient a few questions orally to ensure that he/she understood the project and its objectives. Patients will have time to read the informed consent and ask any questions before giving their consent (2) The explanations on the anonymization method are detailed in the patient consent. However, this will again be explained orally to the patients to assure them that their sensitive data will be processed in accordance with Italian and European laws. Patients will be informed that a DPO in the hospital

[98] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 7.
[99] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 7.

Pilot #	Informed Consent (Q. 4)
	guarantees data protection and that a mediator is at their disposal for any complaint.[100]
Pilot 4	N/A
Pilot 5 (IM)	A consent letter must be signed by each participant at the recruitment phase. The letter of consent is standardized and is always attached to the submission to the ethics committee.[101]
(UKCM)	A consent letter must be signed by each participant at the recruitment phase. The letter of consent is standardized and is always attached to the submission to the ethics committee.[102]
Pilot 6	Please see p.32,35 and 82 of D5.1. The basic elements defined for the informed consent will be followed. There is also a model that will be adapted from the consent form used for the co-creation sessions. (1) Explicit Consent will be obtained in a paper format by the healthcare professionals in the memory clinic and by the older adults included as participants. Additionally, relatives/caregivers will be contacted to be informed and accept the incorporation of the participant. Participants unable to sign the consent form will not be included in the study. (2) A single person will be in charge of entering the data, which will then be passed to the Statistical Package for the Social Sciences (SPSS) for statistical analysis and finally the results will be presented by means of graphic procedures. A database will be designed to include the evaluation scores of each participant in an easier way. The database collects the personal information, inclusion criteria and results in pre- test and post-test evaluation. Subsequently, the information will be analysed using the SPSS, and finally, the results will be interpreted.[103]
Pilot 7	There are 2 parts of the study: AI smart reporting and clinical decision support training and validation study. Data will be retrospective (case already done) and prospective (case to be done). For the first group, the patient will be contacted and an informed consent will be obtained by regular mail and phone. For the prospective part, all patients entering the study will sign an informed consent at hospital admission. The informed consent will be added to the coronary angiogram information document.[104]
Pilot 8	Prior to obtaining the informed consent, a patient will be assessed for eligibility for participation in the trial based on the predefined inclusion and exclusion criteria. *[Here, the inclusion and exclusion criteria in the response to the questionnaire is omitted.]*

[100] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 6.
[101] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 7.
[102] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 7.
[103] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 7.
[104] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 7.

Pilot #	Informed Consent (Q. 4)
	If an eligible patient agrees to be enrolled in the trial, a written informed consent will be dated and signed by the patient and/or his legal representative. The established protocol allows us to process all relevant anonymised clinical information and personal data in the context of this trial. By signing the informed consent, patients allow us to do so.[105]

3.3.3.2 Vulnerable individuals and consent (Q. 5)

The table below provides a summarized description of the informed consent procedure for vulnerable individuals (please note that, here, vulnerable individuals can mean vulnerable within the meaning of medicine or for the purpose of informed consent).

Table 7: Vulnerable individuals and consent (Q. 5).

Pilot #	Vulnerable individuals and consent (Q. 5)
Pilot 1 (ECHO)	Informed consent will be obtained from all prospective participants following the same procedure (described in the previous response to Q. 4). Individuals incapable of providing full consent will not be included in the study. Any participants that require special attention will be treated appropriately. No concerns, risks, or possible negative consequences are foreseen.[106]
(VCE)	Informed consent will be obtained from all prospective participants following the same procedure (described in the previous response to Q. 4). Individuals incapable of providing full consent will not be included in the study. Any participants that require special attention will be treated appropriately. No concerns, risks, or possible negative consequences are foreseen.[107]
(CCTA) (Obstetrics)	Informed consent will be obtained from all prospective participants following the same procedure (described in the previous response to Q. 4). Individuals incapable of providing full consent will not be included in the studies. Any participants that require special attention will be treated appropriately. No concerns, risks, or possible negative consequences are foreseen.[108]
Pilot 2	Although cancer patients are considered vulnerable individuals, only those with sufficient cognitive skills to understand the study and manage a Chatbot will be enrolled. Thus the participants will not need special attention and no risks are linked to their conditions.[109]
Pilot 3	All patients affected by the following comorbidities will be excluded from the study: Non-stabilized fractures; diagnosis of major depression; severe deficits in visual acuity and acoustic perception; dementia; epilepsy not pharmacologically controlled; ideomotor apraxia; neglect; severe

[105] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 7.
[106] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p.7.
[107] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 7.
[108] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 7.
[109] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 7.

Pilot #	Vulnerable individuals and consent (Q. 5)
	impairment of verbal comprehension. Therefore the participants will not need special attention and no risks are linked to their conditions.[110]
Pilot 4	N/A
Pilot 5 (IM)	If the individual cannot not, legally or otherwise sign the letter of consent, the individual cannot be required (consider exclusion criteria)[111]
(UKCM)	If the individual cannot not, legally or otherwise sign the letter of consent, the individual cannot be required (consider exclusion criteria)[112]
Pilot 6	(1) In Pilot 6 case, it is not a special consent, but an adaptation of the consent for the older adults. (2) the participant's cognitive impairment may increase throughout the Project. Also, in respect to covid pandemic, the participants are more vulnerable, not only as in physical health, but also mental health. (3) For the cognitive impairment, the healthcare team will carry out regular assessments throughout the study and the devices used on this pilot will aim for a customized mode that adapts to the person, according to their level of impairment. For covid mitigation measures please see p. 84 of D5.1 for covid measures.[113]
Pilot 7	NA[114]
Pilot 8	N/A[115]

3.3.3.3 Withdrawing consent (Q. 6)

The table below provides summarized description on withdrawal of consent, including how participants may withdraw and its consequences.

Table 8: Withdrawing consent (Q. 6).

Pilot #	Withdrawing consent (Q. 6)
Pilot 1 (ECHO)	The participant information sheet contains all the information related to consent withdrawal, clearly describing participants' rights and the process for withdrawal. Participants will have to carefully review and understand the participant information sheet, before providing consent. Members of the study staff obtaining the consent will inform participants that study participation is voluntary and that they are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice. Participants that wish to withdraw their consent will be able to do so by contacting the principal investigator via mail, telephone, e-

[110] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 7.
[111] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 8.
[112] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 8.
[113] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 7.
[114] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 7.
[115] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 8.

Pilot #	Withdrawing consent (Q. 6)
	mail, or in person. Contact details are included in the participant information sheet, which will be included in the signed copy of the consent form that will be given to each participant after enrolment.[116]
(VCE)	The participant information sheet contains all the information related to consent withdrawal, clearly describing participants' rights and the process for withdrawal. Participants will have to carefully review and understand the participant information sheet, before providing consent. Members of the study staff obtaining the consent will inform participants that study participation is voluntary and that they are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice. Participants that wish to withdraw their consent will be able to do so by contacting the principal investigator via mail, telephone, e-mail, or in person. Contact details are included in the participant information sheet, which will be included in the signed copy of the consent form that will be given to each participant after enrolment.[117]
(CCTA) (Obstetrics)	The participant information sheet contains all the information related to consent withdrawal, clearly describing participants' rights and the process for withdrawal. Participants will have to carefully review and understand the participant information sheet, before providing consent. Members of the studies staff obtaining the consent will inform participants that study participation is voluntary and that they are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice. Participants that wish to withdraw their consent will be able to do so by contacting the principal investigator via mail, telephone, e-mail, or in person. Contact details are included in the participant information sheet, which will be included in the signed copy of the consent form that will be given to each participant after enrolment.[118]
Pilot 2	1) This is well explained in the informed consent but will be explained again orally before the patient agrees to participate 2) The patient can withdraw from the study by contacting either his/her radiotherapist or the project manager. 3) The patients will be aware of the following "Your participation in the study is voluntary and must remain free of any constraint: this means that you have the right not to participate or to withdraw without justification even if you had previously agreed to participate. Your decision will in no way affect your relationship with the investigating doctor or any other nursing staff or the quality of your future therapeutic care"[119]
Pilot 3	Before participants decide to take part in the study, (1), (2) It is important that they understand its objectives and what they will be asked to do, if they decide to take part in it, through correct and complete information so that

[116] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p.7.
[117] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 7.
[118] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 7.
[119] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 8.

Pilot #	Withdrawing consent (Q. 6)
	he/she can express a free and informed choice: therefore, there is an information sheet containing a detailed description of the study, followed by an explicit request for informed consent. In addition to the explanations they will give during an interview, the investigator and his or her staff are available for any clarification. Each informed consent will be signed in duplicate, one for the investigator and one for the patient; the names of the researchers responsible for the study and all their contact details will also be included. (3) Patients' participation in the Pilot is completely free. If they change their mind and withdraw their consent from the study, they are free to do so at any time without explanation and without affecting their care and treatment.[120]
Pilot 4	N/A
Pilot 5 (IM)	In the paper documentation received and during recruitment, each patient is explained participation is voluntary, and she/he can step out of the study at any given time. Upon withdrawing, each patient will be asked if the data collected during the study can be used for research by signing a withdrawal statement. If the patient does not agree. All the data related to him is removed. No negative consequences are foreseen since the gold standard is provided in any case.[121]
(UKCM)	In the paper documentation received and during recruitment, each patient is explained participation is voluntary, and she/he can step out of the study at any given time. Upon withdrawing, each patient will be asked if the data collected during the study can be used for research by signing a withdrawal statement. If the patient does not agree. All the data related to him is removed. No negative consequences are foreseen since the gold standard is provided in any case.[122]
Pilot 6	Like it is explained on the normal consent form, (1) The participant is free to withdraw from this study at any time, without giving a reason. (2) The participant should inform the study responsible(s), whose name will be indicated in the informed consent. (3) In this case, his/her data will be deleted. No disadvantage to the ex-participant.[123]
Pilot 7	By contacting the study nurse or physician identified at the end of the informed consent document.[124]
Pilot 8	A patient may withdraw the written consent at any time and request that we sever any connection between the additional investigation and their identity. However, it is specified in the informed consent that we cannot undo any conclusions already made at that time. Results obtained from the samples before their withdrawal to participate remain the property of the study

[120] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 8.
[121] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 8.
[122] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 8.
[123] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 8.
[124] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 7.

Pilot #	Withdrawing consent (Q. 6)
	sponsor. Withdrawal of the consent will have whatsoever no consequences for their medical supervision and treatment.[125]

3.3.3.4 Assessment/Analysis

In light of elements enumerated in 3.3.3.1, we do not find any of the informed consent procedure insufficient and inadequate. Most importantly, all Pilots designate "[i]ndividuals incapable of providing full consent will not be included in the study."[126] In case elder individuals compose most (or all) of the study population, such as Pilot 6, additional considerations/safeguards are provided. In addition to the response by Pilot 6 in Table 7, the additional safeguards are described in the response to question 3 (which asks: "please describe all the measures you will take in order to prevent any harm or negative consequences to the vulnerable individuals."). The pertinent part reads:

- The documents passed to participants will have the vocabulary appropriate for these people and the size letters will be adapted as well for them to read.
- When signing any document, they can be accompanied by a family member.
- For digital literacy confidence, we enable a learning period with the help of a professional so that the person does not feel frustrated. And these professionals will be available to help.
- Perhaps a satisfaction survey at the end of the intervention (this is still to be defined).[127]

Almost all descriptions by the Pilots are in alignment with the elements enumerated above. Also, most of the Pilots explicitly mentioned "sufficient time to read." Pilot 2, for example, explicitly described the step where they "will ask the patient a few questions orally to ensure that he/she understood the project and its objectives."[128]

However, we do mention and recommend all Pilots to review their informed consent procedure by referring to the elements enumerated above. Especially, reviewing if their informed consent procedure is not "bundled" which asks for "overall general consent to everything" is very relevant. While this issue is also touched in 3.4.4.3 (Data retention/deletion (Q. 18)),[129] we iterate the importance of obtaining consent separately on separate issues (i.e., granularity discussed under the GDPR[130]).

The issue of informed consent is one of the most important and high priority issues for all Pilots, WP8, and for HosmartAI. Thus we will work will continue to communicate with each

[125] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 8.
[126] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 7.
[127] Response by Pilot 6 to the D8.3 IA Questionnaire, p.6.
[128] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 7.
[129] Referring to "future research."
[130] See Guidelines on Consent, p. 12.

Pilot as to its informed consent policy and practice. Importantly, the following documents concerning informed consent will be either submitted as deliverables or will be kept on file:

- D10.1 : H - Requirements No. 1
  - 2.2. The informed consent procedures that will be implemented for the participation of humans must be submitted as a deliverable.
  - 2.3. Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be kept on file.
- D10.2 : POPD - Requirement No. 5
  - 4.11 Detailed information on the informed consent procedures in regard to data processing must be kept on file.
  - 4.12 Templates of the informed consent forms and information sheets (in language and terms intelligible to the participants) must be kept on file.
- D10.3 : GEN - Requirement No. 6
  - A report by the Ethics Board must be submitted as a deliverable in month 18.

3.3.4 EU Medical Devices Regulation (Q. 8)

The issue is whether the AI technology that will be used in Pilot Study will trigger EU Medical Devices Regulation. If Pilot Study triggers, or chooses to trigger (i.e., intend to market), there will be certain compliance procedures to be followed.

Accordingly, we asked in the questionnaire: "In the coming Pilot Study, do you intend to market your technology, such as medical device or software, for the medical purposes?"

The table below provides summarized response of: (1) if the technology falls within the definition of Medical Devices under the EU Medical Devices Regulation, and/or (2) whether they intend to market their technology as Medical Device.

Table 9: Medical Devices Regulation (Q. 8).

Pilot #	Medical Devices Regulation (Q. 8)
Pilot 1 (ECHO)	The technology falls within the definition of Medical Devices.[131]
(VCE)	The technology falls within the definition of Medical Devices.[132]
(CCTA)	The technology falls within the definition of Medical Devices by design, however, within the framework of the HosmartAI project we will not run certification procedures, as we mainly aim at the evaluation of the tools under development at a research level.[133]
(Obstetrics)	The technology falls within the definition of Medical Devices by design, however, within the framework of the HosmartAI project we will not run

[131] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 8.
[132] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 8.
[133] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 8.

