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Project Full Title:	Hospital Smart development based on AI

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DELIVERABLE

D8.4 – SELP Continuous Monitoring Report 1

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Executive Summary

As the HosmartAI project will soon complete the second year and is turning into the third year, it remains equally important and 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. WP8 aims 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 continuous impact assessment and monitoring of risks. The first, second, and third phases are documented as D8.1 SELP Benchmark Report, D8.2 SELP Compliance Report, and D8.3 SELP Impact Assessment respectively.

Built upon these three previous tasks and deliverables, this report, entitled D8.4 "SELP Continuous Monitoring Report 1," documents the activities conducted in task T8.4 SELP Continuous Compliance Report. In the fourth phase, similarly to 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 monitored the risks thereafter.

This Report makes two primary contributions. The first is, as the result of continuous assessment and monitoring, it documents that no critical risk was identified based on available information as of now. Two minor issues are discussed below. The second is, through previous and current tasks, it identifies and narrows down the risks to be continuously assessed and monitored.

Some minor issues to be noted are: (1) two Pilots intend to rely on multiple legal bases under the GDPR when processing personal data; and (2) two Pilots intend to market their HosmartAI technologies as Medical Devices in the future, triggering EU Medical Devices Regulation.

(1) Multiple legal bases. Technically, relying on multiple legal bases can be tricky under the GDPR[1]. While the details would depend on specific facts and would need case-by-case analysis, data controllers relying on multiple legal bases should be aware of and be able to identify and distinguish which type of personal data is processed on what legal basis, and therefore respond to data subjects' request considering its legal basis. This issue is unlikely to pose significant risk, but we will continue to communicate with those Pilots to reduce the risk.

[1] See GDPR Brief: "At Least One" Legal Basis for Processing Under the GDPR: Clarifying Article 6(1), https://www.ga4gh.org/news/gdpr-brief-at-least-one-legal-basis-for-processing-under-the-gdpr-clarifying-article-61/. See also 6 Legal Bases for Processing Personal Data: GDPR Fundamentals | Video, https://kirkpatrickprice.com/video/gdpr-fundamentals-legal-basis-for-processing/; 6 Legal Bases for Processing Personal Data: GDPR Fundamentals | Video, https://kirkpatrickprice.com/video/gdpr-fundamentals-legal-basis-for-processing/; Article 6 GDPR - GDPRhub, https://gdprhub.eu/Article_6_GDPR#Multiple_legal_bases; General Data Protection Regulation (GDPR) Guidance Note for the Research Sector: Appropriate use of different legal bases under the GDPR, https://esomar.org/uploads/attachments/ckv2fj3rh001jbw3vejug72q2-efamro-esomar-gdpr-guidance-note-legal-choice.pdf.

(2) EU Medical Devices Regulation. As two Pilots expressed interest in marketing their HosmartAI technology as medical device, they can be subject to EU Medical Devices Regulation when they actually do so. The issue of whether or not, and how if any, the EU Medical Devices Regulation applies, and what needs to be done in order to comply with the Regulation, requires detailed analysis when their technologies are in fact ready to be marketed as medical device. Considering their plan and intention, we will continue to communicate with those Pilots.

Finally, this activity/process of continuous assessment and monitoring will be further conducted by the subsequent task and deliverable T8.5 & D8.5 “SELP Continuous Monitoring Report 2”, which will be built upon this deliverable.

Deliverable leader:	Paul QUINN (VUB)
Contributors:	Hideyuki MATSUMI (VUB), pilots providing input to questionnaire
Reviewers:	IRCCS, SERMAS
Approved by:	Athanasios Poulakidas, Irene Diamantopoulou (INTRA)

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1.0	2023-01-31	Athanasios Poulakidas, Irene Diamantopoulou	QA and creation of the final submitted version

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Definitions, Acronyms and Abbreviations

Acronym/ Abbreviation	Title
DPO	Data Protection Officer
GDPR	The General Data Protection Regulation (EU) 2016/679 (also officially known as "The Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC")
HTA	Health Technology Assessment
MDR	EU Medical Devices Regulation (specifically the Regulation (EU) 2017/745 on medical devices and the Regulation (EU) 2017/746 on in vitro diagnostic medical devices)
TRL	Technology Readiness Level

Term	Definition
Profiling	"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" defined by Article 4(4) GDPR.

1 Introduction

1.1 Project Information

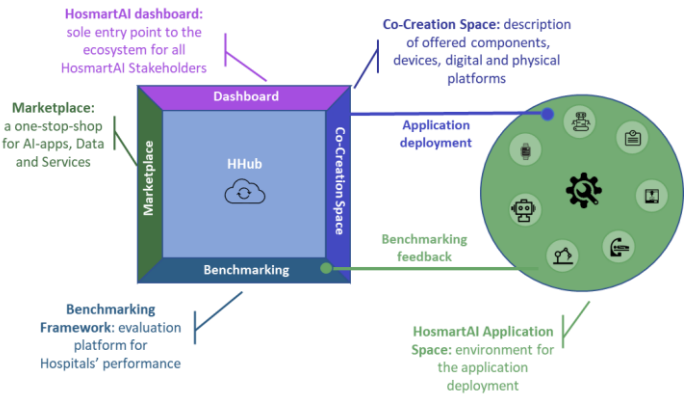
VISION

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 a AI solutions.

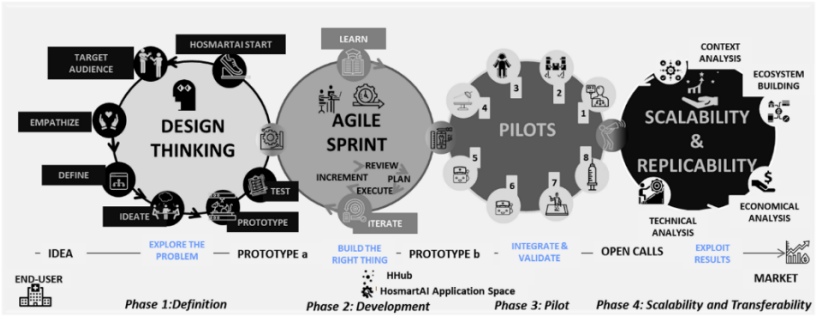
HosmartAI will create a common open Integration **Platform** with the necessary tools to facilitate and measure the benefits of integrating digital technologies (robotics and AI) in the healthcare system.



