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21.06.2024	1.1	New version reviewed internally by KVC
02.07.2024	2.0	New version ready for internal review by CDC and AGE
12.07.2024	3.0	Final version including feedback from CDC, AGE and EMC

EXECUTIVE SUMMARY

Deliverable D7.3 Legal Framework for Exploitation aims to create a comprehensive understanding and regulatory framework for leveraging ValueCare outcomes and managing intellectual property rights (IPRs). This document represents a collaborative effort among project partners to outline a clear and coherent legal framework that aligns with the objectives and principles of maximizing project results. By establishing this framework, the deliverable intends to facilitate the conversion of research Key Exploitable Results (KERs) into practical products, services, and societal benefits. Furthermore, it seeks to promote a legal environment within European Research and Development (R&D) projects that supports knowledge transfer, technology transfer, and the dissemination of innovations across the Health and ICT sectors.

In this regard, D7.3 provides a comprehensive and clear legal framework for the exploitation of KERs and IPRs within the ValueCare project. This includes promoting understanding among project partners regarding legal principles, regulatory requirements, and best practices; identifying ethical considerations and addressing potential challenges in the exploitation process while ensuring alignment with market needs and consortium priorities.

The **methodology** employed for the completion of the current deliverable encompasses several key components: analysis of the wider legal framework governing research, innovation, and business operations within the European Union, and its influence on the utilization of ValueCare project outcomes; statement on the significance of adhering to EU legislation in the exploitation of project resources: focus on intellectual property rights, data protection, and ethical dimensions; identification and categorization of KERs within the ValueCare initiative; assessment of partner involvement levels in the commercial exploitation of identified KERs; and formulation of a roadmap for the Value-Based Health Care (VBHC) certification and the VBHC Consultancy, acknowledged as the KERs designated for commercialization. This includes the development of the Preliminary Participation Agreement (PPA) and the Joint Ownership Agreement (JOA).

The **intended audience** of this deliverable are the ValueCare partners and involved staff. In particular, those in charge of the specific KERs of the project. Moreover, it is also an enlightening piece of content for the general public in terms of transparency about the use and agreements to exploit the results of the project, beyond the project's end.

The **key insights from this deliverable** highlight the importance of aligning with EU legislation, including intellectual property, data protection, and ethical standards, to safeguard the project's integrity and enhance its market credibility. The systematic identification and classification of KERs ensure that the most innovative results, particularly the VBHC Training Program and VBHC

Consultancy, are prioritized for commercial exploitation. Additionally, a clear roadmap for the commercial exploitation of these KERs has been defined, including the development of a PPA and a JOA to formalize the roles and responsibilities of consortium partners.

In **conclusion**, the legal framework established in this deliverable ensures the successful exploitation of ValueCare project KERs by adhering to EU regulations and ethical standards. Collaborative efforts among project partners position ValueCare to achieve its objectives and deliver significant societal value. The emphasis on the VBHC Training Program and VBHC Consultancy highlights the project's dedication to fostering innovation and enhancing healthcare delivery through value-based approaches.

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
CA	Consortium Agreement
D	Deliverable
DoA	Description of the Action
DSA	Digital Services Act
GA	Grant Agreement
GDPR	General Data Protection Regulation
IoT	Internet of Things
ISS	Information Society Service
IPR	Intellectual Property Rights
JOA	Joint Ownership Agreement
KER	Key Exploitable Result
M	Month
PPA	Preliminary Participation Agreement
R&D	Research and Development
TFEU	Treaty on the functioning of the European Union
TLs	Task Leaders
VBHC	Value-based Health Care
VLOPs	Very Large Online Platforms
VLOSEs	Very Large Online Search Engines
WHO	World Health Organisation
WP	Work Package

1 Introduction to the ValueCare project

Healthy ageing along with independent living have become fundamental challenges for Europe as all EU member states (and virtually every country in the world) are experiencing growth in the number and proportion of older persons in their population. Several international organisations (Council of Europe, 2014; International Longevity Centre Brazil, 2014; WHO, 2002) have remarked on the importance of the independence, participation and autonomy of older people to remain healthy and, consequently, to ensure their quality of life.

The World Health Organisation (WHO) defines health as "…a state of complete physical, mental and social well-being and not merely the absence of disease". The idea of health as the absence of disease has long been considered insufficiently broad and does not cover all aspects of health. Unfortunately, it is at present likely unobtainable for many, particularly with the rise in chronic disease and an ageing population, with many people with multi-morbidity and frailty who require a coordinated care plan involving numerous health providers, and social and other care services. The concept of health promoted by WHO is also hard to measure, is not tailored to the individual and is of limited use for assessing whether a health system is providing value to citizens. Greater acknowledgment of areas of wellbeing providing wider value to older people and those with chronic illnesses, such as societal participation and coping capacity, may allow for a more practical and thorough assessment of value in healthcare, particularly in high-income countries. Shilton et al. (2011) propose a definition of health focussed on giving people the income, education, and power to control their lives, highlighting the role of supportive systems, environments, and policies in enabling health.

In this context, ValueCare's vision of healthy ageing is that any older individual in society can live the best life possible according to what is important for each one. This is facilitated by accessing to high quality, person-centred, evidence-based, and affordable health and social care services, and supported by strong and integrated health and social services. ValueCare partners believe that taking an "enhanced value-based approach" (including not only health but also lifestyle and social care in the concept of value-based care) supported by secure and robust digital technologies will help to achieve this. In addition, the project will also take into account the job satisfaction and the wellbeing of the health and social service providers. For that, ValueCare satisfies the Triple Aim; i.e. (i) improving the experience of care (including quality and satisfaction); (ii) improving the health of populations; and (iii) containing and potentially reducing, by means of a better use of the available resources, the per capita cost of care, which mainly focuses on the person's side. Moreover, the project also considers the care providers and integrating their satisfaction in the job and wellbeing in order to truly optimize ValueCare's performance.

1.1 Objectives of the project

ValueCare addresses Horizon 2020 Call: SC1-DTH-2018-2020 – Digital transformation in Health and Care. The project aims to deliver personalised integrated (health and social) care services in an innovative value-based way. It seeks to achieve better outcomes for older people, and improve the care experience while enhancing staff satisfaction and greater efficiency in the use of resources and care coordination. Additionally, the project focuses on ensuring the trust of users and policymakers concerning data access, protection and sharing.

Designed to be replicated and deployed at a large scale in other EU countries, ValueCare focuses on the following general objectives:

- **Objective 1**. To deliver efficient outcome-based integrated (health and social) care to older people suffering from cognitive impairment, frailty and multiple chronic health conditions in order to improve their quality of life (and of their families)
- **Objective 2**. To contribute to the sustainability of health and social care systems in Europe
- **Objective 3.** To provide a secure, scalable and robust digital solution for integrated care

2 Introduction to the deliverable

Deliverable 7.3 Legal Framework for Exploitation serves as a usable component within the ValueCare project, aiming to establish a comprehensive understanding and regulatory infrastructure for the exploitation of project outcomes and intellectual property rights (IPRs). In the landscape of innovation and research, the effective management of intellectual property and the navigation of legal frameworks surrounding exploitation are paramount to fostering innovation, promoting collaboration among consortium partners and ensuring equitable benefits for all partners involved.

This document reflects a collaborative effort among project partners to delineate a clear and coherent legal framework that aligns with the objectives and principles of the further exploitation of project results. It seeks to address the complexities in the exploitation process, including IPRs, licensing agreements and ethical considerations.

By establishing the legal framework for exploitation, the deliverable endeavours to facilitate the translation of research KERs into tangible products, services and societal benefits.

Moreover, it aims to foster a European R&D projects legal environment for knowledge transfer, technology transfer and innovation dissemination across Health and ICT sectors.

Throughout the legal framework roadmap for exploitation, key legal principles of the project execution and regulatory requirements for the effective exploitation of project results are established. This will aim to maximize the impact and sustainability of research and innovation supported by Horizon Europe funding schemes. The roadmap will also reinforce the commitment to transparency and fairness in the management of intellectual knowledge, assets, and collaborative partnerships. These efforts will extend beyond the completion of the ValueCare project implementation duration.

2.1 Deliverable objectives and scope

The deliverable explores key legal principles and regulatory requirements relevant to the exploitation of project KERs and its roadmap execution during ValueCare project implementation, including IPRs and licensing agreements management and compliance with relevant legislation.

- **Objective 1.** To provide clarity on the legal framework governing the exploitation of KERs and IPRs within ValueCare project.
- **Objective 2**. To promote understanding among project partners regarding the legal principles, regulatory requirements and best practices associated with exploitation.
- **Objective 3.** To identify potential challenges in the exploitation process of KERs and best practices in the development and implementation of the legal framework for exploitation, ensuring alignment with the needs and priorities of the market and the consortium partners.

- **Objective 4.** To identify legal aspects related with ethical considerations associated with the exploitation of project results, including issues related to, inter alia, privacy and data protection.