Pilot #	Medical Devices Regulation (Q. 8)
	certification procedures, as we mainly aim at the evaluation of the tools under development at a research level.[134]
Pilot 2	Pilot#2 AI-based software for appointment scheduling Following the paragraph here below, Hospital Information Systems Hospital information systems support the process of patient management: from patient admission, through scheduling appointments, to insurance and billing purposes. According to the EU MDR, such Hospital Information Systems aren't qualified as medical devices[135]
Pilot 3	CE-marked medical devices and sensors (position sensors, lights on/off, etc.) will be used to control the therapy room.[136]
Pilot 4	N/A
Pilot 5 (IM)	NO[137]
(UKCM)	NO[138]
Pilot 6	GRADIOR device is currently in the market, but it is not credited as a medical device. INTRAS team are enquiring whether it is necessary to credit GRADIOR as a medical device. If yes, the team will proceed to credit it. The iPrognosis technologies fall within the definition of Medical Devices. i-MAT?[139]
Pilot 7	Yes[140]
Pilot 8	No[141]

3.3.4.1 Assessment/Analysis

Majority of the Pilots do not implicate EU Medical Devices Regulation. Either they do not intend to market as Medical Device in the Pilot Study or their technology does not fall within the definition of Medical Devices under the regulation (e.g., Pilot 1 (CCTA, Obstetrics), Pilot 2, Pilot 3, Pilot 5 (both Studies), and Pilot 8).

There are, however, Pilots that will or may be subject to EU Medical Devices Regulation, namely Pilot 1 (ECHO, VCE), Pilot 6 (provided it chooses to do so), and Pilot 7.

Next steps: WP8 will communicate with Pilot 1 (ECHO, VCE), Pilot 6, and Pilot 7 to discuss compliance procedure and will track each development.

[134] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 8.
[135] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 8.
[136] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 9.
[137] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 9.
[138] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 9.
[139] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 9.
[140] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 8.
[141] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 9.

3.4 Data Protection/Privacy, including Profiling

The overall issue is whether the Pilot's Study Protocol or the policy on processing of personal data applicable to the Study is compliant with the GDPR.

Here, we take a risk-based approach. It means we will not ask all questions inquiring about their policies and practices to assess if they are likely to comply. Instead, we take a twofold approach. First, as touched above, we look into if they have been complying with the data protection/privacy laws with the support of its DPO and/or relevant department/team. However, this is only indicative of the minimum requirement. Thus, second, we select and focus on the fundamental and specific sub-issues in this first impact assessment report in order to assess the data protection/privacy related risks. These 7 sub-issues, discussed in the following sub-sections.

1. Are the types of personal data, including sensitive personal data, to be collected/processed specifically identified?
2. How will data subjects be informed of their rights under the GDPR? Will the legal basis for the processing of personal data be on consent, or will there be any other legal basis?
3. Is the data controller(s) and data processor(s) identified?
4. Is there a policy on access control, anonymisation/pseudonymisation, and data retention/deletion?
5. What is the scale of processing of personal data?
6. Is there a less privacy invasive mean to achieve the same objective?
7. Will there be profiling or automated decision-making?

The assessment and analysis of these sub-issues are done comprehensively or holistically. That means, it is not merely a yes or no type of analysis, but we view it in totality, as a whole. How each sub-issue is viewed or assessed/analysed (e.g., what is considered lower/high risk) is explained in the relevant sub-section.

3.4.1 Types of personal data, including sensitive personal data (Q. 10, 11)

The issue is: Are the types of personal data, including sensitive personal data, to be collected/processed identified, and if identified, how specific they are. The more it is specifically identified, (while not conclusive) it is suggestive that the type of personal data to be processed is being properly managed as "data inventory."

The table below provides summarized response of: (1) are the types of personal data to be processed identified; and (2) are the types of "sensitive" (or "special categories of") personal data to be processed identified. The detailed specification can also be found in D5.1 and/or D6.7.

Table 10: Personal Data (Q. 10) and Sensitive Personal Data (Q. 11).

Pilot #	Personal Data (Q. 10)	Sensitive Personal Data (Q. 11)
Pilot 1 (ECHO)	The personal data to be collected from the ECHO subjects participating in the study comprise the: *[omitted as it's long because the response is specific and detailed]*[142]	The following data are health-relevant and therefore considered sensitive: 1) Known cardiovascular conditions 2) Arterial pressure before the examination 3) Echocardiograms 4) Measurements of the Left Ventricular Ejection Fraction 5) Measurements of the Left Ventricular Global Longitudinal Strain 6) Diagnoses of left ventricular function[143]
(VCE)	The personal data to be collected from the VCE subjects participating in the study comprise the: *[omitted as it's long because the response is specific and detailed]*[144]	The following data are health-relevant and therefore considered sensitive: 1) Relevant medical history 2) CE videos 3) Identified small bowel abnormalities 4) Diagnoses of small bowel condition[145]
(CCTA)	The personal data to be collected from the subjects who undergo CCTA and participating in the study comprise the: *[omitted as it's long because the response is specific and detailed]*[146]	All data to be collected in both studies are health-relevant and therefore considered as sensitive.[147]
(Obstetrics)	The personal data to be collected from the pregnant women participating in the study comprise the: *[omitted as it's long because the response is specific and detailed]*[148]	All data to be collected in both studies are health-relevant and therefore considered as sensitive.[149]

[142] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 9.
[143] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 10.
[144] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 9.
[145] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 10.
[146] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 9.
[147] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 11.
[148] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 10.
[149] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 11.

Pilot #	Personal Data (Q. 10)	Sensitive Personal Data (Q. 11)
Pilot 2	Pilot # 2 will collect and use personal data from different sources such as electronic health records, Mosaiq software (radiotherapy treatment planning), UltrAgenda (complete patient medical appointments). In addition to the above data, the pilot will discover (1) data related to patient and healthcare professional satisfaction and (2) patient preferences regarding the time slot they wish to be irradiated.[150]	All data related to the description of the patient's health status constitutes sensitive personal data. Moreover, the data related to the patient's appointment preferences as well as the data related to the appointment proposals processed by chatbot constitute sensitive data because they allow to deduce information on the patient's health condition or even the type of pathology he/she is suffering from. Indeed, both in terms of patients' appointment preferences and in terms of the proposals made by chatbot, the qualification of the appointment is specified. Therefore, it is reasonable to consider that a patient who is proposed an appointment for irradiation is suffering from cancer.[151]
Pilot 3	The participation of patients in the study will be compulsorily recorded in the medical file and some personal data will be requested, such as age, sex, date of birth, schooling. Researchers will handle personal data and all health-related information in a strictly confidential manner. Confidentiality of all information will be ensured by using ID codes and pseudonymisation to ensure privacy.[152]	The study will be conducted in accordance with the ethical principles set out in the 'Declaration of Helsinki' and the 'Convention on Human Rights and Biomedicine' (Oviedo Convention). The derived/inferred data will not be sensitive data.[153]
Pilot 4	N/A	N/A
Pilot 5 (IM)	The prospective data will include personal information such as age, gender education, occupation. The data will be linked with patient ids. Thus pseudo-anonymized since personal information may be	The prospective data will include personal information such as age, gender education, occupation. The data will also be linked with patient ids. Thus, pseudo-anonymized since personal information may be

[150] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 10.
[151] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 10.
[152] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 10.
[153] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 10.

Pilot #	Personal Data (Q. 10)	Sensitive Personal Data (Q. 11)
	retrieved if access to UKCMs Medical System is granted. For details on data collection, please refer to D5.1.[154]	retrieved if access to UKCMs Medical System is granted. The access to the Medical System is managed by the legal framework of the sponsor and is not subject of this study. In the study, we will collect data regarding psychological distress and health markers. For details on data collection, please refer to D5.1.[155]
(UKCM)	The prospective data will include personal information such as age, gender education, occupation. The data will be linked with patient ids. Thus pseudo-anonymized since personal information may be retrieved if access to UKCMs Medical System is granted. For details on data collection, please refer to D5.1.[156]	The prospective data will include personal information such as age, gender education, occupation. The data will also be linked with patient ids. Thus, pseudo-anonymized since personal information may be retrieved if access to UKCMs Medical System is granted. The access to the Medical System is managed by the legal framework of the sponsor and is not subject of this study. In the study, we will collect data regarding psychological distress and health markers. For details on data collection, please refer to D5.1.[157]
Pilot 6	Some data is still being decided. However, here is what is expected to the different devices that Pilot 6 will integrate: For GRADIOR: *[omitted as it's long because the response is specific and detailed]* The personal data that are going to be collected with the iPrognosis smartphone application comprise the: *[omitted as it's long because the response is specific and detailed]*	Each partner is responsible for their data and the data sent to the HosmartAI platform will be pseudonymized. The following data produced by the iPrognosis tools are health-relevant and therefore are considered sensitive: 1) Bradykinesia and rigidity scores 2) Flags of tremor detected/not detected in call 3) Flags of voice sample corresponding to a person with/without Parkinson's disease 4) Similarity scores with reference movement[159]

[154] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 10.
[155] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 10.
[156] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 10.
[157] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 10.
[159] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 10.

Pilot #	Personal Data (Q. 10)	Sensitive Personal Data (Q. 11)
	Tests (iMAT) comprise the: *[omitted as it's long because the response is specific and detailed]* The data that are going to be derived/inferred from the aforementioned data comprise the: 1) Bradykinesia and rigidity scores 2) Flags of tremor detected/not detected in call 3) Flags of voice sample corresponding to a person with/without Parkinson's disease 4) Similarity scores with reference movement[158]	
Pilot 7	Response by Pilot 6 to the D8.3 IA Questionnaire, p. 10.[160]	
Pilot 8	• All relevant personal and clinical data of the participating patients will be processed by the PI of this study or anyone working directly under his supervision. The only investigators with access to personal and clinical data are investigators with a medical background (physicians) and physicians caring for the patient. All other involved parties and investigators will only be able to view anonymized data. • The gathered data will only be used to investigate the endpoints. • There will be no transfer of personal data to any other countries.[161]	The clinical and personal data gathered in line with this trial is very sensitive since it contains identifiers and information regarding the health status of the patients.[162]

[158] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 10.
[160] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 9.
[161] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 10.
[162] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 10.

3.4.1.1 Assessment/Analysis

Most of the Pilots have identified and stipulated the types of personal data, including "sensitive" personal data, to be processed in a detailed and specific way either in the response to the questionnaire and/or in deliverables D5.1 or D6.7. Furthermore, few Pilots (Two Studies from Pilot 1, Pilot 2, Pilot 6) distinguish derived/inferred or discovered data (as output of AI technology) from collected personal data. This demonstrates the extent to which the type of personal data to be processed is being properly managed as "data inventory" (See also "data mapping"). This practice would be an advantage when addressing issues concerning profiling and automated decision-making, which will be discussed in the relevant sub-section (3.4.7), *infra*. Also, the exact explanations required by the GDPR will be submitted as D10.2.

Some Pilots are still in the process of determining what types of personal data to be processed. The further detailed specifications of the Pilot Study will be documented in D5.2, and WP8 will follow the updates.

3.4.2 The rights of data subject and legal basis (Q. 13 and Q. 14)

The two central issues are: (1) how participants will be informed of their rights as a data subject under the GDPR; and (2) what will be the legal basis for processing of personal data.

Regarding the first issue. It is suggestive that the risk is relatively lower if the response (alone or in conjunction with other responses and specifications on deliverables) sufficiently explains when/what/how the information will be provided to, or can be accessed by, the data subject. Regarding the second issue. The risk is considered to be higher if it is not identified, or the Pilot seeks to rely on multiple legal bases.

The table below provides summarized information of: (1) how participants will be informed of their rights as a data subject under the GDPR; and (2) whether the Pilot seeks to use a legal basis other than consent.

Table 11: Rights of data subject (Q. 13) and Legal basis (Q. 14).

Pilot #	Info re rights of data subject (Q. 13)	Other legal bases (Q. 14)
Pilot 1 (ECHO)	All information regarding subject rights and processing of personal data will be provided in the participant information sheet.[163]	No.[164]
(VCE)	All information regarding subject rights and processing of personal data will be provided in the participant information sheet.[165]	No.[166]

[163] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 11.
[164] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 11.
[165] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 10.
[166] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 10.

Pilot #	Info re rights of data subject (Q. 13)	Other legal bases (Q. 14)
(CCTA)	All information regarding subject rights and processing of personal data will be provided in the participant information sheet.[167]	No.[168]
(Obstetrics)	All information regarding subject rights and processing of personal data will be provided in the participant information sheet.[169]	No.[170]
Pilot 2	Upon recruitment, patients will receive full explanations of the project, including how their data will be anonymized and protected by the hospital. In addition, we will explain to them that in the event of a data leak, they can contact the DPO, the legal service and the hospital mediation service. The emails and contact phones of these 3 entities will be clearly indicated to patients. Cancer patients, considered as vulnerable, will be informed of their rights. All the personal data collected are detailed in the informed consent.[171]	Yes, eventually. GDPR articles 9.2.j and 89 entitles member states to define special derogation for the processing of personal data for scientific research. Those derogations have been translated into Belgian Law 30 July 2018 on the Protection of Individuals with regard to the Processing of Personal Data for scientific research purposes and describes the necessary measures to put in place. D5.1 foresees the adjustment of the AI-based software with retrospective data within Pilot#2.[172]
Pilot 3	See Q.6[173]	No.[174]
Pilot 4	N/A	N/A
Pilot 5 (IM)	This will be well elaborated in the paper documentation given to the subjects and explained in detail upon recruitment.[175]	NO[176]
(UKCM)	This will be well elaborated in the paper documentation given to the subjects and explained in detail upon recruitment.[177]	NO[178]

[167] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 12.
[168] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 12.
[169] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 12.
[170] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 12.
[171] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 11.
[172] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 11.
[173] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 11.
[174] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 11.
[175] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 11.
[176] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 11.
[177] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 11.
[178] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 11.

