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D10.1 Exploitation Plan for ADLIFE project

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Executive summary

The main goal of ADLIFE is to provide coordinated, anticipated and personalized integrated care to the elderly population with advanced chronic diseases. To achieve this goal, the ADLIFE toolbox containing various digital solutions will be developed and implemented.

The overall objective of WP10 is to maximize the exploitation of the innovative findings. This involves both non-commercial and commercial exploitation efforts. This deliverable presents the exploitation plan for the ADLIFE project.

We identified various conceptual models to guide the assessment of the innovation adoption and potential exploitation of the innovation findings. Various variants of the Damschroeder Implementation Science Framework and the HOT-FIT model were considered appropriate, as they require an assessment of Human, Organizational and Technological factors in relation to local/regional contexts to guide exploitation and scaling up of innovation findings. These conceptual models will guide the overall WP implementation.

Tasks of the WP include: T10.1 – identification of policy and regulatory frame-works/standards relevant to the introduction of ADLIFE, T10.2 – analysis of contextual factors relevant for the translation of the innovation action into routine practice, T10.3 – hosting of workshops with industry and SMEs to identify business opportunities, T10.4 – organization of hackathons to address opportunities and barriers to exploitation, T10.5 – developing business plans for the (commercial) exploitation of the innovation findings.

For the non-commercial exploitation, the key aim is to support health system changes towards more integrated care. Specific aims of non-commercial exploitation include adding value to on-going digital health innovation, research and health ecosystem transformation, improving efficiency and sustainability, creating and maintaining multi-professional health networks, demonstrating benefits of public-private collaboration and creating new direct collaboration with digital health industry.

In terms of commercial exploitation, ADLIFE aims to create new opportunities for companies in the digital health sector. Business models for digital health solutions will be generated addressing the heterogeneity of health systems in Europe. The ADLIFE digital toolbox/platform is going to be the main exploitable result as well as their components thereof (Personalized Care Plan Management Platform, Patient Empowerment Platform, ADLIFE Clinical Decision Support Services (CDSS)). Market size for such innovative tools is expected to grow significantly in the next years and ADLIFE will aim to access this market through its end users such as hospitals, healthcare payers, and pharmaceutical and biotechnology companies. Different business models, pricing and licensing strategies will be developed to address the needs of different partners and stakeholders.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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Introduction

1.1 Aim of the overall project

The main goal of ADLIFE is to provide coordinated, anticipated and personalised integrated care to the elderly population with advanced chronic diseases. This project focuses on people over 55 years of age suffering from chronic, acute diseases and a potential reduction of their life expectancy due to a drop in their functionality and capacities.

In order to achieve its goal, ADLIFE will develop and implement a toolkit containing various digital solutions that will integrate therapies and approaches which target early detection and assessment of deterioration and facilitate advanced and well-coordinated care planning and integrated supportive care to enhance quality of life, reduce suffering and accelerate recovery for patients and their families. The ADLIFE toolbox contains novel digital solutions such as a personalised care plan management platform, clinical decision support ser-vices, interoperability solutions and a patient empowerment platform with just-in-time adaptive intervention delivery engine.

1.2 Objectives of the Exploitation work package

The overall objective of this work package (WP) is to maximize the exploitation of the Innovation findings (the process experiences, outputs and outcomes of implementing the ADLIFE toolbox). The findings of ADLIFE have the potential to be scaled up from large scale pilots to routine practice; however, the translation of the findings requires a targeted effort. To achieve routine integration into clinical and managerial care, dissemination of the findings beyond the research and clinical community is needed with a focus on developing the business case for (commercial) exploitation. Tasks in this work package include:

- an analysis of relevant policy and regulatory frameworks/standards relevant for the introduction of the ADLIFE innovation findings in routine practice in different health care systems
- an analysis of contextual factors relevant for the translation of the Innovation action into routine practice
- organization of workshops to identify business opportunities resulting from the Innovation findings
- organization of hackathons to address opportunities and barriers to ADLIFE exploitation
- development of business plans for the exploitation of the research findings

The exploitation work package foresees two deliverables: D10.1 – a presentation of the exploitation plan for the ADLIFE project (due month 6) and D10.2 the business case for the innovation findings of the ADLIFE project (due month 48).

1.3 Objectives of this deliverable

The objective of this deliverable (10.1.) is to present the exploitation plan for the ADLIFE project, to define how research results will be implemented and how they will impact on the market, the future development and policy making.

This plan is based on the proposal in the grant agreement, a review of the literature on conceptual models reflecting pertinent areas for business exploitation and interviews with key project partners.

2 Overall approach to exploitation of the project outputs and outcomes

Due to the different nature of the partners participating in ADLIFE as well as of that of the results, the preliminary exploitation strategy will be different for the different types of organizations, since all of them expect to obtain different benefits and/or revenues from the exploitation of the different outcomes. The exploitation strategy will be twofold: (1) exploitation of the knowledge generated (non-commercial), and (2) exploitation of the results (commercial). In order to integrate the different exploitation perspectives, we propose to use a unifying framework rooted in implementation science.