2.2 Relation to other WPs and deliverables

This deliverable is strongly linked with the following WPs and deliverables, please see Table 1

Table 1. D7.3 relation to other WPs and deliverables

WP	Deliverable	Relationship
WP1	All	D7.3 considers all the Consortium Agreement (CA) and the Grant Agreement (GA) regulations regarding the IPR procedures for the European Projects.
WP2	All	Since the VBHC Certification will be the only result that will be commercially exploited, D7.3 sets out the exploitation process for this KER.
WP5	D5.4 User feedback and feasibility report	Since the exploitation of the ValueCare results depends on their feasibility, D7.3 is related to D5.4 which collects the pilot sites feedback and the feasibility report required to deliver the final version of the ValueCare concept.
WP7	D7.2 VALUECARE business models D7.4 Strategy for VALUECARE replication and exploitation	D7.3 is completely aligned with D7.2, which details the business models to commercialise the ValueCare results, and with D7.4, since it includes practical guidelines for the replication of the ValueCare approach.
WP8	D8.1 VALUECARE ethical management plan D8.2 VALUECARE ethical guidelines and templates D8.3 VALUECARE data management plan	Ethical considerations will be identified and considered for the exploitation roadmap of the KERs. These include data protection and privacy, among others.

3 Legal Framework for exploitation at European Level

3.1 Examination of the broader legal framework within the European Union that could impact the exploitation of the ValueCare project results

The exploitation of ValueCare project results is profoundly influenced by the comprehensive legal framework governing research, innovation, and business activities within the European Union. This framework encompasses several key regulations and directives designed to foster innovation while ensuring ethical and legal compliance.

- **Treaty on the Functioning of the European Union (TFEU)**

The Treaty on the Functioning of the European Union (TFEU), (Treaty 2012/C 326/01) states, in its Article 168(7), that the "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them."

This general principle defines the scope of the EU legislation on health. It would be limiting, however, to infer that all competences regarding this area fall under the sole jurisdiction of the Member States (MS). In this case, general provisions shall be complemented with other principles of the same rank. In particular, Articles 56 and 57 of the TFEU and the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, clearly specify that Member States are not allowed to impose any limitations to the right to free provision of health services, including telemedicine services across borders, unless justified based on considerations of general interest, such as public health.

Directive 2011/24 along with the aforementioned provisions of the treaties on the freedom to provide services remains the cornerstone of the EU legislation covering the scope of telemedicine services. They are defined in the directive as "the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients".

In relation to the KERs of the ValueCare project, the provision of telemedicine as a health care service apply to its full extent. In the first place, telemedicine in its dimension of service falls under the provisions of the TFEU[1]. Secondly, telemedicine services fall within the scope of Directive 2011/24 on

[1] The European Court of Justice (ECJ) has, on several occasions, stated that health services fall within the scope of the freedom to provide services and neither the special nature of health services nor the way in which they are organised or financed removes them from the ambit of this fundamental freedom. See ECJ judgment of 31 January 1984 in joined cases 286/82 and 26/83 Luisi and Carbone, ECJ judgment of 28

the application of patients' rights in cross-border healthcare. In particular, the Directive explicitly mentions "telemedicine" as a service for which "rights are established to ensure that the essential information on prices, quality and safety of care are accessible to the patient to ensure informed decision. […] – and – the Member State of treatment (that in case of telemedicine is the Member State where the service provider is established must ensure that the healthcare in question is provided in accordance with its legislation." (Article 4(1) of the Directive). Thirdly, telemedicine services can also vest the role of an information society service (ISS), for which, inter alia, Directive 2000/31/EC on Electronic Commerce (eCommerce), and Directive 98/34/EC on Regulatory Transparency apply. In order for a telemedicine service to qualify as an information society service, the Article 2(a) of the e-Commerce Directive and Article 1(2) of the Regulatory Transparency Directive define a ISS as a "service normally provided for remuneration, at a distance, by electronic means, at the individual request of a recipient of service" (Directive 2000/31/EC). While the first text establishes a legal framework to ensure the free movement of ISSs; for instance providing for information requirements, rules on commercial communications, on electronically executed contracts and on the liability of intermediary service providers. The latter complements the legal framework by adding provisions related to the law applicable to an eCommerce activity. This law is the law of the Member State in which the service provider is established, meaning the place where a service provider effectively pursues an economic activity using a fixed establishment for an indefinite period. Additionally, it includes provisions related to the duty of information for ISS providers. Finally, it addresses commercial communications in relation to ISSs. Subsequent adoption of other legal instruments at EU level have in many cases replaced and complemented this legislation (e.g. the Data Protection Regulation (GDPR) or the Digital Services Act (DSA).

- **Digital Services Act (DSA)**

DSA the European Union introduces several significant legal implications for online services, emphasizing transparency, accountability, and user protection (DSA, 2022). Concerning liability and accountability, the DSA clarifies that platforms are not accountable for illegal content hosted, provided they promptly remove it upon becoming aware of its presence. However, these platforms must ensure they do not knowingly host illegal content or services, adhering to specific due diligence requirements. Transparency is another critical aspect covered by the DSA. Telemedicine platforms, may be required to disclose their content moderation practices, including the number of instances where illegal content was removed and the rationale behind these actions (DSA, 2022). Additionally,

April 1998,in case C-158/96 Kohll; ECJ judgment of 12 July 2001 in case C-368/98, Vanbraekel; ECJ judgment of 13 May 2003 in case C-385/99, Müller-Fauré and Van Riet; ECJ judgment of 12 July 2001 in case C-157/99, Smits and Peerbooms; ECJ judgment of 16 May 2006 in case C-372/04, Watts.

any adverts must be clearly identified as such, and platforms must reveal the main criteria used for targeting adverts to users and inform them about the entities behind sponsored content. In terms of user protection, the DSA mandates that online platforms implement straightforward systems for users to report illegal content or activities. These systems must be transparent and efficient, ensuring prompt responses to user notifications. Users also have the right to challenge decisions made by platforms regarding content removal or account suspension. Consumer protection is also strengthened under the DSA. There are stricter regulations against the sale of counterfeit medical products and services, ensuring that platforms verify the legitimacy of the products and services they offer, additionally, they must implement appropriate measures to protect users from scams, fraud, and other malicious activities that could harm their health or safety (DSA, 2022). While the DSA might only be applicable to telemedicine platforms to the extent that they fall under the definition contained in it. The obligations vary according to the role, size, and impact of different online entities within the digital ecosystem. A pyramid chart showing various service categories:

- Very Large Online Platforms and Search Engines: These pose significant risks in the spread of illegal content and societal harms. Specific rules apply to platforms serving more than 10% of Europe's 450 million consumers. The designated platforms are listed on DSA: Very Large Online Platforms and Search Engines.
- Online Platforms: These connect sellers and consumers, such as online marketplaces, app stores, collaborative economy platforms, and social media platforms.
- Hosting Services: These include cloud and web hosting services, encompassing online platforms.
- Intermediary Services: These provide network infrastructure, such as internet access providers and domain name registrars, which also include hosting services.

All online intermediaries offering services within the single market, regardless of whether they are based in the EU or outside, must comply with the new regulations. Micro and small companies will have obligations proportional to their capacity and size, ensuring accountability. Moreover, micro and small companies experiencing significant growth will benefit from a targeted exemption from certain obligations for a transitional period of 12 months.

Started on 17th February 2024, the DSA regulations are applicable to all online platforms. Previously, since late August 2023, these regulations were already in effect for platforms with over 45 million users in the EU (equivalent to 10% of the EU's population), classified as Very Large Online Platforms (VLOPs) or Very Large Online Search Engines (VLOSEs).

The enforcement of the DSA will be a collaborative effort between the European Commission and national authorities, who will oversee the compliance of platforms operating within their jurisdictions.

The Commission will take the lead in monitoring and enforcing the additional requirements imposed on VLOPs and VLOSEs, including measures aimed at mitigating systemic risks.

By navigating these legal and regulatory landscapes, the ValueCare project can effectively exploit its results, maximizing impact across the health and ICT sectors. This comprehensive approach not only enhances the project's outcomes but also contributes to the broader objectives of the European Union in promoting innovation, competitiveness, and societal well-being.

3.2 The importance of ensuring compliance with EU legislation in the project exploitation, including intellectual property, data protection and ethical considerations.

Ensuring compliance with EU legislation in areas such as intellectual property, data protection, and ethical considerations is crucial for the successful exploitation of project results. This compliance is not only a legal obligation but also fundamental to fostering trust, innovation, and sustainability in research and business activities. Below, we discuss the importance of these aspects in the context of the ValueCare project.

- **Intellectual Property Rights (IPR) Compliance**

  Ensuring compliance with IPR laws safeguards the innovations and ideas generated during the project. This protection encourages creativity and investment by securing the rights of creators and inventors, ensuring they benefit from their work.