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[2]	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**

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

Number[2]	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 "D8.4 SELP Continuous Monitoring Report 1," is the fourth deliverable in Work Package 8 ("WP8"). It documents the activities conducted in task T8.4 SELP Continuous Compliance Report as well as the result of continuous assessment and monitoring.

WP8 aims 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 three tasks already. The first, second, and third tasks are documented as D8.1 SELP Benchmark Report, D8.2 SELP Compliance Report, and D8.3 SELP Impact Assessment, respectively.

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". 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.

Built upon these three previous tasks/deliverables, this Report, entitled D8.4 "SELP Continuous Monitoring Report 1," documents the activities conducted in task T8.4 SELP Continuous Compliance Report. In the fourth 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 monitored the risks after T8.3.

This deliverable D8.4 "SELP Continuous Monitoring Report 1" will be followed up with subsequent deliverable: D8.5 "SELP Continuous Monitoring Report 2" (due in Month 41).

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 context of this report.

Chapter 3 provides the findings as the results of continuous impact assessment or continuous monitoring. As explained in the first section (entitled Preface), all issues are discussed and analysed in three different sections, namely (1) Medical Ethics, (2) Data Protection/Privacy, including Profiling, and (3) Ethical and Societal Issues, including AI ethics.

Chapter 4 provides a summarized conclusion of this report.

Chapter 5 provides a list of references.

Annex 1 provides the original questionnaire used (without responses).

2 Background and Context

This chapter provides background and context of tasks and deliverables of WP8. WP8 focuses on social, ethical, and legal issues. WP8's tasks/deliverables aim to ensure compliance with applicable laws and regulations as well as ethical and social norms. To that end, WP8 has conducted three tasks so far. Results of the first, second, and third tasks are documented as D8.1 SELP Benchmark Report, D8.2 SELP Compliance Report, and D8.3 SELP Impact Assessment, respectively.

T8.4 SELP Continuous Monitoring Report 1 builds upon T8.3/D8.3 and is followed by T8.5 SELP Continuous Monitoring Report 2. This report, D8.4 SELP Continuous Monitoring Report 1 documents the results of T8.4. Each of the task and how each is relates to another can be describe as the following:

1. Define and describe the laws and regulations as well as ethical and social norms applicable or relevant HosmartAI's Pilot Studies (T8.1);
2. Suggest a preliminary compliance framework for HosmartAI describing how the project seeks to comply with laws and ethical/social norms (T8.2);
3. Conduct the follow-up research on two previous Tasks/Deliverables in light of more detailed specifications and information of each Pilot Studies, namely D5.1[3] (conducted as part of T8.3).
4. Conduct an impact assessment/analysis that consists of the following steps (T8.3):
    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.
5. As a follow-up impact assessment, conduct a continuous risk assessment and monitoring which consists similar steps as the previous tasks (T8.4):
    a. Formulate a questionnaire depending on risks or issues identified in the T8.3.
    b. Collect responses from each Pilot.
    c. Assess and analyse each risk or issue.

[3] "D5.1 – Detailed Pilot Specification and Report on Pilot Sites Preparation – First version" by WP5.

3 Findings

3.1 Preface

This chapter provides the findings and presents the results of the continuous impact assessment and monitoring. This chapter proceeds in three parts. The first section will consider medical ethics issues, including Medical Devices Regulation issue. The second section will examine issues concerning data protection/privacy. Finally, the third section addresses AI ethics in the context of ethics and social issues. Each section is composed of five sub-sections focusing on a particular topic/issue. Below we provide a visual organization of this chapter:

1. Medical Ethics, including Medical Devices
    a. Q. 1. Human participants
    b. Q. 2. Vulnerable individuals
    c. Q. 3. Informed consent
    d. Q. 4. Ethics Committee or Legal Dept
    e. Q. 5. EU Medical Devices Regulation
2. Data Protection/Privacy, including Profiling
    a. Q. 6. Personal data
    b. Q. 7. Legal basis other than informed consent
    c. Q. 8. International data transfer
    d. Q. 9. Profiling
    e. Q. 10. Anything from the DPO/legal dept
3. Ethical and Societal Issues, including AI ethics
    a. Q. 11. Potential Risks
    b. Q. 12. Detection and deterrence
    c. Q. 13. Mitigation
    d. Q. 14. Any comments, opinions, questions, suggestions or anything similar from anybody in connection to AI ethics issues
    e. Q. 15. Any ethical, legal, or social issues that you are concerned while conducting your Pilot Study

Sources of information for the findings: Results of continuous impact assessment and monitoring are based on information obtained from the Grant Agreement, other deliverables D5.1, D6.7, D8.3, and response to the Questionnaire by each Pilot and follow-up questions and answers via email during T8.3 and T8.4.

3.2 Medical Ethics, including EU Medical Devices

This section addresses risks in the context of medical ethics, including EU Medical Devices Regulation. This section will explore the following topics/issues: Specifically, the section includes topics, such as ethical issues due to human participation, vulnerable individuals, informed consent, ethical issues in general, and EU Medical Devices Regulation.

3.2.1 Q. 1. Human participants

This question is twofold. First, it asks if there are human participants in the Pilot Study. If there are no human participants, generally ethical, legal, or social risks are lower. Second, if there are human participants, it addresses whether there were: (1) any comments, concerns, opinions, questions, thoughts, or anything else that was communicated or expressed to your Pilot by the participants; and (2) any ethical, legal, or social issue that the Pilot noticed or became aware of, due to human participation.

All Pilots, except for Pilot 4, involve human participants. Of these 7 Pilots, all Pilots reported that: (1) no concerns or the like were communicated by participants; and (2) they did not become aware of any issues due to human participation. The table below provides summarized response by each Pilot to the question that asks: "If there any human participants, please describe if any of the two applies: (1) any comments, concerns, opinions, questions, thoughts, or anything else that was communicated or expressed to your Pilot by the participants; and (2) any ethical, legal, or social issue that your Pilot noticed or became aware of, due to human participation."

Table 2: Human Participants.

