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|---|---|
| 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

DELIVERABLE

# D7.5 – Business Plan – Final Version

| | |
|---|---|
| Dissemination level: | PU -Public |
| Type of deliverable: | R -Report |
| Contractual date of delivery: | 31 May 2024 |
| Deliverable leader: | VIMAR |
| Status - version, date: | Final – v1.0, 2024-05-20 |
| Keywords: | Business Plan, Business Model, Markets, Products, Services |

# Executive Summary

This document describes the process that has been followed to select the commercially exploitable assets of HosmartAI and how the partnership has been working to deliver the 10 confidential business plans that have been included in the D7.3 “Exploitation Plans and Activities – Final Version”.

D7.5 provides an overview of the overall business planning process - and its most significant quantitative results – that has been implemented from M25 until the end of the project together with summary outcomes taken from the confidential individual business plans. Key figures like the number of competitors, customers and key activities are summarized. A focus on the business & innovation management approach is described, together with an overview of IPR management adopted approaches and the market maturity levels of all KERs. Furthermore, the deliverable describes how the identified commercial KERs have tackled the typical business challenges of a business plan: problem statement, how they met requirements and needs, their positioning compared to market leaders, value proposition, inconvenience, timing of the innovation, compliance, partnership and economic estimations. HosmartAI delivered more than 20 innovations: this brought to a prioritization need which has been solved via a long process that has been described in this deliverable. An updated overview of HosmartAI’s markets and customers is also provided. The deliverable also provides insights into the preconditions or pillars of each business plan, specifically: ownership, pricing, protection strategies, certifications, standards, and regulatory compliance, adopted open licensing schemes and their impact on commercialization strategies. Finally, D7.5 introduces the Helsinki Radical Health Festival, the initiative that has been selected to connect investors to HosmartAI’s innovators. Due to time constraints (the event closed on May 23rd it was not possible to include the outcomes of that event in this document).

| | |
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| **Document History** | | | |
|---|---|---|---|
| **Version** | **Date** | **Contributor(s)** | **Description** |
| 0.1 | 2024-31-01 | Andrea Jester (VIMAR) | Document structure draft |
| 0.2 | 2024-23-02 | Andrea Jester (VIMAR) | Detailing chapters |
| 0.3 | 2024-01-03 | Andrea Jester (VIMAR) | Align D7.5 with D7.4 & D7.8 |
| 0.4 | 2024-12-03 | Andrea Jester (VIMAR) | Licensing check |
| 0.5 | 2024-15-03 | Andrea Jester (VIMAR) | New structure to be validated by project partners |
| 0.6 | 2024-08-04 | Andrea Jester (VIMAR) | All chapters have been reviewed again |
| 0.7 | 2024-08-04 | Andrea Jester, Michele Ferramola, Sara Canella, (VIMAR) | Review of chapter order, new chapter 8 added |
| 0.8 | 2024-23-04 | Andrea Jester (VIMAR) | Pages that will have to be checked at the end of this version: 14, 16, 22, 23, 26, 32, 33, 34, 38, 44, 48, 50 |
| 0.9 | 2024-24-04 | Andrea Jester (VIMAR) | Platform market analysis, Pilot 4 market analysis, Pilot market analysis |
| 0.10 | 2024-26-04 | Andrea Jester (VIMAR) | Pages that will have to be checked at the end of this version: 14 (n° of competitors / customers), 19 (n° of competitors), 20 (n° of competitors), 39 (Pilot 7 TRL). |

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|---|---|---|---|
| 0.11 | 2024-29-04 | Andrea Jester (VIMAR), Magda Chatzikou (PhE) | Missing data have been added; description of the economic impact analysis has been added. |
| 0.12 | 2024-15-05 | Andrea Jester (VIMAR) | Final reviewed version |
| 1.0 | 2024-05-20 | Athanasios Poulakidas, Anastasia Panitsa (INTRA) | Final version for submission after QA |

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# Definitions, Acronyms and Abbreviations

| Acronym/ Abbreviation | Title |
|---|---|
| **AI** | Artificial Intelligence |
| **API** | Application Programming Interface |
| **B2B** | Business To Business |
| **B2C** | Business To Consumer |
| **Bln** | Billion |
| **CAD** | Coronary Artery Disease |
| **CAGR** | Compound Annual Growth Rate |
| **Cathlab** | Catheterization laboratory |
| **CBM** | Canvas Business Model |
| **D** | Deliverable |
| **DaaS** | Data as a Service |
| **DoA** | Description of the Action |
| **EF** | Ejection Fraction |
| **EGov** | Electronic Government |
| **FGR** | Fetal Growth Restriction |
| **FHIR** | Fast Healthcare Interoperability Resources |
| **GDPR** | General Data Protection Regulation |
| **IPR** | Intellectual Property Rights |
| **KER** | Key Exploitable Result |
| **KPI** | Key Performance Indicator |
| **Mln** | Million |
| **PaaS** | Platform as a Service |
| **SaaS** | Software as a Service |
| **SMEs** | Small and Medium Sized Enterprises |
| **TRL** | Technology Readiness Level |
| **USD** | US Dollars |
| **UI** | User Interface |
| **WP** | Work Package |

# 1 Introduction

## 1.1 Project Information

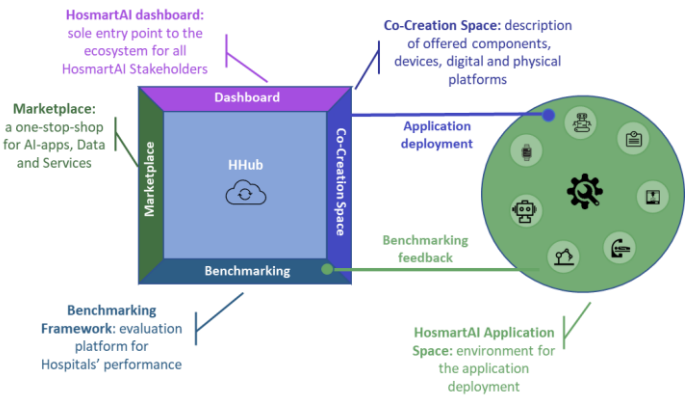
VISION

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 an AI solution.

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.

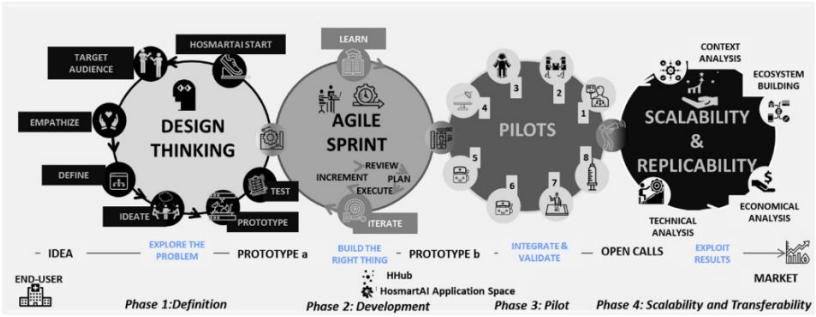



A central **hub** will offer multifaceted lasting functionalities (Marketplace, Co-creation space, Benchmarking) to healthcare stakeholders, combined with a collection of methods, tools and solutions to integrate and deploy AI-enabled solutions. The **Benchmarking** tool will promote the adoption in 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 11 different medical scenarios and 1 administrative scenario such as 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) along with several more committed organizations.

*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** |

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

| Number[1] | Name | Short name |
|---|---|---|
| 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** |
| 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 Background & Scope

Deliverable 7.5 is the result of several activities which have been implemented during and in parallel to dedicated business planning sessions. Specifically: 1) an ongoing analysis of the innovative nature of each commercially exploitable KER, 2) a prioritization process that helped to focus on the most promising and mature KERs, 3) a continuous check of technology and market trends related to these KERs, 4) long iterative business planning sessions.

While all confidential outcomes have been described in a dedicated chapter of D7.3 ("Exploitation Plans and Activities – Final Version"), this public deliverable provides aggregated insights about the following topics:

- the overall innovation management process adopted during the project
- how the business challenges described in D7.4 have been addressed
- how KERs have been prioritized in terms of market readiness
- an updated overview of the market landscape and initial customer base
- an overview of key pre-requisites of each business plan, namely: ownership models, pricing, protection strategies, the approach towards certifications – standards and regulatory compliance, licensing fact checking (to avoid constraints during commercialization)
- the strategy adopted to connect HosmartAI's innovators to investors or potential customers at the end of the project.

## 1.3 Document Structure

This document is composed of 9 main chapters.

**Chapter 1** introduces the deliverable and its scope.

**Chapter 2** provides an overview of the overall business planning process - and it most significant quantitative results – that has been implemented from M25 until the end of the project.

**Chapter 3** describes HosmartAI's business & innovation management approach and describes IPR management adopted approaches together with the maturity levels of all KERs.

**Chapter 4** focuses on the business challenges and how HosmartAI tackled them during the business planning related activities.

**Chapter 5** describes how KERs have been prioritized and which strategies have been chosen to enter the identified markets.

**Chapter 6** provides an updated overview of HosmartAI's markets.

**Chapter 7** focuses on the preconditions or pillars of each business plan, specifically: ownership, pricing, protection strategies, certifications, standards and regulatory compliance, adopted open licensing schemes and their impact on commercialization strategies.

**Chapter 8** introduces the Helsinki Radical Health Festival, the initiative that has been selected to connect investors to HosmartAI's innovators.

**Chapter 9** describes the conclusions of this deliverable.

**References** closes the document.

# 2 HosmartAI's business development workflow

## 2.1 Planned and implemented actions

| M20-M24 (September – December 2022) | The Action |
|---|---|
| *Plan according to Deliverable 7.4:*<br>These months will be dedicated to<br>• run **Lean Business Canvas modelling sessions** will all Pilot and Platform exploitable asset owners<br>• collect end **user & stakeholder feedback during Sprint 3**, which is supposed to close in December 2022: specific business questions have been prepared to be answered during these sessions<br>• finalize the **first market surveillance round** (in cooperation with Task 7.3 leader, PHILIPS)<br>• harmonize inputs provided with the **Innovation Radar questionnaire**: these inputs will help to align business assumptions with an overall picture of the level of innovation of the exploitable assets (in cooperation with Task 7.3 leader, PHILIPS) | *Implemented activities until December 31st, 2022:*<br>• *2 sessions with each pilot & platform representatives (**TOTAL: 18 sessions of 1.5 hours each**) that led to the identification of the final commercially exploitable solutions*<br>• *VIMAR joined the WP1 meetings dedicated to sprint sessions to understand the potential of the innovations from the perspective of the end users (**TOTAL: 8 sessions**)*<br>• *the market surveillance round has been designed as a permanent activity: potential competitors & industry trends have been identified and analysed based on the identified MVPs & innovations; the results have been included in the confidential business plans annexed to D7.3 (**TOTAL analysed competitors at this stage: 43**)*<br>• *the harmonization process with the Innovation Radar questionnaire consisted in including complementary information provided with the questionnaires to the lean business canvas models; this part of the work has been relevant to identify and address ownership issues and IP protection strategies* |
| **M25-M31 (January 2023 - July 2023)** | **The Action** |
| *Plan according to Deliverable 7.4:* | *Implemented activities until July 31st, 2023:* |

| | |
|---|---|
| These months will be dedicated to<br>• run a **full Business Canvas modelling sessions** will all Pilot and Platform exploitable asset owners<br>• collect end **user & stakeholder feedback during Sprint 4**, which is supposed to close in June 2023: specific business questions have been prepared to be answered during these sessions<br>• finalize a **second market surveillance round** (in cooperation with Task 7.3 leader, PHILIPS)<br>• harmonize inputs provided with the **Innovation Radar questionnaire**: these inputs will help to align business assumptions with an overall picture of the level of innovation of the exploitable assets (in cooperation with Task 7.3 leader, PHILIPS)<br>• initial drafting of **the of 10 business plans** | • *3 additional sessions with each pilot & platform representatives (**TOTAL: 24 sessions**) have been done: each round focused on specific topics this leading already to a more comprehensive business plan (Round 1 core topics: Ownership, Protection Strategies, Product; Round 2 core topics: Customers, Value Proposition, Market; Round 3 core topics: Marketing & Sales strategies, pricing hypothesis)*<br>• *The final round of the Sprint has been used to collect feedback on possible pricing options (not in terms of "amount" but in terms of type of pricing) of the solutions*<br>• *Market surveillance rounds continued. (**TOTAL accumulated analysed competitors at this stage: 67**)*<br>• *By June 2023, the core groups of the pilots and the HosmartAI platform involved partners prepared a plan to co-write the confidential business plans. The identified groups were*<br>  ○ *Pilot 1, 2 groups – 1 for each business plan (5 people each)*<br>  ○ *Pilot 2, 1 group (4 people)*<br>  ○ *Pilot 3, 2 groups – 1 for each business plan (6 people)*<br>  ○ *Pilot 4, 1 group (3 people)*<br>  ○ *Pilot 5, 1 group (4 people)*<br>  ○ *Pilot 6, 1 group (3 people)*<br>  ○ *Pilot 7, 1 group (3 people)*<br>  ○ *HosmartAI platform, 1 group (7 people)* |
| **M32-M41 (August 2023 – May 2024)** | **The Action** |
| *Plan according to Deliverable 7.4:* | *Implemented activities until May 31st, 2024:* |

| | |
|---|---|
| This period will be dedicated to validating the business models / plans with at least the following actions<br>• observation of the roll out of pilots / platform (goals: understand end users & market acceptance)<br>• analysis of economic KPIs (in cooperation with Task 1.4 leader PhE)<br>• delivery and validation rounds of **individual (pilot based) business models / plans and the overall aggregating (platform) business model / plan** thanks to<br>  ○ a structured interaction with synergic initiatives, projects and stakeholders (goals: check robustness of business assumptions and – ideally – identify synergies)<br>  ○ the organization of individual business meetings & pitches<br>  ○ the participation to relevant business focused events (fairs, conferences, etc.)<br>In **M40** the detailed business plans will be ready for the final review. | • *The pilots' clinical studies have been observed to double check the consistency of the value proposition of the identified commercial exploitable assets.*<br>• *Economic KPIs have been analysed under WP1 and the most significant results used during dedicated pitches, B2B and investor meetings. A paragraph of this deliverable explains the methodology that has been adopted.*<br>• *Rounds with each pilot & platform groups have continued: the total number of these meetings was different for each group* ***(TOTAL NUMBER OF MEETINGS: 42)***<br>• *Market analysis also continued, reaching to a final amount of analysed competitive solutions of* ***85 competitors****:*<br>• *Interactions with synergic initiatives & B2B meetings:*<br>  ○ *MEDICA Trade (November 2023)*<br>  ○ *DigitalHealthUptake (B2B meetings)*<br>  ○ *TEF Health (B2B meetings)*<br>  ○ *Radical Health Festival (May 2024)*<br>  ○ *EHTEL (April 2024)*<br>• *Identified aggregated potential customers:* ***712***<br>• *Delivery of 10 individual business plans (May 2024)* |

# 3 Business & Innovation management

## 3.1 The Innovation management approach

D7.8 described the overall **innovation and IPR management** approach that the Consortium decided to follow during the implementation of the HosmartAI project, such as to maximize the impact of the project's results. The HosmartAI innovation management plan was based on procedures inspired by the European Standard for Innovation Management, CEN/TS 16555-12 [REF-01].

PHILIPS and VIMAR, together with partners involved under WP1 (during the Sprints sessions), assured:

1. **Interface Management,** by analysing science, technology, and business actors to spot new knowledge crucial for the project and create awareness for the results.
2. **Idea Management,** ensuring that new ideas were captured, intellectual property requirements analysed, market surveillance activities' have been shared and business models for the most close-to-market results have been designed.
3. **Innovation Portfolio and Project Management**, by prioritizing innovations' go to market and coordinating efforts (from "idea" to "action")

These innovation management procedures guaranteed that:

- The expected results were aligned with market needs.
- The results were disseminated and reach its target groups.
- A clear business exploitation strategy has been designed.
- The commercial exploitation strategy described in this deliverable is based on market observation and on a realistic perception of the strengths (and weaknesses) of the innovations introduced with project activities.

## 3.2 IPR Management

D7.8 also presented the overall IPR management strategy of the project. The document described an accurate IP handling system which has been carefully shared with all partners and their Technology Transfer Offices, where available.

The nature of HosmartAI's innovations did not lead to patents while specific sessions have been organized to increase the overall awareness of project partners about IPR and protection strategies. The strategies adopted to protect and ensure value to the delivered

commercial key exploitable results[3] is summarized hereunder and – additionally – described in D7.3:

*Table 2: HosmartAI's protection strategies.*

| Platform / Pilots' solutions & KERs | Protection Strategy |
|---|---|
| **Pilot 1 – Gutscanner / ER5** | Agreed with AUTH's TTO |
| **Pilot 1 – CADXpert / ER2 & ER4** | Agreed with AUTH's TTO |
| **Pilot 2 – ZinaRT Scheduler / ER7** | Agreed with the TTOs of involved partners. Specific internal agreement has also been signed among involved partners. |
| **Pilot 3 – UWB / ER9** | No significant actions required. Vimar's internal procedure has been applied to ensure that no specific protection mechanisms had to be applied. |
| **Pilot 3 – REST API / ER11** | No significant actions required. Internal procedure has been applied to ensure that no specific protection mechanisms had to be applied. |
| **Pilot 4 – Heart+ Map / ER12** | No significant actions required. |
| **Pilot 5 – SIGEDA** | SIGEDA's IP was registered on the 7th of June 2023 |
| **Pilot 6 – MovasCare / ER 16** | The primary modules' IP is shared between INTRAS, ITCL and AUTH. The software will initially be treated as **trade secret.** It is also protected by standard copyright, as any software is, and it may be officially registered in the future. |
| **Pilot 7 – Customer Innovation Lab / ER17** | Philip's internal procedure has been applied. |
| **HosmartAI Platform / ER1** | Internal agreement has been defined and signed among platform participating partners. |

## 3.3 Innovation Radar Methodology

PHILIPS also ensured the adoption of the Innovation Radar methodology[4], which means that data about KERs have been gathered to categorise them in terms of market maturity and disruptive potential, based on indicator systems developed by the Joint Research Centre [REF-02].