  - Protection of Innovations: Compliance with EU IPR legislation, including the Unitary Patent system (European Commission, 2023) and the Directive on the Enforcement of Intellectual Property Rights (Directive 2004/48/EC), is essential to protect the innovations generated by the project. This protection enables the creators to secure exclusive rights to their inventions, thus fostering innovation by ensuring that they can reap the benefits of their work.
  - Facilitating Commercialization: Properly managed intellectual property allows for efficient commercialization strategies. This can include licensing agreements, partnerships, and other forms of technology transfer that can generate revenue and promote further research and development.
  - Avoiding Legal Disputes: Ensuring that all intellectual property is adequately protected and that any potential conflicts over ownership or usage rights are resolved early can prevent costly legal disputes that could delay or derail project outcomes.

► **Data Protection Compliance:**

Data protection compliance is vital for legal adherence, building trust, ethical responsibility, risk management, data security, international collaboration, safeguarding participant rights, project sustainability, and enhancing project outcomes.

- Safeguarding Personal Data: Adhering to the General Data Protection Regulation (GDPR) is critical in projects like ValueCare that involve the collection and processing of personal data. Compliance ensures that personal data is handled with the highest standards of privacy and security, protecting individuals' rights and fostering trust among stakeholders (Regulation 2016/679).
- Ethical Data Management: GDPR compliance also underscores the ethical management of data. It necessitates obtaining informed consent, ensuring transparency, and providing individuals with control over their personal information, thus aligning project activities with ethical standards and societal expectations.
- Enabling Cross-Border Collaboration: GDPR compliance facilitates cross-border research collaborations within the EU, as it provides a harmonized framework for data protection that is recognized and trusted across member states.

► **Ethical Considerations:**

Compliance with ethical considerations in the ValueCare project is vital for upholding rights, legal and regulatory adherence, enhancing public trust, promoting fairness and equity, ensuring informed consent, protecting vulnerable populations, enhancing data integrity and reliability, facilitating international collaboration, supporting sustainable development, and ensuring ethical governance.

- Promoting Social Responsibility: Adhering to ethical standards in research, as outlined in the Charter of Fundamental Rights of the European Union and other EU ethical guidelines, ensures that the project respects human dignity, rights, and welfare. This includes considerations related to privacy, data protection, and informed consent (Charter 2012/C 326/02).
- Enhancing Credibility and Acceptance: Ethical compliance enhances the credibility of the project and its findings. Stakeholders, including participants, partners, and the wider public, are more likely to support and engage with a project that demonstrates a commitment to ethical standards.
- Mitigating Risks: Addressing ethical considerations proactively can mitigate risks associated with public backlash, regulatory penalties, and potential harm to participants. This proactive approach ensures the project's long-term viability and acceptance.

- **Overall Impact on Project Success:**
  - Building Trust and Reputation: Compliance with EU legislation in IPR, data protection, and ethical conduct builds trust among stakeholders, including participants, collaborators, funding bodies, and the public. A reputation for legal and ethical integrity can enhance stakeholder engagement and support.
  - Ensuring Market Readiness: By aligning with regulatory requirements, the project ensures that its results are market-ready and can be deployed without legal hindrances. This readiness includes meeting standards for product safety, user privacy, and ethical transparency, which are critical for market acceptance and success.
  - Supporting Sustainable Development: Compliance contributes to sustainable development by promoting responsible research and innovation. It ensures that the project's outcomes not only meet current legal and ethical standards but also set a precedent for future projects, thus fostering a culture of continuous improvement and societal benefit.

In conclusion, ensuring compliance with EU legislation in intellectual property, data protection, and ethical considerations is fundamental to the exploitation of project results. It provides a foundation for protecting innovations, safeguarding personal data, and upholding ethical standards, all of which are essential for achieving the project's objectives and securing its long-term impact and success.

4 Key Exploitable Results

4.1 Identification and selection of KERs

Exploiting the results of the ValueCare project involves leveraging them to create tangible value and societal impact. This utilisation extends beyond commercial purposes to include further research endeavours. Through an open innovation approach, ValueCare fostered collaboration and innovation in the field of VBHC, engaging with a diverse array of stakeholders such as end-users, informal careers and healthcare professionals. These interactions led to the identification of the ValueCare KERs, which were described by the consortium partners (see Annex 1). Following this characterisation, KERs were prioritised based on three main criteria: innovation, exploitability, and maturity and those with the highest potential for joint exploitation by the consortium were selected. Table 2 summarises the KERs of the ValueCare project, including technical products, newly acquired knowledge, and innovative services.

Table 2. ValueCare Key Exploitable Results

Name of the result	WP	Lead Owner	Description
VBHC Training Program	WP2	ISRAA	The training program aims to offer a holistic approach to adopting Value-Based Health Care (VBHC). The Green Belt training intervention facilitates the adoption of the model in older people care and adult population with chronic diseases. It is a step-by-step program designed to guide healthcare organizations from initial evaluation to certified VBHC implementation, ensuring that they are able to improve patient outcomes and increase care value. The Green Belt ValueCare Training will give the knowledge and skills to managers and experts about: • The core concept of VBHC • How to implement the VBHC in health and social care domains • How to redesign the care pathway and define the value calculation and the cost reduction • Define the role of the doctors and care teams within the VBHC Model It is a two-day training that could be deployed hybrid all over the World. It is based upon the ageing domain and social care organisation's needs. VBHC has been created and implemented mainly in the health care domain, but it has not affected, in a sensitive manner, the social care one. That is why there is the need to have useful and flexible tools for the VBHC adoption also in the Long Term Care and in the Home Care service deployment.

VBHC Consultancy	WP2	ISRAA	The VBHC consultancy offers a comprehensive service for care unit certification according to the value-based healthcare model. This service includes the use of the VBHC assessment toolkit, Care Pathways redesign tool, and organizational shift planning. These components are designed to facilitate a seamless transition to VBHC, ensuring that care units are fully equipped to implement this model effectively, thereby enhancing patient outcomes and optimizing healthcare delivery. In terms of business model, the organisations that will have joined the certification process will have the opportunity to sell the training Worldwide and at Country level. It is worth to say that the training will be a lever for further consultancy to the care managers to deploy the model along with the organisational changes required. It is the unique training and consultancy VBHC training proposition in social care domain
Co-creation methodology	WP2	KVC	Engagement toolkit: how to map the local target population and the local stakeholders that support the VBHC implementation and transition. Codesign toolkit: set of "how to": organize and plan dedicated focus groups with the target users, informal caregivers, and formal ones. Items and sequences that should be followed and how to lead each codesign session and further data gathering, analysis and reporting. World Café: how to set up a World Café session to engage local stakeholder and gather a highest amount of information and feedbacks to shape the local collaboration among institutions and public/private care providers.
ValueCare Book	WP2	ISRAA	The book " The ValueCare experience: creating value for older people with chronic conditions in Europe with a transition towards outcome-based integrated care supported by technology," is a versatile resource suitable for healthcare providers, policymakers, researchers, and students. It offers information on the ValueCare project, explains the value-based approach to healthcare and social care, and describes innovative solutions piloted in the project. Additionally, the book discusses the challenges and opportunities of implementing value-based care and gives practical advice for those considering its adoption in their organisations or regions. The ValueCare Book will be unique in the manual panorama for the VBHC adoption. Up to now after "Redefining health care" (M.E. Porter and E. Teisberg, 2006) and "Patient Priority", 2022 there are not book aiming for the VBHC adoption in the social care domain. The book will show not only the model creation and deployment but also its adaptation in 7 clinical conditions and Country specific health social care frameworks.
Integrated ValueCare Digital Solution	WP3	VODAFONE INNOVUS	The ValueCare Digital Solution consists of an infrastructure enabling the interaction among the different components of the ValueCare system such as the web Dashboard, the mobile app and the virtual coach. It allows to interconnect such modules with the repositories in which patients' data are stored and maintained.

ValueCare Digital Solution **Web Dashboard**	WP3	VIDAVO	A dashboard for healthcare professionals to register and monitor the patients' evolution in time, and the mobile app providing different self-tracking features and capable of hosting other components (such as the virtual coach for empowering older people on their self-management of prescribed health/care-related tasks).
ValueCare Digital Solution **Mobile Health App**	WP3	VODAFONE INNOVUS	It is a mobile application aiming at providing access to various functionalities including browsing certified educational multimedia materials, access to clinical professionals, statistics about care path compliance and access to the personalised virtual coach.
ValueCare Digital Solution - MODULE 3 - **Virtual Coaching Semantic-enabled Digital Solution**	WP3	FBK	A personalised tool for interactive dialogues between the end-user and an AI-enabled coach integrating hybrid, knowledge-based (evidence-base content) and data-driven technologies (patterns of app usage) to support the achievement of a personalised care pathway. It offers a personalised and interactive tool that combines evidence-based content and data-driven technologies to support individualised care plans. By integrating AI and hybrid knowledge, patients can receive contextually relevant information to maximise their health outcomes and improve their experiences. The immediate transfer of existing bots to new regions and promotion of the virtual coach as a reusable component demonstrates our commitment to expanding access to quality care. In the long term, we aim to identify new clinical settings and enrich the virtual coach with novel technological approaches to continuously improve older people's outcomes across various clinical conditions and locations
Policy Recommendations	WP6	UVEG	Policy recommendations for scaling up ValueCare outcomes, promote the implementation of value-based integrated care at the regional or national level. Policy makers can use these guidelines to promote the delivery of value-based integrated health and social care for older adults supported by digital solutions and anchored in a human rights-based approach. The unique value proposition of such policy recommendations lies in its comprehensive approach to addressing the complex needs of older adults in the context of health and social care delivery. It emphasizes a shift towards value-based care, focusing on outcomes that matter most to older adults, such as improved quality of life, functional independence, and overall well-being. Finally, these guidelines are informed by evidence-based practices and lessons learned from the implementation of the ValueCare project, incorporating perspectives from a wide range of stakeholders, including older adults themselves, caregivers, healthcare providers, policymakers, and technology experts and recognizing the dynamic nature of healthcare systems.