Pilot #	Q. 1. Human Participants
Pilot 1 (ECHO)	(1) No comment until Dec. 2022 (2) No issue until Dec. 2022
Pilot 1 (VCE)	(1) No comment until Dec. 2022 (2) No issue until Dec. 2022
Pilot 2	(1) • Cancer patients with primary breast or lung tumor or bone metastases. • 40 patients • 18 months • Brochure guiding them how to use a Chatbot (2) The CHUL staff became aware that chances of profiling could occur during the study among the enrolled patients. A paragraph has been included in the Patient Consent and submitted as an amendment to the Ethic Committee
Pilot 3	(1) During sprint 2 and 3 we interviewed 9 potential participants (they will not be enrolled but they participated in the co-design sprints). No concerns were raised about privacy, data management nor other issues about the service. (2) No issues raised at the moment, but monitoring is constant.
Pilot 4	Not a clinical pilot, it is in vitro. Just consent to review electroanatomical maps acquired during the ablation procedure, ECG, X ray or other media data (1) No concerns expressed from the participants about personal data because everything is anonymous and offline (2) None ethical, legal, or social issue in the Pilot
Pilot 5	(1) YES (2) NO
Pilot 6	Yes.

	(1) No concerns shared. (2)
Pilot 7	(1) No comments (2) No
Pilot 8	(1) No concerns have been communicated by the participants. (2) Access to pseudonymized genetic data is possible only in the hospital environment therefore, a putative computer will used for the deployment of the genetic and image analysis tools developed for Glioma data.

3.2.2 Q. 2. Vulnerable individuals

This question is twofold. First, it asks if there are any "vulnerable individuals"[4] participating the Pilot Study. Second, if there are "vulnerable individuals" participating, it asks: (1) why those individual(s) were included; (2) implications of such participation; and (3) measures Pilot took to address the issue and to prevent similar events happening in the future. The question focuses more on whether or not individuals who are incapable to consent to the Pilot Study are properly excluded from the Study.

In sum, no vulnerable individuals are included as participants. The response by few Pilots may indicate that "vulnerable individuals" are included as participants, but in fact they are not vulnerable individuals for the purpose of this question because those individuals with a specific disease are explicitly excluded in the definition. The table below provides summarized response by each Pilot to the question asking: "Were there any vulnerable groups or individuals participating your Pilot Study that you did not anticipate or expect? If yes, please describe (1) causes why those individual(s) were included; (2) implications of such participation; and (3) measures you took to address the issue and to prevent similar events happening in the future."

Table 3: Vulnerable individuals.

Pilot #	Q. 2. Vulnerable individuals
Pilot 1 (ECHO)	No, there is not any vulnerable individual participating in the study. Any individual who cannot provide consent is excluded from the study according to the study protocol ("Characteristics of the study population", p.53 of D5.1)
Pilot 1 (VCE)	No, there is not any vulnerable individual participating in the study. Any individual who cannot provide consent is excluded from the study according to the study protocol ("Characteristics of the study population", p.53 of D5.1)
Pilot 2	(1) YES. Cancer patients fall under the definition of vulnerable individuals because they are suffering from a serious illness. (2) The schedule of appointments in the radiotherapy department differs from that of other hospital units. Indeed, it must take into account more than

[4] Vulnerable individuals in this questionnaire are defined as "individuals who is incapable to consent due to his or her diminished capacity." If, however, Pilot Study is seeking individuals with a particular disease because of the Pilot Study focuses on that disease, those individuals don't need to be counted as "vulnerable individuals" for the purpose of this question.

	10 medical and personal parameters of each patient. Due to advances in medicine, the number of parameters will increase in the future. The ability to handle such a date scheduling has reached human limits, requiring the help of AI. (3) In theory, if the AI-based program is effective, it should offer patients an irradiation program that best matches their wishes and medical situation. In addition, by using a Chatbot, the patient will have the possibility of accepting or refusing more quickly a new appointment proposed by the radiotherapy department, avoiding him to come to the hospital for nothing during a machine breakdown, for example.
Pilot 3	(1) Adult people affected by neurological diseases (i.e. Stroke, Parkinson's Disease or Multiple Sclerosis, or other) are the subject of the pilot study. They were included because San Camillo IRCCS is an institute of Hospitalization and Care of a Scientific Nature (IRCCS), accredited by the Italian Ministry of Health and specialized in neurorehabilitation. Patients are already treated in the hospital and they will freely agree to participate in the study after reading the informed consent and receive all the necessary informations to be fully aware of their choices. So there will be no unexpected participation in the pilot. (2) There will be no modifications of the ordinary and expected treatment. (3) Ordinary hospital procedures are granted to all participants, no modifications expected.
Pilot 4	(1) No vulnerable individuals in the Pilot
Pilot 5	(1) NO (2) N/A (3) N/A
Pilot 6	No vulnerable groups or individuals that were not anticipated or expected, only the ones mentioned in D8.3.
Pilot 7	No
Pilot 8	N/A (as mentioned in the previous questionnaire)

3.2.3 Q. 3. Informed consent

This question focuses on issues relating to informed consent procedure. The question is trifold. First issue is whether or not there's a deviation from the original procedure. The second and the third issues ask if there're any comments, concerns, opinions, questions, thoughts: (2) communicated, expressed, or otherwise raise by participants; or (3) noticed, discovered, or otherwise became aware by each Pilot.

The table below provides summarized response by each Pilot to the following three questions: "(1) Were there any deviation from the informed consent procedure your Pilot stipulated in the previous questionnaire; (2) any comments, concerns, opinions, questions, thoughts, or anything else that was communicated or expressed to your Pilot by the participants during

the informed consent procedure; and (3) any ethical, legal, or social issue that your Pilot noticed or became aware of, because of the informed consent procedure." As the table shows, no Pilots reported deviation from their originally planned informed consent procedures. Also, as of now, no Pilots have received any concerns or the like.

Table 4: Informed consent.