Pilot #	Info re rights of data subject (Q. 13)	Other legal bases (Q. 14)
Pilot 6	Along with the consent form, the participant will receive an informative sheet. The informed consent signed in duplicated, and the procedure and a form to withdraw. Within these documents, participants will have the contact of the healthcare professional responsible to monitor the health data.[179]	No.[180]
Pilot 7	We make use of standard information that the hospital provides the patient. If the patients are included in a study they can be visualised in the hospital data management system.[181]	No[182]
Pilot 8	All relevant information regarding their rights as participants and purpose of data processing is described in the signed informed consent and protocol.[183]	N/A[184]

3.4.2.1 Assessment/Analysis

All Pilots will provide all necessary information (e.g., subject rights and processing of personal data) either in the informed consent document or additional document. Pilot 8 has "a webpage of our neurosurgery department which contains relevant information regarding ongoing trials at our center []. Besides this webpage, we recently created our consortium webpage [] containing information about our team and ongoing projects."[185] In our view, having a dedicated webpage for the Pilot Study which contains, *inter alia*, information regarding the rights as a data subject as well as a patient is a good practice.

All Pilots will basically rely on consent as its legal basis for processing. Pilot 2 will eventually seek to rely on scientific research purpose provision under the Belgium data protection law, provide it describes the necessary measures to put in place.

3.4.3 Data Controller and Data Processor (Q. 12)

The issue is whether data controller(s) and data processor(s) are specifically identified. If specifically identified, it would be a basis to presume that the roles and responsibilities under the GDPR are understood by each organization.

[179] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 11.
[180] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 12.
[181] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 10.
[182] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 10.
[183] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 11.
[184] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 11.
[185] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 6.

The table below provides the name or the identity information of: (1) data controller(s); and (2) data processor(s).

Table 12: Data Controllers and Data Processors (Q. 12).

Pilot #	Data Controller(s)	Data Processor(s)
Pilot 1 (ECHO)	Third Department of Cardiology of the AUTH at the Hippokration General Hospital[186]	The Signal Processing and Biomedical Technology Unit (SPBTU) of the Department of Electrical and Computer Engineering (ECE) of the AUTH[187]
(VCE)	First Department of Internal Medicine of the AHEPA Hospital[188]	Signal Processing and Biomedical Technology Unit (SPBTU) of the Department of Electrical and Computer Engineering (ECE) of the Aristotle University of Thessaloniki (AUTH) [189]
(CCTA)	the First Department of Cardiology and the Laboratory of Radiology and Radiodiagnostics, of the School of Medicine, of the Aristotle University of Thessaloniki, at the AHEPA General Hospital of Thessaloniki[190]	the Laboratory of Medical Physics and Digital Innovation, of the School of Medicine, at Aristotle University of Thessaloniki[191]
(Obstetrics)	the Third Department of Obstetrics & Gynaecology of the Aristotle University of Thessaloniki at the Hippokration General Hospital of Thessaloniki[192]	the Laboratory of Medical Physics and Digital Innovation, of the School of Medicine, at Aristotle University of Thessaloniki[193]
Pilot 2	Centre Hospitalier Universitaire de Liège[194] *However, there's a possibility of*: "Either CHU Liège and technical partners jointly act as Data Controllers. To be decided."[195]	University of Maribor, ICTL, MTA[196]

[186] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 10.
[187] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 10.
[188] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 10.
[189] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 10.
[190] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 11.
[191] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 11.
[192] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 11.
[193] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 11.
[194] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 11.
[195] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 11.
[196] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 11.

Pilot #	Data Controller(s)	Data Processor(s)
Pilot 3	*(waiting for update)*[197]	*(waiting for update)*[198]
Pilot 4	N/A	N/A
Pilot 5 (IM)	UKCM (sponsor of the study)[199]	UM[200] *Possibility*: We might also consider GC and ITCL as Data Processors.[201]
(UKCM)	UKCM (sponsor of the study)[202]	UM[203] *Possibility*: We might also consider GC and ITCL as Data Processors.[204]
Pilot 6	[205]	[206]
Pilot 7	*[redacted]* (UZ Brussel), *[redacted]* (UZ Brussel) and senior cathlab staff (UZ Brussel)[207]	*[redacted]* (UZ Brussel), *[redacted]* (UZ Brussel), UZ Brussels IT, Philips IT specialist in charge of the study.[208]
Pilot 8	*[redacted]*, the Principal Investigator of the trial[209]	*[redacted]*, a pre-doctoral researcher[210]

3.4.3.1 Assessment/Analysis

All Pilots identified the data controller(s) and data processor(s), including the possibility of identifying additional entity as data processor(s).

3.4.4 Access control, anonymisation / pseudonymisation, data retention / deletion

This sub-section consolidates and touches upon three issues: access control, anonymisation/pseudonymisation, and data retention/deletion.

3.4.4.1 Access Control (Q. 15)

The issue is whether access control is properly managed by the Pilot (i.e., granting access to individual(s) who should/can have access to personal data, as well as revoking access).

Technically, all individuals in the organization named as data controller (or processor) can be granted access. Obviously, this is not a practice that is encouraged. We consider the risk is

[197] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 10.
[198] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 10.
[199] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 11.
[200] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 11.
[201] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 11.
[202] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 11.
[203] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 11.
[204] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 11.
[205] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 12.
[206] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 12.
[207] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 10.
[208] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 10.
[209] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 10.
[210] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 10.

relatively lowered if the Pilot can identify who will be granted access as narrow and specific as possible.

The table below provides summarized information of: (1) characteristics of study population; and (2) whether Pilot Study anticipates vulnerable groups/individuals as participants.

Table 13: Access control (Q. 15).

Pilot #	Access control (Q. 15)
Pilot 1 (ECHO)	Investigators from the Third Department of Cardiology of the AUTH and the SPBTU of the Department of ECE of the AUTH who are authorized by the Principal Investigator (PI) will be given access to (de-identified) data. Only the PI and study staff members of the Third Department of Cardiology of the AUTH, authorized by the PI to obtain consent, will have access to records that contain names or other personal identifiers, such as signed consent documents, as well as records that link participant ID numbers to other identifying information.[211]
(VCE)	Investigators from the First Department of Internal Medicine of the AHEPA Hospital and the SPBTU of the Department of ECE of the AUTH who are authorized by the Principal Investigator will be given access to (de-identified) data. Only the PI and study staff members of the Department of Internal Medicine of the AHEPA Hospital, authorized by the PI to obtain consent, will have access to records that contain names or other personal identifiers, such as signed consent documents, as well as records that link participant ID numbers to other identifying information.[212]
(CCTA) (Obstetrics)	Investigators who are authorized by the Principal Investigator (PI) will be given access to (de-identified) data. Only the PI and staff members of the studies, authorized by the PI to obtain consent, will have access to records that contain names or other personal identifiers, such as signed consent documents, as well as records that link participant ID numbers to other identifying information.[213]
Pilot 2	The health care professionals (doctors, nurses, physicists) and responsible for the scheduling at the Radiotherapy department have access right to the patient personal data. Given that their jobs at CHU de Liège automatically grant them access to the patient personal data, the Pilot does not need a process to grant them access right. All these professionals are subject to medical confidentiality. The technical partners of the Pilot will have access to anonymised data.[214]
Pilot 3	The health care professionals of San Camillo IRCCS Hospital have access right to the patient personal data; the Pilot does not need a process to grant them access right.

[211] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 11.
[212] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 11.
[213] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 12.
[214] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 12.

Pilot #	Access control (Q. 15)
	All these professionals are subject to medical confidentiality. The technical partners of the Pilot will have access to anonymised data.[215]
Pilot 4	N/A
Pilot 5 (IM)	Only researchers from UM and UKCM.[216]
(UKCM)	Only researchers from UM and UKCM.[217]
Pilot 6	As stated above, partners' applications (Gradior, I-prognosis, i-MAT) process personal data and each partner will receive the data in the corresponding applications. For the clinical study, it is expected that a single person from the research team will be in charge of entering the personal data. Also, as explained in the protocol, there will be limited access to the data management of the team responsible for the project (INTRAS Foundation data managers: *[redacted]* and *[redacted]*).[218]
Pilot 7	Clinicians (*[redacted]* and *[redacted]*) and IT Team in Philips working for the development of pilot 7.[219]
Pilot 8	All relevant personal and clinical data of the participating patients will be processed by the PI of this study or anyone working directly under his supervision. The only investigators with access to personal and clinical data are investigators with a medical background (physicians) and physicians caring for the patient. All other involved parties and investigators will only be able to view pseudonymized data.[220]

3.4.4.1.1 Assessment/Analysis

Most Pilots identified specifically who/which team will be granted access to the personal data. Further, some Pilots explained who is in charge of deciding who will be granted access, which clarifies the roles and responsibility within the organization on this risk/issue.

We suggest all Pilots to review their plan/policy on who will be granted access to personal data processed for the purpose of HosmartAI especially if the Pilot tends to grant access to a wide range of individuals/groups of its organization. Instead, Pilots should seek to grant access to a particular individuals/group/team within the organization.

3.4.4.2 Anonymisation/Pseudonymisation (Q. 17)

The issue is whether Pilot has a specific plan or policy with regard to anonymising and/or pseudonymising personal data.

Several elements will be factored in when assessing/analysing the risk. Risk is relatively lowered if the Pilot specific plan/policy on: (1) what personal will be

[215] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 11.
[216] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 12.
[217] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 12.
[218] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 12.
[219] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 11.
[220] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 11.

anonymised/pseudonymised; (2) when it will be anonymised/pseudonymised; and (3) how it will be anonymised/pseudonymised.

The table below provides summarized responses on: (1) anonymisation; and (2) pseudonymisation.

Table 14: Anonymisation/Pseudonymisation (Q. 17).

Pilot #	Anonymisation	Pseudonymisation
Pilot 1 (ECHO)	Not applicable.[221]	Upon provision of consent, participants will be assigned a coded ID number that will be used for reference in all data records, both electronic and hard-copy, to maintain confidentiality. Identification of participants using information other than the coded ID number assignment, will not be possible.[222]
(VCE)	Not applicable.[223]	Upon provision of consent, participants will be assigned a coded ID number that will be used for reference in all data records, both electronic and hard-copy, to maintain confidentiality. Identification of participants using information other than the coded ID number assignment, will not be possible.[224]
(CCTA) (Obstetrics)	Not applicable.[225]	Upon provision of consent, participants will be assigned a coded ID number that will be used for reference in all data records, both electronic and hard-copy, to maintain confidentiality. Identification of participants using information other than the coded ID number assignment, will not be possible.[226]
Pilot 2	D5.1 foresees the adjustment of the AI-based software with retrospective data within Pilot#2. Anonymisation will be the preferred data minimization technique to comply with national law and GDPR.[227]	D5.1 foresees the adjustment of the AI-based software with retrospective data within Pilot#2. If anonymisation cannot be used to reach the research objectives, pseudonymisation can be used. In this case, the reasons to use pseudonymisation shall be documented in the register of personal data processing.[228]

[221] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 12.
[222] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 12.
[223] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 11.
[224] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 12.
[225] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 13.
[226] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 13.
[227] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 13.
[228] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 13.

Pilot #	Anonymisation	Pseudonymisation
Pilot 3		Personal Data such as age, sex, date of birth, schooling will be pseudonymised after patient enrolment.[229]
Pilot 4	N/A	N/A
Pilot 5 (IM)	Statistical Cohorts ISO/IEC 20889:2018[230]	Data linked with hospital's internal ids. However, those IDs will not be published in the datasets.[231]
(UKCM)	Statistical Cohorts ISO/IEC 20889:2018[232]	Data linked with hospital's internal ids. However, those IDs will not be published in the datasets.[233]
Pilot 6	Anonymization and/or Pseudonymisation: by attributing a participant code and keeping the original file on a protected server to which only the main data administrator (coordinator) will have access.[234]	
Pilot 7		Please refer to D2.1 (page 91). The variable body temperature is now omitted from the study. Data send outside UZB will be pseudonymized.[235]
Pilot 8		The obtained imaging information (in DICOM format) will be also pseudonymized and coded as it will be used for training our deep learning algorithm. Video information will be pseudonymized if it is to be viewed by anyone other than the trial investigators with a medical background (physicians) or physicians caring for the patient. The only investigators with access to specific patient data are investigators with a medical background (physicians) and physicians caring for the patient. All other involved parties and investigators will only be able to view pseudonymized data.[236]

[229] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 12.
[230] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 12.
[231] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 12.
[232] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 13.
[233] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 13.
[234] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 13.
[235] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 13.
[236] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 12.

3.4.4.2.1 Assessment/Analysis

All Pilots will pseudonymise personal data by using some kind of ID instead of the participants real identity. Pilot 5, and possibly Pilot 2 and 6, will also use data after anonymising. Also, D5.1[237] mentions that two international standards by the ISO, namely ISO/IEC 20889:2018 and ISO 25237:2017, will be followed when anonymising or pseudonymising.

3.4.4.3 Data retention/deletion (Q. 18)

The issue is whether there is a policy on data retention/deletion applicable to processing of personal data for the purpose of HosmartAI.

Many organizations have data retention/deletion policy, and these policies are applicable to the ordinary course of business/practice and often to research projects like HosmartAI. We consider the risk is heightened if there is no applicable policy on personal data processed for the purpose of HosmartAI.

The table below provides a summarized description of data retention/deletion policy of each Pilot.

Table 15: Data retention/deletion (Q. 18).