4.2 KERs Selected to be Commercially Exploited

After identifying the KERs for the ValueCare project, an internal consultation was conducted to evaluate the exploitation strategy for each KER and the desired type of partners' participation in their exploitation; and to establish intentions for future collaboration through the Joint Ownership Agreement (JOA), which is detailed in the following sections. Annex 1 details the ValueCare partners intentions of commercially or not-commercially exploit the KERs identified in the previous table as well as the preliminary strategy for the exploitation of the KERs identified in the previous step (table 3). Ultimately, the ValueCare partners concluded that the KERs to be commercially exploited are the VBHC Training Program and the VBHC Consultancy. Consequently, the subsequent section 4.4 focuses specifically on these two project outcomes.

4.3 IPR strategy in relation to ValueCare KERs

4.3.1 Principles of IPRs in European Projects: Consortium Agreement & Grant Agreement regulations

Obligation of protect and exploit results of the project

Several articles in the Description of the Action (DoA) and also in the Consortium Agreement (CA) and in the Grant Agreement (GA) of the project, develop IPRs management procedures within ValueCare project. This subchapter outlines all the articles in the DoA, CA and GA that are related to IPR.

DOA

- The results are considered **jointly owned if they have been generated by two or more partners, and it is not possible to establish the respective concrete contribution of each beneficiary**.
- Once these results are developed, the partners can agree on a different alternative regime, ownership and legal framework: e.g., spin-offs or start-ups.
- **The joint ownership refers, exclusively, to the intellectual property and not necessarily to the exploitation strategy**: in spite the fact that the IPR could be considered under a joint ownership regime, the **exploitation rights and policy must be defined during the project lifecycle.**

CONSORTIUM AGREEMENT

- **CA 8.3.2**

  It may identify specific third parties it intends to transfer the ownership of its Results. The other Parties hereby waive their right **to prior notice** and their right to object to a transfer to listed third parties according to the Grant Agreement Article 30.1.

- **CA 8.3.3**

  The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties will not be affected by such transfer.

- **CA 27.1 | Obligation to protect of results**

  Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

  - the results can reasonably be expected to be commercially or industrially exploited and
  - protecting them is possible, reasonable and justified (given the circumstances). When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

- **CA – ANNEX 1**

Table 3 IPR conditions detailed in the CA-ANNEX 1

Partner	Background	Implementation conditions (during the project)	Conditions for exploitation
FBK	HORUS AI (virtual coach)	Free	Fair and reasonable conditions to be agreed
VI	IoT asset control + IoT platform	Proprietary, Closed-source	Proprietary, Closed-source
VIDAVO	Vida24 (certified according to EU medical devices Regulation)	Free, Proprietary, Closed-source	Proprietary, Closed-source Fair and reasonable conditions to be agreed
CDC	Integrated pathway concepts		Fair and reasonable conditions to be agreed
Most partners have indicated previous background with no limiting its exploitation			

GRANT AGREEMENT

- **GA – SECTION 3**

  Commitments related to collaborative research: ownership of the foreground should stay with the party that has generated it but can be allocated to the different parties based on a contractual agreement concluded in advance, adequately reflecting the parties' respective interests, tasks and financial or other contributions to the project. In the case of contract research, the foreground generated by the public research organisation is owned by the private-sector party. The ownership of background should not be affected by the project.

  Results are owned by the beneficiary that generates them *(the same as in the CA 8.1 + DoA).*

- **GA 25.3 Access rights for other beneficiaries, for exploiting their own results**

  The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

- **GA 26 | Join Ownership**

  Ownership of the foreground should stay with the party that has generated it, but can be allocated to the different parties **based on a contractual agreement** concluded in advance, adequately reflecting the parties' respective interests, tasks and financial or other contributions to the project. In the case of contract research, the foreground generated by the public research organisation is owned by the private-sector party. The ownership of background should not be affected by the project.

  - **Results are owned by the beneficiary that generates them** *(the same as in the CA 8.1 + DoA).*
  - **Joint ownership (GA 26,2):** Two or more beneficiaries own results jointly if:
    - they have jointly generated them and
    - it is not possible to:
      - establish the respective contribution of each beneficiary, or
      - separate them for the purpose of applying for, obtaining, or maintaining their protection (see Article 27).

- **GA 28.1 Obligation to exploit the results**

Each beneficiary must — up to four years after the project — take measures aiming to ensure 'exploitation' of its results (either directly or indirectly, in particular through transfer or licensing) by:

- using them in further research activities (outside the action);
- developing, creating or marketing a product or process;
- creating and providing a service, or
- using them in standardisation activities.

- **GA 30.1 | Transfer Ownership**

  Each beneficiary may transfer ownership of its results. It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer. This does not change the security obligations in Article 37, which still apply.

4.4 IPR roadmap

To ensure all partners agree and are aware on the IP ownership situation, the following roadmap was elaborated and presented to all consortium partners, actively maintained and updated during the project execution to minimize the possibility of misunderstanding and disagreement between partners.

1. **Identification of KERs (described above; see section 4.1)**
2. **Ownership determination.** Ownership determination is a crucial aspect of IPR, establishing who holds the rights to a particular piece of intellectual property. It involves legal and factual analyses to identify the rightful owners of an IP asset. Accurate ownership determination is essential for protecting IPR, ensuring proper usage, facilitating commercialization and licensing activities. By understanding the principles of creation, employment, assignments, and licensing, and following meticulous processes of documentation, registration, and legal agreements, partners can effectively establish and safeguard their IP ownership rights. Accurate ownership determination facilitates the proper use and exploitation of IP and contributes to innovation and economic growth by ensuring that creators and owners can reap the benefits of their intellectual contributions. Thus, clear ownership of IPRs must be established from the outputs, typically done

in agreements among project partners. Ownership will depend on various factors such as contributions to the creation of the output, contractual arrangements and the project regulations.

In the case of the ValueCare project, a tool (excel file) was created for each partner to establish the knowledge and contribution that, under their ownership, they brought to each WP and deliverable/output of the project. In addition, all the information collected was agreed.

3. **Protection of Intellectual Property Rights (IPRs).** The protection of IPR is essential for fostering innovation, creativity, and economic growth. It ensures that results owners can reap the benefits of their efforts, thereby incentivising further advancements. The protection of IPR encompasses a range of legal mechanisms designed to safeguard different outputs of the project. Thus, once the ValueCare KERs are identified and ownership is established, the following licensing agreements will define the terms and conditions under which partners manage their intellectual property rights.

- **Preliminary Participation Agreement (PPA)**

  This document serves as the initial step in determining each partner's commitment to participate in the exploitation of the project. It lays the groundwork for mutual understanding and cooperation by defining the roles, responsibilities, and expectations of all parties involved. Annex 2 shows an example of the PPA.

  Within the PPA, partners have three options:

  - **Renounce Participation**, for those partners who wish to relinquish their involvement in the exploitation. By selecting this, they are effectively transferring the associated rights and obligations to the remaining partners.
  - **Active Participation,** for those partners who are actively interested in participating in the exploitation of the project.
  - **Passive Participation,** for partners who wish to passively participate. Passive participants are also required to sign and engage in negotiations outlined in the second document, the JOA.

- **Joint Operating Agreement (JOA)**

  For partners choosing to participate in the exploitation actively or passively, the JOA is a crucial legal and comprehensive document that outlines the operational framework for collaboration. The JOA details the specifics of the product to be exploited and the corresponding reward mechanisms. In the JOA, the exact product for exploitation is defined and reward regimes for all participants are established. This includes partners

directly involved in product exploitation and those entitled to payments based on shared authorship rights for their contributions to the overall project. After signing the Preliminary Participation Agreement, active participants will be required to engage in the signing and negotiation process for the JOA. Annex 3 is an example of JOA.