The table summarizes our activities compared to the initial plan:

*Table 3: IRQ timetable.*

| Innovation Radar Questionnaire – Planned | Delivered |
|---|---|
| When the Final set of AI Solutions and Autonomous Smart Components will be available (D3.3 - M31). | All questionnaires were submitted in May 2023 (M29). |
| When the Platform Architecture Design will be available (D4.3 - M37). | |

[3] Reminder: this deliverable focuses on commercial exploitation and, therefore, does not necessarily consider all KERs

[4] https://innovation-radar.ec.europa.eu/methodology

| Innovation Radar Questionnaire – Planned | Delivered |
|---|---|
| by the end of the piloting activities where we expect that "service" innovation could be captured (5.6 - M41) | All questionnaires have been delivered in M41. |
| At the end of each Open Calls process (M20 & M32). | |

### 3.3.1 Innovation Potential Indicator

As known[5], the Innovation Potential Indicator encompasses three indicators that capture essential steps in the innovation development process. This paragraph summarizes the qualitative evidence for each indicator within HosmartAI.

**Innovation Readiness**

The technical maturity of the project's innovations and defines the development phase of innovations reached by M41. All commercially exploitable innovations have reached a high technology readiness level and partners have secured technological resources to continue their development. This indicator takes also into account the time to the potential commercialisation which is described in detail in the confidential exploitation plan. Most of the commercially exploitable innovations can be considered ready to market.

**Innovation Management**

It addresses the project consortium and its commitment to bring innovations to the market. For the identified commercially exploitable results, the management teams behind the innovations are fully committed to transform their results into marketable products or services. All of them have been associated with a detailed business plan.

**Market Potential**

This indicator relates to the demand and supply side of innovations. Regarding the demand side, the prospective market conditions and the chances of successful commercialisation have been analysed in the individual business plans. With respect to the supply side, potential barriers have been assessed.

### 3.3.2 Innovation Capacity Indicator

The Innovator Capacity Indicator encompasses two indicators that capture the capacity of innovators in conducting and delivering successful innovations:

**Innovator's ability**

This indicator relates to the ability of organisations in developing innovations within the EC-funded activities. Among other aspects, it accounts for the number of times organisations have been identified by the Innovation Radar as key innovators.

[5] Innovation Radar > Methodology (europa.eu)

**Innovator's environment**

This indicator aims to capture the overall conditions in the project consortium which an innovator faces. The composition and activity of partner organisations, the performance of the project in terms of innovations, and the commitment of relevant partners to exploiting innovations can be rated as very high.

### 3.3.3 Maturity Levels of Innovations

The figure below shows how HosmartAI's commercially exploitable results have been positioned in terms of maturity levels.

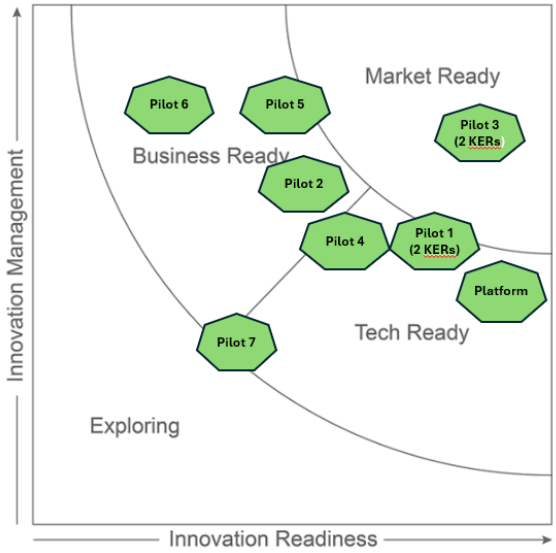



*Figure 1: Maturity Levels.*

*Market Ready (2 KERs)*

This category includes innovations outperforming in innovation management and innovation readiness. These innovations are technologically mature and show high commitment of the project consortium to bring them to the market. They are considered 'Ready for the market'.

*Tech Ready (4 KERs)*

This category includes innovations progressing on technology development process (e.g. pilots, prototypes, demonstration). They are considered 'Advanced on technology preparation'. To capitalise on the potential of these innovations, the management team needs to focus on transforming a novel technology or research results into a marketable product or service and to prepare its commercialisation.

*Business ready (2 KERs)*

This category includes innovations for which concrete market-oriented ideas have been put together (e.g. market studies, business plans, end-user engagement). They are considered 'Advanced on market preparation'. Their commercialisation depends on progressing on technology development.

*Exploring (0 KERs)*

This category includes innovations, which actively explore value creation opportunities. They are considered 'Getting things started'. These innovations are in the early phases of technological readiness, but already show high commitment levels from the organisations developing them. Their commercialisation requires efforts in transforming technology into marketable products. Alternatively, this category includes concrete market-oriented ideas, which depend on further progressing on technology development process.

## 3.4 Market Surveillance

Furthermore, the exploitation team (SMARTSOL & VIMAR) conducted an ongoing in-depth market surveillance to ensure the innovative nature of HosmartAI results and to better position KERs on the market. Information about competitors' strengths and weaknesses in a legal and ethical manner to enhance business decision-making. The process followed has been more complex than the one described in D7.8. Also, the frequency of this activity has been distributed all over the KER development process. This means that while originally specific deadlines were identified, this data collection process has been performed on a permanent basis using several channels:

- secondary market research (Market Reports and companies' websites) based on specific keywords describing the key features of HosmartAI's commercial KERs
- participation to Trade Fairs and online B2B meetings
- interviews with the core development team of project partners

The feedback collected has been used to properly position the commercial KERs in the market. A set of the most market relevant competitive attributes have been discussed internally and a final market competitive analysis has been prepared to shape the 10 confidential individual business plans.

Additionally, a total amount of **85 competitors** have been analysed in detail for all commercially exploitable results.

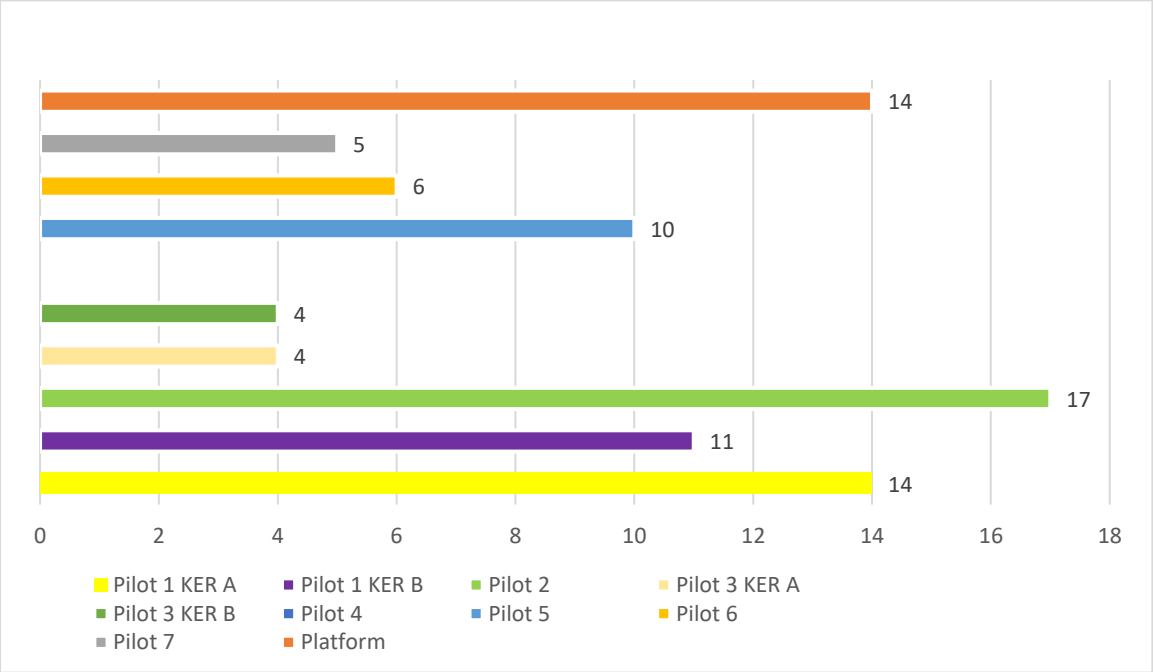



*Figure 2: Aggregated Competitors.*

# 4 Business challenges

Deliverable 7.4 described the core challenges that business models (and their plans) have to face to avoid failures and linked them to the most relevant boxes of the Lean Business Canvas Model, the tool used until M26 (February 2023) to describe the business potential of HosmartAI's commercial KERs. Specifically, the identified challenges are:

- Challenge #1: Initial Problem Statement
- Challenge #2: Meet Requirements and Needs
- Challenge #3: Follow or Competing with Market Leaders
- Challenge #4: Failing in accurately communicate the Product's Value Proposition
- Challenge #5: Inconvenience
- Challenge #6 Not Compatible with Current Systems
- Challenge #7: Not being inclusive
- Challenge #8: Product Innovation is coming too late OR too early
- Challenge #9 Comply with healthcare regulations
- Challenge #10 Wrong initial technology and partners
- Challenge #11 Errors in estimating economics

All these challenges have been considered during all group sessions and this paragraph summarizes the core outcomes of all discussions.

**Challenge #1: Initial Problem Statement**

Existing market need out there or, at least, a niche in a market.

*Table 4: Initial problem statement.*

| Focus | Evidence |
|---|---|
| **Market needs or niche** | Each identified solution tackles one or more identified needs and clearly refers to a market. Most of the analysed solutions have more than one target market. |
| **Market Research** | Market research has been done for each solution using a) desk research (market reports & available market data), b) anonymized interviews with industry players and stakeholders belonging to the healthcare industry, c) competitive analysis |
| **Gap Analysis (business rivals)** | A deeper gap analysis has been done. The first inputs were provided by HosmartAI's innovators while a more comprehensive secondary market analysis, including an analysis of available product descriptions of possible competitors. The analysis also led to the identification of **85 competitors** even though quite many of them have been also identified as possible "ideal" customers. |
| **Customers / Specialists engagement** | Customers & specialists feedback has been collected during the Sprints, the clinical studies and B2B sessions. |
| **Niche Overcrowded** | Market is not overcrowded. |

**Challenge #2: Meet Requirements and Needs and Challenge #6 Not Compatible with Current Systems**

Proving that a solution can be easily integrated is not enough if it is not "friendly" with the existing IT healthcare facility, the processes behind and the daily professional workflows. The latter issue is as relevant as the technical compatibility: innovations are not acceptable if they put management burdens on employees or requires them to invest a lot of time to get further digitally educated to use the new healthcare solution.

**Challenge #7: Not being inclusive**

First of all, it is essential to understand the needs of patients. Furthermore, solutions developed during the HosmartAI project will be sold to care providers, not patients, which means there are much more stakeholders to please: the insurer, doctors, pharmaceutical companies, etc.

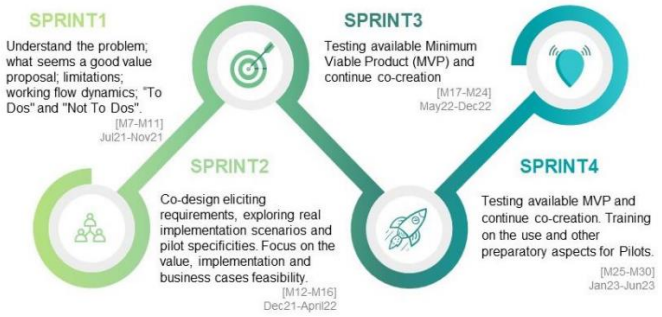



*Figure 3: HosmartAI's sprints.*

As described in D1.4, the HosmartAI consortium dedicated time and efforts to participatory action research, co-creation processes, living lab methodology, and agile development. This flexible methodology allowed to deploy solutions that are optimized in a co-participatory way to increase value, use and acceptance by end-users (Figure 5) thus providing an effective answer to challenges #2 and #7. Such strategy underscores user-centeredness and flexibility, and with a multi-level co-creation and agile development process, actively involves stakeholders. 4 Sprints were activated, and the table below provides an overview of the engaged stakeholder base.

*Table 5: Sprints' participants.*

| | | Gender (F) | | Gender (M) | |
|---|---|---|---|---|---|
| **Participants' roles** | **Participant** | **Nº** | **%** | **Nº** | **%** |
| Patients | 111 | 58 | 52,25% | 53 | 47,75% |
| Caregivers | 4 | 3 | 75,00% | 1 | 25,00% |
| Clinicians | 85 | 42 | 49,41% | 43 | 50,59% |
| Healthcare services managers | 10 | 7 | 70,00% | 3 | 30,00% |
| Researchers/partners/IT personnel | 64 | 16 | 25,00% | 48 | 75,00% |
| Students/Professors/Guests | 31 | 26 | 83,87% | 5 | 16,13% |
| **TOTAL** | **305** | **152** | **49,84%** | **153** | **50,16%** |

The KPIs and achieved results of participant engagement across the eight pilot solutions reflect an interesting range of stakeholder involvement, aligning with the different user profiles identified in the user stories for each pilot, in which, caregivers where not identified as primary users of the solutions. Deliverables 5.6 (HosmartAI's Pilots Final Version) and 5.7 (Report on Evaluation, Lessons learnt and recommendations) provide further insights about this.

**Challenge #3: Follow or Competing with Market Leaders**

*Table 6: Positioning.*

| **Positioning** | |
|---|---|
| **Focus** | **Relationship with Market Leaders** |
| **Pilot 1** | Competing |
| **Pilot 2** | Following |
| **Pilot 3** | Competing / Partner is a market leader |
| **Pilot 4** | Competing |
| **Pilot 5** | Partner can be considered a market leader |
| **Pilot 6** | Following |
| **Pilot 7** | Competing / Partner is a market leader |
| **Pilot 8** | No clear evidence of competition |
| **HosmartAI Platform** | Following |

**Challenge #4: Failing in accurately communicating the Product's Value Proposition**

*Table 7: Value Proposition.*

| **Focus** | **Value Proposition** |
|---|---|
| **Pilot 1** | VCE: vendor-independent CE video reading support combining cutting-edge AI algorithms to identify a range of small intestine pathologies; the innovation |

| Focus | Value Proposition |
|---|---|
| | allows gastroenterologists to achieve faster and more precise diagnosis with less effort.<br>Obstetrics: A tool that elevates the standard of prenatal care and empowers healthcare providers with reliable, data-driven insights thus reducing the likelihood of misdiagnosis or delayed treatment. |
| **Pilot 2** | Optimize radiotherapy scheduling service by minimizing costs and waiting time, improving the efficiency of patients' treatments, increasing the use of available machines, reducing stress and overcoming the limits of processing capacity of administrative staff and ensure a structured and well-organized doctor's workday |
| **Pilot 3** | UWB & API: a) for patients: Personalized Rehabilitation, Engagement and Motivation; b) for healthcare providers: Enhanced Monitoring and Insights, Operational Efficiency, Improved Resource Management, Data-Driven Decisions; c) for the healthcare ecosystem: Integration and Scalability; Security and Interoperability. |
| **Pilot 4** | A Real-Time Analysis and Visualization of Electrophysiology Mapping Data during Catheter Ablation Procedures using ML, an innovation which is able to generate cardiac maps out of collected data and analyse them for insights and predictions |
| **Pilot 5** | The solution developers (computer vision) to enlarge image/video datasets for training of deep learning algorithms for computer vision, 1) with as many images/videos as needed, 2) all automatically labelled, 3) with precisely known subject location (ground truth), and 4) avoiding bias and ethics issues. |
| **Pilot 6** | The solution allows therapists to base their daily work on a dynamic "Prevent-Detect-Connect" chain while, at the same time, it guarantees that older people will benefit from the 4 key factors of Active and Healthy Ageing, namely: Health, Safety, Avoid Loneliness, Keep Learning |
| **Pilot 7** | A cloud-based solution that offers the valuable capability to do scalable co-creation with customers and partners. |
| **HosmartAI Platform** | The HosmartAI Platform offers a unique combination of features, tools and capabilities in facilitating the development of development and small-scale experimentation of AI solutions & prototypes in healthcare. |

### Challenge #5: Inconvenience

Any amazing digital innovation will most probably fail if it is not convenient for end users. Convenience is not just a matter of money to spend to get the new technology: it has to do with contexts (where can I use the new technology), compatibility (does it fit to other tools already in use in the professional community), ease of use, etc.

*Table 8: Inconvenience.*

| Focus | Inconvenience |
|---|---|
| **Pilot 1** | Context: specific (and targeted) for both KERs<br>Compatibility: yes<br>Ease of use: feedback from clinical studies is positive |
| **Pilot 2** | Context: specific but can be expanded to additional scenarios<br>Compatibility: yes |

| Focus | Inconvenience |
|---|---|
| | Ease of use: feedback from clinical study is positive |
| **Pilot 3** | Context: specific (and targeted) for both KERs<br>Compatibility: yes<br>Ease of use: both KERs are technical and designed to be used by specific end users |
| **Pilot 4** | Context: very specific<br>Compatibility: yes<br>Ease of use: feedback from clinical study is positive |
| **Pilot 5** | Context: the KER can be exploited in several contexts<br>Compatibility: yes<br>Ease of use: KER is technical and designed to be used by specific end users |
| **Pilot 6** | Context: KER can be applied in different settings given the fact that it has been designed for a specific target (elderly people)<br>Compatibility: yes<br>Ease of use: feedback from clinical study is positive |
| **Pilot 7** | Context: very specific<br>Compatibility: yes<br>Ease of use: KER is technical and designed to be used by specific end users |
| **HosmartAI Platform** | Context: specific (and targeted) for both KERs<br>Compatibility: yes<br>Ease of use: feedback from first end users is positive |

**Challenge #8: Product Innovation is coming too late OR too early**

An innovative solution must come with an innovative functionality, fit to a niche in the market and be a genuine solution to a challenge or problem that has not been resolved in the current time. At the same time, if a new product or service is delivered too early, users may write it off as not good enough (mainly because they do not understand it or the need behind the innovation is not that clear yet) and getting them back may be difficult if their first impression of you is negative. The Sprints sessions as well as the meetings (public and private ones) that have been organized during the project show that the commercial KERs are “on time” for their markets.

**Challenge #9 Comply with healthcare regulations**

*Table 9: Compliance.*

| Focus | Compliance |
|---|---|
| **Pilot 1** | No specific healthcare regulations to comply with. |
| **Pilot 2** | At the current stage of development, it is not a medical device. |
| **Pilot 3** | No specific healthcare regulations to comply with. |
| **Pilot 4** | A regulatory approval strategy will be defined near the end of 2024 |
| **Pilot 5** | No specific healthcare regulations to comply with |
| **Pilot 6** | No specific healthcare regulations to comply with. |
| **Pilot 7** | No specific healthcare regulations to comply with. |
| **HosmartAI Platform** | No specific healthcare regulations to comply with. |

**Challenge #10 Wrong initial technology and partners**

The overall innovation environment of the project has been positive. By the time of writing, we can confirm that the composition of each working group (technology and clinical partners) has been appropriate and in line with initial expectations.