Pilot #	Q. 3. Informed consent
Pilot 1 (ECHO)	(1) No deviation (2) None (3) None
Pilot 1 (VCE)	(1) No deviation (2) None (3) None
Pilot 2	(1) Yes, a new consent form was presented to the Ethical Committee (2) No concerns shared. (3) No issue detected.
Pilot 3	(1) No (2) No informed consent addressed yet (3) No informed consent addressed yet
Pilot 4	(1) No deviation from the informed consent (2) No comments or concerns communicated during the informed consent procedure The electrophysiologist will explain the project to the patient. It will be emphasized that it is just for off-line analysis of the electro anatomical maps and/or other media used during the ablation procedure. We will ask to the patient 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. The explanations on the anonymization method are detailed in the patient consent. (3) No ethical, legal or social issues communicated during the informed consent procedure
Pilot 5	(1) NO (2) NO (3) NO
Pilot 6	(1) New consent form was delivered to participants. See Q.4 of the present questionnaire for clarification. (2) No concerns shared. (3) No issue detected.
Pilot 7	(1) N/A (2) N/A (3) N/A
Pilot 8	No deviation from informed consent procedure pilot 8 has communicated in the previous questionnaire. Prior to obtain the informed consent, a patient will be assessed for eligibility for participation in the trial based on the predefined inclusion and exclusion criteria. 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 the 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.

3.2.4 Q. 4. Ethics Committee; Legal Dept

This question focuses on the fact whether or not the Pilot has received any comments, opinions, questions, suggestions, or anything similar in connection to medical ethics issues.

As of now, no Pilots have received any comments or the like with regard to medical ethics issues. The table below provides summarized response by each Pilot to the question: "Please describe if you have received any comments, opinions, questions, suggestions from your Ethics Committee and/or legal department/DPO of your institution."

Table 5: Ethics Committee; Legal Dept.

Pilot #	Q. 4. Ethics committee, Legal department, or any other entities
Pilot 1 (ECHO)	We have not received anything.
Pilot 1 (VCE)	We have not received anything.
Pilot 2	CHUL DPO was aware that profiling issues needed to be take in consideration in the Pilot 2
Pilot 3	No, the study has been approved with no concerns and suggestions from the ethics committee
Pilot 4	We have not received any comments from our Ethics Committee
Pilot 5	N/A, we have received and uploaded Ethical approval for the two studies under the following ref, numbers: UKC-MB-KME-77/21 (HosmartAI-SRS-CDSS) , UKC-MB-KME-76/21 (HosmartAI-IDA)
Pilot 6	From the institutional ethical committee, it was requested to update the content initially sent – Clarify the roles of each part (what is the social and clinical part); the whole role of the INTRAS foundation in the project (involving users/participants); the whole team; shorter ethical knowledge From the regional ethical committee, it was requested to: • Divide the protocol into sub-studies: the main study focused in the intervention with patients, another is the focus groups with professionals and family members. • In the informed consent forms, the part of the information sheet has to be more concrete. To allude less to the generality of the project and the expected overall participation such as "help define..." and to make explicit what is going to be done with the subjects "X cognitive intervention sessions X days a week of X hours' duration for X months in X location" (or at least an orientation).

	• Specify that the professionals interviewed are external (otherwise there is bias). So we will look for professionals from other collaborating centres. • Specify well the recruitment: where the sample is taken from specifically. - Include reference to whether the manufacturer of Pepper consents to our programming. • Include in each protocol's study reference to INTRAS insurance. The requests were carried out and both committees approved the pilot study.
Pilot 7	Feedback from the METC (Ethical Committee) on the study protocol was to arrange for a data sharing agreement between the pilot partners.
Pilot 8	We have acquired permission of our local ethics committee at the UZ Brussels to perform this trial. The committee wishes to obtain an annual trial status from the investigators.

3.2.5 Q. 5. EU Medical Devices Regulation

This question focuses on issue whether or not each Pilot intends to market their HosmartAI AI technology as medical device, and if so, their plan to comply with the EU Medical Devices Regulation (EU MDR).

Most Pilots -- Pilots 1, 2, 3, 5, 7, and 8 -- will not be subject to EU MDR either because they do not intent to market their technology as a Medical Device and/or their technology does not fall within the definition. EU MDR likely become applicable to technology by one of the Partners (i.e., mapping software by 91) of Pilot 4 and one technology of Pilot 6 (i.e., GRADIOR by INTRAS) because these Pilots have intention to market their technologies as Medical Devices in the future. We discuss this in the Conclusion, *infra*, and will keep track of this issue as part of our task. The table below provides summarized response by each Pilot to the question asking: "do you intend to market your technology, such as medical device or software, for medical purposes? If yes, please describe your Pilot's plan to comply with the EU Medical Devices Regulation."

Table 6: EU Medical Devices Regulation.

Pilot #	Q. 5. EU Medical Devices Regulation
Pilot 1 (ECHO)	The technology falls within the definition as Medical Devices, however, go-to-market is not an objective of the Pilot Study. Thus, no regulatory compliance plan is described.
Pilot 1 (VCE)	The technology falls within the definition as Medical Devices, however, go-to-market is not an objective of the Pilot Study. Thus, no regulatory compliance plan is described.
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 Plan: At the end of the study, we will not have reached a sufficient TRL to market the AIbased scheduling software. Nevertheless, if in a future project we complete a TRL9, we will submit all the documents to the FAMHP which is in Belgium the Federal Agency for Medicines and health Products
Pilot 3	No, medical devices that will be used in the pilot are already validated and used in the hospital for everyday care patients receive. Our innovation solution don't involve new medical devices.
Pilot 4	(4-1) Robotic magnetic navigation system developed by ETHZ will only test in-vitro 91 would be interested in putting the software solutions to market. They would seek any needed certifications at that time (4-2) Robotic magnetic navigation system developed by ETHZ will only test in-vitro The mapping software developed by 91 will be available for further exploitation in the market
Pilot 5	NO, It is a feasibility study that will not go beyond the study protocols. Thus, HTA is not required. The HTA will be necessary for integration in clinical workflow, however this is out of scope at this point.
Pilot 6	In Gradior device, yes, it falls within the technology of Medical devices. INTRAS team is in process to credit GRADIOR as a medical device. The specific E-pokratis devices do not fall under the EU definition of Medical Devices. For i-Prognosis (i-MAT app), AUTH does not have a plan regarding the medical devices regulation.
Pilot 7	The intended solution is a reporting application and can be considered as non-medical device.
Pilot 8	No

3.3 Data Protection/Privacy, including Profiling

This section addresses risks in the context of data protection/privacy, including profiling. The GDPR, inter alia, regulates processing of personal data, and because processing of personal data in involved in most Pilot Studies in HosmartAI, whether or not each Pilot Study is conducted in a way that is compliant and compatible with the regulation is critically important and is the overarching issue of this section.