4. Also, the following **procedures** have also been taken into account for the protection of the Intellectual Property:
    - **Copyright**: Copyrights protect original works of authorship, such as literary works, graphic works, and computer software. With copyright protection, the consortium has the exclusive rights to modify, distribute, perform, create, display and copy the generated results of the project. A copyright exists from the moment the work gets done in the framework of the project, without any registration procedures.
    - **Trademarks & Patents**: An expert information on this subject was requested by the free assistance service of EUIPO – Intellectual Property Office of the EU, which was granted to ValueCare, giving the following recommendation:
        - It is recommended to always register a trademark as the image of a project to establish its identity. The name can include the name of an application, courses, services…
        - Trademark registration should cover all services to be promoted under that name/brand. The benefit of registering a trademark is that it grants exclusivity and identification of the project compared to others.
        - It is recommended to choose a non-generic name for the services being requested. For example "CARE" is generic for medical or care services, or an application offering medical services, thus it does not provide distinction. In the case of wanting to register generic names, it is recommended to add a logo, which would make the difference and prevent the Trademark Office from denying the trademark.
        - The trademark is requested for specific services. There is a classification where desired services can be selected, such as education, software, medical services, but it is requested in a generic manner, not for a specific software or methodology but for software in general or education in general.
        - Protection is acquired from the moment the trademark is requested, provided there are no prior rights. The trademark processing period lasts approximately 6 months if there are no oppositions or issues.

- Regarding the cost of applying for a European trademark, the official costs for this type of registration are as follows:
  - Initial file or deposit:395€
  - Subsequent files or updates: 195€
- Regarding methodology, books, know-how, or copyright, it is recommended to protect them through a timestamp (blockchain) to be able to prove authorship.
- Through the blockchain system, a certificate of existence for the deposited file is generated. When generating the Certificate of Existence for a document, image... poof is created anonymously and securely that the file exists at a specific date and time. This proof is registered on the public and decentralized network "ALASTRIA", based on blockchain, which most major companies belong to. The Certificate in PDF format, includes two links that allow verification, if necessary, that everything was correctly registered, and that the certified document is exactly what you indicated.

The summary of the process for the IPR management is described in Figure 1:

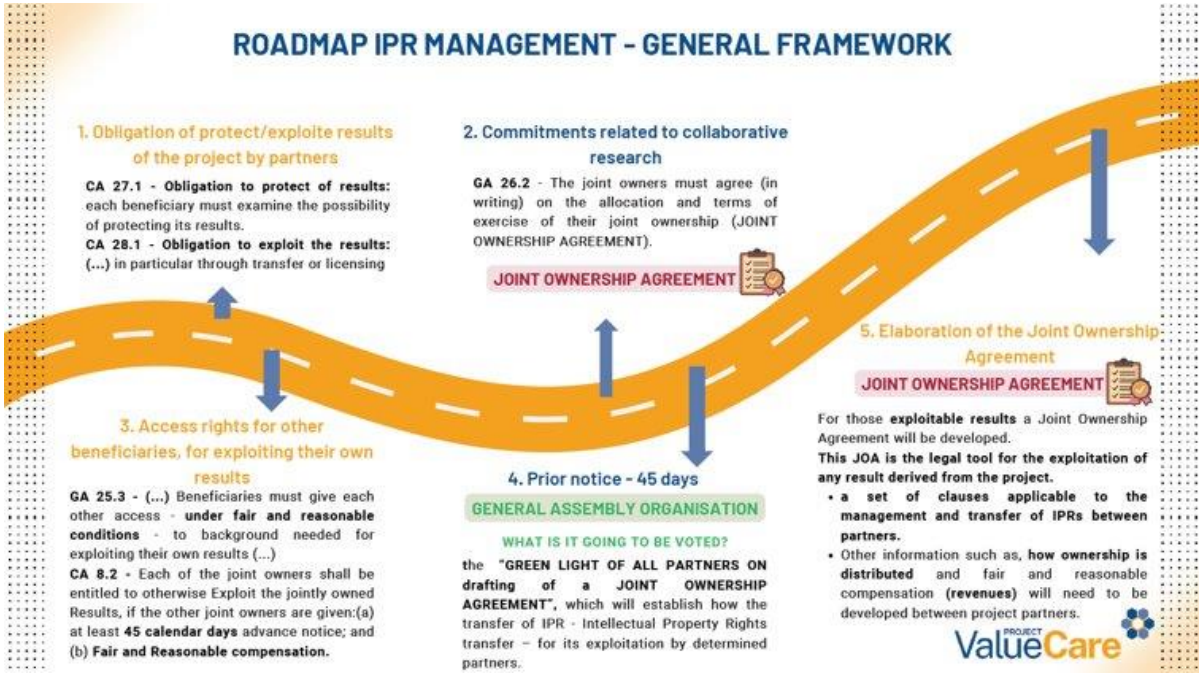

Figure 1. Roadmap for IPR Management

5 Conclusions

The establishment of a comprehensive legal framework for the exploitation of ValueCare project results is pivotal to the success and sustainability of the project's outcomes. The legal framework aims to facilitate the translation of research outputs into tangible products, services, and societal benefits while ensuring compliance with European Union legislation.

This deliverable delineates a clear and coherent legal framework that aligns with the objectives and principles of the ValueCare project. Through the examination of the broader legal environment regulating research, innovation, and business activities within the EU, this framework has been tailored to support the commercial exploitation of identified KERs in a manner that upholds ethical standards and protects intellectual property.

Thus, the key insights from this deliverable include:

- Alignment with EU Legislation: Ensuring compliance with EU laws, including those governing intellectual property, data protection, and ethical standards, is essential. This compliance not only safeguards the project's integrity but also enhances its credibility and acceptance within the market and among stakeholders.

- Identification and Classification of KERs: The process of identifying and classifying KERs has been systematic and thorough, ensuring that the most promising and innovative results are prioritized for exploitation. The VBHC Training Program and the VBHC Consultancy have been identified as the primary KERs for commercial exploitation.

- Roadmap for Commercial Exploitation: A clear roadmap has been defined for the commercial exploitation of the VBHC Training Program and VBHC Consultancy. This includes the development of a Preliminary Participation Agreement (PPA) and a Joint Ownership Agreement (JOA) to formalize the roles and responsibilities of consortium partners in the exploitation process.

In conclusion, the legal framework established through this deliverable provides a solid foundation for the successful exploitation of ValueCare project KERs. By adhering to EU regulations and ethical standards, and through the collaborative efforts of all project partners, the ValueCare project is well-positioned to achieve its objectives and deliver substantial value to society. The focus on the VBHC Training Program and VBHC Consultancy as primary KERs underscores the project's commitment to fostering innovation and improving health care delivery through value-based approaches.

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ANNEXES

Annex 1. Exploitation Plan for Key Exploitable Results Identified

The results identified within the ValueCare project, which include technical products, newly acquired knowledge, and innovative services, hold significant commercial and intellectual value.

To effectively harness this potential, it is crucial to establish a solid legal framework for the project's **Key Exploitable Results (KERs)**. In this context, **ECHA** and **KVC**, under **Work Package 7 - Exploitation, Innovation, and Business Models**, have collaboratively developed the following tables for each KER.

These tables are vital as they lay the groundwork for clarifying each partner's commitment level towards exploiting the project's outcomes.

Each partner, with a special focus on the Lead Owner, is responsible for regularly updating the KER table to reflect current and future commitments accurately. This coordinated approach is key to ensuring a unified and effective strategy for exploiting the outcomes of the ValueCare project, maximising its commercial and intellectual potential.

<table>
<tr><th colspan="2">Name of result: ValueCare Care Model Methodology
VBHC Training Program Elderly Care</th></tr>
<tr><td>Outcome: WP2</td><td rowspan="4">Description:
The training program aims to offer a holistic approach to adopting Value-Based Health Care (VBHC). The Green Belt training intervention facilitates the adoption of the model in older people care and adult population with chronic diseases. It is a step-by-step program designed to guide healthcare organizations from initial evaluation to certified VBHC implementation, ensuring improved patient outcomes and increased care value.
The Green Belt ValueCare Training will give the knowledge and skills to managers and experts about:
• The core concept of VBHC
• How to implement the VBHC in health and social care domains
• How to redesign the care pathway and define the value calculation and the cost reduction
• Define the role of the doctors and care teams within the VBHC Model
It is a two days training that could be deployed hybrid all over the World.</td></tr>
<tr><td>LEAD Owner: ISRAA</td></tr>
<tr><td>Type: Innovative solutions (new products/services/processes)</td></tr>
<tr><td>Expected TRL (end of project): (If relevant)</td></tr>
</table>

	Unique Value Proposition (UVP): The main UVP of the Green Belt Training is that it is based upon the ageing domain and social care organisation's needs. VBHC as been created and implemented mainly in the health care domain but it has not affected, in a sensitive manner, the social care one. That is why there is the need to have useful and flexible tools for the VBHC adoption also in the Long Term Care and in the Home Care service deployment. **Target user/customer/audience:** • Healthcare Organizations • Healthcare Administrators and Managers • Healthcare Professionals • Policy makers • Healthcare Consultants and Experts **Benefits:** The benefit are twofold: • Form the ValueCare Partner participant perspective, the organisations who joined the certification process has expanded and will expand the knowledge and skills in terms of VBHC adaptation to the several kind of care provider services that will get in touch throughout the training deployment and exchanges **Long term exploitation and preconditions:** The purpose is to build a group of interested care organisations that would like to get to know and to adopt the VBHC Model in their context of care delivery. The preconditions will be to create a cultural change, overall, from managers, perspective, in such a way to deploy the VBHC model both in terms of practitioners' skills upgrade and in terms of organisational change.
Preliminary Participation Agreement	
Renounce Participation[1]	AfIC, AMC, UCD, Vodafone Innovus, FBK, VIDAVO, LAS NAVES
Active Participation[2]	EMC, MEDRI, ISRAA
Passive Participation[3]	KVC, UVEG, IFIC, CDC, AGE