**Challenge #11 Errors in estimating economics**

By the time of writing, the economic & financial forecasting tables were – indeed – still under development. Revenues were estimated considering the most prudential scenarios while costs have been estimated considering real data (development costs until the end of the project), b) future development scenarios (which have been double checked with all development teams); c) maintenance & operations.

# 5 Defining priorities for market entry

When D7.4 was delivered, initial assumptions and a process were identified that would have guided the following business planning activities. This chapter describes how each team moved from those assumptions to the final ones.

The main decision in terms of which innovation should be commercially prioritized was based on 3 factors:

- Final TRL (Technology Readiness Level)
- Market Maturity (Innovation Radar)[6]
- A final internal strategic decision of each key player which was based on
    - alignment of the innovation with the organization's mission
    - an analysis of the competitive (and cooperative) market landscape

## 5.1 HosmartAI platform

The "Platform facilitating development of AI-powered solutions in healthcare" is the Key exploitable results which has been development under the coordination of

- Netcompany
- TMA
- ITCL
- Philips

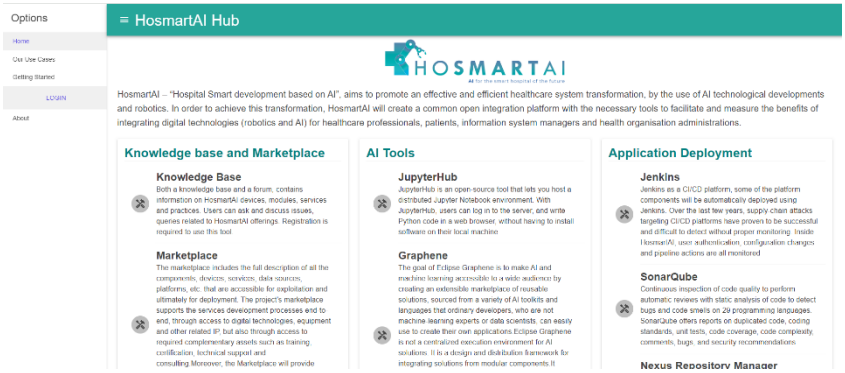



*Figure 4: HosmartAI Platform Home Page.*

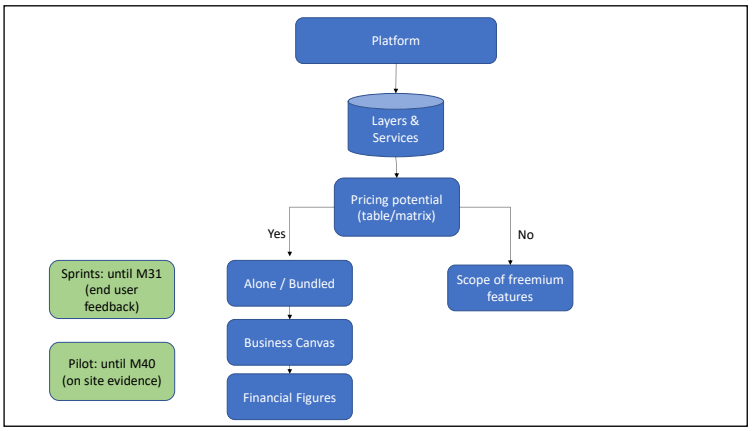
[6] **Market ready**: Innovations that are technologically mature and show high commitment of the project consortium to bring them to the market. They are considered 'Ready for the market' (about 10% of all innovations).

**Tech ready**: Innovations that are progressing on the technology development process (e.g. pilots, prototypes, demonstration). Further action in terms concrete market-oriented actions (e.g. market studies, business plans, end-user engagement) are required to capitalise on the market potential of these innovations (about 20% of all innovations).

**Business ready**: Innovations for which concrete market-oriented ideas have been put together (e.g. market studies, business plans, end-user engagement). They are considered advanced on market preparation but further progress on technology development is required (about 20% of all innovations are in this category).

**Exploring**: Innovations that are actively explore value creation opportunities. These innovations are in the early phases of technological readiness, but already show high commitment levels from the organisations developing them. Their commercialisation requires efforts in transforming technology into marketable products (about 50% of all innovations are in this category).

**The decision tree as for D7.4 (M19)**




The platform was still in its development stage and discussions about its core value proposition were still in progress. From a business perspective, several entry points were identified in D7.4 to assess the business potential (Software / components, Infrastructure, Data related capabilities, Services). The interaction with the pilots and the market analysis helped to understand which features of the platform should be prioritized (also in terms of pricing).

**Technology Readiness and Market Maturity in M41**

| TRL | Market Maturity |
|---|---|
| **7** | Market Maturity: **Exploring**<br>These are innovations that are actively exploring value creation opportunities. Learn more →<br><br>Market Creation Potential<br>This innovation was assessed by the JRC's Market Creation Potential indicator framework as having a **"Noteworthy" level of Market Creation Potential**. Only innovations that are showing multiple signals of market creation potential are assigned a value under this indicator system. Learn more →<br><br>Go to Market needs<br>Needs that, if addressed, can increase the chances this innovation gets to (or closer to) the market incude:<br>• Scale-up market opportunities |

*Table 10: Platform's business decision making process.*

| Step | Decision |
|---|---|
| **Product Bundle** | The platform has been designed and developed as a combined set of applications and functionalities offered as a bundle of applications and services. |
| **Selection process** | 1 innovation |
| **Core Product(s) in a nutshell** | A digital open innovation platform, open to the demand and supply side, focused on development and small-scale experimentation of AI solutions & prototypes in healthcare |
| **Business strategy** | A federated for-profit business unit without any new legal entity in the short term |
| **Business Plan & Financial Figures** | 1 business plan delivered |

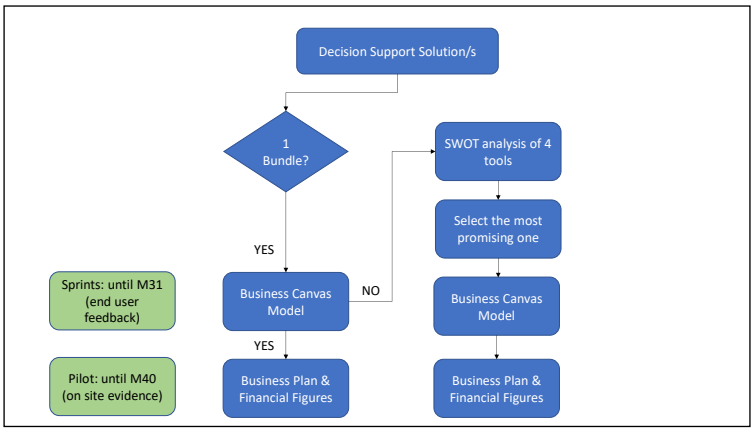
## 5.2 Diagnosis Revolution Tools Development – Pilot 1

Five innovations belong to this Pilot, namely:

1. "AI-based Decision support application that predicts adverse effects on cases of Fetal Growth Restriction" (alias "Obstetric Tool")
2. "AI-based PTB Prediction App with Explainable Ensemble Models" (also part of "Obstetric Tool")
3. "Video capsule endoscopy abnormality detector"
4. "AI-based Obstructive CAD Prediction with Explainable Ensemble Models"
5. "Device-independent AI-powered echocardiographic assessment of left ventricle function"

AUTH. has coordinated the development.

**The decision tree as for D7.4 (M19)**




D7.4 identified 4 tools that were ideally exploitable from a commercial point of view. The business analysis evaluated if there could be a common ground to create a bundle out of the 4 separate solutions.

From a marketing perspective, this meant to work on an umbrella concept like "AI assisted tools for clinical decision making". From a technical perspective, to check the possibility of offering an "AI as a service" model, offered to customers that can "call" one or more of these services based on their needs and integrate them into their applications. The Technology Transfer Office of the University has been involved during the process.

**Technology Readiness and Market Maturity in M41**

| TRL | Market Maturity |
|---|---|
| **VCE Tool: 7** | VCE<br>Market Maturity: **Exploring**<br>These are innovations that are actively exploring value creation opportunities. Learn more →<br>Market Creation Potential<br>This innovation was assessed by the JRC's Market Creation Potential indicator framework as having a **"High" level of Market Creation Potential**. Only innovations that are showing multiple signals of market creation potential are assigned a value under this indicator system. Learn more →<br>Go to Market needs<br>Needs that, if addressed, can increase the chances this innovation gets to (or closer to) the market incude:<br>• Prepare for Market entry<br>• Secure capital |

| TRL | Market Maturity |
|---|---|
| **Obstetrics Tool: 7** | Obstetrics Tool<br>Market Maturity: **Exploring**<br>These are innovations that are actively exploring value creation opportunities. Learn more →<br>Market Creation Potential<br>This innovation was assessed by the JRC's Market Creation Potential indicator framework as addressing the needs of **existing markets and existing customers**. Learn more →<br>Go to Market needs<br>Needs that, if addressed, can increase the chances this innovation gets to (or closer to) the market incude:<br>• Prepare for Market entry<br>• Secure capital |

*Table 11: Pilot 1 business decision making process.*

| Step | Decision |
|---|---|
| **Product Bundle** | No |
| **Selection process** | 3 innovations (2 of them belong to 1 "suite") out of the 5 have been selected as the most promising ones:<br>• GutScanner (VCE)<br>• CADXpert (Obstetric Tool: FGR and PTB) |
| **Core Product(s) in a nutshell** | • **GutScanner**: a computer-aided diagnosis web platform that is a user-friendly environment where the end-user can watch capsule endoscopy videos accompanied with AI generated recommendations for the segments of interest along with pathology estimations.<br>• **CADXpert**: an AI-powered tool designed for gynaecologists and obstetricians to assist in the early detection of Preterm Birth (PTB) and Fetal Growth Restriction (FGR) |
| **Business strategy** | • GutScanner: Spin Off |

| Step | Decision |
|---|---|
| | • CADXpert: Business Plan and spin off at a later stage |
| **Business Plan & Financial Figures** | • GutScanner: detailed business plan<br>• CADXpert: detailed business plan |

## 5.3 Logistic Improvement Tools – Pilot 2

The "Automatic appointment scheduling based on Artificial Intelligence" is the Key exploitable result that has been development under the coordination of ITCL in cooperation with CHUL.

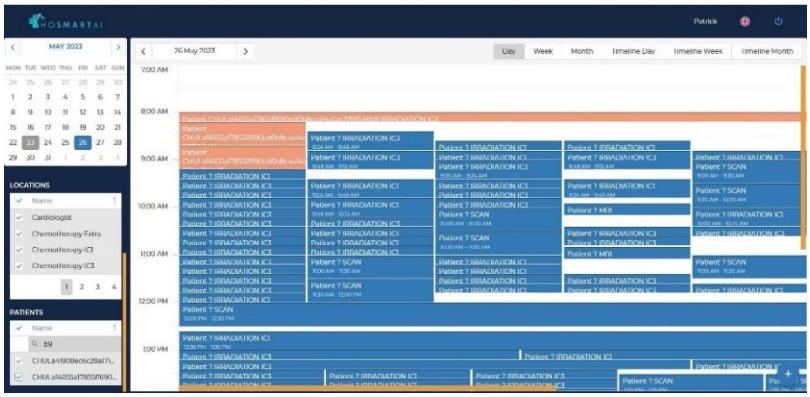
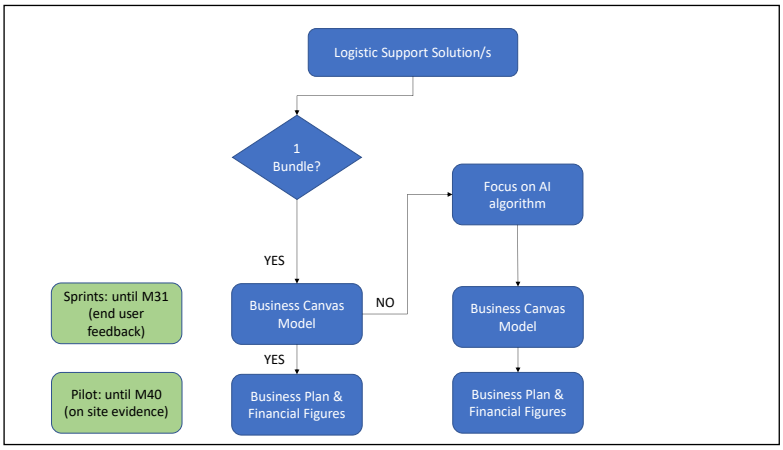


*Figure 5: Pilot 2 KER.*

**The decision tree as for D7.4 (M19)**




In D7.4 the business scenario consisted of one main "owner" that is developing an AI algorithm and secondary owners which will provide an add-on (chatbot) and know-how in the field of radiotherapy and related data (CHU de Liège) that are decisive in the creation of AI software. The AI algorithm was considered as the core product and its combination with the Chatbot was considered as being part of one unique offer.

The business analysis focused on the value of a possible a product bundle (AI + chatbot). The Technology Transfer Office of the Hospital has been involved during the business analysis. Hospitals with similar needs have been involved in the "business review" process to fully understand the potential of the solution.

**Technology Readiness and Market Maturity in M41**

| TRL | Market Maturity |
|---|---|
| **7** | Market Maturity: **Exploring**<br>These are innovations that are actively exploring value creation opportunities. Learn more →<br><br>Market Creation Potential<br>This innovation was assessed by the JRC's Market Creation Potential indicator framework as having a **"High" level of Market Creation Potential**. Only innovations that are showing multiple signals of market creation potential are assigned a value under this indicator system. Learn more →<br><br>Go to Market needs<br>Needs that, if addressed, can increase the chances this innovation gets to (or closer to) the market incude:<br>• Scale-up market opportunities |

*Table 12: Pilot 2 business decision making process.*

| Step | Decision |
|---|---|
| **Product Bundle** | No |
| **Selection process** | 1 core solution (Smart Scheduler) that can be integrated with an additional module (Chatbot). |
| **Core Product(s) in a nutshell** | Optimisation software for serial radiation appointments consisting of<br>A primary module:<br>• an algorithm providing automated scheduling of treatments<br>• a web-based interface for the hospital staff to run the scheduler and verify the results<br>An additional module:<br>• a chatbot allowing the patient to accept or refuse schedules |
| **Business strategy** | • Negotiations with significant IT players<br>• Contacts with ideal end users |
| **Business Plan & Financial Figures** | • Detailed business plan has been delivered |

## 5.4 Treatment Improvement Tools – Pilot 3

The "New small dimension, flush mounted, UWB Radar Device" and the "New Secure REST API Cloud interface" are the 2 Key exploitable results that has been development under the coordination of VIMAR.

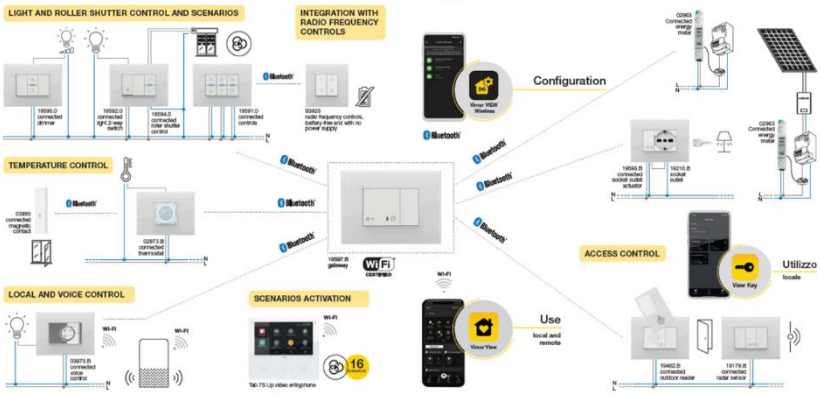



*Figure 6: Pilot 3 KER API Rest.*

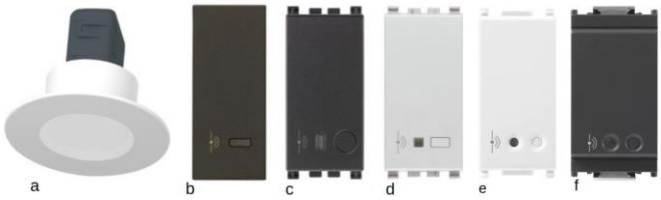
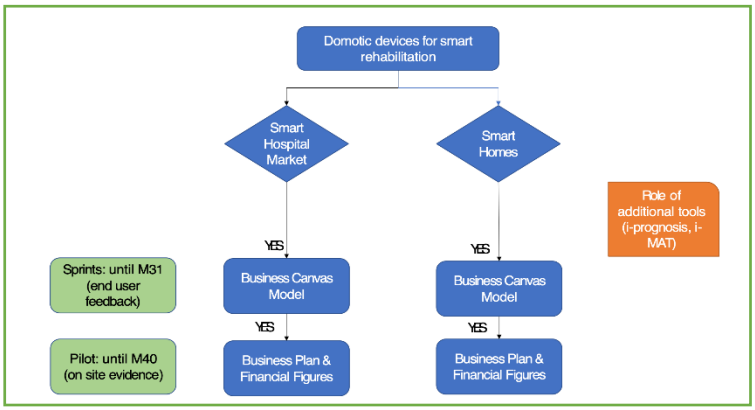



*Figure 7: Pilot 3 KER UWB.*

Other 2 KERs have been developed under this Pilot but not analysed from a business perspective, namely "Home-automation system applied for smart rehabilitation of neurological patients with motor impairments" (SAN CAMILLO) and the "Smartphone camera-based body tracking for assessment of motor function (AUTH).

**The decision tree as for D7.4 (M19)**




D7.4 described a scenario where VIMAR had to decide which technologies (and for which market) could be part of a business offer. At the same time there were some additional technologies that were still part of a possible unique offer.

The business scenario consisted of one primary owner which is targeting its solutions to a specific market made of hospitals (with their labs and rehab rooms) and home environments (where patients will have to comply with rehabilitation protocols and may be monitored & assisted remotely).

The confidential business plan focused on the first scenario (hospitals).