3.3.1 Q. 6. Personal data

This question focuses on the issue relating to types of personal data being processed, which triggers the GDPR. Intention behind this question is clarify the difference between how it was originally planned (up until the previous questionnaire[5]) and the how it is being conducted presently (since the previous questionnaire) by asking if there are: (1) any types of personal data that was originally not planned to be processed but is being processed or will be processed any way; and (2) any types of personal data that was originally planned to be processed but is not being processed any way.

No Pilots mentioned that they intend to process additional personal data. One Pilot, namely Pilot 6, expressed that they collect less types of personal data than they originally planned due to subsequent change. In any case, none of the Pilots indicate significant risk regarding types of personal data being processed. The table below provides summarized response by each Pilot to the question asking: "Are there any: (1) additional types of personal data you intend to process or did process in your Pilot Study; and (2) types of personal data you chose not to process despite you planned to process?"

Table 7: Personal data.

Pilot #	Q. 6. Personal data
Pilot 1 (ECHO)	(1) No additional types of data collected/processed in the study. (2) No deviation on chosen types of data to process.
Pilot 1 (VCE)	(1) No additional types of data collected/processed in the study. (2) No deviation on chosen types of data to process.
Pilot 2	N/A
Pilot 3	(1) No. We will keep on monitoring this issue. No differences compared to the other questionnaire (2) No. We will keep on monitoring this issue. No differences compared to the other questionnaire
Pilot 4	(1) No additional personal data will be processed in our Pilot study. (2) No changes in our planned processing of data.
Pilot 5	(1) NO, all information collected and processed is already specified in the ethics approval and informed consents. (2) N/A
Pilot 6	(1) Not foreseen. (2) The iPrognosis smartphone application will not be used. Therefore, all corresponding data (keyboard touch time stamps, IMU sensor data, and microphone data, corresponding to personal data items 2, 3, and 4 in the D8.3 questionnaire) will not be collected. Connected to this, bradykinesia scores, tremor flags, and voice flags (corresponding to inferred data items 1, 2, and 3 in the D8.3 questionnaire) will not be derived.
Pilot 7	(1) No

[5] D8.3 SELP Impact Assessment Questionnaire.

	(2) No
Pilot 8	(1) Same as communicated in the previous questionnaire. (2) Same as communicated in the previous questionnaire

3.3.2 Q. 7. Legal basis other than informed consent

This question focuses on the issue of what the legal basis for processing of personal data is or will be. Intention behind this question is to assess and monitor the risk related to the legal basis as the risk is considered to increase if it is not identified, or the Pilot seeks to rely on multiple legal bases.[6]

The responses to this question can be categorized into two groups: (1) Pilot Studies that rely on informed consent; and (2) Pilot Studies that relies on multiple legal bases (e.g., informed consent for specific types of personal data and other legal basis for other types of personal data). Most Pilots -- namely Pilots 1, 3, 4, 5, 6, and 8 -- expressed they rely on informed consent as the legal bases for the processing of personal data. The rest of Pilots -- Pilots 2 and 7 -- rely also on other legal bases. As relying on multiple legal bases can be tricky, we address this issue in the Conclusion, *infra*. The table below provides summarized response by each Pilot to the question asking: "What is the legal basis for processing personal data you collected and are using in your Pilot Study? If it is based on informed consent, please state so. If other than informed consent, please explain the legal basis for each of the relevant personal data."

Table 8: Legal basis.

Pilot #	Q. 7. Legal basis
Pilot 1 (ECHO)	Informed consent
Pilot 1 (VCE)	Informed consent
Pilot 2	Informed consent. AND 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.
Pilot 3	Informed consent clearly and simply worded to ensure understanding by participants.
Pilot 4	Any personal data that may be eventually processed in our Pilot is based on informed consent
Pilot 5	Ethical approval of the study protocols and explicit informed consent.
Pilot 6	Informed consent.

[6] See D8.3 SELP Impact Assessment Report, at 48.

Pilot 7	Legitimate interest. Explanation included in study protocol.[7]
Pilot 8	All relevant information regarding their rights as participants and purpose of data processing is described in the signed informed consent and protocol.

3.3.3 Q. 8. International data transfer

This question focuses on the issue on international data transfer. Intention behind this question is to assess and monitor the risk related to the legal basis as the GDPR has additional regulations if there's an element of international data transfer.[8]

No Pilots mentioned that they intend to transfer or has in fact transferred personal data to countries/regions outside of EU/EFF. The table below provides summarized response by each Pilot to the question asking: "(1) If your Pilot has any intention to transfer personal data to countries/regions outside of European Union, please explain the measures you will take to comply with the GDPR; and (2) If your Pilot transferred personal data to countries/regions outside of European Union, please explain the measures you took to comply with the GDPR."

Table 9: International data transfer.

Pilot #	Q. 8. International data transfer
Pilot 1 (ECHO)	(1) There is no intention to transfer personal data outside EU. (2) -
Pilot 1 (VCE)	(1) There is no intention to transfer personal data outside EU. (2) -
Pilot 2	Data will be transferred by complying to GDPR as follow Anonymisation: 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 to national law and GDPR. Pseudonymisation: 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
Pilot 3	(1) No intention to do it. (2) Not expected.

[7] While the response to T8.4 questionnaire indicates they rely on legitimate interest, Pilot 7 has provided that they rely on informed consent previously in T8.3. Thus, for the purpose of this report, we have assumed that reply on both informed consent as well as legitimate interest for their legal, and categorizing Pilot 7 as a group that relies on multiple legal bases.

[8] In short, in the context of GDPR, there's an international data transfer if personal data is being transferred to countries or regions outside of the European Economic Area (EEA), which is comprised of Norway, Lichtenstein, Iceland, and EU.