Name of result: ValueCare Care Model Methodology - VBHC Consultancy	
Outcome: WP2	**Description:** The VBHC consultancy offers a comprehensive service for care unit certification according to the value-based healthcare model. This service includes the use of the VBHC assessment toolkit, Care Pathways redesign tool, and organizational shift planning. These components are designed to facilitate a seamless transition to VBHC, ensuring that care units are fully equipped to implement this model effectively, thereby enhancing patient outcomes and optimizing healthcare delivery.
LEAD Owner: ISRAA	
Type: *Innovative solutions (new products/services/processes)*	
Expected TRL (end of project): *(If relevant)*	

	In terms of business model, the organisations that will have joined the certification process will have the opportunity to sell the training World wide and at Country level. It is worth to say that the training will be a lever for further consultancy to the care managers to deploy the model along with the organisational changes required. **Short term exploitation (1 year after the end of the project):** *Realising at least two VBHC Green training per year* **Unique Value Proposition (UVP):** *Unique training and consultancy VBHC training proposition in social care domain* **Target user/customer/audience:** • Healthcare Organizations • Healthcare Administrators and Managers • Healthcare Professionals • Policy makers • Healthcare Consultants and Experts **Benefits:** • Expanding the quality of care services • Improve the competitivity of the services • Improving the cost effectiveness • Improve the attractiveness of the service care provider **Short term exploitation (1 year after the end of the project):** Having 3 care provider organisations as clients for the VBHC adoption receiving consultancy **Long term exploitation and preconditions:** *The VBHC Model will be adopted by ISRAA is at least 3 care units and in the home care services for people suffering of dementia disease. In terms of national exploitation it will be shared among the LTC community expanding the number of adopters*
Preliminary Participation Agreement	
Renounce Participation[4]	AfIC, AMC, UCD, Vodafone Innovus, FBK, VIDAVO, CDC, LAS NAVES
Active Participation[5]	EMC, AULSS2, MEDRI, ISRAA
Passive Participation[6]	KVC, UVEG, IFIC, AGE

Name of result: Co-creation methodology	
Outcome: WP2	**Description:** **Engagement toolkit:** how to map the local target population and the local stakeholders that support the VBHC implementation and transition. **Codesign toolkit:** set of "how to": organize and plan dedicated focus groups with the target users, informal caregivers, and formal ones. Items and sequences that should be followed and how to lead each
LEAD Owner: KVC	
Type: *Innovative solutions (new products/services/processes)*	
Expected TRL (end of project): *(If relevant)*	

	codesign session and further data gathering, analysis and reporting **World Café:** how to set up a World Café session to engage local stakeholder and gather a highest amount of information and feedbacks to shape the local collaboration among institutions and public/private care providers. **Target user/customer/audience:** • Local Health Care Providers and Professionals • Policy Makers and Health Care Administrators • Health Care Organizations • Beneficiaries • Formal and Informal Caregivers

Name of result: ValueCare Book	
Outcome: WP2 **LEAD Owner:** ISRAA **Type**: *Innovative solutions (new products/services/processes)* **Expected TRL (end of project):** *(If relevant)*	**Description:** The book "ValueCare Experience: A Pathway Towards a Value-Based Transition," is a versatile resource suitable for healthcare providers, policymakers, researchers, and students. It offers information on the ValueCare project, explains the value-based approach to healthcare and social care, and describes innovative solutions piloted in the project. Additionally, the book discusses the challenges and opportunities of implementing value-based care and gives practical advice for those considering its adoption in their organisations or regions. **Unique Value Proposition (UVP):** The ValueCare Book will be unique in the manual panorama for the VBHC adoption. Up to now after "Redefining health care" (M.E. Porter and E.Teisberg, 2006) and "Patient Priority", 2022 there are not book aiming for the VBHC adoption in the social care domain. The book will show not only the model creation and deplyment but also its adaptation in 7 disease and Country specific health social care frameworks. **Target user/customer/audience:** • Healthcare professionals • Policy Makers • Researchers and Students • Healthcare Administrators and Managers • Older people • Advocacy Groups **Benefits:** • Enhanced Knowledge and Skills • Policy Development and Reform • Research and Innovation • Care quality improvement • Sustainability of the welfare system **Short term exploitation (1 year after the end of the project):**

	• Materials readily available in both print and digital formats **Long term exploitation and preconditions:** • Webinar and public book presentations that will aim to foster and expand the debate and the awareness of the VBHC model potential form an European perspective

Name of result: Integrated ValueCare Platform	
Outcome: WP3 **LEAD Owner:** Vodafone Innovus **Type**: *Innovative solutions (new products/services/processes)* **Expected TRL (end of project):** *(If relevant)*	**Description:** The ValueCare integrated platform consists of an infrastructure enabling the interaction among the different components of the ValueCare system such as the web Dashboard, the mobile app and the virtual coach. It allows to interconnect such modules with the repositories in which patients' data are stored and maintained. **Target user/customer/audience:** • Healthcare Information Systems Integrators • Healthcare providers • Clinicians • Researchers • Patients • Caregivers • Health and Wellness Coaches **Benefits:** A main advantage of the ValueCare platform against other state-of-the-art solutions is the possibility to integrate in a one-stop-shop a series of healthcare services and tools in an accessible platform independently of the device manufacturers and specific solution providers.
Preliminary Participation Agreement	
Renounce Participation[7]	AfIC, AMC, FBK, VIDAVO, AGE, LAS NAVES
Active Participation[8]	KVC, EMC, UVEG, MEDRI, ISRAA
Passive Participation[9]	Vodafone Innovus AULSS2, UCD, IFIC, CDC

Name of result: Integrated ValueCare Platform MODULE 1 - Web Dashboard	
Outcome: Wp3 **LEAD Owner:** VIDAVO **Type**: *Innovative solutions (new products/services/processes)* **Expected TRL (end of project):** *(If relevant)*	**Description:** A dashboard for clinicians to register and monitor the patients' evolution in time, and the mobile app providing different self-tracking features and capable of hosting other components (such as the virtual coach for empowering patients on their self-management of prescribed health-related tasks). **Target user/customer/audience:** • Clinicians • Caregivers

	• Health and Wellness Coaches **Benefits:** ValueCare web dashboard allows health professionals to register and monitor the status of recruited patients for supporting their compliance with treatment.
Preliminary Participation Agreement	
Renounce Participation[10]	AfIC, AMC, Vodafone Innovus, FBK, CDC, AGE, LAS NAVES
Active Participation[11]	
Passive Participation[12]	KVC, EMC, UVEG, AULSS2, VIDAVO, MEDRI, UCD, IFIC, ISRAA

Name of result: Integrated ValueCare Platform - MODULE 2 - Mobile Health App	
Outcome: Wp3	**Description:** It provides access to various functionalities including browsing certified educational multimedia materials, access to clinical professionals, statistics about care path compliance and access to the personalised virtual coach. **Target user/customer/audience:** • Patients **Benefits:** The main benefit provided by the ValueCare Mobile App is that of empowering patients and their relatives/caregivers to continuously monitor and support patients for increasing the achievement of treatment compliance through awareness raising (i.e. through graphs, notes, etc.) and through system and user-initiated interactions delivered by the virtual coach component.
LEAD Owner: Vodafone Innovus	
Type: *Innovative solutions (new products/services/processes)*	
Expected TRL (end of project): *(If relevant)*	
Preliminary Participation Agreement	
Renounce Participation[13]	AfIC, AMC, FBK, VIDAVO, CDC, AGE, LAS NAVES
Active Participation[14]	Vodafone Innovus
Passive Participation[15]	KVC, EMC, UVEG, AULSS2, MEDRI, UCD, IFIC

Name of result: Integrated ValueCare Platform - MODULE 3 - Virtual Coaching Semantic-enabled Digital Solution	
Outcome: Wp3	**Description:** A personalised tool for interactive dialogues between the end-user and an AI-enabled coach integrating hybrid, knowledge-based (evidence-base content) and data-driven technologies (patterns of app usage) to support the achievement of a personalised care path. **Unique Value Proposition (UVP):**
LEAD Owner: FBK	
Type: *Innovative solutions (new products/services/processes)*	
Expected TRL (end of project): *TRL8*	