Pilot #	Data retention/deletion (Q. 18)
Pilot 1 (ECHO)	Electronic data are preserved indefinitely. Hard copy documents are stored for five years after the end of the study and afterwards they are destroyed.[238]
(VCE)	Electronic data are preserved indefinitely. Hard copy documents are stored for five years after the end of the study and afterwards they are destroyed.[239]
(CCTA)	Electronic data are preserved indefinitely. Hard copy documents are stored for five years after the end of the study and afterwards they are destroyed.[240]
(Obstetrics)	
Pilot 2	Personal data shall be deleted at the end of the HosmartAI project. This applies to all personal data except the data used to treat and care for the patient which should be kept for 30 years after the patient last visit at the hospital as required by the Belgian Law 2019-04- 22/20, Art. 35.[241]
Pilot 3	It will be indicated in the research project the duration of the research itself, including data collection, statistical processing and the possible time of publication of relevant scientific articles. At the end of this period, the documentation related to the experiment must be retained (without using it for different research purposes unless explicitly requested to Ethics Committee territorial and interested parties through new consent) for a period of at least 7 years (art. 18 of the Legislative Decree 200 of November 6, 2007), or for the time necessary for the fulfilment of further legal obligations.

[237] Chapter 2.5 of D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version.
[238] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 12.
[239] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 12.
[240] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 13.
[241] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 14.

Pilot #	Data retention/deletion (Q. 18)
	At the end of this period (duration of the research + at least 7 years) the aforementioned data and samples are anonymized; if it is not possible to anonymize them, they will be deleted.[242]
Pilot 4	N/A
Pilot 5 (IM)	In the consent, we will ask participants to allow us to process data for future research. Without an explicit agreement, the data will be removed after the final review of HosmartAIm approximately six months after the project ends. This will be elaborated in the informed consent documentation.[243]
(UKCM)	In the consent, we will ask participants to allow us to process data for future research. Without an explicit agreement, the data will be removed after the final review of HosmartAIm approximately six months after the project ends. This will be elaborated in the informed consent documentation.[244]
Pilot 6	The data shall be kept for as long as they are necessary to ensure the adequate healthcare of the patients. Thereafter, the data shall be retained for at least five years from the date of discharge from each care process. After the blocking period has elapsed, they must be destroyed. Personal data may be kept for longer periods provided that they are processed exclusively for archiving purposes in the public interest, for scientific research purposes or for statistical purposes. Also for research purposes, they may be pseudonymised, i.e. the patient's identification data may be separated from health data, although they may be re-associated if necessary.[245]
Pilot 7	Patient administrative data will be deleted.[246]
Pilot 8	Current legislation requires that personal information included in this study be kept for 20 years or 30 years if this data is also part of their medical record.[247]

3.4.4.3.1 Assessment/Analysis

In this first impact assessment report, we do not conduct thorough and case by case analysis on whether or not each period is sound and reasonable in light of GDPR as well as other applicable laws. This is partly because: (1) it will depend on what type of data; and (2) other factors such as periods to retain/store/archive data required, for example, by archiving law may be implicated too. Having said that, we remind one of the general principles of the GDPR, namely the principle of storage limitation, which in short says "organizations cannot keep personal data for longer than necessary in relation to the purpose."[248]

[242] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 13.
[243] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 13.
[244] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 13.
[245] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 13.
[246] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 13.
[247] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 12.
[248] Article 5(1)(e) GDPR.

If a Pilot intends to ask participants to consent to processing of personal data for future research (i.e., research separate from HosmartAI), it shall seek to obtain consent separately from other consent. Further, the "future research" in question needs to be specific, as opposed to "any future research in general."

3.4.5 Scale of processing of personal data (Q. 16)

The issue here is what is the scale of processing of personal data in the Pilot Study. This sub-section and the subsequent sub-section are assessed/analysed in conjunction, which is about less privacy invasive means.

The risk or impact on the individuals' fundamental rights including data protection/privacy is likely to be higher if, *inter alia*, the scale of processing of personal data is greater. At the same time, certain scale of processing of personal data is necessary in order to carry out research study efficiently and effectively. Thus, minimising the scale of processing of personal data and carrying out research study efficiently and effectively are two fundamental requirements that need to be balanced and harmonized.

The table below provides summarized description of the scale of processing with an emphasis on the number of participants engaged and types of personal data as well as (1) frequency of data collection (e.g., once a week or 24/7); (2) granularity of data collection (e.g., from questionnaire to monitoring with sensors); (3) duration of data collection (e.g., for 2 weeks 3 sessions or 2 years).

Table 16: Scale of processing of personal data (Q. 16).

Pilot #	Scale of processing of personal data (Q. 16)
Pilot 1 (ECHO)	Personal data will be collected from all participants only once, except, possibly, for cases in which a follow-up examination is required and falls within the duration of the study. All personal data except for echocardiograms will be collected via case report forms. Echocardiograms will be collected using ultrasound sensors, following the standard clinical procedures. Derived/inferred data will be generated multiple times for each participant; multiple cardiologists will review each ECHO examination, and each cardiologist will review multiple ECHO examinations, with and without AI assistance.[249]
(VCE)	Personal data will be collected from all participants only once, except, possibly, for cases in which a follow-up examination is required and falls within the duration of the study. All personal data except for CE videos will be collected via standard data collection forms. CE videos will be collected using CE equipment, following the standard clinical procedures. Derived/inferred data will be generated multiple times for each participant; multiple gastroenterologists will review each CE examination, and each

[249] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 11.

Pilot #	Scale of processing of personal data (Q. 16)
	gastroenterologist will review multiple CE examinations, with and without AI assistance.[250]
(CCTA) (Obstetrics)	Personal data will be collected from all participants only once, except, possibly, for cases in which a follow-up examination is required and falls within the duration of the study. All personal data will be collected via case report forms. Examinations results (like CCTA results, computerized cardiotocography (cCTG) results, etc.) will be collected following the standard clinical procedures.[251]
Pilot 2	(1) Scale Retrospective Data: data of 100 patients who had completed their treatment at the radiotherapy department. Prospective data of 40 cancer patients. (2) The frequency of data collection 24/7 (3) Granularity: Besides patient health data, 2 types of questionnaires will be presented to the 40 patients at the beginning and the end of the study. Data from the Chatbot for accepting/rejecting new appointments will be collected as well. A satisfaction questionnaire dedicated to healthcare professionals will be completed on a voluntary basis (4) Duration of the data collection: Retrospective data: 9 to 10 months (M18 to M27) Prospective Data: during 10 months (M31to M41)[252]
Pilot 3	Clinical rating scales and qualitative questionnaires will be administered before and after treatments. Clinical data will also be collected through the hospital's robotics and virtual reality devices during the treatments, which will last for each patient 1 hour per day, 5 times a week for 3 weeks for a total of 15 sessions. The domotic sensor system of the treatment room will be available 5 days a week, 8 hours a day.[253]
Pilot 4	N/A
Pilot 5 (IM)	Please refer to the study design in study protocols for the details. We will process data of 200 patients. Any personal data collected for the purpose of this study will be collected during recruitment (i.e. age, gender, occupation, education).[254]
(UKCM)	Please refer to the study design in study protocols for the details. We will process data of 200 patients. Any personal data collected for the purpose of

[250] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 11.
[251] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 12.
[252] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 12.
[253] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 12.
[254] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 12.

Pilot #	Scale of processing of personal data (Q. 16)
	this study will be collected during recruitment (i.e. age, gender, occupation, education).[255]
Pilot 6	Gradior: (1) in the home setting, the data will be collected when the participants' chooses to use the system provided; (2) the data collected is by questionnaire format; (3) data is collected once the system is used. The frequency of data collection with the iPrognosis smartphone application depends on the degree to which the participant uses their smartphone to type or make phone calls. Data are collected on every such occasion. The frequency of data collection with the iPrognosis Motor Assessment Tests (iMAT) depends on how often the participant performs the tests. Data are collected on every such occasion.[256]
Pilot 7	Around 5000 patients data, but the final number is to be confirmed in the function of manpower resources and funding. If CA annotation will be done only by UZB physician and with available funding, the final number of patients will be dramatically reduced. 1) Development phase • Aim: training the Smart Reporting and Clinical Decision Support AI-based tools • All Cases from November 2020 until October 2022 • Expected Number : Around 4000 coronary angiogram including 1400 PCI, 100 FFR/iFR/RFR single point physiological assessment and 100 FFR and iFR/RFR motorized pullback from corfys registry. • Offline analysis of clinical, X-ray imaging data of coronary angiogram and PCI and physiological data by a core lab. Assessment of inter-operator reliability. • On-site assessment of Key Performance Indicators in medical and nurses reporting and sign-off • Measure of post PCI FFR gain. 2) Validation phase • Aim: validation of the Smart Reporting and Clinical Decision Support AI-based tools • All cases from November 2022 until October 2023 • Expected N: Around 2000 coronary angiogram including 700 coronary angiogram with PCI and more than 400 FFR/iFR/RFR pullback assessment • Online analysis of clinical, X-ray imaging data of coronary angiogram and PCI and physiological data by a core lab. Assessment of inter-operator reliability. • On-site assessment of Key Performance Indicators in medical and nurses reporting and sign-off • Measure of post PCI FFR gain.

[255] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 12.
[256] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 12.

Pilot #	Scale of processing of personal data (Q. 16)
	6 main sets of patient data will be processed by the AI-based tool: 1) Clinical data of patients from UZ Brussel's Electonic Health Record called PRIMUZ 2) Coronary angiogram from Philips IntelliSpace CardioVascular (ISCV) Portal 3) Patient X-ray dosimetry from Philips IntelliSpace CardioVascular (ISCV) Portal 4) Coronary physiology data: resting index measure (iFR/RFR) or hyperemic index (FFR) either during a manual or a motorized wire pullback and performed before and after a coronary intervention. 5) Intravascular imaging data of patient evaluated by either Intravascular ultrasound (IVUS) Optical coherence tomography (OCT) technique before and after a coronary intervention 6) Coronary CT data including FFRCT computation of patient referred for an invasive coronary angiogram and/or a coronary intervention (GE revolution and Heartflow software). (1) Frequency of data collection Continuous data extraction on a daily basis (coronary angiogram annotation and sending to Philips) (2) Granularity of data collection DICOM file analyzed by Philips annotation system. (3) duration of data collection 3 years: 11/2020-10/2023[257]
Pilot 8	All relevant clinical and personal information starting from inclusion in the study until death will be collected. Frequency of data collection heavily depends on the current treatment a patient receives. During concomitant radiochemotherapy, patients will be seen weekly on the neuro-oncological consultation for a complete bloodwork and clinical check-up. Starting the adjuvant chemotherapy, consultations are once per month. Imaging will be carried out in between these therapies. Approximate duration of the study and thus of data collection is 2 years.[258]

3.4.6 Less privacy invasive means (Q. 21)

The issue is whether the degree of privacy invasion to the participants by the Study is necessary and proportional to achieve its objective. In other words, is the degree of privacy invasion in alignment with the principles of necessity and proportionality.

[257] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 11.
[258] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 12.

There is no clear line that divides what is necessary or proportionate from what is not. However, one way to test is to see whether a less privacy invasive mean can be conceived. If it is possible to conceive any means that are less privacy invasive to achieve the objective of the Pilot Study, then the proposed Pilot Study is presumed to be incompatible with necessity and proportionality principles (i.e., a particular processing of personal data is either unnecessary and/or not proportionate to achieve the purpose). If the response indicates there is a less privacy invasive mean, we further look into why the Pilot chooses the proposed way and not the alternative.

Accordingly, we asked if Pilots could think or conceive any less privacy invasive ways to achieve the same Pilot goal effectively. The table below provides the response by each Pilot if they can conceive any less privacy invasive means.

Table 17: Less privacy invasive means (Q. 21).

Pilot #	Less privacy invasive means (Q. 21)
Pilot 1 (ECHO)	No.[259]
(VCE)	No.[260]
(CCTA)	No.[261]
(Obstetrics)	No.[262]
Pilot 2	The appointment schedule based on artificial intelligence is in no way intrusive either for the enrolled patient or for the professionals of the CHU. This automatic schedule will be based on the same data/parameters used during the design of the schedule carried out by hand by the planning managers of the radiotherapy department. If there is an intrusion, it is at the Chatbot level because only patients with an acceptable level of digital literacy to communicate via this conversational robot can be enrolled. It is therefore rather the patients who cannot be included due to a low numerical level who, being excluded from the study, may feel that their privacy is affected because they are marginalized due to a certain incompetence.[263]
Pilot 3	No[264]
Pilot 4	N/A
Pilot 5 (IM)	No.[265]
(UKCM)	No.[266]

[259] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 13
[260] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 13.
[261] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 15.
[262] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 15.
[263] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 15.
[264] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 14.
[265] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 13.
[266] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 14.

Pilot #	Less privacy invasive means (Q. 21)
Pilot 6	No.[267]
Pilot 7	No, to develop a solution that eventually might be used in the cathlab it is necessary to build this on real world (complex) data[268]
Pilot 8	No.[269]

3.4.6.1 Assessment/Analysis

All the responses, either by simple "No" or with a detailed explanation, stated all Pilots did not conceive a less privacy invasive mean to achieve the same objective. We do not review the soundness or the veracity of each response from the perspective of medical research. We take them as sound and true. Thus, admittedly, this is a self-evaluation type of question. Nevertheless, we ask this question in order to bring this issue to the attention and remind all Pilots that the Pilot Study should be designed in a way that it is least privacy invasive. We recommend Pilots to ask themselves, and each other, whether their processing of personal data in the Pilot Study is necessary and proportionate in relation to the purpose.

3.4.7 Profiling (Q. 19) and Automated Decision-Making (Q. 20)

The issue is whether the AI technology in the Pilot Study triggers the provisions concerning automated decision-making including profiling under the GDPR. In short, various additional obligations will be implicated if yes.[270] Furthermore, this issue is important because, per the Grant Agreement, HosmartAI will "provide explanation how the data subjects will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded," and will submit as a deliverable D10.2. Finally, this issue is closely related to issues concerning AI Ethics, and thus they will be analysed again in the relevant section, *infra*.