Pilot 4	(1) Yes, to analyse the data we are transferring mapping data (anonymized) within the European Union to 91 which uses Google Cloud servers located in Germany that are compliant with GDPR, German, and Spanish, privacy laws as well. Access is given only to the researchers that need to work on it
Pilot 5	(1) NO (2) N/A
Pilot 6	No intention of transfer personal data to countries/regions outside EU foreseen.
Pilot 7	(1) No (2) N/A
Pilot 8	(1) N/A (2) N/A

3.3.4 Q. 9. Profiling

This question focuses on the issue of whether HosmartAI AI technology[9] in the Pilot Study triggers the provisions concerning profiling under the GDPR. The issue is continuously addressed in this report and was also addressed in the previous report[10] because the issue is important in two ways: (1) the GDPR places additional obligations if HosmartAI AI technology falls within the definition of profiling; (2) the Grant Agreement requires the beneficiary[11] to "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";[12] and (3) issue concerning profiling is closely related to issues concerning AI Ethics, which is touched again in the relevant section,[13] *infra*.

The table below provides summarized response by each Pilot to the question asking: "If your Pilot Study processed personal data in a way that falls within the definition of profiling under the GDPR, please describe the measures you actually took. When answering please focus on: (1) how you provided the explanation of how the data subjects will be informed of the existence of the profiling; (2) possible consequences of profiling; and (3) how participants' fundamental rights will be safeguarded."

The responses to this question can be categorized into two groups: (1) Pilot Studies that do not involved Profiling defined under the GDPR; and (2) Pilot Studies that use AI technology that falls within the definition of Profiling under the GDPR. Pilots 4, 7, and 8 belong to the first group, and these groups will not be required to provide kinds of information asked in the question. Other Pilots, namely Pilots 1, 2, 3, 5, and 6 responded that their HosmartAI AI technologies fall within the definition of Profiling under the GDPR. These Pilots further provided how they will or did provide their explanations. Similar or the same explanations

[9] The term is explained in the subsequent section entitled "Ethical and Societal Issues, including AI ethics," *infra*.
[10] D8.3 SELP Impact Assessment Report, at 64.
[11] I.e., HosmartAI.
[12] The explanations were submitted as deliverable D10.2.
[13] Chapter 3.4, Ethical and Societal Issues, including AI ethics.

were provided in another deliverable D10.2.[14] Considering both the responses to this questionnaire as well as the responses in D10.2,[15] we found none of them to be insufficient.

Table 10: Profiling.

Pilot #	Q. 9. Profiling
Pilot 1 (ECHO)	The data processing that falls within the definition of profiling consists of 1) predicting the health status of a patient participant, and 2) the performance of a doctor participant at diagnosing heart conditions. (1) • The patient participants are informed for their health status following the standard clinical practise of the hospital. • A doctor participant can request for his/her personal results after the end of the study. Information about the request procedure is given to the doctor in the consent form. (2) • There is no possible consequence for the patients as the standard clinical practise is followed, i.e., without HosmartAI pilot study. • A possible consequence for the doctors is the usage of the results, i.e., their performance at diagnosing heart conditions, for professional assessment purposes. (3) For safeguarding the doctors participated in the pilot study, their data are anonymised before the analysis. The only one who has access to the original data is the principal investigator of the study and he affirms in the consent form to not use the data for purposes other than the specific study.
Pilot 1 (VCE)	The data processing that falls within the definition of profiling consists of 1) predicting the health status of a patient participant, and 2) the performance of a doctor participant at diagnosing heart conditions. (1) • The patient participants are informed for their health status following the standard clinical practise of the hospital. • A doctor participant can request for his/her personal results after the end of the study. Information about the request procedure is given to the doctor in the consent form. (2) • There is no possible consequence for the patients as the standard clinical practise is followed, i.e., without HosmartAI pilot study.

[14] D10.2: POPD - Requirement No. 5.
[15] D10.2, pages 24 to 28.

	• A possible consequence for the doctors is the usage of the results, i.e., their performance at diagnosing heart conditions, for professional assessment purposes. (3) For safeguarding the doctors participated in the pilot study, their data are anonymised before the analysis. The only one who has access to the original data is the principal investigator of the study and he affirms in the consent form to not use the data for purposes other than the specific study.
Pilot 2	(1) Consent form and oral explanation during the enrolment. (2) Appointments which are not in line with (1) the personal life of the patients or (2) his medical situation. (3) • The algorithm of this project will not be used for automated decision-making purposes. Indeed, all the appointments generated by the algorithm must be validated beforehand by the staff of the CHUL before offering them to the patient. • Profiling according to the Belgium and European Union legislation and regulation.
Pilot 3	(1) All profiling procedures will be clearly explained in the informed consent to each participant. (2) No harm consequences expected. Anonymization and pseudo-anonymization granted. Only authorized clinicians will use identifiable sociodemographic data and only for clinical purpose and patients care. (3) All processes will be GDPR compliant, respecting paricipants rights.
Pilot 4	Subject data is not intended to profile the subject individually.
Pilot 5	(1) The possibility of profiling in study HosmartAI-SRS-CDSS will be presented to the patients and explained in detail upon recruitment (2) The studies will have no impact on regular care routine, as received outside this study (3) The studies will have no impact on regular care routine, as received outside this study
Pilot 6	(1) Consent form and informative factsheet. (2) Positive consequences. Profiling helps the general application and specifically contributes to the algorithm and the personalization of the therapeutic plans. (3) Profiling according to the Spanish and European Union legislation and regulation.
Pilot 7	(1) N/A (2) N/A (3) N/A
Pilot 8	(1) N/A (2) N/A (3) N/A

3.3.5 Q. 10. Any comments, opinions, questions, or suggestions with regard to issues concerning processing of personal data

This question focuses on the fact whether or not the Pilot has received any comments, opinions, questions, suggestions, or anything similar with regard to issues concerning processing of personal data. The intention of this question is to identify any potential issues regarding processing of personal data.

No Pilots have received anything comments and the with regard to processing of personal data. The table below provides summarized response by each Pilot to the question asking: "Please describe if you have received any comments, opinions, questions, suggestions from your DPO, legal department, or any other department/team of your institution with regard to issues concerning processing of personal data."

Table 11: DPO/legal dept.