	Our ValueCare virtual coach offers a personalized and interactive tool that combines evidence-based content and data-driven technologies to support individualized care paths. By integrating AI and hybrid knowledge, patients can receive contextually relevant information to maximize their health outcomes and improve their experiences. The immediate transfer of existing bots to new regions and promotion of the virtual coach as a reusable component demonstrates our commitment to expanding access to quality care. In the long term, we aim to identify new clinical settings and enrich the virtual coach with novel technological approaches to continuously improve patient outcomes across various diseases and locations. **Target user/customer/audience:** • Patients • Caregivers • Health and Wellness Coaches **Benefits:** The ValueCare virtual coach is an innovative tool that surpasses the standard of care benefiting patients to obtain contextualised and timely information for maximising their health outcomes and experiences (PROMS and PREMS) through a dynamic, personalised bot adapting to assist on therapy compliance. **Short term exploitation (1 year after the end of the project):** In the short term, the ValueCare virtual coach will be exploited to transfer the existing bots (the ones defined for the different ValueCare pilots) to other regions (such as Trentino Province in Italy). Moreover, the exploitation will include the immediate promotion of the virtual coach as a reusable component into other systems and experimentations. **Long term exploitation and preconditions:** Longer term use of the ValueCare virtual coach will be exploited by identifying other potential clinical settings (i.e. other diseases, other locations) in which install and adapt the virtual coach module by enriching it with other novel technological approaches (i.e. including data-driven LLMs together with evidence-based content)
Preliminary Participation Agreement	
Renounce Participation[16]	AfIC, AMC, Vodafone Innovus, VIDAVO, AGE, LAS NAVES
Active Participation[17]	FBK
Passive Participation[18]	KVC, EMC, UVEG, AULSS2, MEDRI, UCD, IFIC, CDC, ISRAA

Name of result: Policy Recommendations	
Outcome: WP6	**Description:** Policy recommendations for scaling up ValueCare outcomes, as well as guidelines on policies to promote the
LEAD Owner: UVEG	

Type: *Innovative solutions (new products/services/processes)* **Expected TRL (end of project):** *(If relevant)*	implementation of the value. integrated care at the regional or national level. Policy makers can use these guidelines to promote the delivery of value-based integrated health and social care for older adults supported by digital solutions and anchored in a human rights-based approach. **Unique Value Proposition (UVP):** The unique value proposition of such policy recommendations lies in its comprehensive approach to addressing the complex needs of older adults in the context of health and social care delivery. It emphasizes a shift towards value-based care, focusing on outcomes that matter most to older adults, such as improved quality of life, functional independence, and overall well-being. Finally, these guidelines are informed by evidence-based practices and lessons learned from successful initiatives within ValueCare project, incorporating perspectives from a wide range of stakeholders, including older adults themselves, caregivers, healthcare providers, policymakers, and technology experts and recognizing the dynamic nature of healthcare systems. **Target user/customer/audience:** • Government Agencies and Policy Makers • Healthcare Providers • Health Insurance Companies • Advocacy Group and Policy influencers • Academic and Research Institutions **Benefits:** • Set the lead on monitoring and evaluation of quality of care • Support alternative payment models that reward high-quality care delivery • Enhance collaboration, coordination and communication mechanisms across sectors • Promote People Engagement and Empowerment • Focus on prevention and population health literacy • Improve working conditions, satisfaction and wellbeing of care providers and professionals **Short term exploitation (1 year after the end of the project)** • Encourage collaboration within pilot sites key stakeholders **Long term exploitation and preconditions:** • Encourage collaboration between government agencies, healthcare providers, payers, and advocacy groups to share best practices and resources. • Develop and communicate clear guidelines, standards, and incentives for healthcare providers to adopt value-based care models.

Annex 2. Example of Preliminary Participation Agreement

EXPLOITATION RIGHTS WAIVER AND ROYALTY WAIVER AGREEMENT

THIS AGREEMENT is made and entered into as of [DATE],

BETWEEN:

- PARTY A:
- PARTY B:
- PARTY C:
- [ALL PARTNERS OF VALUECARE PROJECT]

WHEREAS, the Project encompasses the collaborative development of innovative technologies, research, and initiatives, which may result in the creation of valuable products and intellectual property.

WHEREAS, it is anticipated that the Project will result in the development of a commercially viable product that may be exploited and commercialized;

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Partners agree as follows:

1. **Object.**

All partners hereby unanimously agree that the partners of ValueCare, especially [NAME OF PARTNER] is authorized to fully exploit, commercialize, and otherwise make use of the product resulting from the research conducted under the Project. This authorization encompasses all rights necessary for the development, marketing, and distribution of the said product.

Furthermore, each partner acknowledges and affirms their commitment to support and facilitate the successful exploitation of the resulting product, including but not limited to providing necessary information, cooperation, and assistance as reasonably requested by the Company.

This agreement is a binding commitment among the partners, and any dispute arising from or related to the exploitation of the resulting product shall be resolved in accordance with the dispute resolution mechanisms outlined in any relevant agreements, including but not limited to the Joint Owner Agreement.

2. **Waivers.**

Each partner in the project, of equal standing, has the option to choose between waiving their participation in the exploitation of the resulting product from the project or becoming part of the partners involved in such exploitation.

Any partner choosing to waive their participation in the exploitation should confirm this election in the corresponding section of present contract.

Partners who expressly waive their participation hereby acknowledge and agree that they shall have no claim, financial or otherwise, arising from the exploitation or commercialization of the resulting product.

3. **Participation in Exploitation.**

Partners who choose to participate in the exploitation shall be considered part of the group responsible for the commercialization and exploitation of the resulting product. Details regarding the roles, responsibilities, and remuneration for participating partners will be outlined in the Joint Owner Agreement.

4. **Binding Agreement:**

This Agreement constitutes a binding commitment, and any disputes arising from or related to the waiver of participation or involvement in the exploitation shall be resolved in accordance with the dispute resolution mechanisms outlined in any relevant agreements, including the Joint Owner Agreement.

5. **Signatures**

A. Waivers

B. Participants in Exploitation

Annex 3. Example of Joint Ownership and License Agreement

THIS JOINT OWNERSHIP AND LICENSE AGREEMENT (this "Agreement"), dated as of [DATE] and effective as of the Effective Date (as defined below), is made and entered into by and between

- PARTY A:
- PARTY B:
- PARTY C:

Collectively referred to as the "Co-Owners".

Preamble

WHEREAS, the parties to this Joint Ownership Agreement (the "Agreement") are collaborators and partners in a project funded by the Europe Horizon Fund (the "Project").

WHEREAS, the Project encompasses the collaborative development of innovative technologies, research, and initiatives, which may result in the creation of valuable products and intellectual property.

WHEREAS, certain partners involved in the development of the Project seek to ensure their ability to commercially exploit and derive benefit from the potential products or intellectual property generated during the course of the Project.

WHEREAS, this Agreement is intended to define the relationship, obligations, and rights among the partners of the Project who choose to be bound by its terms, as well as to clarify the status of those partners who choose not to sign this Agreement.

WHEREAS, it is the intention of the signing partners to safeguard their interests in a transparent and mutually agreeable manner.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, the parties to this Agreement hereby set forth their understanding and commitment as follows:

1. **Purpose of Agreement and definitions**

This Agreement is established to define the terms and conditions of co-ownership of a commercial venture. The specific product or object to be commercially exploited under this Agreement shall be described in Section 2.

Certain Defined Terms. The following capitalized terms used in this Agreement shall have the meanings set forth below:

(a) ***"Affiliate"*** means, with respect to a Party, any individual, company, organization or other entity that, directly or indirectly, is controlled by, controls or is under common control with such Party by ownership, directly or indirectly, of more than fifty percent (50%) of the stock

entitled to vote in the election of directors or, if there is no such stock, more than fifty percent (50%) of the ownership interest in such individual or entity.

(b) ***"Agreement"*** has the meaning set forth in the Preamble.

(c) ***"Confidential Information"*** means all source code and any confidential or proprietary documentation, in each case to the extent incorporated in any of the following.

(d) ***"Disclosing Party***" has the meaning set forth in Section 5.01.

(e) ***"Effective Date"*** means immediately prior to the Trigger Date (as defined in the Stockholders Agreement). For the avoidance of doubt, unless and until the Trigger Date occurs, and except as expressly agreed by the Parties in a separate written document signed by both Parties, neither Party will have, nor be deemed to have had, any obligations under the terms of this Agreement.

(f) ***"Intellectual Property"*** means all of the following, whether protected, created or arising under the Laws of Belgium or any foreign jurisdiction: (i) all inventions (whether patentable or unpatentable and whether or not reduced to practice), patent disclosures, industrial designs, all improvements thereto, and Belgium and foreign patents, patent applications (including all patents issuing thereon), statutory invention registrations and invention disclosures, together with all continuation applications of all types, including reissuances, restorations, divisions, continuations, continuations-in-part, revisions, extensions and re-examinations thereof, and all rights therein provided by international treaties or conventions; (ii) all European and non-E.U. copyrightable works (including copyrights in Software), design rights, database rights, all copyrights and applications, registrations and renewals in connection therewith, whether registered or unregistered; (iii) trade secrets, know-how and information that is proprietary and confidential. As used in this Agreement, the term "Intellectual Property" expressly excludes all European and foreign trademarks, service marks, trade dress, logos, trade names, Internet domain names, moral rights, designs, slogans and corporate names and general intangibles of like nature, whether registered or unregistered, together with all translations, adaptations, derivations and combinations thereof and other identifiers of source and including all goodwill associated therewith and all rights therein provided by international treaties or conventions, common law rights, applications, registrations, pending registrations, applications to register, reissues, extensions of the foregoing and renewals in connection therewith.