The concepts of profiling[271] and automated decision-making[272] under the GDPR are closely related to each other. Automated decision-making "may partially overlap with or result from profiling." [273] Moreover, "[a]utomated decisions can be made with or without profiling;

[267] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 15.
[268] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 15.
[269] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 13.
[270] See generally Article 29 Data Protection Working Party, Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679 (2018), https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=612053 [hereinafter *Guidelines on Profiling*].
[271] A particular type of processing of personal data. Under the GDPR, profiling is defined as "any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements." Article 4(4) GDPR.
[272] "Automated decision-making" is not defined under the GDPR. See II. Definitions, B. Automated decision-making of Guidelines on Profiling.
[273] Guidelines on Profiling, p. 8.

profiling can take place without making automated decisions."[274] Profiling consists of three elements:

1. automated form of processing (automated processing element);
2. carried out on personal data (use of personal data element);
3. to evaluate or predict the personal aspects about an individual (Objective or purpose element).[275]

The GDPR addresses profiling and automated decision-making is threefold:

1. Profiling in general
2. Decision-making based on profiling; and
3. Solely automated decision-making, including profiling, which produces legal effects or similarly significantly affects the data subject[276]

Guidelines on Profiling explains the difference between the second (ii) and the third (iii) type using the following examples.

- an individual applies for a loan online
    - a human decides whether to agree the loan based on a profile produced by purely automated means (ii);
    - an algorithm decides whether the loan is agreed and the decision is automatically delivered to the individual, without any prior and meaningful assessment by a human (iii).[277]

In short, data controllers can carry out profiling (i) and automated decision-making (ii) as long as they can meet all the principles and have a lawful basis for the processing[278] under the GDPR. The third (iii) will implicate additional safeguards and restrictions stipulated in Article 22(1).[279] Additionally, the data controller is required to carry out data protection impact assessment (DPIA) particularly in the case of:

- decision-making including profiling with legal or similarly significant effects that is *not* wholly automated, as well as
- solely automated decision-making defined in Article 22(1)[280]

3.4.7.1 Profiling (Q. 19)

The table below provides summarized responses by each Pilot when asked: "is the technology you plan to use in the Pilot Study capable to profile data subjects?"[281]

[274] Guidelines on Profiling, p. 8.
[275] Guidelines on Profiling, p. 6.
[276] Guidelines on Profiling, p. 8.
[277] Guidelines on Profiling, p. 9.
[278] Guidelines on Profiling, p. 9.
[279] Guidelines on Profiling, p. 9.
[280] Article 35(3)(a). See Guidelines on Profiling, p. 29.
[281] The questionnaire also provides brief explanation of what it means to "profile data subjects." See Annex for the Questionnaire.

Table 18: Profiling (Q. 19).

Pilot #	Profiling (Q. 19)
Pilot 1 (ECHO)	The technology to be evaluated in the study is an AI-based software for automatic estimation of cardiac functional parameters from ECHO scans. Deep learning-based AI is used to process ECHO scans and automatically identify regions that correspond to cardiac structures of interest (i.e., the left ventricular endocardium and myocardium), which are further processed by conventional techniques to derive estimates of the functional parameters. These estimates are used by cardiologists, who would otherwise have to calculate them using time-consuming semi-manual methods, to assess and diagnose cardiac function.[282]
(VCE)	The technology to be used in the study is an AI-based software for automatic detection and classification of small bowel abnormalities from CE videos. These abnormalities are related to the subject's gastrointestinal health status.[283]
(CCTA)	The technology to be used in the study is an AI-based software for automatic estimation of the presence of CAD based on the subject's clinical data and CCTA results. These functional parameters are related to the subject's cardiovascular health status.[284]
(Obstetrics)	The technology to be used in the study is an AI-based software for automatic estimation of cases threatened by pre-term labor and/or FGR based on the subject's clinical data and cCTG results. These functional parameters are related to the subject's pregnancy and the health status of both the mother and fetus.[285]
Pilot 2	The technology of the Pilot 2 is not capable of profiling subjects[286]
Pilot 3	Yes. There will be clinical profiling of patients by automatic detection of behaviours based on continuous data acquisition from wearable devices.[287]
Pilot 4	N/A
Pilot 5 (IM)	No.[288]
(UKCM)	No.[289]
Pilot 6	Gradior: through login, the application will differentiate patients from healthcare professional and which person profile. This is made by associating an individual code for each account. The iPrognosis technologies are capable of monitoring participants longitudinally, by capturing and processing data as described in the response

[282] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 12.
[283] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 12.
[284] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 14.
[285] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 14.
[286] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 14.
[287] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 13.
[288] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 13.
[289] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 13.

Pilot #	Profiling (Q. 19)
	to Q. 10. The captured data as well as the generated results are related to the participant's health status in terms of Parkinson's disease symptoms severity. Social robot: through the interaction with the patient, the robot will invite the user to identify him/herself. After this, the system will make the association of this information to the user identification.[290]
Pilot 7	No[291]
Pilot 8	N/A[292]

3.4.7.2 Automated Decision-Making (Q. 20)

The table below provides summarized responses by each Pilot when asked: "Is the technology you plan to use in the Pilot Study capable of making decisions or providing information that supports human to make decisions?" The response on automated decision-making by each Pilot consists of two descriptions. The first description is the kind of decision/information that will be provided as an output of AI technology. The second description is how human actors will use such decision/information. These two descriptions are important for the following reasons:

1. The aim of the first part of the question is to ensure whether the AI technology in the Pilot Study would likely trigger the automated decision-making including profiling regulation under the GDPR. Even if the response to the previous question (i.e., profiling question)[293] is negative, nevertheless we ask this question because the AI technology may still trigger the provisions of automated decision-making.
2. The aim of the second part of the question is to find how the output (i.e., decision or information) is being used by the human participant. We consider it poses a higher risk if the output: (1) makes a decision on (or determines the outcome of), (2) a matter of consequence,[294] (3) without any human intervention.[295] While on the contrary, and while not conclusive, the posed risk may be smaller if the output of AI technology is used as one of the multiple sources of information when a human actor makes the decision, for example.

[290] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 14.
[291] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 14.
[292] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 12.
[293] Part of the text of the question, Q. 19, in the Questionnaire reads: "Is the technology you plan to use in the Pilot Study capable to profile data subjects (i.e., participants, whether as a patient or a healthcare provider)? If yes, please explain . . ."
[294] Cf. Article 22(1) GDPR (stating ". . . produces legal effects concerning him or her or similarly significantly affects him or her.").
[295] Cf. Article 22(3) GDPR (stating ". . . the right to obtain human intervention on the part of the controller, to express his or her point of view and to contest the decision.").

Table 19: Automated decision-making (Q. 20).

Pilot #	Automated decision-making (Q. 20)
Pilot 1 (ECHO)	(1) Kind of decisions/information: The technology to be used in the study is an AI-based software for automatic estimation of cardiac functional parameters from ECHO scans. (2) How humans use such decision/information: The functional parameter estimates are expressive of cardiovascular health. Cardiologists use such estimates (in addition to other information) in routine clinical practice, to examine and diagnose cardiac function. After diagnosis, patients are treated accordingly.[296]
(VCE)	(1) Kind of decisions/information: The technology to be used in the study is an AI-based software for automatic detection and classification of small bowel abnormalities from CE videos. (2) How humans use such decision/information: Any abnormalities identified in the CE videos are indicators of possible small bowel conditions. Gastroenterologists inspect the findings and, consulting also other information, arrive at a diagnosis. After diagnosis, patients are treated accordingly.[297]
(CCTA)	(1) Kind of decisions/information: Automatic estimation of presence of CAD based on the subject's clinical data and CCTA results (CCTA medical scenario). (2) How humans use such decision/information: Physicians will use the estimations/predictions (for both medical scenarios) in conjunction with the rest of the medical information to draw conclusions and decisions about additional/next examinations that need to be done.[298]
(Obstetrics)	(1) Kind of decisions/information: Automatic estimation of cases threatened by pre-term labor and/or FGR based on subject's clinical data and cCTG results (Obstetrics medical scenario). (2) How humans use such decision/information: Physicians will use the estimations/predictions (for both medical scenarios) in conjunction with the rest of the medical information to draw conclusions and decisions about additional/next examinations that need to be done.[299]
Pilot 2	(1) Kind of decisions/information: The technology will establish an automated decision of the patient flow as part of the appointment planning of successive irradiations. Therefore, the automation of pilot 2 is not part of a clinical decision-making.

[296] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 13.
[297] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 13.
[298] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 14.
[299] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 14.

Pilot #	Automated decision-making (Q. 20)
	(2) How humans use such decision/information: The AI-based software will propose a schedule that will be accepted (validated) or refused by the professionals of the CHU. Moreover, these professionals will interact with the software when it will be necessary to restart a calculation in the event that one or more parameters must be modified.[300]
Pilot 3	(1) Kind of decisions/information: To be defined (2) How humans use such decision/information: To be defined[301]
Pilot 4	N/A
Pilot 5 (IM)	(1) Kind of decisions/information: - risks of psychological distress - rule-based engine for raising alerts based on health quality measures (2) How humans use such decision/information: - data visualization and analysis during grand round routine - improved decision making during grand round routine[302]
(UKCM)	(1) Kind of decisions/information: - risks of psychological distress - rule-based engine for raising alerts based on health quality measures (2) How humans use such decision/information: - data visualization and analysis during grand round routine - improved decision making during grand round routine[303]
Pilot 6	(1) Kind of decisions/information: Plan editor and chat. To cognitively stimulate the participant, the solution will propose activities according to the behaviour of the participant. Also, regarding the chat, the solution (either social robot, either e-coach system) will respond to the participant according to the answer provided, in a conversation mode. The iPrognosis technologies generate information related to the participant's health status in terms of Parkinson's disease symptoms severity. The information has been described in the derived/inferred data, in the response to Q. 10. (2) How humans use such decision/information: The participants can communicate with the system once is on. And the participant can decide if they will follow the recommendations or not.

[300] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 15.
[301] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 14.
[302] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 14.
[303] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 14.

Pilot #	Automated decision-making (Q. 20)
	In i-Prognosis, the generated information may be used by medical professionals to assess the health status of a person with Parkinson's disease in terms of symptoms severity, and therefore disease development and progression.[304]
Pilot 7	(1) Kind of decisions/information: The AI-based application will not perform automated decision making but is primarily intended to provide automated documentation during/after PCI interventions. (2) How humans use such decision/information: The interventional cardiologist and the logging nurse will be supported by the algorithm to enhance their workflow. The interventional cardiologist/nurse will be able to view and correct the AI-enabled data output if necessary.[305]
Pilot 8	(1) Kind of information: By feeding standard MRI imaging sequences (T1 +/- Gd, T2/FLAIR, Diffusion weighted imaging,..) into our algorithm, the AI system will propose different biopsy locations (of distinct tumoral regions on imaging) which will be resected during the planned surgery of the glioblastoma. These regions will subsequently be thoroughly analysed using NGS. With each surgery, this will process be repeated. (2) How humans use such decision/information: The proposed locations will be evaluated by neurosurgeons pre-operatively to assess feasibility and to minimize additional peri-operative complications. If deemed not feasible, the surgeon can decide not to take a sample in this location.[306]

3.4.7.3 Assessment/Analysis

1. Re profiling. Please note that these responses in the first table are not conclusive as to whether the technology in question does, or does not, fall within the definition of profiling or automated decision-making under the GDPR. The responses indicate how each technical partner categorized or conceived of their technology.

We apply given facts/evidence to the three elements provided by the Guidelines on Profiling:

1. automated form of processing (automated processing element);
2. carried out on personal data (use of personal data element);
3. to evaluate or predict the personal aspects about an individual (Objective or purpose element)

[304] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 14.
[305] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 14.
[306] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 13.

Considering these elements, some Pilot's technologies are less likely to fall within the definition of "profiling" under the GDPR. Some Pilot's technologies are indicated as "profiling" in the response, and in our view, it seems to suffice all three elements (Pilot 1 and 3). In Pilot 6, at least or more technologies seem to fall within the definition, making the technology as a whole "capable of profiling."

Next steps. In any case, WP8 will work with each Pilot, especially with the ones that fall within the definition of profiling, to ensure each Pilot complies with the profiling regulation under the GDPR. Specifically, how each Pilot with profiling technology will provide the explanations -- how the data subjects will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded -- will be submitted as deliverable D10.2.

2. Re automated decision-making. In all cases,[307] the output of AI technology does not make decisions. Instead, the output by the technology is intended to be used by either the healthcare professional (e.g., Cardiologists/Gastroenterologists/Physicians (Pilot 1), professionals of the CHU (Pilot 2), interventional cardiologist and the logging nurse (Pilot 7), or neurosurgeons (Pilot 8)) or by participants (Pilot 6). Moreover, in these cases where AI technologies are used by healthcare professionals, the output is considered as one of the multiple sources of information, and decisions by healthcare professionals are considered to be the ground truth. In other words, humans can, do, and are expected to override the output by technology as an integral part of the Pilot Study. This lowers the risk or concerns of humans semi-automatically following the output by technology or circumventing the rule by fabricating human involvement.

3. Re solely automated decision-making. Finally, we have not found any Pilot Studies that may be classified as "solely automated decision-making, including profiling, which produces legal effects or similarly significantly affects the data subject" that implicates Article 22 GDPR on two grounds. First, we do not find any Pilot Study that suffices the element of "solely automated decision" because humans (healthcare providers) are involved in the decision-making process (if there is any decision making).[308] Second, arguably, we do not find any Pilot Study that suffices the element of "'legal' or 'similarly significant' effects."

3.5 AI Ethics: Ethical and Societal Issues

This section addresses risks concerning the use of technologies referred to as Artificial Intelligence in HosmartAI ("AI technologies") in the context of ethical and social issues, while the previous section was in the context of legal issues.

The overarching issue is whether the anticipated use of AI technologies in each Pilot is likely to trigger risks in the context of ethical or social issues.

[307] Except for Pilot 3 where the responses are to be determined, and Pilot 4 where the current Pilot Study is in-vitro.
[308] It means there is no human involvement in the decision process. See Guidelines on Profiling, p. 20.