**Technology Readiness and Market Maturity in M41**

| TRL | Market Maturity |
|---|---|
| **UWB: 9** | UWB<br>Market Maturity: **Exploring**<br>These are innovations that are actively exploring value creation opportunities. Learn more →<br>Market Creation Potential<br>This innovation was assessed by the JRC's Market Creation Potential indicator framework as having a **"High" level of Market Creation Potential**. Only innovations that are showing multiple signals of market creation potential are assigned a value under this indicator system. Learn more →<br>Go to Market needs<br>Needs that, if addressed, can increase the chances this innovation gets to (or closer to) the market incude:<br>• Prepare for Market entry |

| TRL | Market Maturity |
|---|---|
| **REST API: 9** | **REST API**<br>Market Maturity: **Exploring**<br>These are innovations that are actively exploring value creation opportunities. Learn more →<br>Market Creation Potential<br>This innovation was assessed by the JRC's Market Creation Potential indicator framework as having a **"Noteworthy" level of Market Creation Potential**. Only innovations that are showing multiple signals of market creation potential are assigned a value under this indicator system. Learn more →<br>Go to Market needs<br>Needs that, if addressed, can increase the chances this innovation gets to (or closer to) the market incude:<br>• Scale-up market opportunities |

*Table 13: Pilot 3 business decision making process.*

| Step | Decision |
|---|---|
| **Product Bundle** | No |
| **Selection process** | 2 innovations out of the 4 have been selected as the most promising ones:<br>• IoT UWB Device<br>• REST API |
| **Core Product(s) in a nutshell** | UWB (radar ultra-wide band) ultra-low power technology: a sensor can detect presence and possible fallen people with the utmost precision.<br>REST API: a communication protocol to connect a cloud-based server with the services (and their interfaces) that have been installed at the customer's site (i.e.: a hospital) |
| **Business strategy** | • Solutions officially launched in 2024<br>• Initial market: Italy |
| **Business Plan & Financial Figures** | 2 business plans have been delivered |

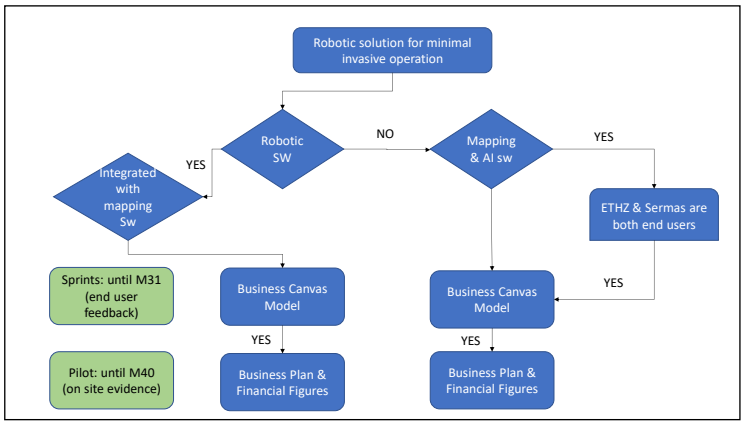
## 5.5 Surgical Support Tools – Pilot 4

The "Real-Time Analysis and Visualization of Electrophysiology Mapping Data" is the Key exploitable result that has been developed by 91Gmbh, in cooperation with SMS.

Specifically, it is a cardiac data analysis software, which is able to generate cardiac maps out of collected data and analyse them for insights and predictions.

*Figure 8: Pilot 4 KER.*

**The decision tree as for D7.4 (M19)**




D7.4 described 2 business scenarios depending on the entry point.

From the perspective of ETHZ, there was robotic software being developed during a PhD work with a potential impact on complementary & innovative solutions which are under development. Subsequently, after the testing, a potential transfer from ETHZ to a business entity may happen even though the potential overall economic value of what will be developed may be – to the current knowledge – limited and will require relevant investments to be fully exploited. The complementary software developed by 91 may be analysed as part of the final solution (complementary modules OR fully integrated)

From the perspective of 91, there was a company investing in mapping and AI solutions that can be applied to remote navigation control of robots. ETHZ (and SERMAS) who could be considered end user of one or more of these tools.

**Technology Readiness and Market Maturity in M41**

| TRL | Market Maturity |
|---|---|
| **6** | Market Maturity: **Exploring**<br>These are innovations that are actively exploring value creation opportunities. Learn more →<br><br>Market Creation Potential<br>This innovation was assessed by the JRC's Market Creation Potential indicator framework as addressing the needs of **existing markets and existing customers**. Learn more →<br><br>Go to Market needs<br>Needs that, if addressed, can increase the chances this innovation gets to (or closer to) the market incude:<br>• Scale-up market opportunities |

*Table 14: Pilot 4 business decision making process.*

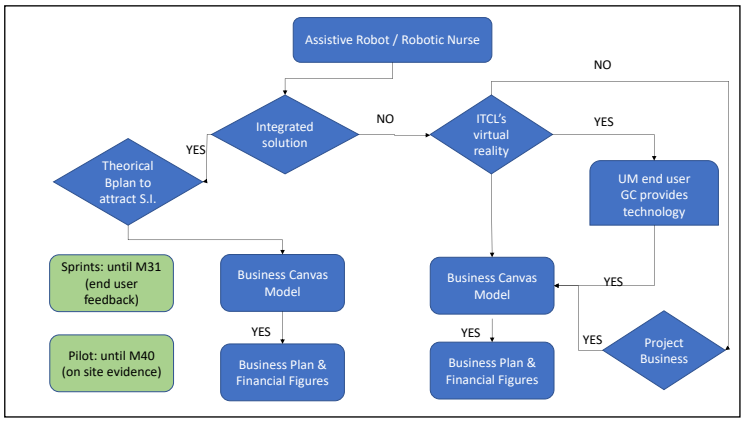
| Step | Decision |
|---|---|
| **Product Bundle** | No |
| **Selection process** | 1 innovation has been identified as the one being most promising in terms of commercialization |
| **Core Product(s) in a nutshell** | **Heart+** is a solution aims to interpret and visualize EP mapping data for catheter ablation procedures in real-time using a machine learning algorithm trained on historic data. Its main functions are: Signal Processing, Image Analysis, Data Integration, Disease Detection and Monitoring, Predictive Analytics, Reporting and Visualization, Integration with Healthcare Systems |
| **Business strategy** | Technology will become part of a wider solution |
| **Business Plan & Financial Figures** | 1 business plan has been delivered |

## 5.6 Assistive Care Tools – Pilot 5

*Figure 9: Pilot 5 enabling technology.*

While UM, ITCL and GC have been cooperating under this Pilot to deliver 3 innovations, namely "Socially assistive humanoid robot FRIDA in grand round routine", "Socially assistive humanoid robot FRIDA to support nurses during hospitalization", and "Embedded Blockchain on IoT", one specific enabling technology (SIGEDA) has been selected as the most promising commercially exploitable asset.

**The decision tree as for D7.4 (M19)**




D7.4 identified an ideal business scenario with 1 product bundle based on several components / technologies: a) ITCL (virtual reality tool), b) GC (connectivity, edge platform/edge-based services for the healthcare market, blockchain), c) UM (sensing network, robotic solution, speech technologies, decision support, health data space). The partners had then 3 different options to consider:

1) to work on a theoretical business plan whose goal is to find who could be the "system integrator" with an interest to make a "product/service" bundle out of all pilot technologies
2) focus on ITCL's further development of its virtual reality solution (applied to the use case) where UM is the end user that validates this piece of technology while GC becomes a supplier of edge "infrastructure" & blockchain technology
3) consider the pilot as a "project-based business" where a successful case, developed together by ITCL, GC and UM can be replicated in other hospitals as "technology transfer projects"

**Technology Readiness and Market Maturity in M41**

| TRL | Market Maturity |
|---|---|
| **8** | Further deployments in operational environments enabling market feedback and ideas for future features. ITCL has an initial customer base from various different backgrounds such as R&T organisations, Public Institutions and Authorities and from various sectors. |

*Table 15: Pilot 5 business decision making process.*

| Step | Decision |
|---|---|
| **Product Bundle** | No |
| **Selection process** | An enabling component (SIGEDA) has been identified as the current commercially most significant exploitable asset |
| **Core Product(s) in a nutshell** | SIGEDA is a service to generate synthetic datasets that allow the rendering of thousands of labelled images and/or videos to train Deep Learning Computer Vision algorithms. |
| **Business strategy** | • Identify significant customers<br>• Start from promising industries |
| **Business Plan & Financial Figures** | Business plan has been delivered |

## 5.7 Assistive Care Tools – Pilot 6

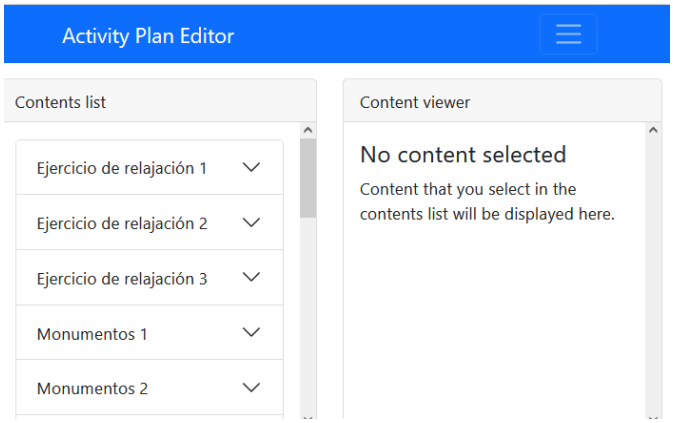
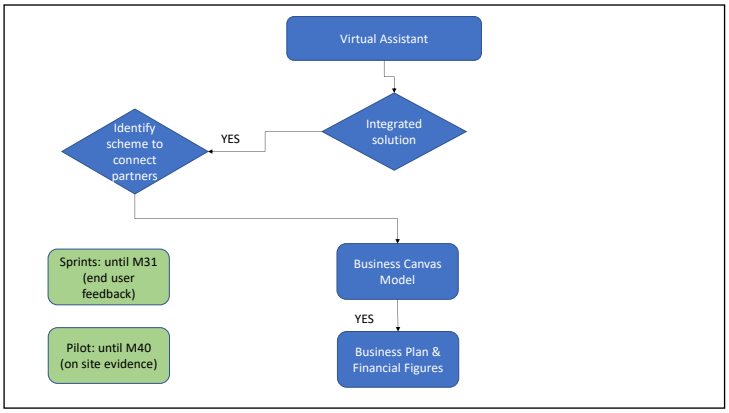



*Figure 10: Pilot 6 KER.*

The "Virtual Assistant and coach for detection, prevention, therapeutic care and active ageing of older adults" is the Key exploitable result that has been development in cooperation with AUTH, ITCL and INTRAS.

**The decision tree as for D7.4 (M19)**




D7.4 described a scenario where the business analysis should have helped to identify the best ownership scheme to be adopted to fully support future improvements (till market readiness) and commercialization of the new service once it will have been tested. It was in any case already clear that the ideal business scenario would have consisted in identifying one main product bundle which is offered to the market via one main actor representing the commercial interests of all involved solution providers. Under this perspective, the combination of ownership scheme and pricing / royalty model has been an essential part of the business analysis.

**Technology Readiness and Market Maturity in M41**

| TRL | Market Maturity |
|---|---|
| **7** | Market Maturity: **Exploring**<br>These are innovations that are actively exploring value creation opportunities. Learn more →<br><br>Market Creation Potential<br>This innovation was assessed by the JRC's Market Creation Potential indicator framework as having a **"High" level of Market Creation Potential**. Only innovations that are showing multiple signals of market creation potential are assigned a value under this indicator system. Learn more →<br><br>Women-led innovation ♀<br>A woman had a leadership role in developing this innovation in at least one of the Key Innovator organisations listed below.<br><br>Go to Market needs<br>Needs that, if addressed, can increase the chances this innovation gets to (or closer to) the market incude:<br>• Prepare for Market entry |

*Table 16: Pilot 6 business decision making process.*

| Step | Decision |
|---|---|
| **Product Bundle** | Yes |
| **Selection process** | 3 core modules and 2 secondary modules have been identified: |
| **Core Product(s) in a nutshell** | **MOVASCare**: a solution to enhance continuity of care. This tool integrates a comprehensive technological suite aimed at facilitating nuanced care strategies encompassing screening, intervention, and systematic rehabilitation planning |
| **Business strategy** | A federated business approach has been chosen at least for the first 2 years. |
| **Business Plan & Financial Figures** | 1 business plan has been delivered |

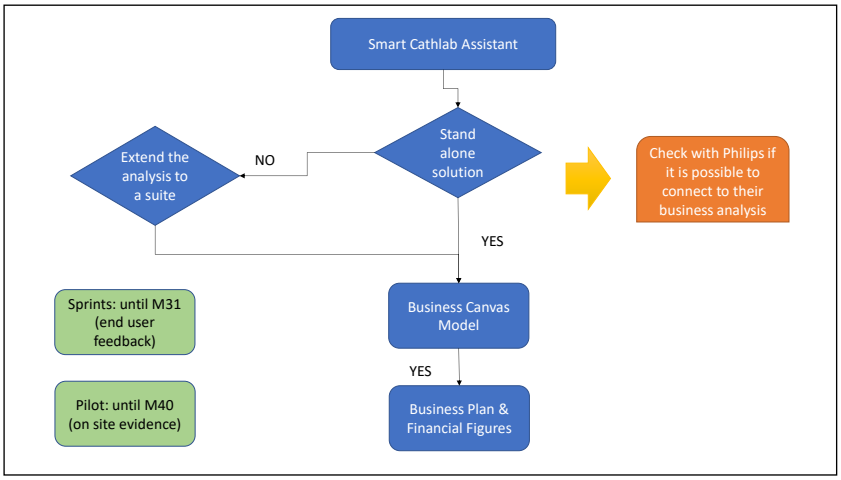
## 5.8 Surgical Support Tools – Pilot 7

The scope of pilot 7 changed in 2023 and the rationale was presented during Maribor's partner meeting in Nov 2023. As a result of a major reorganization in 2023 many internal projects were either stopped or pivoted, including many layoffs. For the case of the smart reporting, it was found that there was not sufficient traction for post-procedural reporting (which resulted in stopping our carrier project for HosmartAI) and more attention should be given to procedural guidance. These developments matched well with Philip's efforts to create a digital co-creation environment (the digital Customer First Innovation lab) to accelerate the development of data/AI based applications, primarily still focused on coronary procedures.


*Figure 11: Pilot's 7 new focus.*

The focus remains on the interventional cardiology domain, but now broadening Philip's efforts to strengthen our co-creation capabilities with physicians, such that the company can deliver clinical applications to them faster.

**The decision tree as for D7.4 (M19)**




A first internal business analysis was already in place by the time of D7.4. The business analysis could have been linked to a more detailed analysis that Philips is doing internally, but this possibility was under discussion.

Anyway, the business scenario under pilot 7 was quite clear: there is one owner that has identified a market, and which is investing in the development & testing of one solution that may be part of a bigger suite in the future. As described above, there has been a shift towards a new solution that offers the valuable capability to do scalable co-creation with customers and partners.

**Technology Readiness and Market Maturity in M41**

| TRL | Market Maturity |
|---|---|
| **7** | Market maturity indexes could not be generated by the time of deliverable submission**.** |

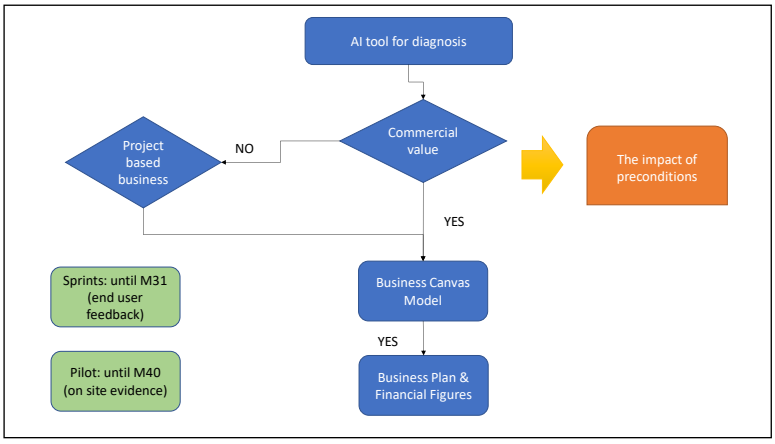
*Table 17: Pilot 7 business decision making process.*

| Step | Decision |
|---|---|
| **Product Bundle** | No |
| **Selection process** | 1 core platform has been designed which is part of a global co-creation infrastructure. |
| **Core Product(s) in a nutshell** | **Customer Innovation Lab**: a cloud-based solution to do scalable co-creation with customers and partners. It allows to try out apps and algorithms with real-world data and provide feedback to develop better clinical solutions and supports rapid iterations with customers through web-enabled structured feedback collection. |
| **Business strategy** | The product is part of Philips innovative products |
| **Business Plan & Financial Figures** | 1 business plan has been delivered |

## 5.9 Personalised Treatment Tools – Pilot 8

There are three KERs that have been developed by VUB under this pilot and namely "AI-based tumor image segmentation tools", the "Digital health research platform for cancer" and the "Tool for genetic analysis of tumor data".

**The decision tree as for D7.4 (M19)**




VUB was assessing if and how these technologies could be appealing for the market or if they needed more research work to attract investors and / or buyers / users.

Indeed, the solution had a business potential even though 2 main preconditions had to be taken into consideration, namely:

1) How much regulation can limit the use of such kind of "platform" (GDPR, Medical device regulations, AI regulations

2) Additionally (this may affect the possible "target" of the solution), as soon as data are used for diagnosis purposes, validation comes into action (which may limit the use of such a "tool") while at research level it would not be a problem
3) How far the developed algorithms can be used with data from different hospitals

One business scenario was already clear: there is one owner which is investing in the development & testing of a solution with a theoretical high value that could be exploited as a project-based business model (reselling the initiative on a project / research-based model) or via a purely commercial model (even though the impact of some essential preconditions has to be verified).