(g) ***"Law"*** means any European, national or local law constitution, treaty, convention, ordinance, code, rule, regulation, order, injunction, judgment, decree, ruling or other similar requirement enacted, adopted, promulgated or applied by a Governmental Entity.

(h) ***"Party" and "Parties"*** have the meanings set forth in the Preamble.

(i) ***"Person"*** means an individual, corporation, partnership, joint venture, association, trust, unincorporated organization, limited liability company or governmental or other entity.

(j) ***"Receiving Party"*** has the meaning set forth in Section 5.01.

(k) ***"Representatives"*** means, with respect to a Person, the Affiliates of such Person and the directors, officers, partners, employees, agents, consultants, contractors, advisors, legal counsel, accountants and other representatives of such Person and its Affiliates.

2. Description of the Product/Object

The product/object to be commercially exploited under this Agreement is described as follows:

[Insert detailed description of the product/object, including any unique identifiers or specifications.]

3. Co-Ownership Percentage

The Co-Owners agree to co-own the product/object specified in Section 2, with the following ownership percentages:

- Party A: [Specify ownership percentage, e.g., 50%]
- Party B: [Specify ownership percentage, e.g., 50%]

4. Responsibilities of the Co-Owners

Each Co-Owner shall have the following responsibilities:

[List the responsibilities of each co-owner, such as financial contributions, management, marketing, or any other relevant duties. SELECT OPTION OR ADD]

I. Financial Contributions:

Each co-owner agrees to contribute capital as specified in [Section/Exhibit] to fund the operations and expenses of the business or asset.

II. Management and Decision-Making:

- All major decisions concerning the business or asset, including but not limited to financial matters, marketing strategies, and significant operational changes, require unanimous agreement among the co-owners.
- Day-to-day management responsibilities shall be divided among the co-owners as follows: [Specify roles and responsibilities for each co-owner].

III. Operational Duties:

Co-owners agree to fulfill the specific operational duties and responsibilities assigned to them as detailed in [Section/Exhibit]. These responsibilities may include, but are not limited to, overseeing daily operations, managing employees, handling customer relations, or other relevant tasks.

IV. Financial Reporting:

Co-owners shall collectively ensure that accurate financial records are maintained. Regular financial reports shall be prepared and distributed to all co-owners on a [Specify frequency, e.g., quarterly] basis, providing a transparent overview of the business's financial health and performance.

V. Contributions of Expertise:

Each co-owner shall contribute their respective expertise, skills, and industry knowledge to the benefit of the business or asset. Co-owners shall collaborate to leverage their collective knowledge and capabilities to achieve the business's goals and objectives.

VI. ####

VII. Consequential and Other Damages.

Without limiting or expanding anything in the transition services agreement, neither party shall be liable to the other party for any special, indirect, incidental, punitive or consequential damages (provided that any such liability with respect to a third-party claim shall be considered direct damages) of the other party arising in connection with this agreement, whether arising from breach of contract, tort, negligence, strict liability or otherwise and regardless of whether such damages were foreseeable or the party against whom such liability is claimed has been advised of the possibility of such damages.

5. Confidentiality

5.01 Confidential Information:

Except as set forth in Section 5.02, each Party (as the "Receiving Party") shall keep all Confidential Information of the other Party (the "Disclosing Party") confidential and shall not disclose any such Confidential Information to any third party without the prior written consent of the Disclosing Party, except, under obligations of confidentiality no less restrictive than those set forth herein, to the Receiving Party's and its Affiliates' (a) third party service providers, solely for the purposes permitted by prior written consent (except with respect to customers) or, (b) other Representatives who have a "need-to-know" such Confidential Information and are authorized to receive such Confidential Information, or (c) legal counsel, accountants, auditors or lenders solely for the purpose of providing the applicable professional services to the Receiving Party or its Affiliates. The Receiving Party shall exercise at least the same degree of care to safeguard the confidentiality of the Confidential Information of the Disclosing Party as it does to safeguard its other proprietary or confidential information of equal importance, but not less than a reasonable degree of care.

5.02 Exclusions:

The confidentiality obligations in this Article V shall not apply to any Confidential Information which:

(a) is or becomes generally available to and known by the public (other than as a result of a non-permitted disclosure or other wrongful act or failure to act directly or indirectly by the Receiving Party or its Affiliates, or any Representatives acting on behalf of the Receiving Party or its Affiliates;

(b) is or becomes available to the Receiving Party on a non-confidential basis from a source other than the Disclosing Party or its Affiliates; provided that (i) the Receiving Party has no knowledge that such source was at the time of disclosure to the Receiving Party bound by a confidentiality agreement with the Disclosing Party or its Affiliates or other obligation of secrecy which was breached by the disclosure, and (ii) this clause (b) shall not apply to any source code for the Co-Developed PRODUCT;

(c) has been or is hereafter independently acquired or developed by the Receiving Party without reference to such Confidential Information and without otherwise violating any confidentiality agreement with or other obligation of secrecy to the Disclosing Party or its Affiliates; provided that this clause (c) shall not apply to any source code for the Co-Developed PRODUCT; or

(d) is required (by oral question, interrogatories, requests for information or documents, subpoena, civil investigative demand or similar process) to be disclosed by any Governmental Entity or pursuant to applicable Law; provided that the Receiving Party: (i) uses all reasonable efforts to provide the Disclosing Party with written notice of such request or demand as promptly as practicable under the circumstances so that the Disclosing Party shall have an opportunity to seek an appropriate protective order or other appropriate remedy; (ii) furnishes only that portion of the Confidential Information which is in the opinion of the Receiving Party's counsel legally required; and (iii) takes, and causes its Representatives to take, all other reasonable steps necessary to obtain confidential treatment for any such Confidential Information required to be furnished.

Section 5.03 Confidentiality Obligations:

Each Party shall ensure, by instruction, contract or otherwise with its Representatives that such Representatives comply with the provisions of this Section 5. Each Party shall indemnify and hold harmless the other Party and its Affiliates in the event of any breach by such first Party's Representatives of this Section. Each Party shall promptly notify the other Party in the event that the first Party learns of any unauthorized use or disclosure of such Confidential Information by it or its Representatives and shall promptly take all actions necessary to correct and prevent such use or disclosure.

6. Profits and Losses

SHALL NOT APPLY

7. Dispute Resolution

In the event of disputes or disagreements between co-owners related to the co-owned business or asset, the co-owners shall make a good-faith effort to resolve the matter through mediation or arbitration, as outlined in [Section/Exhibit]. If mediation and arbitration fail to reach a resolution, legal remedies may be pursued, as a last resort.

8. Term of Agreement

This Agreement shall remain in effect until terminated by mutual agreement of the Co-Owners.

9. Governing Law

(a) This Agreement shall be governed by and construed and interpreted in accordance with the Laws of Belgium.

(b) The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. Each Party agrees that, in the event of any breach or threatened breach by any other Party of any covenant or obligation contained in this Agreement, the non-breaching Party shall be entitled (in addition to any other remedy that may be available to it whether in law or equity, including monetary damages) to (i) a decree or order of specific performance to enforce the observance and performance of such covenant or obligation, and (ii) an injunction restraining such breach or threatened breach.

Severability. If any term or other provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or incapable of being enforced under any Law or as a matter of public policy, all other conditions and provisions of this Agreement shall nevertheless remain in full force and effect. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated by this Agreement be consummated as originally contemplated to the greatest extent possible.

Amendment. No provision of this Agreement may be amended or modified except by a written instrument signed by the Parties to this Agreement. No waiver by any Party of any provision hereof shall be effective unless explicitly set forth in writing and executed by the Party so waiving. The waiver by either Party of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any other subsequent breach.

10. Notices.

All notices, requests, claims, demands and other communications under this Agreement shall be in writing or electronic mail and shall be given or made (and shall be deemed to have been duly given or made upon receipt) by electronic delivery with receipt confirmed, delivery in person, by overnight courier service, by facsimile with receipt confirmed (followed by delivery of an original via overnight courier service) or by registered or certified mail (postage prepaid, return receipt requested) to the respective Parties at the following addresses (or at such other address for a Party as shall be specified in a notice given in accordance with this Section 6.06):

If to PARTY A and its Affiliates, to:

- Adress:
- ####
- Attention:
- Telephone:
- Email:

If to PARTY B to:

- Adress:
- ####
- Attention:
- Telephone:
- Email:

with a copy to (which copy will not constitute notice):

- Adress:
- ####
- Attention:
- Telephone:
- Email:

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed on the date first written above by their respective duly authorized officers.

Signature Page to Joint Ownership Agreement