One of the critical differences between risks in the context of ethical/social issues and those in the legal context is the fact that the line distinguishing acts/conditions in accordance with the norm from those that are not, is less clear. Generally, and arguably, the law provides clearer line when or what act/condition constitute a violation of a law, partly because providing a clear guidance is one of the characteristics of law (or at least is a requirement as a matter of legal principle). However, ethical norms, which sets the standard for which or what act/condition is ethical and is not ethical, tend to be less clear compared to the law. This is especially the case with social norms, as they are often not written, and there could be multiple competing views (unless the norm is enacted as a law or documented as code of conduct, for example). Use of facial recognition technology (FRT), for example, illustrates this point. Absent law governing use of FRT, some welcome and favour the use of FRT arguing that it helps reduce or solve crimes, while some strongly oppose to it arguing it has irreversible consequences once it is used on large scale.

The same is true in the use of AI and robotic technologies in the medical/healthcare context. Apart from applicable laws and regulations, the line distinguishing what constitutes ethical from what does not, is less clear. The line may be even less clear for what is socially acceptable, and what is not socially acceptable.

Here, in the first impact assessment report, we aim to assess/analyse the ethical and social impact of Pilot technologies by: (1) suppose that the AI technology will err and will make mistakes during the Pilot Study; (2) ask what is the added or heightened risk due to the use of AI technology in question; and (3) ask how the Pilot Study is designed to detect and deter the risk as well as mitigate the risk.

3.5.1 AI technologies involved (Q. 22)

First, we clarify the AI technology involved, this time with the emphasis on how humans get involved or interact with the AI technology. Thus, we asked: ". . . will you use a technology that is generally considered as "Artificial Intelligence" (i.e., different from conventional procedure-oriented programming method; uses machine/deep/reinforced learning techniques; . . .). Please describe the AI technologies . . ., including how humans get involved or interact with the AI technologies? E.g., AI technologies and: (1) participants; (2) health care providers; or (3) HosmartAI researchers." The table below provides the responses of each Pilot.

Table 20: AI technologies involved (Q. 22).

Pilot #	Short description of the AI technologies involved (Q. 22)
Pilot 1 (ECHO)	The technology to be evaluated in the study is an AI-based software for automatic estimation of cardiac functional parameters from ECHO scans. Deep learning-based AI is used to process ECHO scans and automatically identify regions that correspond to cardiac structures of interest (i.e., the left ventricular endocardium and myocardium), which are further processed by conventional techniques to derive estimates of the functional parameters. These estimates are used by cardiologists, who would otherwise have to

Pilot #	Short description of the AI technologies involved (Q. 22)
	calculate them using time-consuming semi-manual methods, to assess and diagnose cardiac function.[309]
(VCE)	The technology to be used in the study is an AI-based software for automatic detection and classification of small bowel abnormalities from CE videos. Deep learning-based AI is used to process CE videos and automatically detect and classify abnormalities in every video frame. The findings are used by gastroenterologists, who would otherwise have to manually inspect the entire video, to arrive at a diagnosis regarding small bowel health.[310]
(CCTA)	The technology to be used in the study is an AI-based software for automatic estimation of presence of CAD based on the subject's clinical data and CCTA results. Machine learning-based AI is used to process both clinical and CCTA-derived data and automatically identify cases with possible CAD.[311]
(Obstetrics)	The technology to be used in the study is an AI-based software for automatic estimation of cases threatened by pre-term labor and/or FGR based on the subject's clinical data and cCTG results. Machine learning-based AI is used to process both clinical and cCTG derived data and automatically identify possible pre-term labor and FGR threatened cases.[312]
Pilot 2	Pilot 2 will establish AI-based software to support patient treatment planning. The software will be built on retrospective database and will have to "learn" through this same data. Several data located in different computer programs of the hospital will form the basis of the software. The software will be connected to a Chatbot which will suggest appointment changes to patients when one must be deleted due to a case of force majeure (machine failure, illness of a healthcare professional or urgent treatment of another patient., etc). *[. . .]* the software will be tested on 40 patients in a RWD environment. The software will take the form of a calendar where doctors and those responsible for hospital planning will be able to interact by modifying the dates and / or the duration of care.[313]
Pilot 3	Robotics and virtual reality technologies will be used for motor recovery of the upper limb, lower limb and balance in subjects suffering from neurological diseases. These technologies will be incorporated into a dedicated, fully sensorised area, which will aim to control actively the hospital environment, monitoring the largest number of activities that can be performed by the patient, both autonomously and under therapists' supervision.[314]
Pilot 4	N/A
Pilot 5	Please consider section 1.5 of the two study protocols for details.[315]

[309] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 14.
[310] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 14.
[311] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 15.
[312] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 15.
[313] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 16.
[314] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 15.
[315] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 15.

Pilot #	Short description of the AI technologies involved (Q. 22)
(IM)	
(UKCM)	Please consider section 1.5 of the two study protocols for details.[316]
Pilot 6	Yes,[317] (1) participants will have direct contact with the social robot (in clinical centres) or with the e-coach provided at their homes. (2) healthcare providers, not sure. (3) HosmartAI researchers and clinicians involved will have access to the big data only to monitor and collect data for the study.[318] The iPrognosis tools use machine learning models to convert smartphone-captured typing-related data, motion data and voice spectro-temporal characteristics of users to indicators of bradykinesia/rigidity, postural tremor and voice-based PD presence, respectively. These indicators will be provided as feedback via suitable dashboards to persons with PD (PwP) and to healthcare professionals (HCPs) in order to evaluate their utility in assisting the former in gaining insights regarding their health and the latter in remote monitoring of patients and clinical decision making.[319]
Pilot 7	Pilot 7 will develop and deploy Deep Learning (DL) based applications to automatically analyse X-ray image sequences and recognize key events from the image data. The interventional cardiologist will see the output of the DL-based application as an auto- populated report covering the key events of the clinical procedure and will have the ability to check and correct the output where needed.[320]
Pilot 8	The AI technology in question is an unsupervised clustering algorithm that classifies voxels of an image into different groups (regions), to predict regions that differentiate from each other in imaging characteristics. These regions will guide the neurosurgeons and researchers in the manual selection of multiple biopsy points. There is no direct interaction with the participants. The humans interacting with the final results produced by the AI are the developers and the health care providers (clinicians working on glioma).[321]

3.5.2 Added or heightened risks (Q. 23)

The next issue focuses on added or heightened risk. This means the question aims to compares the difference in the risk level in two different settings. I.e., one in the standard clinical/medical practice (without HosmartAI) and the other in Pilot Study research (with

[316] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 15.
[317] Response to the question: "will you use a technology that is generally considered as "Artificial Intelligence" (i.e., different from conventional procedure- oriented programming method; uses machine/deep/reinforced learning techniques; etc. Referred to as "AI technologies")?"
[318] Response to the question: "Please describe the AI technologies in your Pilot Study, including how humans get involved or interact with the AI technologies? E.g., AI technologies and: (1) participants; (2) health care providers; or (3) HosmartAI researchers."
[319] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 15.
[320] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 15.
[321] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 14.

HosmartAI). This question is asked because our impact assessment/analysis focuses on how the risks are increased due to AI technologies in HosmartAI, compared to standard clinical/medical practice. In other words, we presume the use of technologies in the standard clinical/medical practice are widely accepted by society. The point may be evident in the following simplified scenario. Use of X-ray may have several risks. If, however, the use of X-ray is accepted in ordinary clinical/medical practice, the use of the same X-ray technology in HosmartAI will not add or heighten the risks associated with the use of X-ray. On the contrary, if "X-ray fully controlled by AI" is to be used, there may be added/heightened risk.

The table below provides summarized response by each Pilot when asked: "Under the presumption that the AI technologies can err and make mistakes during the Pilot Study, whether due to the inaccurate/incomplete/incorrect data set or model chosen, etc. Are there any added risks due to the use of the AI technologies? What is the worst-case scenario, if any, that can happen in the Pilot Study? If there are any, please explain the foreseeable risks and their scenario(s), presuming that AI technologies may err."

Table 21: Added or heightened risks (Q.23).

Pilot #	Added or heightened risks (Q.23)
Pilot 1 (ECHO)	The use of AI technologies in the study adds no risks. Estimates and diagnoses obtained with the assistance of the AI tool will be used for evaluating its performance and utility within the scopes of the study, and they will not affect the formal diagnosis and potential treatment of participants, which will be based on the established, routine clinical practice.[322]
(VCE)	The use of AI technologies in the study adds no risks. Findings and diagnoses obtained with the assistance of the AI tool will be used for evaluating its performance and utility within the scopes of the study, and they will not affect the formal diagnosis and potential treatment of participants, which will be based on the established, routine clinical practice.[323]
(CCTA)	The use of AI technologies in the studies adds no risks. Estimations and diagnoses obtained with the assistance of the AI tool will be used for evaluating its performance and utility within the scopes of the study, and they will not affect the formal diagnosis and potential treatment of participants, which will be based on the established, routine clinical practice.[324]
(Obstetrics)	The use of AI technologies in the studies adds no risks. Estimations and diagnoses obtained with the assistance of the AI tool will be used for evaluating its performance and utility within the scopes of the study, and they will not affect the formal diagnosis and potential treatment of participants, which will be based on the established, routine clinical practice.[325]

[322] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 14.
[323] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 14.
[324] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 16.
[325] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 16.

Pilot #	Added or heightened risks (Q.23)
Pilot 2	The 40 patients included in the study will be informed upon enrolment that their real schedule is the one validated and provided by hospital professionals. The Chatbot can present a risk by offering incorrect appointments. To minimize this risk, each time the Chatbot is activated, the result of its interaction with the patient will be validated again by the healthcare professionals. The patient will receive a call from a hospital professional to confirm or cancel their new appointment generated by the software via the Chatbot. Thus, from the start of their participation, patients will be aware that the Chatbot is part of a study and that any Chatbot proposal must be validated by a hospital professional.[326]
Pilot 3	There are no known risks in participating in this type of study. The only discomforts that may occur are headaches and visual fatigue, however at any time the patient may decide to stop the trial.[327]
Pilot 4	N/A
Pilot 5 (IM)	NO. Gold standards will be followed in the interventional and control group. Please refer to study protocols for details.[328]
(UKCM)	NO. Gold standards will be followed in the interventional and control group. Please refer to study protocols for details.[329]
Pilot 6	The risk is the same inside/outside HosmartAI. If AI improves patient outcomes, it is a competitive advantage, but this does not influence in the standard clinical / medical practice.[330]
Pilot 7	The AI-application will not add risks to the clinical procedure itself because the clinical decision making is still done by the cardiologist. The pilot will demonstrate a proof of concept and will not be included in the daily clinical practice.[331]
Pilot 8	A risk is that the algorithms might make mistakes when for example encountering images with artefacts. However, the results of the algorithm will always be visualized before further use, and form but an indication of differentiated regions. The real selection of biopsy points within the regions suggested by the algorithms will happen manually, thus no immediate added risk comes from the use of the algorithm. The worst case scenario is that the AI will not be able to pinpoint anything useful in the patient data that might help the clinician's decision. The final responsibility for clinical decisions is always with the clinician, and the AI only serves to highlight possible useful connections in the patient data.[332]

[326] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 16.
[327] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 15.
[328] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 15.
[329] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 16.
[330] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 16.
[331] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 16.
[332] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 14.

3.5.3 Detection and deterrence (Q. 24)

The table below provides summarized response by each Pilot when asked: "Under the presumption that the AI technologies can err and make mistakes during the Pilot Study. Is your Pilot Study designed to detect that the AI technologies erred and made a mistake? Are there any safeguards aiming to deter such errors or mistakes? If yes, please describe them."

Table 22: Detection and deterrence (Q. 24).

Pilot #	Detection and deterrence (Q. 24)
Pilot 1 (ECHO)	The study is designed to evaluate, inter alia, the accuracy of estimates generated by the involved AI technologies. All such estimates will be compared to reference, ground truth estimates derived by a panel of expert cardiologists. Therefore, errors will be possible to detect. There are no safeguards to deter such errors, as the study is concerned with preliminary evaluation of the technologies involved; AI-generated estimates will only be used for evaluation purposes and will not affect any actual decisions.[333]
(VCE)	The study is designed to evaluate, inter alia, the accuracy of findings generated by the involved AI technologies. All such findings will be compared to reference, ground truth findings derived by a panel of expert gastroenterologists. Therefore, errors will be possible to detect. There are no safeguards to deter such errors, as the study is concerned with preliminary evaluation of the technologies involved; the AI-generated findings will only be used for evaluation purposes and will not affect any actual decisions.[334]
(CCTA)	The studies are designed to evaluate, inter alia, the accuracy of estimates generated by the involved AI technologies. All such estimates will be compared to reference, ground truth estimates derived by a panel of expert physicians. Therefore, errors will be possible to detect. There are no safeguards to deter such errors, as the studies are concerned with preliminary evaluation of the technologies involved; AI-generated estimates will only be used for evaluation purposes and will not affect any actual decisions.[335]
(Obstetrics)	The studies are designed to evaluate, inter alia, the accuracy of estimates generated by the involved AI technologies. All such estimates will be compared to reference, ground truth estimates derived by a panel of expert physicians. Therefore, errors will be possible to detect. There are no safeguards to deter such errors, as the studies are concerned with preliminary evaluation of the technologies involved; AI-generated estimates will only be used for evaluation purposes and will not affect any actual decisions.[336]

[333] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 15.
[334] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 14.
[335] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 16.
[336] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 16.