**Technology Readiness and Market Maturity in M41**

| TRL | Market Maturity |
|---|---|
| **Tumor Image segmentation: 6** | Market Maturity: **Exploring**<br>These are innovations that are actively exploring value creation opportunities. Learn more →<br>Market Creation Potential<br>This innovation was assessed by the JRC's Market Creation Potential indicator framework as having a **"High" level of Market Creation Potential**. Only innovations that are showing multiple signals of market creation potential are assigned a value under this indicator system. Learn more →<br>Go to Market needs<br>Needs that, if addressed, can increase the chances this innovation gets to (or closer to) the market incude:<br>• Prepare for Market entry |

| TRL | Market Maturity |
|---|---|
| **Research platform: 6** | Market Maturity: **Exploring**<br>These are innovations that are actively exploring value creation opportunities. Learn more →<br>Market Creation Potential<br>This innovation was assessed by the JRC's Market Creation Potential indicator framework as addressing the needs of **existing markets and existing customers**. Learn more →<br>Go to Market needs<br>Needs that, if addressed, can increase the chances this innovation gets to (or closer to) the market incude:<br>• Prepare for Market entry |

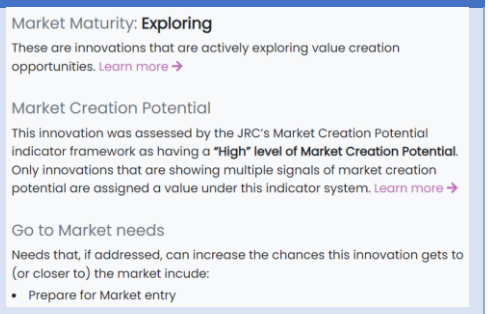
| TRL | Market Maturity |
|---|---|
| **Tumor Image segmentation: 6** |  |

*Table 18: Pilot 8 business decision making process.*

| Step | Decision |
|---|---|
| **Product Bundle** | No |
| **Selection process** | These innovations, even if promising, have not been analysed from a business point of view.<br>The ongoing research on Glioma in Pilot 8 (image segmentation and genetic analysis) requires further effort to mature into technologies that can be readily applied in hospital settings. Due to the rare occurrence of this disease, patient availability for validation of our findings within a research setting remains limited. Any business decisions have to be based on thorough evaluation and analysis using the patient data within the complex and dynamic setting of the health industry. The team therefore will continue to advance the research on the combined image segmentation and genetic analysis tool for delivering innovative and effective treatment for Glioma patients. |
| **Core Product(s) in a nutshell** | N.A. |
| **Business strategy** | N.A. |
| **Business Plan & Financial Figures** | N.A. |

## 5.10 List of individual business plans

All confidential Business Plans have been annexed to Deliverable 7.3 Exploitation Plans and Activities – Final version. Specifically:

- **ANNEX 1 – Confidential Business Plans**
  - Pilot 1 - CADXpert / Obstetrics Tool
- **ANNEX 2 – Confidential Business Plans**
  - Pilot 1 – GutScanner / VCE Tool
- **ANNEX 3 – Confidential Business Plans**
  - Pilot 2 – ZinaRT / Smart Scheduler
- **ANNEX 4 - Confidential Business Plans**
  - Pilot 3 – IoT Radar UWB Device
- **ANNEX 5 – Confidential Business Plans**

  - Pilot 3 – API Rest
- **ANNEX 6 – Confidential Business Plans**
  - Pilot 4 – Heart + Map
- **ANNEX 7 – Confidential Business Plans**
  - Pilot 5 - SIGEDA
- **ANNEX 8 – Confidential Business Plans**
  - Pilot 6 - MovasCare
- **ANNEX 9 – Confidential Business Plans**
  - Pilot 7 – Customer Innovation Lab
- **ANNEX 10 – Confidential Business Plans**
  - HosmartAI Platform

# 6 Market Analysis

## 6.1 Updated global market figures

Having the pilots' technology focus in mind, the Business Plan First Version identified these potential markets:

A computer-aided detection/diagnosis is expected to reach USD 1.9 Bln by 2022 (**Pilots 1 & 8**),

B **healthcare smart supply chain** is projected to reach USD 3.3 Bln by 2025 from USD 2.2 billion in 020 (**Pilot 2**),

C **rehabilitation technology** was valued at USD 10.53 Bln in 2016 and is expected to grow at a CAGR of 6.0% during the forecast period (up to 2025) (**Pilot 3**).

D **tech-enabled operating rooms** was valued at USD 26.24 Bln in 2016 and is projected to grow with a CAGR of 7.2% during the forecast period (up to 2025) (**Pilots 4 & 7**)

E **silver economy** was estimated at €3.7 Trl in 2015 and will amount to €5.7 Trl in 2025, (**Pilot 6**).

Besides these markets, the first 18 months of the project led us to include also additional ones, namely:

- **F** - the wider Smart Hospital market
- **G** - the AI healthcare market
- **H** - the healthcare assistive robot market
- **I –** the surgical robotic market
- **J** - digital platform markets

Based on a better understanding of the market area (and potential) of each identified solution (KER), we can represent the overall "HosmartAI" markets as a layer of 3 "core markets" as visualized in Figure 12.

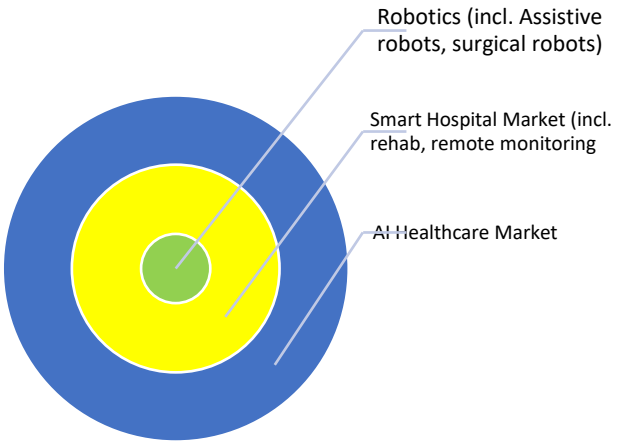



*Figure 12: HosmartAI's core markets.*

**The AI healthcare market**

The AI healthcare market is rapidly expanding indicating its pivotal role in transforming healthcare delivery, diagnostics, and patient management. In 2021, the artificial intelligence (AI) in healthcare market was worth around 11 billion U.S. dollars worldwide. It was forecast that the global healthcare AI market would be worth almost 188 billion U.S. dollars by 2030, increasing at a compound annual growth rate of 37 percent from 2022 to 2030 [REF-03]. This growth is fuelled by technological advancements and the increasing adoption of AI solutions across various healthcare domains. Key applications include predictive analytics for disease management, AI-driven diagnostic tools that enhance imaging precision, virtual health assistants for patient engagement, and robotic surgery for minimally invasive procedures. Additionally, AI plays a crucial role in drug discovery and genomics, where it accelerates the development of personalized medicine by analysing complex genetic information. The market caters to a diverse clientele, ranging from hospitals and clinical research organizations to health tech startups and insurance companies, all seeking to leverage AI to improve care outcomes, operational efficiency, and patient-centric services. With its promise to make healthcare more accessible and effective, the AI healthcare market stands at the forefront of medical innovation.

**Smart Hospital Market**

The growth of the smart hospital market is driven by the integration of advanced digital technologies into healthcare environments. According to Coherent Market Insights, the global smart hospitals market size was valued at US$ 41 Billion in 2022 and is expected to surpass US$ 153.3 Billion by 2030 [REF-04]. This market encapsulates the future of healthcare delivery. Smart hospitals leverage a wide array of technologies such as artificial intelligence (AI), the Internet of Things (IoT), big data analytics, and blockchain to enhance operational efficiency, patient care, and clinical outcomes. These technologies enable real-time patient monitoring, efficient resource management, and improved diagnostics and treatment plans, offering a highly personalized and efficient healthcare experience. Serving a broad clientele that includes healthcare providers, patients, and technology firms, smart hospitals are redefining patient care through automation, connectivity, and digitization. From remote patient monitoring and telemedicine to robotic surgeries and automated workflows, the smart hospital market is pioneering innovative solutions to address contemporary healthcare challenges, making healthcare more accessible, reliable, and efficient for everyone involved.

**Robotics**

The healthcare robotics market size was valued at USD 8.030,68 Million in 2023 and will reach USD 21.122,93 Million in 2030 [REF-05]. This market embodies the cutting-edge intersection of technology and healthcare. Healthcare robots are revolutionizing a wide range of applications, from surgical assistance and rehabilitation to sanitation and logistics within medical facilities. These robotic systems offer unparalleled precision in surgeries, enhance

rehabilitation through advanced physiotherapy robots, and ensure hospital hygiene with disinfection robots, thereby improving patient outcomes and safety. The market caters to a diverse audience including hospitals, rehabilitation centers, research institutions, and elderly care facilities, each seeking to leverage robotic innovation for enhanced care delivery. As robotics technology continues to evolve, the healthcare robotics market is set to expand its influence, promising transformative changes in how healthcare services are delivered and experienced by patients worldwide.

## 6.2 Market trends supporting HosmartAI's business plans

### 6.2.1 HosmartAI platform

**Trends**

The evolving landscape of machine learning and AI development increasingly underscores the necessity and advantages of utilizing comprehensive platforms that enhance the entire lifecycle of AI model development. Such platforms not only streamline processes but also profoundly impact the productivity and effectiveness of developers. A systematic mapping study by Yuanhao Xie et al. (2021) [REF-06] identifies the complex challenges developers face throughout the AI model lifecycle, highlighting significant gaps particularly in data management and model production. This advocates for a more integrated approach to address these challenges, emphasizing the need for development environments that support holistic management from inception through deployment and maintenance.

Supporting this notion, Siamak Farshidi et al. (2021) [REF-07] provide insights from various industry case studies on the selection process of development platforms. Their research illustrates how the right platform can significantly reduce time and cost in the development process while enhancing decision-making capabilities. These platforms cater to specific needs of developers, thereby boosting efficiency and productivity in software development processes. Furthermore, M. Alamin and Gias Uddin (2022) [REF-08] discuss the practical difficulties encountered with low-code platforms in machine learning contexts. While acknowledging their democratization potential, the paper highlights crucial areas where low-code solutions need to evolve to better support complex requirements of machine learning development, such as model validation and lifecycle management. These insights point to the importance of developing more robust, flexible platforms that can handle the intricacies of AI and machine learning, ultimately enhancing the developer experience and the effectiveness of the models produced. These studies form a compelling argument for the benefits of using sophisticated development platforms that integrate marketplace features. Such platforms are poised to significantly impact the efficiency and success of developers by offering streamlined workflows, enhanced data management capabilities, and improved lifecycle management of AI models. This integrated approach would not only solve existing challenges but also pave the way for future innovations in AI and machine learning development.

**Market**

The target market may be seen as a combination of the machine learning (ML) platform and the Low or No Code development platform market. The global AI in the healthcare market can be divided into software, hardware, and services. The software segment has the largest share, it accounts for 40.5% of the entire market, and is expected to have the fastest growth. This segment includes Machine Learning platforms, Natural Language Processing (NLP) and text analysis tools, Deep Learning Platforms, Computer Vision, Speech and Audio Recognition, Integrated Development environments (IDEs) and AI frameworks. The global ML platforms market size was USD 5512.8 million in 2021 and the market is expected to reach USD 74781 million in 2031, exhibiting a CAGR of 33.6% during the forecast period[7].

The global no-code AI platform market size was estimated at USD 3.83 billion in 2023 and is projected to grow at a CAGR of 30.6% from 2024 to 2030. No-code Al platforms are also known as Al development platforms. They provide non-programmers, and non-Al experts the tools they need to implement Al projects. Al practitioners and specialists can also utilize them in their initiatives[8].

### 6.2.2 Pilot 1: GutScanner

**Trends**

Capsule endoscopy, an innovative and minimally invasive tool, has broadened its scope beyond the small intestine to evaluate the entire gastrointestinal (GI) tract. This technology has been increasingly utilized for various diagnostic purposes, including the assessment of inflammatory bowel disease (IBD), with the advent of pan-enteric capsule endoscopy allowing for a comprehensive examination of both the small and large intestine. Recent advancements also highlight the role of artificial intelligence (AI) in enhancing the diagnostic accuracy of capsule endoscopy, addressing challenges such as lengthy reading times and the potential for missed lesions. Moreover, studies continue to explore the utility of capsule endoscopy in diverse populations, including children and the elderly, indicating its broad applicability and potential for non-invasive GI diagnostics (Tziortziotis, Laskaratos, & Coda, 2021) [REF-09]. As previously mentioned, one of the most promising research areas involving capsule endoscopy is associated with advancements in AI. Specifically, the use of convolutional neural networks (CNN) is demonstrating promising results. Integrating a computer vision tool into the software could significantly reduce report times and minimize human errors, particularly in diagnosing lesions such as erosions, angioectasias, polyps, and bleeding (Yang, 2020) [REF-10]. Additionally, research is investigating new methods to directly control the movement of the

[7] Business Research Insights, Report ID: BRI102699

[8] GVR - Report coverNo-code AI Platform Market Size, Share & Trends Report. No-code AI Platform Market Size, Share & Trends Analysis Report Forecasts, 2024 - 2030. Report ID: GVR-4-68040-090-3

endoscopy capsule, like magnetic forces, to enhance its clinical applicability. This technique allows for more precise procedures and the ability to perform tasks such as biopsies or targeted drug delivery more effectively in specific areas of the gastrointestinal tract (Kim & Nam, 2021) [REF-11]. Furthermore, innovations are being explored in capsule endoscopy for evaluating the entire gastrointestinal tract, including the stomach, and in developing capsules capable of functional analysis, such as measuring pH or detecting specific disease markers (Brown & Jayatissa, 2020) [REF-12].

**Market**

From a market size perspective, the future of the global smart pill capsule endoscopy market looks promising with opportunities in the stomach, oesophagus, small intestine, and large intestine applications. The global smart pill capsule endoscopy market is expected to reach an estimated $1.1 billion by 2030 with a CAGR of 12.1% from 2024 to 2030. The major drivers for this market are growing demand for non-invasive diagnostic and monitoring devices and rising prevalence of gastrointestinal disorders. North America is expected to witness highest growth over the forecast period due to rising number of stomach cancer cases and growing population demand for the smart and painless diagnosis and treatment for the gastrointestinal diseases in the region. The region with the highest concentration of capsule endoscopy manufacturers is Japan, where Olympus Corporation, a significant entity in this sector, holds approximately 70% of the global market share for gastrointestinal endoscopic equipment as of October 2022. In 2023, Olympus declared to have spent about € 470 Millions in R&D activities [REF-13].

### 6.2.3 Pilot 1: CADXpert

**Trends**

Advanced imaging technologies are transforming obstetric care by offering detailed insights into placental and fetal health, promising significant advancements in diagnosing and managing pregnancy-related complications. Functional imaging techniques, as discussed by Clark et al. (2022) [REF-14], enhance our understanding of complex conditions like fetal growth restriction and placenta accreta. Similarly, the potential of photoacoustic imaging for placental monitoring, highlighted by Vincely & Bayer (2023) [REF-15], and the application of Quantitative Magnetic Resonance Imaging (qMRI) for in-vivo placental development assessment by Andescavage et al. (2021) [REF-16], represent groundbreaking steps towards precise prenatal diagnostics. Furthermore, the advancements in fetal cardiac function imaging reviewed by Kühle et al. (2023) [REF-17] underline the importance of continuous technological development in fetal echocardiography and cardiovascular magnetic resonance. Together, these studies underscore the critical role of advanced imaging in ushering in a new era of personalized and effective obstetric care, leveraging cutting-edge technology to improve outcomes for mothers and babies alike.

Artificial Intelligence (AI) is emerging as a revolutionary tool in obstetrics, with the potential to significantly enhance early diagnosis, prediction, and management of complications such as preterm birth and fetal anomalies. Predictive models based on machine learning, like the one developed by Sun et al. (2022) [REF-18] using the Random Forest algorithm, demonstrate considerable value in predicting preterm birth in the early stages of pregnancy. Similarly, Kyparissidis, Kokkinidis et al. (2023) [REF-19] have improved the reliability of preterm birth prediction through ensemble machine learning models, highlighting AI's ability to provide understandable explanations to physicians. Van Boven et al. (2022) [REF-20] explored the use of AI in predicting neurological outcomes in premature infants, achieving promising results. Moreover, Dr. Chinnaiyan R and Stalin Alex (2021) [REF-21] illustrated how AI could assist in the early diagnosis of fetal anomalies. These developments underscore AI's crucial role in innovating obstetric care, promising more informed and personalized pregnancy management.

**Market**

From a market size perspective, the global fetal monitoring market in terms of revenue was estimated to be worth $3.7 billion in 2022 and is poised to reach $5.2 billion by 2027, growing at a CAGR of 7.3% from 2022 to 2027. North America was the largest regional market for fetal monitoring. The availability of experts and availability of Neonatal Intensive Care Units (NICUs) are the major factors that supports the growth of the market in North America. However, the Asia Pacific region offers high-growth opportunities for players in the market (MarketsandMarkets) [REF-22]

### 6.2.4 Pilot 2: Smart Scheduler

**Trends**

In Europe, demand for radiotherapy services has been estimated to increase by 16%, in total, during the period from 2012 to 2025. With the growing demand for RT services, the number of treatment sessions to be booked amongst the available machines has been continuously increasing. This makes the problem of scheduling RT sessions increasingly complex for RT centers, which aim at managing their resources in the most efficient manner in order to provide the patient-centered care while keeping waiting times low. Therefore, several indicators, possibly distinct between RT centers, must be considered when designing a methodology for scheduling RT treatments, with timeliness, patient-centeredness, and staff satisfaction being amongst the most important ones. From a patient’s perspective, research shows that the professional staffing standards and low waiting times for both diagnosis and treatment are the most important factors [REF-23]. To keep quality of labour high, a predictable work schedule and an appropriate amount of assigned workload are necessary from a staff viewpoint. Given the high number of technical and medical constraints to be considered for each patient the manual execution of such a schedule is a difficult, time-consuming task that often leads to solutions that are far from optimal. Therefore, the

development, validation, and implementation of scheduling algorithms can be a solution to support RT centers to schedule radiation sessions in an optimized manner regarding the relevant performance indicators.