Pilot #	Q. 10. Any comments, opinions, questions, or suggestions re personal data
Pilot 1 (ECHO)	No
Pilot 1 (VCE)	No
Pilot 2	No comment shared.
Pilot 3	No relevant comments received. Periodical checks with DPO are programmed.
Pilot 4	We have not received any comments, opinions, questions or suggestions from our DPO
Pilot 5	N/A
Pilot 6	No comment shared.
Pilot 7	Feedback from the METC (Ethical Committee) on the study protocol was to arrange for a data sharing agreement between the pilot partners.
Pilot 8	N/A

3.4 Ethical and Societal Issues, including AI ethics

This section addresses risks concerning the use of HosmartAI's Artificial Intelligence technologies (referred to as "AI technologies") in the context of ethical and social issues. The overarching issue is whether or not use of AI technologies in each Pilot is likely to introduce risks in ethical or social context.

A preliminary question to ask is, how are risks in ethical or social context different from risks in legal context. Our position is the following: (1) all risks are generally ethical and/or social; (2) some of these risks are addressed by law and are regulated. This makes legal risks the

subset of ethical/social risks. Absent laws or regulations, risks would be considered as ethical and/or social.[16]

In this report,[17] as well as the first impact assessment report,[18] we aim to assess/analyse/monitor the ethical and social risks of AI technologies of each Pilot by: (1) assuming that the AI technology will err and will make mistakes during the Pilot Study; (2) asking what is the added or heightened risk due to the use of AI technology in question; and (3) asking how the Pilot Study is designed to detect and deter the risk as well as mitigate the risk. Each issue is addressed in the following questions, respectively.

3.4.1 Q. 11. Potential Risks (Added or Heightened Risks)

This question focuses on **added or heightened risk(s)**, and the issue is whether or not AI technology used in HosmartAI adds, heightens, increases, introduces any risk. This means the question aims to compares the difference in the risk level in two different settings, namely one in the standard clinical/medical practice (without HosmartAI) and the other in Pilot Study research (with HosmartAI). This question was also asked in the previous task/deliverable,[19] and the reasons and the purposes of the questions are the same in the previous task/deliverable.

No Pilots expressed added or heightened risks. The table below provides summarized response by each Pilot to the question asking: "Are there any added risks due to the use of the AI technologies in your Pilot Study that you anticipated, discovered, noticed, recognized, observed, or otherwise perceived so far? 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 12: Added or heightened risks.

Pilot #	Q. 11. Added or heightened risks
Pilot 1 (ECHO)	The results of the artificial intelligence technology used in the pilot study does not affect the treatment of the patient in any way. The patient is treated following the standard clinical practise.
Pilot 1 (VCE)	The results of the artificial intelligence technology used in the pilot study does not affect the treatment of the patient in any way. The patient is treated following the standard clinical practise.
Pilot 2	Same risks foreseen in D8.3.
Pilot 3	No added risks yet. Monitoring is constant. No deviations from D8.3 questionnaire.
Pilot 4	No potential risk for patients considering it is an experimental off-line Pilot. No changes since the previous questionnaire

[16] See also D8.3 SELP Impact Assessment Report, at 71, for other differences.
[17] D8.4 SELP Continuous Monitoring Report 1.
[18] D8.3 SELP Impact Assessment Report.
[19] T8.3 SELP Impact Assessment & D8.3 SELP Impact Assessment Report.

Pilot 5	NO, the studies have no impact on regular care routine, as received outside this study; i.e. none of the regular routine is changed or any regular services excluded. The studies do not introduce any additional clinical procedures.
Pilot 6	Same risks foreseen in D8.3.
Pilot 7	The proposed application is a post-procedural reporting assistance, and will not introduce added or heightened risks.
Pilot 8	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.

3.4.2 Q. 12. Detection and deterrence

This question focuses on detection and deterrence measures under the assumption that added or heightened risk exists.[20] Some Pilots explained their measure or safeguards to detect and/or deter some anticipated risks. However, as no Pilots expressed added or heightened risks asked in the previous question, all responses are deemed adequate for the purpose of this question. The table below provides summarized response by each Pilot to the question: "If there are any added or heightened risks, how is our 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?"

Table 13: Detection and deterrence.

Pilot #	Q. 12. Detection and deterrence
Pilot 1 (ECHO)	There are no added or heightened risks.
Pilot 1 (VCE)	There are no added or heightened risks.
Pilot 2	The system only proposes appointment options that best suit the current occupation of rooms, doctors and machines, so that ultimately it is a doctor who determines the suitability of one over the other. This does not have a medical impact on patients because there is always an expert review behind the algorithm.
Pilot 3	AI technologies are being development, privacy by design approach will grant risk reduction and detection.
Pilot 4	There are no added or heightened risk in our Pilot
Pilot 5	NO. the studies have no impact on regular care routine. AI makes no decisions related to treatment or care routine. AI made observations must be further interpreted by human experts (i.e. human is always in the loop) and are understood by clinicians and healthcare as such.

[20] Absent added or heightened risk, whether or not detection and deterrence measure exist does not change the risk level.

Pilot 6	There are no safeguards in our AI models because they only make recommendations that are always within the possibilities proposed by a qualified physician. These same healthcare professionals periodically review the system to ensure that they have a personalized plan for each patient.
Pilot 7	N/A
Pilot 8	The AI will give confidence level for the connections which are identified, based on the training data.

3.4.3 Q. 13. Mitigation

This question focuses on detection and deterrence measures under the assumption that added or heightened risk exists.[21] Some Pilots explained their measure to mitigate some anticipated risks. However, similarly to the previous question, no Pilots expressed added or heightened risks, and therefore all responses will be deemed adequate for the purpose of this question. The table below provides summarized response by each Pilot to the question: "how is your Pilot Study designed to mitigate the risks mentioned above? Are there any safeguards to avoid any harms to the human participants?"

Table 14: Mitigation.

Pilot #	Q. 13. Mitigation
Pilot 1 (ECHO)	There are no added or heightened risks.
Pilot 1 (VCE)	There are no added or heightened risks.
Pilot 2	Same plan as stated in D8.3.
Pilot 3	No harms to human participants are expected. No added risks to report.
Pilot 4	Does not apply
Pilot 5	N/A
Pilot 6	Same plan as stated in D8.3.
Pilot 7	N/A
Pilot 8	The AI used in our trial will have no direct influence on the human participants. The clinicians will consider the results from the AI in relation to their normal diagnosis and feedback their interpretation on the usefulness of the AI results to the researchers.