Pilot #	Detection and deterrence (Q. 24)
Pilot 2	The AI-based software is supposed to "learn" from its errors. This will be done during the co-creation of the AI-based software with retrospective data (phases I and II see protocol) During the prospective study (phase III 40 enrolled patients) the errors will be seen by the professionals of the hospital. As stated here above, no appointment planning will be given to the patients without previous validation by these professionals.[337]
Pilot 3	The AI-based software is supposed to "learn" from its errors. This will be done during the co-creation of the AI-based software and platform. Home automation sensors will record any abnormal use of technology or in the performance of clinical activities.[338]
Pilot 4	N/A
Pilot 5 (IM)	YES, the clinicians will re-evaluate every classification (i.e. during grand rounds). This may include further investigation with the patient. A skilled operator will supervise the humanmachine interaction and engagement with patients.[339]
(UKCM)	YES, the clinicians will re-evaluate every classification (i.e. during grand rounds). This may include further investigation with the patient. A skilled operator will supervise the humanmachine interaction and engagement with patients.[340]
Pilot 6	There will be stages of evaluation and readjustment of AI through expert medical observation. In the initial phases, the study patients will obtain direct medical recommendations from the professionals that will be based on the recommendations made by the AI. When the system is validated, there will be an activity monitoring index that will allow the pilot to determine the efficiency of the recommendations made and thereby improve and adapt the system.[341]
Pilot 7	The cardiologist will be able to view and correct the AI output such that they can trust, understand and override AI output.[342]
Pilot 8	The AI will give confidence level for the connections which are identified, based on the training data.[343]

3.5.4 Mitigation (Q. 25)

The table below provides summarized response by each Pilot when asked: "Under the presumption that the AI technology errs and makes mistakes during the Pilot Study. How is

[337] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 17.
[338] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 16.
[339] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 16.
[340] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 16.
[341] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 16.
[342] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 16.
[343] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 15.

your Pilot Study designed to mitigate the risks mentioned above? Are there any safeguards to avoid any harm to the human participants? If yes, please describe the safeguards."

Table 23: Mitigation (Q. 25).

Pilot #	Mitigation (Q. 25)
Pilot 1 (ECHO)	As explained in the responses to Q. 23 and Q. 24, participation in the study does not expose participants to any additional risks or harms.[344]
(VCE)	As explained in the responses to Q. 23 and Q. 24, participation in the study does not expose participants to any additional risks or harms.[345]
(CCTA)	As explained in the responses to Q. 23 and Q. 24, participation in the studies does not expose participants to any additional risks or harms.[346]
(Obstetrics)	As explained in the responses to Q. 23 and Q. 24, participation in the studies does not expose participants to any additional risks or harms.[347]
Pilot 2	See answer Q24[348]
Pilot 3	We do not expect potential errors to cause harm to patients/operators/technology. Each clinician will be trained in the correct use of the technologies and will be instructed on how to behave in the event of a malfunction.[349]
Pilot 4	N/A
Pilot 5 (IM)	YES, the clinicians will re-evaluate every classification (i.e. during grand rounds). This may include further investigation with the patient. A skilled operator will supervise the human-machine interaction and engagement with patients.[350]
(UKCM)	YES, the clinicians will re-evaluate every classification (i.e. during grand rounds). This may include further investigation with the patient. A skilled operator will supervise the human-machine interaction and engagement with patients.[351]
Pilot 6	In pilot 6, the patient is perfectly capable of making the decision to carry out or not any activity for the reasons he considers, not entailing any risk to his health. The system will register an index of follow-up or achievements of the tasks in order to adjust the AI.[352]
Pilot 7	No, the final decision is taken by the clinicians.[353]
Pilot 8	The AI used in our trial will have no direct influence on the human participants. After prediction of the regions by AI, the safety for the human participants is evaluated during the selection of the biopsy points, thus creating a buffer for

[344] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 15.
[345] Response by Pilot 1 (VCE) to the D8.3 IA Questionnaire, p. 15.
[346] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 16.
[347] Response by Pilot 1 (CCTA, Obstetrics) to the D8.3 IA Questionnaire, p. 16.
[348] Response by Pilot 2 to the D8.3 IA Questionnaire, p. 17 (i.e., the response under Detection and deterrence).
[349] Response by Pilot 3 to the D8.3 IA Questionnaire, p. 16.
[350] Response by Pilot 5 (IM) to the D8.3 IA Questionnaire, p. 16.
[351] Response by Pilot 5 (UKCM) to the D8.3 IA Questionnaire, p. 16.
[352] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 17.
[353] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 17.

Pilot #	Mitigation (Q. 25)
	possible mistakes of the AI technology and avoiding any harm to the human participants.[354]

3.5.5 Assessment/Analysis

There are several notable observations or analytical framework on which the assessment/analysis will be based on.

First, the AI technologies in HosmartAI are used not to be the substitute of healthcare providers but are provided intending to be an additional source of information or as an additional tool for them. This is contrasted with a situation where AI technologies are used to make decisions instead of humans, replace/displace humans' roles and responsibilities, or takeover humans' positions. This is important considering that many of the arguments against the use of AI technologies stem from the notion that humans will be less involved and AI technologies are taking over human involvement.

Second, it is critical to ask the question: for whose interest and benefit are the AI technologies used. Take automated acceptance/rejection system (automated decision-making system) based on credit score (profiling) as an example. The system is used primarily for the benefit of the lending organization (i.e., banks) to maximize the efficiency of its lending business, while the benefit for the borrower is not the main concern.[355] In this case, there are two parties -- one party, typically banks, using and benefiting from the AI technology and the other party, borrowers, being subject to the AI technology -- and the interests of the two parties can be considered as "adversarial," or at least not "in alignment" with each other. While all potential borrowers are hoping to borrow, the bank is using AI to differentiate less risk customer (less likely to go default) from high-risk customers (who are less likely to pay back the load) to avoid economic loss.

On the contrary, there are scenarios where the interests of the two parties are more "in alignment" with each other. A typical example can be found in the medical/healthcare context. The best interest of the patient seeking medical treatment is to receive the treatment best for him/her and to fully recover. Generally, the primary objective of healthcare providers is to provide the best available medical treatment to the patient before them. Under such circumstances, the use of AI technology to serve the interest or to fulfilling the objective of one party also serves the interest and fulfils the objective of the other party. Such use of AI technology tends to have lower risk in the context of ethical and social perspective. Obviously, the fact that the AI technology is used in medical/healthcare setting does not automatically make the interests "in alignment" with each other as healthcare providers are also for-profit organizations. A healthcare provider intending to use AI technology to cherry-pick profitable patients likely draw major criticism. While not determinative, this question of "for whose

[354] Response by Pilot 8 to the D8.3 IA Questionnaire, p. 15.
[355] Arguably, there could be incidental benefits to borrowers as the result of increased efficiency and profit of banks.

interest and benefit is the AI technology used," or this perspective of "adversarial v. in alignment," is helpful to assess/analyse the AI technology may be perceived.

With this perspective in mind, the aim of AI technologies in HosmartAI is to serve the interest of both patients and healthcare providers, and thus the use of AI technologies in Pilots is less likely to trigger risks in the ethical or social context in our view.

Third, we were not able to identify added/heightened risk due to the use of AI technologies in Pilot Studies that may have significant impact in ethical or social context because, in short, the use of AI technologies in Pilots does not affect the standard or routine clinical procedure/medical practice. Take the 4 Studies of Pilot 1, for example. The "AI tool" will provide "automatic estimation of cardiac functional parameters from ECHO scans"[356] (or other estimations depending on its medical scenario), but the Study aims to "evaluate the clinical performance and utility of"[357] such automatic estimations by comparing with the ground truth (i.e., "cardiologists' semimanual measurement"[358]). The same is true in Pilot 6, 7, and 9 on similar ground. The use of AI technology in each Pilot "does not influence in the standard clinical / medical practice"[359] and "the clinical decision making is still done by the"[360] healthcare provider/professionals. Therefore, we are convinced that there are no significant added/heightened risks due to AI technologies in Pilot Studies and that the risk levels are essentially equivalent inside and outside of HosmartAI.

Fourth, concerning detection, deterrence, and mitigation. This point is distinguished from the third as it does not compare the risk level inside/outside of HosmartAI. Instead, it focuses on whether, and how if any, errors and mistakes by AI technologies can be detected/deterred and mitigate the associated risks. There are at least two types of Pilot Studies. One is Pilot Studies that are designed to evaluate "the accuracy of estimates generated by the involved AI technologies."[361] This means the errors and mistakes by AI technologies are part of calculated risk, or further expected circumstances of the Pilot Study. These errors and mistakes are "compared to reference," i.e., "ground truth estimates derived by a panel of expert cardiologists,"[362] or other medical professionals depending on the scenario (4 Studies of Pilot 1). The other type is where AI technologies first provide an output, and humans (e.g., professionals in Pilot 2 and Pilot 6, clinicians in Pilot 5 and Pilot 8, or cardiologist in Pilot 7) validate (or re-evaluate) the output and then use it for the intended purpose. In both cases, the standard or routine clinical procedure/medical practice is essentially unchanged, and the final decision is taken by medical professionals.

With this in mind, and based on available information, we are convinced that: (1) errors and mistakes by AI technologies are part of expected circumstances (cf. calculated risk), (2)

[356] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 12.
[357] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 50.
[358] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version, p. 50.
[359] Response by Pilot 6 to the D8.3 IA Questionnaire, p. 16.
[360] Response by Pilot 7 to the D8.3 IA Questionnaire, p. 16.
[361] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 15.
[362] Response by Pilot 1 (ECHO) to the D8.3 IA Questionnaire, p. 15.

feedback loop to detect, deter and mitigate the associated risk is in place; and therefore (3) risks in ethical or social context are less likely to be materialized in the forthcoming Pilot Studies.

This does not mean, however, that the risks remain low throughout the entire duration of HosmartAI or outside of HosmartAI. This is perspective is discussed in Chapter 4, *infra*.

4 Conclusion

This deliverable documented the task T8.3 SELP Impact Assessment. The main contributions of this document are the finding and the result of assessment/analysis. The key findings and assessment/analysis illuminated several critical and essential issues. The most critical and essential issues concern: (1) informed consent; (2) profiling and automated decision-making in the context of GDRP; and (3) AI technologies in the context of ethical and social issues.

The informed consent procedure of each Pilot was assessed/analyzed in light of various elements (such as: requirements by GDPR and Oviedo Convention/Oviedo Additional Protocol; additional considerations for elder individuals or those who are unable to provide valid consent; time and opportunities to ask questions; various elements concerning withdrawal). No informed consent procedure of each Pilot was found to be insufficient or inadequate in this first assessment/analysis conducted as part of T8.3. However, this Report recommends all Pilots to review their informed consent procedure by referring to the elements enumerated in the relevant section. Specifically, but not limited to, reviewing if their informed consent procedure is not "bundled" which asks for "overall general consent to everything" is very relevant.

(2) The profiling and automated decision-making is another most important issue partly because it implicates legal compliance/risk. Findings and assessment/analysis identified AI technologies of some Pilots falls within the definition of profiling under the GDPR, thus making them subject to the relevant provisions. Also, the findings and assessment/analysis indicated that AI technologies of Pilots are least likely to trigger the provision concerning *solely* automated decision-making.

(3) This document also assessed/analysed the same AI technologies in the context of ethical and social issues. It provided four notable observations or analytical framework to help assess/analyse the potential risks concerning the use of AI technology. As the result, we view that risks in an ethical or social context are less likely to be materialized in the forthcoming Pilot Studies.

It is also important to be aware that the process of risk management/assessment is an ongoing activity. The dynamics and the dimensions of risks and impact may change and fluctuate due to various factors. An incident elsewhere triggering public backlash against the use of AI technologies, a relevant bill (draft law) being promulgated and come into force, and/or a modification of Study Protocol may change the dynamics and the dimensions.

With this in mind, and with emphasis on three key issues, WP8 will continue the dialogue with the technical partners to fulfil our role.

5 References

[REF-01]	Ethical and legal challenges of artificial intelligence-driven healthcare, Sara Gerke, Timo Minssen and Glenn Cohen (Chap. 12), USA 2020 (EthicalAspects of AI in healthcare.pdf).
[REF-02]	TRUSTWORTHY AI IN HEALTH, Background paper for the G20 AI Dialogue, Digital Economy Task Force, OECD, Saudi Arabia 1-2 April 2020 (trustworthy-artificial- intelligence-in-health.pdf)
[REF-03]	Robots in healthcare: a solution or a problem?, Zrinjka DOLIC, Milieu Consulting Rosa CASTRO, Milieu Consulting Andrei MOARCAS, Milieu Consulting, European Parliament, April 2019 (Robots in healthcare _ IPOL_IDA(2019)638391_EN.pdf)
[REF-04]	The Institute of Internal Auditors (IIA), The Three Lines of Defense in Effective Risk Management and Control.pdf (2013).
[REF-05]	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (GDPR), https://eur-lex.europa.eu/eli/reg/2016/679/oj.
[REF-06]	Dariusz Kloza et al., Data protection impact assessment in the European Union: developing a template for a report from the assessment process (2020), https://osf.io/preprints/lawarxiv/7qrfp/.
[REF-07]	Dariusz Kloza et al., Towards a method for data protection impact assessment: Making sense of GDPR requirements (2020), https://osf.io/es8bm.
[REF-08]	Dariusz Kloza et al., Data protection impact assessments in the European Union: complementing the new legal framework towards a more robust protection of individuals (2020), https://osf.io/b68em.

Appendix A Original Questionnaire

Project Acronym:	HosmartAI
Grant Agreement number:	101016834 (H2020-DT-2020-1 – Innovation Action)
Project Full Title:	Hospital Smart development based on AI

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016834

INTERNAL DOCUMENT

Questionnaire for Pilot Partners

Dissemination level:	CO -Confidential, only for members of the consortium (including the Commission Services)
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Version	Date	Contributor(s)	Description
0.1	2021-02-09		
0.2	2021-12-10	A.Consoli & L. Gilardi (EXYS)	
1.0	2021-12-14	Hideyuki ("Yuki") Matsumi	To be shared with Pilot Partners.

1 Introduction

Dear HosmartAI Pilot Partners,

The present questionnaire is the part of D8.3 SELP Impact Assessment by WP for HosmartAI project.

In HosmartAI, to make sure all Pilot Studies are conducted in accordance with the applicable laws and regulations as well as ethical and societal norms, WP8 is charged with conducting impact assessment of each Pilot Study in terms of ethical, legal, and social issues. The key legal and ethical issues that might be relevant and/or applicable to the project are preliminary described in the D8.1 - SELP Benchmark Report. The methodology to conduct the impact assessment in the project is presented in the D8.2 - SELP Compliance Framework.