**Market**

In terms of market size, the Radiation Oncology Treatment Planning Software Market refers to the segment of the healthcare industry that specializes in developing software solutions for planning and optimizing radiation therapy treatments for cancer patients. This software plays a crucial role in the radiation oncology workflow by assisting radiation oncologists, medical physicists, and dosimetrists in designing personalized treatment plans that deliver precise doses of radiation to cancerous tumors while minimizing damage to surrounding healthy tissues. These software solutions utilize advanced algorithms and modelling techniques to simulate radiation dose distributions within the patient's body, enabling healthcare providers to tailor treatment plans based on individual patient characteristics and tumor properties [REF-24]. If we look at the numbers, Data Bridge Market Research[9] analyses that the radiation oncology treatment planning software market which was USD 2.18 billion in 2022, would increase up to USD 4.34 billion by 2030, and is expected to undergo a CAGR of 9.00% during the forecast period 2023 to 2030. Furthermore, according to Future Markets Insights, Radiation Therapy Software Market Outlook (2022-2032), Europe radiation therapy software market to hold 31% share in the global market. This region is accountable for the second largest radiation therapy software market share after North America owing to increasing awareness pertaining to the treatment demands. Accessibility to more accurate and efficient cancer treatments, increasing research and development activities, and partnerships among manufacturers are predicted to boost the radiation therapy software market in Europe. In Europe, Germany is anticipated to progress at a higher CAGR during the forecast period. This is because healthcare providers are focusing more on radiotherapy patient positioning, as this technique assists patients with multiple radiations in lesser sessions, therefore saving on money and time.

### 6.2.5 Pilot 3: API Rest & IoT Radar UWB Device

**Trends**

As we are talking about devices supporting “telemonitoring” practices, we have to keep in mind that there are 2 perspectives that should be considered: telemonitoring at home and telemonitoring in the hospital.

Systems for telemonitoring of patients at home can have a huge impact on patients’ life and on health care systems in general. There is much evidence that proves the efficacy of these

[9] DataBridge, Global Radiation Oncology Treatment Planning Software Market – Industry Trends and Forecast to 2030

system in their respective domain. For example, Studies such as the one by Rumi et al. (2022) [REF-32] analyse the economic impact of introducing telemonitoring devices like Turbo+ in the management of asthmatic patients in Italy, highlighting potential savings for the National Health Service thanks to increased adherence to therapy. Moreover, Raso et al. (2021) [REF-33] evaluated the effectiveness of a new telemonitoring system for home monitoring of patients in a vegetative state or minimal consciousness after a head injury, suggesting potential benefits in the long-term management of these patients through telemonitoring. And studies like the one by Chow et al. (2023) [REF-34] have examined the feasibility of telemonitoring in the early stages of managing chronic diseases, highlighting how patients reported an improvement in understanding their health conditions and increased confidence in managing their own health autonomously with the support of telemonitoring.

Recent advancements in healthcare technology have demonstrated significant benefits in solving critical issues within hospital environments through the integration of REST APIs, smart devices, and IoT combined with cloud computing. These innovations have proven instrumental in enhancing patient care, operational efficiency, and data management. For instance, the development and rigorous testing of healthcare IoT applications, as explored by Hassan Sartaj et al. (2023) [REF-25], underscore the importance of dependable REST API testing in healthcare settings. Their findings reveal that effective testing strategies can detect numerous failures and faults, ensuring the reliability and robustness of IoT systems crucial for patient monitoring and data integrity. Furthermore, the integration of a smart bed infrastructure with hospital information systems using FHIR protocol, detailed by David Portugal et al. (2023) [REF-26], showcases how seamless connectivity between various healthcare devices can be achieved. This integration facilitates the effective monitoring of patients' vital signs and improves the overall management of health data, leading to enhanced patient care and safety. Additionally, the combined use of cloud computing and IoT technologies, discussed by Junaid Latief Shah et al. (2021) [REF-27], provides a structured approach for handling the vast amounts of data generated by IoT devices in healthcare. This integration supports real-time data processing and analysis, crucial for making informed decisions and providing timely healthcare interventions. Lastly, the SEMAR IoT server platform, developed by Y. Panduman et al. (2022) [REF-28], exemplifies how IoT application systems can be effectively integrated using standardized REST APIs. This platform allows for the synchronization and aggregation of data from diverse healthcare monitoring devices, facilitating efficient resource management and improved service delivery within healthcare facilities.

**Market**

In terms of market size, there are several estimations which are quite different in terms of final figures, depending on the type and variety of involved technologies and settings. Datam Intelligence (March 2024) [REF-35] valued the global remote patient monitoring market US$ 48.2 billion in 2022 and made a projection of lucrative growth by reaching up to US$ 338.9 billion by 2030. The global remote patient monitoring market is expected to exhibit a CAGR of 28.8% during the forecast period (2023-2030).

If we look at the market for IoT sensors in healthcare was valued at US$ 3,876.1 Million in 2022, and it is expected to have grown to US$ 14,416.8 Million by the end of 2033. The market for IoT sensors in healthcare is appraised to evaluate to US$ 4,310.2 Million in 2023 and projected to grow at a CAGR of 12.8% from 2023 to 2033. The IoT sensors in healthcare are part of a larger trend towards connected health, which seeks to leverage technology to improve patient outcomes and reduce healthcare costs. As such, they are expected to play an increasingly important role in the future of healthcare as the industry continues to embrace digital health solutions. IoT Sensors in healthcare market accounts for 25% market share in global IoT sensors market, and the demand for IoT Sensors in Healthcare in the Europe region it held around 20.8% of the market in 2022[10].

### 6.2.6 Pilot 4: Heart+

**Trends**

Hearth+ fits into a context of technological evolution in the healthcare sector, adopting cloud-native technologies and artificial intelligence (AI) to improve the management of cardiovascular diseases in cardiology clinics. These approaches are supported by studies confirming their effectiveness in enhancing operational efficiency and diagnostic accuracy while simultaneously reducing costs. Scientific literature illustrates how the integration of advanced wearable devices and data automation optimizes clinical workflows and enhances operational efficiency (Wang et al., 2023 [REF-36]). The adoption of mobile devices and cloud services for automatic high-quality ECG data collection facilitates proactive cardiovascular health management, ensuring immediate detection of cardiac anomalies through sophisticated AI algorithms (Fu et al., 2021) [REF-37]. Furthermore, the use of AI-based frameworks for data analysis and monitoring makes healthcare solutions more accessible, reliable, and scalable, contributing to further democratizing healthcare (Attia et al., 2021) [REF-38], (Sodhro & Zahid, 2021) [REF-39]. These innovations represent a significant step towards improving care quality and managing cardiovascular diseases more effectively and efficiently.

91Life has been very committed into the research around the development of the digital twin of the human heart. As for the applied research into that field, recent advancements in digital twin technology for cardiac applications have demonstrated promising results in enhancing cardiac care, particularly through the precise modelling of heart functions and the optimization of treatment strategies. The framework introduced by K. Gillette et al. (2021) [REF-40] lays a foundational approach for generating digital twins of cardiac electrophysiology from clinical 12-lead ECGs. This method allows for detailed biophysical modelling, paving the way for improved clinical decision-making and the testing of novel electrophysiology therapies, thereby enhancing the safety and efficacy of treatments. Building on this

[10] Persistence market research, IoT Sensors in Healthcare Market

foundation, T. Gerach et al. (2021) [REF-41] developed a comprehensive multi-scale model of the human heart that includes electrophysiology, mechanics, and circulation. This model has been instrumental in evaluating the effects of atrial ablation scars, offering critical insights that can guide the refinement of ablation strategies, thus significantly improving patient outcomes and treatment personalization. Furthermore, C. Herrero Martín et al. (2023) [REF-42] demonstrated the use of Electrocardiographic Imaging (ECGI) in generating non-invasive digital twins for ablation planning. This approach significantly enhances the accuracy of modeling cardiac activity, which is crucial for devising effective ablation strategies that are tailored to individual patient needs. Additionally, T. Hwang et al. (2023) [REF-43] explored the clinical application of digital twins in testing antiarrhythmic drugs for patients with recurrent atrial fibrillation after catheter ablation. Their study highlights the potential of digital twins to provide personalized predictions that optimize drug efficacy and patient safety, further demonstrating the significant role of digital twins in personalized patient care.

**Market**

The market for cardiac data analysis, particularly in areas like cardiac mapping and imaging software, is projected to experience significant growth over the next decade. For instance, the cardiac mapping market is forecasted to reach USD 6.98 billion by 2034, growing at a compound annual growth rate (CAGR) of 6.28% from 2024 to 2034. This growth is driven by technological advancements, increasing awareness of cardiovascular diseases, and the need for state-of-the-art solutions for diagnosing and treating heart-related complications.

Similarly, the cardiac imaging software market is also on an upward trajectory. In 2022, the market was valued at USD 0.6 billion and is projected to grow to USD 1.25 billion by 2032, exhibiting a CAGR of 8.5% during the forecast period. This growth is attributed to the rising incidence of cardiovascular diseases, advancements in imaging software, and increasing healthcare expenditures for cardiovascular care. The market is seeing substantial investments in research and development by major companies, aiming to expand product lines and adapt to the growing demand for more sophisticated diagnostic tools.

These forecasts indicate a robust demand for advanced cardiac care technologies, reflecting the ongoing evolution of healthcare towards more precise, efficient, and effective diagnosis and treatment of cardiac conditions.

### 6.2.7 Pilot 5: SIGEDA

**Trends**

Robotic nurse assistants are custom-built service robots capable of autonomous navigation in hospital environments and performing duties as nursing assistants. The robotic nurses are used for various activities like supporting disabled, critically ill patients, and older people in performing their day-to-day tasks, interacting with patients, monitoring patients, and collecting information about patients. These robots are overcoming the shortfall of

healthcare workers in regions where the proportion of nurses and patients is not equal. According to the Health, Labor, and Welfare Ministry, there will be a shortfall of around 377,000 healthcare workers in Japan by 2026.

At present, robotics-based nurse assistance is among the most researched area that specifically focuses on patient aid. Over the last decade, the role of robotics in the healthcare sector has increased significantly owing to the requirement to improve the quality and safety of care while controlling expenses. To address such requirements, multi-purpose intelligent nurse aid is required that will provide assistance to patients and accomplish teleoperation tasks with an easy-to-use graphical user interface[11].

Several studies are contributing to exploring the advantages and the issues of Robotic assistants in hospital environments. For example, a study by S. K. Sahoo and B. B. Choudhury in 2023 [REF-31] examine the use of mobile robots in healthcare settings, addressing the potential of these systems to improve patient care and the difficulties that must be overcome to fully exploit their advantages. According to them, the issues related to the use of mobile robots in healthcare settings mainly concern the safety of the tools, the working precision of the robots, the specificity of the context as the main determinant of the effectiveness of the implementation, interoperability with the environment, staff training, and issues related to privacy and compliance with regulations.

**Market**

In terms of market size, the global robotic nurse assistant market size was valued at USD 1.0 billion in 2022 and is expected to expand at a compound annual growth rate (CAGR) of 14.8% from 2023 to 2030. The growing population of older adults across the globe is encouraging the demand for robotic nurse assistants for various assistive day-to-day functions.

### 6.2.8 Pilot 6: MOVASCare

**Trends**

The world of digitally transformed health is leading the way to consumer-centred mobile health applications. These more recent developments promise to enhance patient outcomes, promote early diagnoses and interventions, and engage patients in practising a healthier lifestyle. In fact, adopting digital health models has proven its growing importance to every stakeholder across the healthcare industry[12].

The effect of continuity of care on chronic diseases was analysed by M. Abdullah et al. in 2023. This study emphasizes that continuity of care can significantly reduce morbidity and mortality

[11] Grand View Research, Report ID: GVR-3-68038-962-3

[12] https://knokcare.com/continuity-of-care-the-optimal-experience-for-healthcare/

in patients with chronic diseases. It has been shown to increase adherence to follow-up appointments, the use of prevention programs, and reduce emergency room visits and hospital admissions. Continuity of care is associated with better mental health, increased satisfaction, and quality of life [REF-29]. However, the full potential of digital health remains elusive, and providers have to fully understand how it can really change healthcare for the better. Still there are numerous challenges that must be addressed to fully unlock the potential of this practice. The work of García-Vivar et al. (2022) highlights the central role of nurses in promoting continuity of care, addressing the complex challenges this entails in a rapidly changing healthcare environment. The challenges they identified fall into three main areas: relational, informational, and managerial. By promoting nursing research and innovation in practice, it is possible to significantly improve the quality of care for patients with chronic conditions, contributing to better health and long-term well-being management [REF-30].

**Market**

In terms of potential market size, the global **Elderly Care Apps** revenue **in Europe** is expected to show an annual growth rate more than 11%, with a projected market value of over US$ 1.2 Bn by 2024. As per the World Health Organization, Europe saved US$ 126 billion worth healthcare costs through the adoption of mHealth services. This is majorly driven by the rising demand for affordable, accessible and advanced healthcare services[13].

### 6.2.9 Pilot 7: Customer Innovation Lab

**Trends**

The integration of Artificial Intelligence (AI) into medical diagnostics marks a pivotal shift in healthcare, significantly enhancing the precision, efficiency, and outcomes of medical interventions. This transformative impact is widely recognized and supported by emerging scholarly research that underscores the critical role of AI in modernizing and improving healthcare systems globally. As the medical field continues to evolve, AI technologies stand at the forefront, revolutionizing diagnostic processes and setting new standards for patient care. In "The Power of AI-Assisted Diagnosis," Jiaji Wang (2023) [REF-44] validates the critical role of AI in revolutionizing healthcare practices. Wang's insights support the notion that AI enhances the precision and effectiveness of diagnostics across various medical fields, aligning with the broader industry perspective on AI as a cornerstone of modern medical innovation. Similarly, David Ismail and Edi Gunawan (2023) [REF-45] underscore the benefits of AI in radiology, highlighting its role in improving diagnostic processes. Their findings emphasize AI's capacity to refine image analysis and support more accurate and timely patient evaluations, further substantiating the value of AI in enhancing clinical workflows. The necessity for a

[13] Fact.MR, Elderly Care Apps Market Forecast. Global Review 2021 to 2030

structured framework to manage the lifecycle of AI-driven diagnostic tools becomes apparent when considering the complexities involved in their development, integration, and operational deployment. An effective framework not only supports the technical aspects of AI but also ensures compliance with healthcare standards and ethical considerations, which are paramount in medical applications. Building on these foundational insights, the "AI-Driven Medical Imaging Platform: Advancements in Image Analysis and Healthcare Diagnosis" by Waleed Salah Eldin and Ahmed Kaboudan (2023) [REF-46] exemplifies the practical application of AI in medical imaging. This platform leverages deep learning to significantly enhance diagnostic accuracy across various imaging modalities. By improving the speed and precision of medical imaging, the platform not only streamlines diagnostic processes but also ensures faster and more reliable diagnoses, crucial for effective treatment planning.

**Market**

Starting from a quite broad perspective, the medical technology platform market size is expected to reach **US$ 54.08 billion by 2030, from US$ 25.46 billion in 2023, at a compound annual growth rate (CAGR) of 11.4%** during the forecast period. Medical technology platforms refer to advanced systems and solutions used for diagnosis, monitoring, treatment, and management of various medical conditions. The key advantages of these platforms include improved accuracy, faster results, remote accessibility, better data integration and analysis[14]. If we narrow it down to more specific areas, the global **image-guided therapy systems market size** was valued at **USD 4.6 billion in 2022** and is expected to grow at a compound annual growth rate (CAGR) of 5.2% from 2023 to 2030. The rise in the geriatric population and shifting preference for minimally invasive surgeries, along with technological advancements in imaging systems, are the key factors driving the market. Among all, the endoscopes segment accounted for the largest share of 32.3% in 2022. Increased adoption of robot-assisted endoscopic surgeries and the high cost of the systems are the key factors behind its largest revenue share. Magnetic Resonance Imaging (MRI)-guided therapy system, instead, is the second-largest product segment with promising growth opportunities. For what concerns the end user segmentation, the hospitals segment is expected to account for the largest revenue share of 37.0% in 2022, while the ambulatory surgery centers segment is anticipated to exhibit the fastest CAGR over the forecast period. The cardiac surgery segment accounted for the largest share of 31.1% in 2022. Cardiovascular diseases are the leading cause of death globally. The rise in the geriatric population, coupled with the increasing burden of such diseases, is the major factor contributing to the segment growth. The urology segment accounted for the second-largest revenue share in 2022, while the

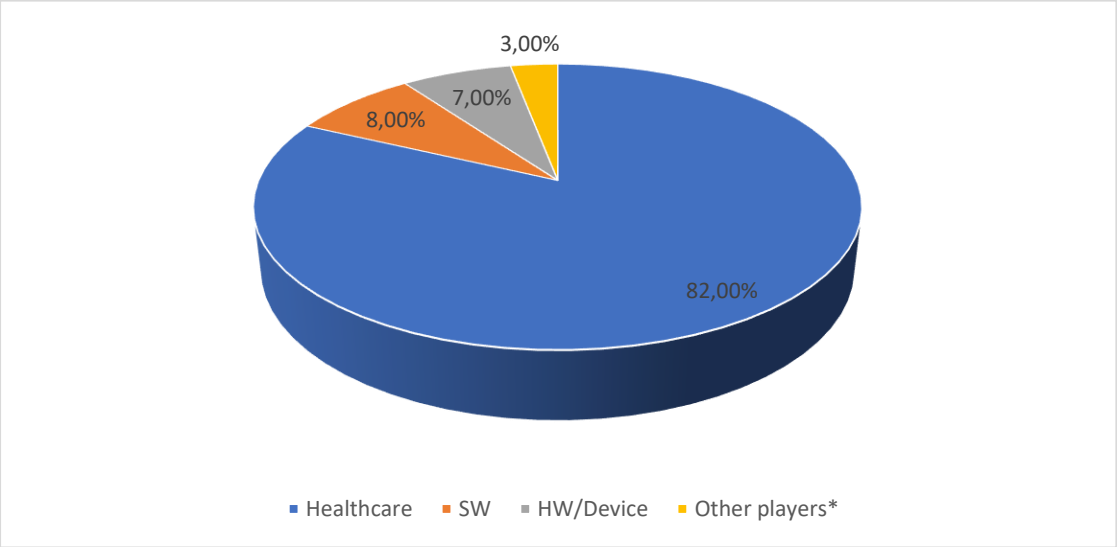
[14] Coherent Market Insights, Code: CMI6365

neurosurgery segment is likely to expand at a lucrative CAGR of 6.1% over the forecast period[15].

## 6.3 HosmartAI's market segments & customer base

HosmartAI's innovators have identified specific market segments and the individual business plans provide numbers in terms of specific potential customers that will be approached in the next 6-12 months.

A total amount of **516 potential customers** have been identified[16] belonging to the following segments:




* Other players include: residential market, developers, academia & research related stakeholders,

[15] Grand View Research. Report ID: GVR-2-68038-536-6

[16] Only prospects with known names and contact details have been counted.