3.4.4 Q. 14. Any comments, opinions, questions, suggestions, or anything similar from anybody in connection to AI ethics issues

This question focuses on the fact whether or not the Pilot has received any comments, opinions, questions, suggestions, or anything similar in connection to AI ethics issues. As of now, no Pilots have received any comments or the like in connection to AI ethics issues. The

[21] Absent added or heightened risk, whether or not mitigation measure exist does not change the risk level.

table below provides summarized response by each Pilot to the question: "Please describe if your Pilot has received any comments, opinions, questions, suggestions or anything similar from anybody (e.g., Pilot Study participants, your DPO, legal department, or any other department/team of your institution) in connection to AI ethics issues that may be relevant to this questionnaire."

Table 15: Any comments, opinions, questions, suggestions in connection to AI ethics.

Pilot #	Q. 14. Any comments, opinions, questions, suggestions re AI ethics
Pilot 1 (ECHO)	No comments until Dec. 2022.
Pilot 1 (VCE)	No comments until Dec. 2022.
Pilot 2	No relevant comments shared.
Pilot 3	No relevant comments received. Periodical checks with DPO are programmed.
Pilot 4	No comments, opinions, questions, suggestions from anybody in connection to AI ethics issues
Pilot 5	N/A The interventions carried out are not clinical in nature.
Pilot 6	No relevant comments shared.
Pilot 7	N/A
Pilot 8	N/A

3.4.5 Q. 15. Any ethical, legal, or social issues while conducting your Pilot Study

This final question asks whether or not Pilot has any ethical, legal, or social issue relevant to WP8's tasks that they wish to raise. The purpose of this question is to enable and encourage Pilots to share their concerns with WP8, so HosmartAI, as the Consortium, can effectively and efficiently address ethical, legal, or social issues.

As of now, no Pilots raised their concern. The table below provides summarized response by each Pilot to the question: "If you have any ethical, legal, or social issues that you are concerned while conducting your Pilot Study, please share."

Table 16: Any other concerns while conducting Pilot Study.

Pilot #	Q. 15. Any ethical, legal, or social concerns while conducting Pilot Study
Pilot 1 (ECHO)	No issues until Dec. 2022.
Pilot 1 (VCE)	No issues until Dec. 2022.
Pilot 2	None
Pilot 3	No concerns to report at the moment. We will keep on monitoring these aspects
Pilot 4	We are not concerned on any ethical, legal or social issues while conducting our Pilot

Pilot 5	N/A
Pilot 6	N/A
Pilot 7	No
Pilot 8	N/A

4 Conclusion

This deliverable documented the task T8.4 SELP Continuous Compliance Report. It makes two primary contributions. The first is, as the result of continuous assessment and monitoring, it documents that no critical risk was identified based on available information as of now. Two minor issues are discussed below. The second is, through previous and current tasks, it identifies and narrows down the risks to be continuously assessed and monitored.

(1) Multiple legal bases. Technically, reply on multiple legal bases can be tricky under the GDPR.[22] Article 6(1) GDPR anticipates multiple legal bases.[23] While Recital 40, providing guidance as to lawfulness of data processing, does not provide any hint on the issue, Article 13(1) uses a singular form of "legal *basis*"[24] as information to be provided to the data subject. While the details would depend on specific facts and would need case by case analysis, data controllers relying on multiple legal bases should be aware of and be able to identify and distinguish which type of personal data is processed on what legal basis, and therefore respond to data subjects' request considering its legal basis. This issue is unlikely to pose significant risk. However, we will continue to communicate with those Pilots to reduce the risk.

(2) EU Medical Devices Regulation. As two Pilots expressed interest in marketing their HosmartAI technology as medical device, they can be subject to EU Medical Devices Regulation when they actually do so. The issue of whether or not, and how if any, the EU Medical Devices Regulation applies, and what needs to be done in order to comply with the Regulation, requires detailed analysis when their technologies are in fact ready to be marketed as medical device. Considering their plan and intention, we will continue to communicate with those Pilots.

As said in D8.3 as well, it is important to be aware that the process of risk assessment is an ongoing activity. The dynamics and the dimensions of risks may change and fluctuate due to various factors. For example, a serious issue may be raise elsewhere triggering public backlash against the use of AI technologies, a relevant bill (draft law) can be issued or come into effect, or a modification of Study Protocol may change the dynamics and the dimensions of relevant

[22] See GDPR Brief: "At Least One" Legal Basis for Processing Under the GDPR: Clarifying Article 6(1), https://www.ga4gh.org/news/gdpr-brief-at-least-one-legal-basis-for-processing-under-the-gdpr-clarifying-article-61/. See also 6 Legal Bases for Processing Personal Data: GDPR Fundamentals | Video, https://kirkpatrickprice.com/video/gdpr-fundamentals-legal-basis-for-processing/; 6 Legal Bases for Processing Personal Data: GDPR Fundamentals | Video, https://kirkpatrickprice.com/video/gdpr-fundamentals-legal-basis-for-processing/; Article 6 GDPR - GDPRhub, https://gdprhub.eu/Article_6_GDPR#Multiple_legal_bases; General Data Protection Regulation (GDPR) Guidance Note for the Research Sector: Appropriate use of different legal bases under the GDPR, https://esomar.org/uploads/attachments/ckv2fj3rh001jbw3vejug72q2-efamro-esomar-gdpr-guidance-note-legal-choice.pdf.

[23] Article 6(1) reads: "Processing shall be lawful only if and to the extent that *at least one of the following* applies" (emphasis added).

[24] Article 13(1)(c) GDPR reads "The purposes of the processing for which the personal data are intended as well as the legal *basis* for the processing" (emphasis added).

risks. With this in mind, WP8 will conduct the next task and continue the dialogue with the technical partners to fulfil our role.

5 References

[REF-01]	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-02]	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-03]	Dariusz Kloza et al., Towards a method for data protection impact assessment: Making sense of GDPR requirements (2020), https://osf.io/es8bm.
[REF-04]	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.
[REF-05]	GDPR Brief: "At Least One" Legal Basis for Processing Under the GDPR: Clarifying Article 6(1), https://www.ga4gh.org/news/gdpr-brief-at-least-one-legal-basis-for-processing-under-the-gdpr-clarifying-article-61/.