This questionnaire is addressed to all HosmartAI Pilot Partners, and it aims to collect the information necessary or relevant to the SELP impact assessment. The questionnaire is created based on other HosmartAI deliverables, such as D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version (Chapter 4. Study Protocols in particular).[1] Your responses will be the valuable input for the task T8.3 SELP Impact Assessment as well as deliverable D8.3 SELP Impact Assessment Report. As part of the impact assessment process, a series of recommendations will be provided concerning the implementation of the project.

In order to guarantee the compliance of our Pilot Studies in HosmartAI, **the cooperation of the Pilots' Partners of the project is of paramount importance. For this reason, we thank you very much in advance for the highly appreciated contributions you will give to the survey by filling the present questionnaire**.

[1] D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version.

1.1 Instruction how to fill in the questionnaire

- Please provide answers to the questions by fulfilling in this Word document. If the response you're about to fill in is provided in other deliverables, you can refer to it too (e.g., "Please see p.XX of D.YY"). Furthermore, if you think anything is relevant, please provide additional information or any other updates.
- Reading all questions first may be helpful. If you have any question or find anything unclear, please do not hesitate to contact us for further explanation.
- **Deadline**. Please email back the Word file which you filled in by **Thursday, 23rd of December 2021**.
- We will review your responses and contact you in case any additional information or clarification is needed.

1.2 Organization of this questionnaire

There are total of 27 questions, and they are categorized into 3 sub-groups:

1. **Medical Ethics**, including **Medical Devices**
2. **Data Protection/Privacy**, including **Profiling**
3. **Ethical and Societal Issues**, including **AI ethics** and **Gender Equality**

The questionnaire begins next page.

2 Questionnaire

Please provide you Pilot information below.

Table 1: Information about the Pilot

Pilot Partner's Information	
Pilot #	
Name of the respondent(s)	
Email Contact	

2.1 Medical Ethics, including Medical Devices

2.1.1 Human Participants

Q. 1. Are there any **human participants** invited to participate in the Pilot Study? If **yes**, please describe: (1) the characteristics of groups/individuals you will invite to participate; (2) approximate number (scale) of participants; (3) duration of the Pilot Study; and (4) whether you have a plan to provide a webpage, or something similar, containing relevant information that can benefit the participants.

Response to Q. 1

Q. 2. **Vulnerable individuals**. Will there be any vulnerable groups or individuals participating your Pilot Study? If **yes**, please describe (1) the characteristics; and please briefly explain: (2) why the research cannot be carried out with a non-vulnerable group; and (3) how the vulnerable group would benefit from the research.[2]
Note: This question is asked because the paragraph 20 of the Declaration of Helsinki requires justifications for medical research with a vulnerable group.

Response to Q. 2

[2] Declaration of Helsinki, Para 20.

Q. 3. If the response to the previous question is **Yes**, please describe all the measures you will take in order to **prevent** any harm or negative consequences to the vulnerable individuals.

Response to Q. 3

2.1.2 Informed Consent

Informed consent is one of the most important key factors in HosmartAI, especially in the context of SELP.[3] This section asks questions regarding various procedures of informed consent.

Q. 4. **Informed consent**. Please describe the basic procedure to obtain the informed consent: (1) to **participate in the HosmartAI** project; and (2) to **process their personal data**.

Response to Q. 4

Q. 5. **Vulnerable individuals and consent**. Please describe the procedure to obtain the informed consent from individuals who require special attention ("vulnerable group") to invite to participate in the Pilot Study. When describing, please make sure to include: (1) why these potential participants need **special attention** (e.g., characteristics, circumstance); (2) what are the **concerns** or **risks** or possible negative consequences you anticipate due to such characteristics; and (3) what measures will you implement in the Pilot Study to **mitigate** the risks?

Response to Q. 5

[3] A number of instruments emphases the importance of informed consent: Nuremberg Code; Declaration of Helsinki; International Ethical Guidelines for Health-Related Research Involving Humans; Good Clinical Practice; Handbook for Good Clinical Research Practice; International Covenant on Civil and Political Rights; Universal Declaration on Bioethics and Human Rights; Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.

Q. 6. **Withdrawing consent**. Please explain how a participant can withdraw his/her consent? When explaining, please include: (1) means or opportunities how a participant can know that s/he can withdraw his/her consent; (2) how s/he can actually withdraw participating the Pilot Study; and (3) whether or not there would be any disadvantage or negative consequence to the ex-participant.

Response to Q. 6

2.1.3 Ethics Committee

Q. 7. What is the name of the **institutional/regional/national ethics board** that your Pilot will seek the approval? Please provide basic information, such as the name, address, and contact info.

Response to Q. 7

2.1.4 Medical Devices

Q. 8. I**n the coming Pilot Study**, do you **intend to market** your technology, such as medical device or software, for the **medical purposes**? (In other words, does your technology falls within the definition of Medical Devices under the EU Medical Devices Regulation and trigger the Regulation?)

Response to Q. 8.

2.2 Data Protection/Privacy, including Profiling

This section asks questions concerning data protection regulations, namely the GDPR.

Q. 9. Do you have department/team/personnel in your organization in charge of complying with the **data protection laws and regulation**? Will the department/team oversee data processing activities in your Pilot Study or support in any ways? If yes, please provide basic information, such as the name of the department, person in charge, and contact info.

Response to Q. 9

Q. 10. **Type of personal data**. What type of personal data do you intend to process (i.e., collect, use, store, send, etc) for the Pilot Study? Would there be any additional personal data you would find out or discovery as the result of use of the AI technologies ("derived/inferred personal data")?
Note: For instance, if the response to this question is provided in a different deliverable, such as D6.7,[4] you can refer to it. If there are any updates and/or additions, please also provide below.

Response to Q. 10

Q. 11. **Sensitive data**. Of the types of personal data you process, which type of personal data is sensitive in nature? Is any of the "derived/inferred personal data," as mentioned above, is sensitive in nature?
Note: "derived/inferred data" is a type of personal data that is neither: (1) data provided directly by the individuals; or (2) data observed about the individuals. In a way, it is "created" by use of technologies (including what is often referred to as "AI") in the Pilot Study.

Response to Q. 11

[4] D6.7 – Data Management Handling Plan – First Version.

Q. 12. **Data controller and data processor**. Please describe which entity will be the **data controller** of the personal data collected. Also, if you intend to use any **data processor**, please describe who they will be.
Note: In short, **data controller** is someone who gets to determine the purposes and means of personal data processing. Two or more entities can **jointly** be data controllers if they can determine the purposes and means of processing. **Data processor** is an entity that processes personal data on behalf of data controller.

Response to Q. 12

Q. 13. **The rights of data subject**. Please describe how you plan to provide **data subjects** with **information** relevant to the processing of personal data as well as their **rights** as a data subject. When describing, please include a case where a data subject is considered a vulnerable person, if applicable.
Notes: Participants have the **rights as a data subject under the GDPR**, and they are entitled to be notified of various information, such as the identity and the contact details of the data controller, the contact details of the data protection officer, the purposes of the processing, and the like.

Response to Q. 12

Q. 14. **Legal basis**. Do you intend to process any type of personal data outside of the **scope of informed consent**? In other words, is there a possibility that you will rely on **legal basis** other than "**consent**"? If yes, please describe in detail.
Note: Generally, if a data subject (i.e., a patient) consents to the processing of personal data, the legal basis is "consent."

Response to Q. 14

Q. 15. **Granting/revoking access right**. Who will have access to personal data collected and stored? For example, will it be everybody of the department/organization, or will it be a particular group of individuals? Please briefly describe the applicable process for granting/revoking access right.

Response to Q. 15

Q. 16. What is the **scale** of personal data you will process? In addition to the approximate number of participants engaged and types of personal data, please include other aspects, such as: (1) frequency of data collection (e.g., once a week or 24/7); (2) granularity of data collection (e.g., from questionnaire to monitoring with sensors); (3) duration of data collection (e.g., for 2 weeks 3 sessions or 2 years).

Response to Q. 16

Q. 17. **Anonymisation and Pseudonymisation**. If you intend to anonymise and/or pseudonymise personal data, please describe the following: (1) to which type of personal data; and (2) at what point. Also, if you intend to follow a specific standard/technique/procedure other than two standards by the ISO (i.e., ISO/IEC 20889:2018 and ISO 25237:2017) mentioned in D5.1,[5] please explain in detail.

Response to Q. 17

Anonymisation:

Pseudonymisation:

[5] Chapter 2.5 of D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version.

Q. 18. **Data retention/deletion**. Is there a data retention and/or deletion policy that will be applicable to the personal data you process under the Pilot Study? Does it define various periods (e.g., period to retain or period when deletion begins)? If there is a policy applicable, please describe.
Note: An organization may have data retention/deletion policy that is applicable to research project like HosmartAI or to ordinary course of business/practice.

Response to Q. 18

Q. 19. **Profiling**. Is the technology you plan to use in the Pilot Study capable to **profile** data subjects (i.e., participants, whether as a patient or a healthcare provider)? If **yes**, please explain what kind of information may became available as the result of profiling.
Note: When you process personal data to **evaluate** certain personal aspects of an individual, it can be **profiling** under the GDPR. Particularly, profiling can happen when you analyse or predict aspects concerning that person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements.

Response to Q. 19

Q. 20. **Automated decision-making**. Is the technology you plan to use in the Pilot Study capable of **making decisions** or providing **information that supports human to make decisions**? If **yes**, please explain: (1) what kind of decisions or information can it provide; and (2) how does a human use such decisions or information? When you explain, please include the **relationship between the humans and technology** and how they interact.
Note:
- What is **automated decision-making**? For example, if the technology can provide following decision/information, it is **automated decision-making** here: which patient is selected (or not selected) for a particular purpose, such as testing or treatment; when a patient will need (or does not need) to go through a testing or treatment; or how the treatment will be conducted on a particular patient.
- What do you mean by **relationship between the technology and humans**? There are several possibilities, for example: humans use the information as one of many sources to

make his/her own decision; humans (i.e., a user of the technology) simply chooses to agree or disagree with the decision/information provided; or decisions by the technology are made without any human involvement and are generally final.

Response to Q. 20

(1) Kind of decisions/information:

(2) How humans use such decision/information:

Q. 21. **Less privacy invasive means**. Conducting Pilot Study would entail certain degree of privacy invasion. Would you be able to think or perceive any **less privacy invasive ways** to achieve the same Pilot goal effectively? If **yes**, please explain why you opt not to choose alternative ways and why your proposed way is adequate and necessary to achieve the goal?

Response to Q. 21

2.3 Ethical and Societal Issues, including AI and Gender Equality

2.3.1 Concerning technologies referred to as Artificial Intelligence ("AI")

There are several concerns with regard to use of AI. Namely, bias, discrimination, lack of transparency (so-called "black box"), and the like. This section asks questions related to these concerns.

Q. 22. **AI technologies**. In your Pilot Study, will you use a technology that is generally considered as "Artificial Intelligence" (i.e., different from conventional procedure-oriented programming method; uses machine/deep/reinforced learning techniques; etc. Referred to as "**AI technologies**"). Please describe the AI technologies in your Pilot Study, including how humans get involved or interact with the AI technologies? E.g., AI technologies and: (1) participants; (2) health care providers; or (3) HosmartAI researchers.

Response to Q. 22

Q. 23. **Potential Risks**. Under the presumption that the AI technologies can err and make mistakes during the Pilot Study, whether due to the inaccurate/incomplete/incorrect data set or model chosen, etc. Are there any **added risks** due to the use of the AI technologies? What is the worst-case scenario, if any, that can happen in the Pilot Study? If there are any, please explain the foreseeable risks and their scenario(s), presuming that AI technologies may err.

Note: This question emphasises on **added or heightened risks**, which means it aims to compares between the standard clinical/medical practice (without HosmartAI) and the Pilot Study research (with HosmartAI). For example, using electricity can be a risk in various ways, but generally speaking, the risk level is the same whether it is in a regular medical practice context or medical research context. If the risk is generally the same regardless of inside/outside HosmartAI, please indicate so.

Response to Q. 23

Q. 24. **Detection and deterrence**. Under the presumption that the AI technologies can err and make mistakes during the Pilot Study. Is your Pilot Study designed to **detect** that the AI technologies erred and made a mistake? Are there any safeguards aiming to **deter** such errors or mistakes? If yes, please describe them.

Response to Q. 24

Q. 25. **Mitigation**. Under the presumption that the AI technology errs and makes mistakes during the Pilot Study. How is your Pilot Study designed to **mitigate** the risks mentioned above? Are there any safeguards to avoid any harms to the human participants? If yes, please describe the safeguards.

Response to Q. 25

2.3.2 Gender Related Issues

HosmartAI emphasizes the importance of gender related issues and is committed to address them during the project.[6] This section asks questions relating to gender related issues touched in the Proposal/Grant Agreement.

Q. 26. **Sex and Gender Analysis**. Does Sex and Gender Analysis[7] have any relevance to your Pilot Study? If yes, please describe how Sex and Gender Analysis will be incorporated into the Pilot Study.

Response to Q. 26

Q. 27. **"Balanced sampling."** What does "balanced sampling of human participants"[8] mean in your Pilot Study and how do you achieve it? In other words, what is the circumstance in which "balanced sampling of human participants" is achieved in the context of your Pilot Study?

Note: As an example, achieving 50% male and 50% female in the participants is one way, while affirmatively achieving uneven ratio can be another necessary way, in order to address the gender related issues. This may largely depend on the research question, objective, methodology, and the like.

Response to Q. 27

END OF QUESTIONNAIRE

[6] See e.g., The Grant Agreement, page 39, 71, and 72 of 257.
[7] The Grant Agreement, page 39 of 257.
[8] The Grant Agreement, at page 39 of 257, states: "balanced sampling of human participants as part of the services design, taking into account gender and diversity by balancing involved workers in terms of sex, age, culture and social factors like education, occupation and residence."

Thank you very much taking your time and providing your response to the questionnaire!