# 7 Preconditions of the business plans

## 7.1 Economic analysis

An economic analysis was performed to assess the optimal use of resource to produce beneficial outcome for society. Cost analysis for various treatments is a useful component of outcome analysis to allow the weighting of other outcomes against unit cost or the inverse, cost per unit effect [REF-48]. Costs may be categorized as capital (amortized or one off) and resource which are recurrent costs. While all costs will need a unit cost record by tier, recurrent costs will also need a volume per unit time. Accordingly, economic evaluation of health care treatment options assesses among other outcomes, cost, a common component of health care economic evaluations. Other outcomes include clinical effectiveness and health economic outcomes such as PROMs including utility measures such as "QALYs". As demand typically exceeds supply for health care, health care suppliers seek value for money. Accordingly, economic evaluations use opportunity cost to identify the best value option out of a choice of the intervention and the next best alternative treatment, the comparator, typically usual care, the current treatment [REF-49].

In order to produce important outcomes, the cost alone does not translate the value of a specific treatment or technology without considering the effect of the specific technology. The combination of the lower cost and higher beneficial effect outcomes is the desired composition for the decision-making process. Yet, if each outcome falls on a different treatment option, a determination is still needed between options, with a consistent approach i.e., without reverting to personnel preference which can create a varied health care accessibility landscape for treatments across a country. The answer lies in using a ratio of incremental cost divided by incremental effect where the intervention's outcomes are used after subtraction of the comparator's equivalent outcomes e.g., intervention cost-comparator cost divided by intervention effect minus comparator effect [REF-50]. This creates the incremental cost-effectiveness ratio ("ICER") which may be written as indicated in Figure 15 below:

$$ICER = \frac{\text{Cost of intervention – cost of comparator}}{\text{Effect of intervention – effect of comparator}}$$

*Figure 13: ICER.*

For economic outcome, an analysis of direct medical costs, direct non-medical costs, indirect non-medical costs, symptom impact & adverse event costs should be measured per patient per unit time, with unit being the duration of each treatment strategy. One off and recurrent costs should be assessed for unit cost and resource quantity. Cost can be estimated from broadly 2 perspectives: the payer's or National Health System and the patient's or Society's perspective. For the latter, one must add the cost of carers unremunerated time and the patient's time off when sick [REF-50]. For the analysis of HosmartAI, the NHS provider perspective will be adopted. The NHS provider perspective includes treatment costs such as medicine costs, administration and monitoring, other health

service resource use costs associated with the managing the disease (e.g., GP visits, hospital admissions), and costs of managing adverse events caused by treatment. It does not include patients' costs of obtaining care such as transportation, over the-counter purchases, co-payments or time off work. Yet, it is up to technology pilots if they wish to gather more data e.g., on productivity losses arising from patients' inability to work, charged according to their policy at either a common minimum rate or the national average wage in order to be able to present the social perspective.

The cost to health payer whether government department or insurer for each treatment strategy equates to:

**Departmental Cost = n patients * mean patient cost per treatment strategy**

Costs are separated in three categories which are furtherly analysed below: a) direct medical costs, b) direct non-medical costs, c) indirect non-medical costs.

- Direct Medical Costs can include hospitalization (short- and long-term), outpatient follow-up, residential and day care, pharmaceutical interventions, laboratory testing. Costs of treatment adverse events should also be noted by severity.
- Direct non-medical costs include transport costs to and from hospital e.g., non-emergency ambulance for non-motile patients and paid carer giver time.
- Indirect non-medical costs include patient and unpaid carer time off work, charged either at a country's minimum wage or social security payments.

For the economic analysis of HosmartAI technologies, an analysis of direct medical costs, direct non-medical costs, indirect non-medical costs, symptom impact & adverse event costs will be performed. The resource utilization should be measured per patient per unit time, following the micro-costing methodology, including the number and type of major resources of the patient needs. The product of unit cost and volume is used to determine overall cost of each treatment strategy, noting recurrent costs quantity. Incremental outcomes from intervention and comparator may be calculated for clinical, health economic and economic outcomes whereby economic incremental outcome would be the sum of costs across treatment duration for each treatment strategy with comparator subtracted from intervention's cost. The equations are presented below:

**Incremental Cost = Cost of intervention (new AI technology) – cost of comparator (current technology)**

**Incremental Effect = Effect of intervention (new AI technology) – Effect of comparator (current technology)**

Due to agglomeration of technologies at HosmartAI project, the research team decided to proceed with a cost consequence analysis per pilot as like for like comparison was not possible.

Cost-consequences analysis (CCA) is a form of economic evaluation where disaggregated costs and a range of outcomes are presented to allow readers to form their own opinion on relevance and relative importance to their decision-making context [REF-48]. This is usually done using a descriptive table to present the effectiveness results (primary and secondary outcomes) in a disaggregated format, together with the estimates of the mean costs with appropriate measures of dispersion associated with each intervention. The aim of the study determines the construction and assumption of any analysis.

CCAs have been recommended for complex interventions that have multiple effects [REF-48], and public health interventions which have an array of health and non-health benefits that are difficult to measure in a common unit. CCAs are not restricted to any viewpoint and so readers and decision makers can see the impact of their decisions in the whole spectrum of costs and outcomes. CCAs have been recommended for complex interventions that have multiple effects for example, lifestyle education in diabetes[REF-48], and public health interventions which have an array of health and non-health benefits that are difficult to measure in a common unit [REF-49]. CCAs are not restricted to any viewpoint and so readers and decision makers can see the impact of their decisions on patient costs or on other sectors such as criminal justice [REF-51]. Similarly, outcomes are not restricted to health outcomes such as QALYs and can include other measures of wellbeing such as patient, or indeed staff, satisfaction. These non-health considerations are becoming increasingly relevant to NHS decision makers. CCA may be of particularly value to funders that are more concerned with patient-orientated outcomes and intervention costs such as Charities and some NIHR research programmes, particularly those with less focus on final stage randomised control trials. CCAs may also be particularly useful in feasibility or pilot studies when it is not clear which costs and outcomes will be most relevant to future definitive trials. Given the limited funding available for feasibility studies and the scarcity of health economists, CCA can provide a less resource intensive alternative if interventions have important economic consequences or a full comparative analysis is premature, but still provide an opportunity to pilot instruments used to collect economic data such as resource use and health-related quality of life [REF-49]. Similarly, outcomes are not restricted to health outcomes such as QALYs and can include other measures of wellbeing such as patient, or indeed staff, satisfaction. These non-health considerations are becoming increasingly relevant to NHS decision makers. CCA may be of particularly value to funders that are more concerned with patient-orientated outcomes and intervention costs such as Charities and some NIHR research programmes, particularly those with less focus on final stage randomised control trials. CCAs may also be particularly useful in feasibility or pilot studies when it is not clear which costs and outcomes will be most relevant to future definitive trials. CCA can provide a less resource intensive alternative if interventions have important economic consequences or a full comparative analysis is premature, but still provide an opportunity to pilot instruments used to collect economic data such as resource use and health-related quality of life.

The CCA approach helps to refine economic methods, identify relevant costs and outcomes and generate hypotheses for definitive cost-effectiveness studies and perhaps most importantly, provides a broader and richer source of economic information increasingly needed by NHS decision makers. It provides a straightforward way to present cost and outcome data alongside each other for a new health technology and its comparator(s) in situations where complexity in the research design might otherwise be pervasive. An example would be comparing the costs and consequences of different models of care across a care pathway in an observational study. Given the methodological issues associated with this design, an initial CCA can provide initial information on where further focus might be beneficial.

Models describing the disease aetiology/care pathway route through which a patient will transition as discrete states to allow costs and effects to be appropriately assigned and so through quantify the effect of introducing a new technology into current health care pathways and routine health and social care system use. Model time horizons for accrual of effects and costs should be stated.

Health and social care system and personal social services costs resulting from or associated with the use of the intervention should also include acquisition (including infrastructure) and maintenance costs.

Cost consequence analysis provides a comprehensive presentation of the cost and value of the intervention of scope. It is a listing of all the relevant costs and outcomes or consequences of the interventions and may include the following components:

- Direct Medical costs
- Direct non-medical costs
- Indirect costs (time costs, productivity costs)
- Health-related quality of life impact
- Utility impact
- Clinical outcomes (including adverse events)

The ideal cost-consequence analysis would include all possible health outcomes or consequences in order to allow decision makers the ability to determine the intervention's likely impact on their budgets and on the health of their patients.

## 7.2 Ownership[17]

| HosmartAI Platform |
|---|
| ***Business ownership (M19)*** |
| **The platform is being developed with the contribution of several partners. The most appropriate ownership model will be analysed during the business modelling & planning phase, based on the interest and willingness of partners with an interest in further exploiting it.** |
| **Ownership (M41)** |
| A federated for-profit ownership agreement has been defined among the core technology contributors. |

| Pilot 1 |
|---|
| ***Business ownership (M19)*** |
| **The Aristotle University of Thessaloniki. To fully understand the business potential of the 4 solutions, the Technology Transfer Office of the University should be involved to investigate which type of ownership will best fit to the identified business models / plans.** |
| **Ownership (M41)** |
| At least one spin off will be launched and become the owner of 1 KER. |

| Pilot 2 |
|---|
| ***Business ownership (M19)*** |
| **ITCL is the owner of the AI based software while UM will provide the chatbot.** |
| **Ownership (M41)** |
| Agreement among innovators have been signed. |

| Pilot 3 |
|---|
| ***Business ownership (M19)*** |
| **Vimar is the first main owner: in this case the business case could focus on a (potential) market segment made of hospitals and ambient assisted living environments (including the possibility of offering technologies to guarantee the continuity of care).**<br>**San Camillo is a potential second owner (possibly together with Khymeia). Even though it is a private actor, 90% of the revenues are based on public reimbursement schemes therefore the increased quality and efficiency of the service will not necessarily lead to dramatic changes of the business model (this statement will be verified, anyway). A commercial value which might be investigated (even though it is probably out of the** |

[17] Please note that the ownership refers to the innovation (KER) which has been associated with an individual business plan.

| |
|---|
| **scope of HosmartAI) is the market potential of agreements with technology providers to act as an "official lab" to accelerate the design and development of new solutions (and add possible royalties on top of this)** |
| **Ownership (M41)**<br>Vimar |

| **Pilot 4** |
|---|
| ***Business ownership (M19)***<br>**Option 1 - 91: the business case focuses, under this perspective, on a player which is developing vector mapping and AI based tools which will be integrated into the robotic solution developed by**<br>**Option 2 - ETHZ: as a second option, the business case could start from the idea of having a player which is investing in a robotic solution which will have to be integrated with additional tools (91) and – more relevant – further deployed later on as soon as the testing phase with SERMAS will have been completed** |
| **Ownership (M41)**<br>91 |

| **Pilot 5** |
|---|
| ***Business ownership (M19)***<br>**ITCL (the first main owner): expand the virtual reality tool developed in another project (and published on the EU innovation radar: http://www.innoradar.eu/innovation/38828) with video capabilities which will be relevant to detect, for instance, if a) patients are falling, b) patients are present in their beds, c) if they are asking for help, d) if they are doing breathing exercises, etc.**<br>**GC (the second main owner): edge platform and blockchain to secure the deployment of the social robots (AI reliability)**<br>**UM: even though it does not have a primary business focus, it is providing basic components which have been developed under the Persist (Patients-centred SurvivorShIp care plan after Cancer treatments based on Big Data and Artificial Intelligence technologies) which will be further developed and adapted to the purpose of the clinical studies (i.e.: how to collect data using speech technologies, risk assessment of patients, motivate patients, etc.)** |
| **Ownership (M41)**<br>ITCL |

| **Pilot 6** |
|---|
| ***Business ownership (M19)***<br>**Different actors owned different pieces of the new service, specifically:** |

| |
|---|
| **INTRAS**: Pilot coordinator and provider of Gradior Cognitive http://www.gradior.es/**,**<br>**ITCL: Pilot technical coordinator and responsible for integrating data diagnosis support system**.<br>**AUTH: responsible** for the integration of the real-life monitoring solution i-PROGNOSIS and for **developing a component of the "e-coach", namely, activity plan editor**,<br>**GC: responsible for integrating the** networking, edge cloud and blockchain technologies,<br>**TMA: p**rovides medical equipment, the e-Pokratis telemedicine platform (only the smartwatch module) and will perform any required integration between e-Pokratis and HosmartAI,<br>**UM**: responsible for transferring **pilot 5 knowledge and the emphatic user interfaces to the social robot integrated within this pilot.** |
| **Ownership (M41)**<br>While the ownerships of the technologies still belong to their innovators, an agreement has been signed to identify revenue sharing mechanisms. |

| **Pilot 7** |
|---|
| ***Business ownership (M19)***<br>**One main owner, PHILIPS, and the solution deployed under HosmartAI might be part of a bigger offer. Specifically, the module developed under HosmartAI is an AI-based image interpretation solution.** |
| **Ownership (M41)**<br>Philips |

## 7.3 A guide on pricing

The pricing, in terms of values and models, has been carefully analysed within each working group involved in delivering the individual business plans. The following key topics have been analysed

1) **Costs**. All KERs still have further development costs to consider, together with all other fix and variable costs associated with ongoing support and customer care, maintenance costs, customization costs, further R&D costs, sales & marketing, operations. Prices have to cover them and allow to generate profit. For each innovation margins have been defined.
2) **Value Proposition**. Sprint sessions and the clinical studies proved the playground to assess the value of the innovations to customers (buyers) and end users (who are not necessarily those who are going to pay for it). Specific KPIs have been monitored under WP1. Even if complicated, pricing had to reflect the software's value to its users (i.e.: less costs, increased productivity, improved working environment and processes, etc.).

3) **Market Research**. A detailed market research has been done to understand how similar products have been positioned on the market and how they have been priced. For most of the competitors it has been almost impossible to get the final pricing figures. Nevertheless, a wide range of pricing strategies & models have been detected like subscription, perpetual license, usage-based, project based, etc. Customer willingness to pay has been positively assessed during all B2B meetings that were already arranged during the project.
4) **Pricing Models** which have been identified are:
    a. Project based: similar to a consulting contractual price which is due to tailor one or more technologies to a specific need.
    b. Perpetual license: One-time payment for indefinite use.
    c. Subscription-based: regular payments for continued access.
    d. Usage-based: Pricing based on the extent of use.
    e. Freemium: Basic features for free, with premium features at a cost.
5) **Pricing Strategies**. Several strategies have been discussed internally even though their application will depend on a case base:
    a. Cost-plus pricing: the price is set at a markup over the cost.
    b. Value-based pricing: the price is based on the perceived value to the customer rather than the cost.
    c. Penetration pricing: a lower initial price to enter the market to later increasing it.
6) **Customer Feedback**. Feedback from all first customers will be monitored to collect insights into how much value HosmartAI's solutions add and how much they would be willing to pay. Before a full market entry, partners may consider a pilot phase where they will test the pricing with a small group of customers/prospects. This can provide valuable feedback and allow adjustments before wider implementation.
7) **Monitor and Adjust**. Market and costs will evolve, so it will be necessary to monitor both, along with customer feedback and sales data, to adjust the pricing as needed.

## 7.4 Protection strategies

The paragraph "IPR Management" already described how partners decided to approach their protection strategies. Partners have been made aware of the necessity to involve their Technology Transfer Offices and/or, where relevant, a legal department, to understand if and how their innovations (most of them based on software and algorithms) should (or could) be protected.

Several rounds of questionnaires have been done to understand if and how partners' strategies evolved during the project.

The graph below provides an overall summary of the strategies that have been adopted for the commercially exploitable results. Details about these strategies are considered as confidential information and therefore not provided under this document.

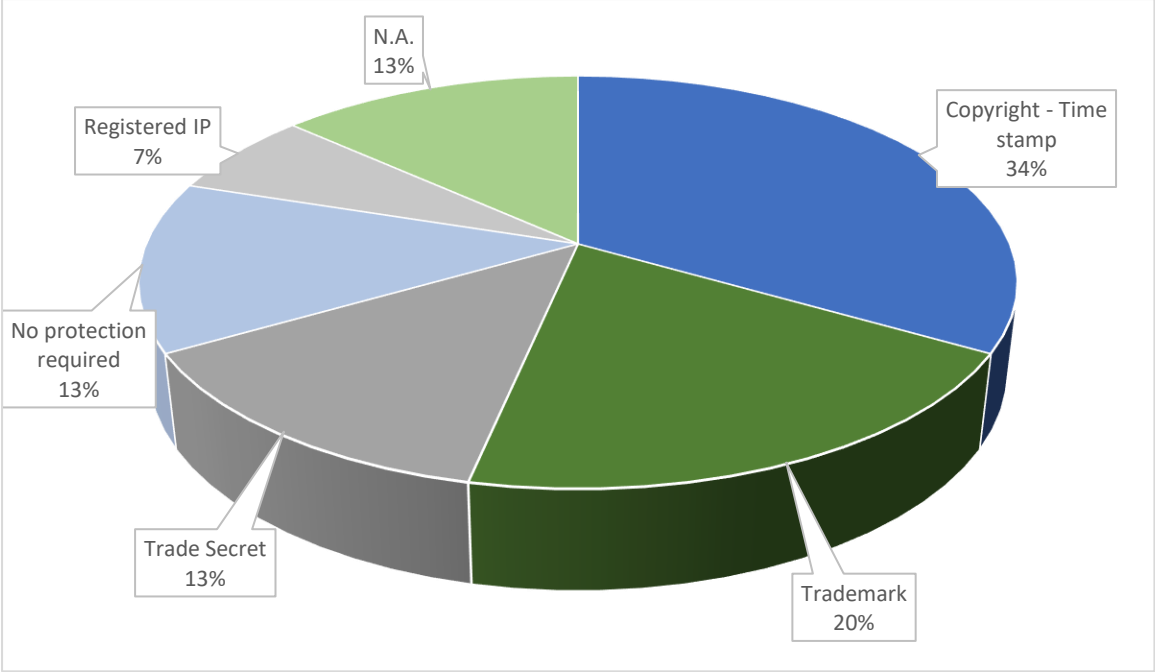



*Figure 14: Adopted Protection Strategies.*

## 7.5 Certifications, standards and regulatory compliance

### 7.5.1 Certifications

HosmartAI's commercial KERs were not designed to become MD and, therefore, did not have the medical device certification process as a "product milestone". Nevertheless, a focused training activity has been arranged in Madrid by VIMAR, PHILIPS and 91 (25/5/2023) to raise awareness about the process and double check the necessity of applying for it.

The session covered:

- MDR
  - Overview of the MDR regulation
  - Focus on Software as a Medical Device
  - The qualification process
  - The classification process
  - AI based SaMD
- FDA
  - Overview
  - When it is required
  - The submission process
  - AI-ML-based SaMD
  - Examples

Furthermore, as most of the commercially exploitable results deal with AI-powered or AI-based solutions, the conformity, quality, and safety requirements of the EU AI Act in addition

to those contained in the Medical Devices Regulation (even though none of our KERs has been identified as a potential MD), will need to be considered, in addition to product safety and other sectoral laws. Furthermore, if any solutions are to be coupled with Electronic Health Record systems (which is still not the case in M41 but may be an option in the future), then the requirements for EHRs contained in the current proposal for the European Health Data Space will also apply.

The recently approved European Artificial Intelligence Act[18] is a significant step towards regulating the use of AI across various sectors, including healthcare. This landmark legislation aims to ensure that AI technologies developed or deployed in Europe adhere to high standards of ethics, transparency, and safety. The AI Act introduces a risk-based classification system for AI technologies, which is one of its cornerstone features. AI systems are categorized into four risk levels: unacceptable, high, limited, and minimal. This classification dictates the level of regulatory scrutiny and compliance requirements. For instance, AI systems posing an unacceptable risk, such as real-time biometric identification in public spaces, are broadly prohibited. Meanwhile, high-risk applications, which could include certain healthcare AI technologies, are permitted but subject to stringent requirements. These requirements encompass rigorous testing, thorough documentation of data handling and quality, and detailed accountability mechanisms, including human oversight. In healthcare, where AI has the potential to significantly impact patient outcomes and the efficiency of healthcare delivery, this legislation underscores the importance of trust and safety. It aims to balance the innovative potential of AI technologies with the need to protect patients and ensure equitable, transparent, and responsible use of AI. The AI Act also addresses the implications of general-purpose AI systems, like large language models, which can be adapted for various uses, including those with varying risk levels. Such technologies are subject to regulations that reflect their potential impacts. This regulatory framework represents a proactive approach to managing the complex ethical, social, and technical challenges posed by AI, ensuring that AI technologies serve the public good while safeguarding fundamental rights and values. With its emphasis on risk management, transparency, and accountability, the AI Act could serve as a model for global AI governance, setting a precedent for how other regions might approach the regulation of emerging technologies. For healthcare AI, the act reinforces the necessity for developers and users to diligently assess and mitigate risks, prioritize data protection and privacy, and maintain high ethical standards throughout the lifecycle of AI technologies.

Further regulations & standards which have been shared and recommended to consider are:

- General Data Protection Regulation (GDPR)[19] [REF-47]

[18] https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai
[19] https://eur-lex.europa.eu/eli/reg/2016/679/oj

- ISO/IEC 27001 (Information security, cybersecurity and privacy protection. Information security management systems. Requirements)[20]: An international standard on how to manage information security, which is highly relevant for healthcare AI software handling sensitive health data in Europe.

- ISO 27799[21]: Health informatics - Information security management in health using ISO/IEC 27002, providing guidelines on maintaining the confidentiality, integrity, and availability of personal health information.

- IEC 62304[22]: A standard for medical device software lifecycle processes, offering a framework for the development, maintenance, and risk management of medical software, including AI-based applications.

- ISO 14971[23]: This standard focuses on the application of risk management to medical devices and is pertinent for AI software utilized within such devices to ensure safety and efficacy.

- EU Ethics Guidelines for Trustworthy AI[24]: they outline a framework for achieving trustworthy AI, emphasizing ethical principles and values that AI systems should adhere to, including those used in healthcare.

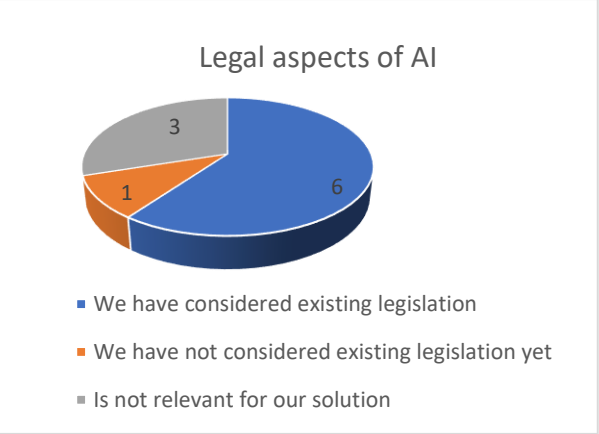
- WHO (World Health Organization) Ethics & Governance of Artificial Intelligence for Health[25]: global in scope, these guidelines are also relevant to European entities developing or deploying AI in healthcare settings, focusing on ethical considerations and governance principles.

- Data Governance and Cross-border Data Transfers: Given the GDPR's strict stance on data privacy and the cross-border transfer of personal data, healthcare AI applications in Europe must have robust data governance policies in place, especially if they involve data from multiple countries within or outside the EU.

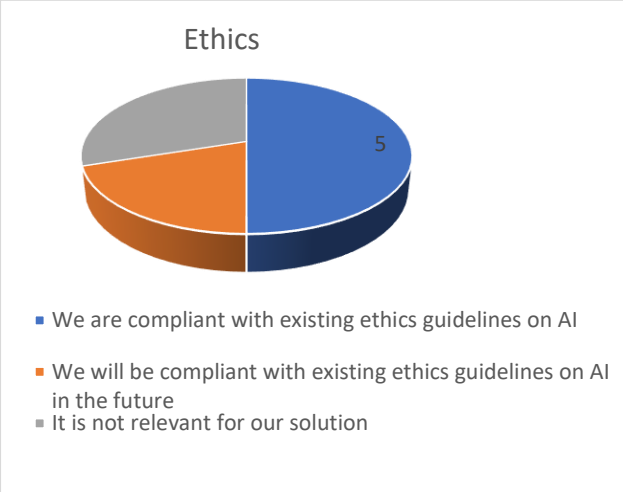
### 7.5.2 Overview of adopted approaches

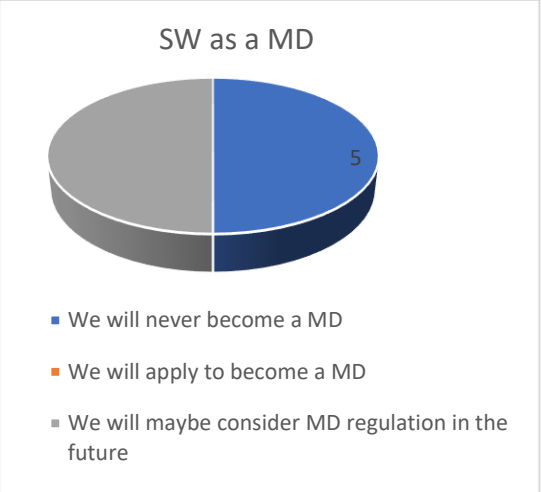
The following charts graphs summarize the approaches adopted by HosmartAI's innovators:

[20] https://www.iso.org/standard/27001
[21] https://www.iso.org/standard/62777.html
[22] https://www.iso.org/standard/38421.html
[23] https://www.iso.org/standard/72704.html
[24] https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai
[25] https://www.who.int/publications/i/item/9789240029200




## 7.6 Licensing

To avoid commercialization issues due to the use of open-source software, an in depth analysis of all types of licences has been done by TMA. Three licensing constraints were

identified and shared with project partners to be sure that their commercialization strategies fully consider them, namely

- DevExpress licenses its products under proprietary terms, which means they have to be purchased to use them, especially for commercial purposes.
- The EnSite Mapping System by Abbott is a proprietary medical device system used in electrophysiology procedures. The use for commercial purposes depends on several factors.
- The Creative Commons Attribution-NonCommercial-ShareAlike 3.0 Unported License (CC BY-NC-SA 3.0) has specific terms you need to be aware of, especially when considering commercial use. Works licensed under CC BY-NC-SA 3.0 cannot be used for commercial purposes. The "NC" component of the license specifically prohibits commercial use.

The complete results of the analysis are reported hereunder. To preserve confidentiality, the link to each innovation has been removed.

| GPL |
|---|

GPL (GNU General Public License) libraries can be used for commercial purposes, but there are important requirements and implications to consider:

- Commercial Use is allowed: GPL-licensed software can be used, modified, and distributed in a commercial setting.
- Source Code Distribution: If a software that uses or is linked to a GPL library is distributed, access to the entire source code of your software must be provided, and it must also be licensed under the GPL. This is the "copyleft" or "share-alike" principle of the GPL. Essentially, any derivative work or software that uses GPL components must itself be open source and GPL-licensed.
- Standalone Use: If GPL software is used internally in a business (without distributing it), it is not required to release software's source code. The obligation to release the source code under the GPL terms only triggers when the software is distributed.
- Dynamic vs. Static Linking: Some believe that dynamically linking to a GPL library (as opposed to statically linking) might avoid the requirement to GPL-license your entire software. However, this is a matter of debate and the Free Software Foundation (FSF), which authored the GPL, holds that both dynamic and static linking create a derivative work. This is a grey area, and legal consultation should be considered if this approach is an option.
- No Additional Restrictions: additional restrictions to the software that are not part of the GPL cannot be applied. For example, if a GPL-licensed library is distributed with a software, users must be free to modify that library and distribute their modified versions.

- Compatibility: Not all open-source licenses are compatible with the GPL. If libraries with different licenses are used, it has to be ensured that those licenses are compatible with the GPL.
- GPL vs. LGPL: The GNU Lesser General Public License (LGPL) is a more permissive license than the GPL, specifically designed for libraries. With the LGPL, the library can be linked to your software without having to release your software's source code under the LGPL/GPL. If the library is licensed under the LGPL, its requirements are less stringent than the GPL in terms of derivative works.
- Disclaimer: GPL-licensed software usually comes with a disclaimer that it is provided "as is", without warranties of any kind.

| JupyterHub |
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JupyterHub can be used for commercial purposes. JupyterHub, like many components of the Jupyter ecosystem, is an open-source software and is distributed under the terms of the Modified BSD License (often just called the BSD License).

Key points:

- Freedom of Use: The BSD License allows for the free use, modification, and distribution of the software, including for commercial purposes.
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- Compatibility: The BSD License is generally compatible with many other licenses and can be used in a variety of scenarios, including in proprietary software.

| NET Core |
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.NET Core can be used for commercial purposes. .NET Core, which has been integrated into the broader .NET 5 (and subsequent versions) is a free and open-source platform developed by Microsoft.

Key points

- MIT License: .NET Core is licensed under the MIT License, which is one of the most permissive open-source licenses. It allows for commercial use, modification, and distribution with minimal restrictions.
- Requirement to Retain License and Copyright Notice: If any part of .NET Core is distributed (either in its original form or as a modified version), the original copyright notice and the MIT License text must be included.
- Cross-Platform: One of the notable features of .NET Core (and now .NET 5 and beyond) is its cross-platform nature. It is designed to run on Windows, Linux, and macOS, giving you flexibility in deploying commercial applications.
- Broad Ecosystem: .NET Core is part of a larger .NET ecosystem, and there are numerous libraries, tools, and extensions available. While .NET Core itself is under the MIT License, it has to be checked that any additional libraries or tools which are integrated are also licensed in a manner compatible with the intended commercial use.
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- Official Support: Since .NET Core is developed by Microsoft, there is an official channel of support, documentation, and regular updates. This can be advantageous for commercial projects that require stability and reliability.

| Keycloak |
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Keycloak can be used for commercial purposes. Keycloak is an open-source identity and access management solution developed by Red Hat.

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- Support and Services: While Keycloak is open-source and can be used for free, Red Hat and other vendors might offer commercial support, consulting, or additional services around Keycloak for businesses that require them.

| Drupal |
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Drupal can be used for commercial purposes. Drupal is an open-source content management system (CMS) and is distributed under the terms of the GNU General Public License (GPL), specifically GPLv2 or later.

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- Derivative Works: Derivative works of Drupal (like custom modules or themes) are generally considered to be under the GPL if they are distributed. If they are used internally or for a specific client without distribution, it is not necessary to release their source code.
- No Warranty: Drupal, like most open-source software, is provided "as is", without warranties of any kind.
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- Services and SaaS: If users provide Drupal as a service (like hosting) or in a Software-as-a-Service (SaaS) model, the GPL does not require to release modifications or custom modules/themes. The GPL's requirements mainly kick in when users distribute the software.
- Drupal's Interpretation: The Drupal community's interpretation of the GPL in the context of themes and modules is that if they're designed to run exclusively with Drupal, they would be considered derivatives and should be GPL-compatible when distributed.

| Discourse |
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- SaaS Model: If users are hosting Discourse for others in a Software-as-a-Service (SaaS) model, the GPL does not require them to release their modifications. The GPL requirements mainly apply when the software is distributed.
- Support and Hosting: While Discourse is free and open source, the Discourse team offers commercial hosting solutions and support, which can be a viable option for businesses looking for a hassle-free and supported deployment.

| HapiFHIR |
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HAPI FHIR is an open-source implementation of the HL7 FHIR (Fast Healthcare Interoperability Resources) specification in Java, licensed under the Apache License, Version 2.0.

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| SonarQube |
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Sonatype Nexus comes in multiple editions, and the ability to use it for commercial purposes depends on the edition chosen:

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- Nexus Repository Pro (Professional Edition): This is the commercial version of Nexus Repository, which comes with additional features and support compared to the OSS version. This edition requires a paid license for use. The terms of use, including for commercial purposes, would be defined in the licensing agreement with Sonatype.
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Consul can be used for commercial purposes. Consul is a product from HashiCorp that provides service discovery, service mesh, and key-value storage functionalities.

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- Requires Preservation of Notices: If users distribute the software or derivative works, they must give credit to the original authors and include any original licensing and copyright notices.
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- Does Not Require Open Source Distribution: Unlike "copyleft" licenses like the GPL, the Apache License 2.0 does not require to release derivative works as open source. This means users can integrate Apache 2.0-licensed software into proprietary products.
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Key points:

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Key points:

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- Freedom to Distribute: users can distribute the software, either in its original form or with modifications.
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# 8 Pitch to Match: Helsinki Radical Health Festival


The HosmartAI consortium decided to join the Radical Health Festival Helsinki (May 21-23, 2024) as its final event dedicated to pitching and connecting to investors and new potential customers.

The event has been selected as it brings together an interdisciplinary community of like-minded digital healthcare visionaries aiming to revolutionize modern healthcare and make it sustainable once again.

Specifically, on **May 21st,** 4 partners (CHUL, AUTH, 9Life and INTRAS) and 2 Open Call winners (Aisthesis Medical and Bioengineering Research and Development Centre Kragujevac), together with Vimar, joined the EC2VC Investment Forum and Pitch Match, a session gathering the most active investors and innovators with clinicians and healthcare decision-makers to re-invent healthcare innovation, and accelerate investments and adoption at scale. During this session, STARTUPS had the chance for intimate, meaningful dialogue with top investors, receiving precious and practical advice on building investable, sustainable, successful digital health startups in Europe. With the potential to have follow-up investment discussions right there on site.


*Figure 15: Helsinki Radical Health Festival Pitch to Match.*

To make this work, startups were asked ahead of the event to set up a profile and attach their pitch deck (no separate application this year) on R2GConnect Platform if they do not already

have a profile. The startups could then select up to five EC2VC investors they would like to have a private conversation with. INVESTORS will offer their valuable advice in this exclusive environment to founders, but also gather insights beyond the pitch into who the founding team is, how they see the space and how they will persevere to move digital health forward. They will review the profiles and pitch decks on R2GConnect Platform and select up to five startups they would like to speak with privately.

At the time of writing, participating partner have also been invited to make a speech during the workshop "AI for Clinicians – Opening the Black Box, a session co-designed with the Finnish Medical Association" (May 21, 2024)

The partners also joined a booth where they had the chance to interact and discuss with potential buyers and stakeholders on the 22nd and 23rd of May.


*Figure 16: Helsinki Radical Health Festival.*

# 9 Conclusions

The document provides an overview of the most significant steps and outcomes of the business modelling process from September 2022 until May 2024.

VIMAR's team, together with those project partners with a commercially exploitable result, has been working on identifying the most commercially promising KERs and on guiding KERs' owners in designing proper market strategies and a final business plan.

The figure below summarizes the overall process and the main achieved results. From a pure commercial perspective, all innovations which have been analysed from a business perspective have a robust go to market strategy, have identified their customer base and collected promising feedback during meetings and presentations.

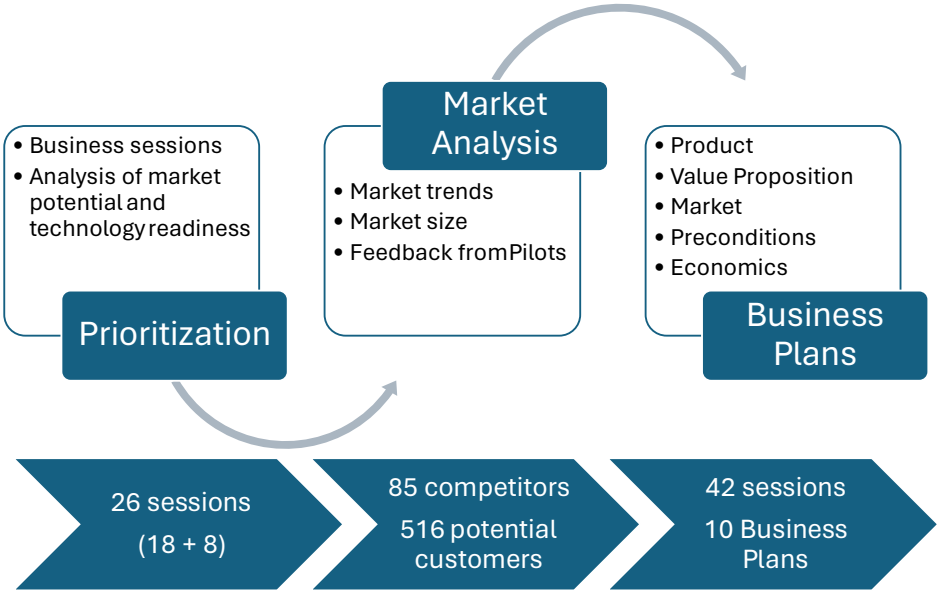


*Figure 17: Overview of HosmartAI's business process.*

To fully support HosmartAI's partners on their way to market, the partnership joined the Helsinki Radical Health Festival (May 21-23). The event has been an opportunity to get in touch with investors, connect to new healthcare ecosystems and further promote HosmartAI's key commercially exploitable results.

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