2.1 Conceptual models underpinning exploitation

It is well known that interventions that succeed in one area can fail when applied to other contexts and settings. Indeed, it has been estimated that as many as two-thirds of change implementation initiatives fail (Burnes et al., 2004), with barriers manifesting at several levels (e.g. patient, organizational level, and market/policy levels) (Ferlie et al., 2001). Numerous frameworks have been developed to better understand the intricacies of adoption and implementation processes (Walker et al., 2003). Examples include the Conceptual Model for Implementation Effectiveness (Klein et al., 2001), Dimensions of Strategic Change (Pettigrew & Whipp, 1993), Conceptual Framework for Transferring Research to Practice (Simpson et al., 2002), and PRIME (Walker et al., 2003). Damschroder et al. (2009) drew on many of these models to develop the Consolidated Framework for Implementation Science (CFIR). These models are of great relevance to base the exploitation plan on prior theory and research evidence and gauge the extent to which exploitation might be hampered by external factors. Eventually, they support processes by which the technology readiness level (TRL) of tech-nologies and interventions can be managed and improved[1]. The majority of the ADLIFE tools are at current at TRL of 5-6 and it is the aim of the project to support evolving them to 7-8 levels. Through our implementation science perspective we will be able to analyse the implementation of ADLIFE tools in different health system contexts, which in turn provide key information that allows us to develop a sound "marketing strategy" and will allow to specify and differentiate our product in terms of: (i) better defining the characteristics and added value in real life settings, (ii) proposing different deployment approaches, modular or comprehensive, linked to pre-existing local systems, (iii) identifying estimated efficiencies and therefore potential economic benefits and orient pricing strategies,

[1] Technology readiness level in the EU (TRL: TRL 5 – Technology validated in relevant environment, TRL 6 – Technology demonstrated in relevant environment, TRL 7 – System prototype demonstration in operational environment, TRL 8 – System complete and qualified, TRL 9 – Actual system proven in operational environment

and (iv) defining advantages over other competing products that can be use in a promotion strategy.

Ultimately, it is the aim of the exploitation plan for the toolbox to continue to mature and reach TRL 9. From an implementation science perspective, ADLIFE addresses a large-scale pilot where the toolbox is scaled-up as a system prototype, the next step is full-scale implementation in a regional health system context. The IHI framework as displayed in figure 1 provides guidance on how to scale an improvement idea from small-scale testing to full scale-up.

Various factors will support or hinder going to full scale: adoption mechanisms (leadership, communication, social networks, culture of urgency and persistence) and support systems

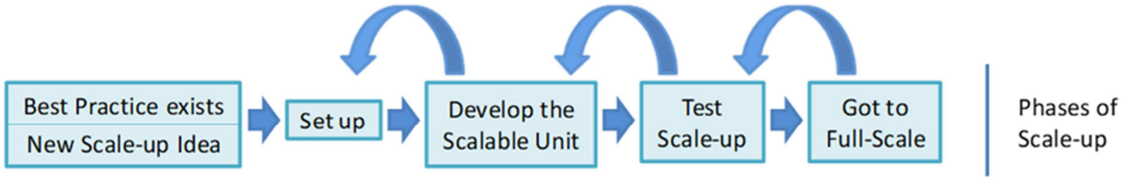

Figure 1- IHI Framework for going to full scale (Barker, 2015)

(learning systems, data systems, infrastructure, human capacity, capability of scale-up, sustainability).

Another central framework used in implementation science is Damschroder's (Damschroder et al., 2009) widely referenced ´Consolidated Framework for Implementation Research (CIFR) which proposes to assess context, in terms of existing or potential barriers and facilitators to successful implementation, using 5 key domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and implementation process. Fisher et al. (2016) further refined this framework by adding two elements: adoption of the innovation and impact of the innovation on health system performance (see Figure 2).

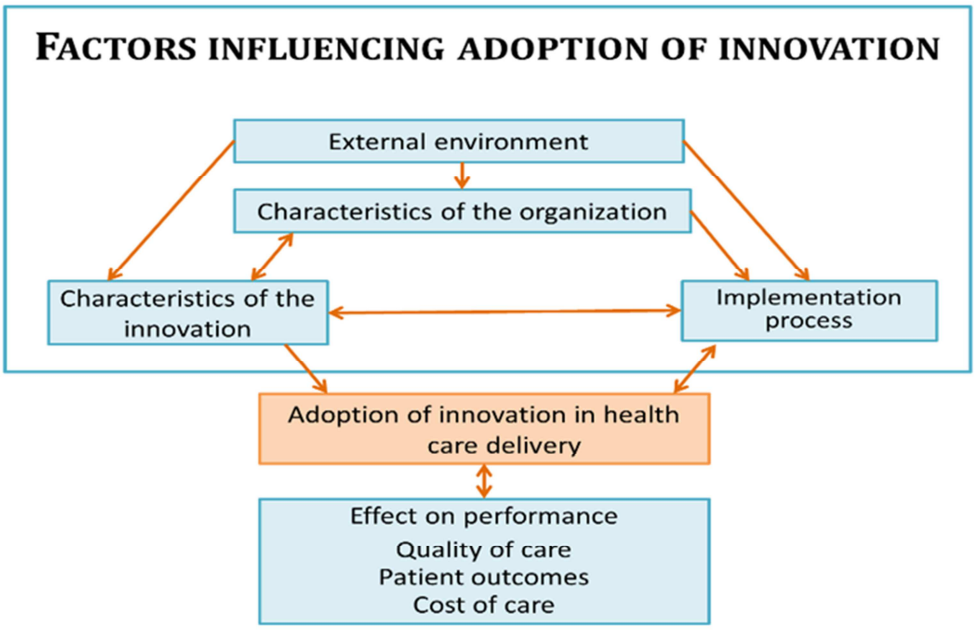

Figure 2. Fisher´s Framework to guide the adoption of innovations (Fisher 2016)

A limitation of these frameworks which are widely applied to health system innovations is that they are not sufficiently specific to capture the characteristic challenges associated with information technology (IT) innovations in health care. The field of information technology research itself has produced relevant frameworks that help specifying the broad scope of the implementation science frameworks, which provide an overarching reference to our understanding of the exploitation tasks.

Information technology value research has investigated how organizations justify and create value from IT investments (Kohli & Grover, 2008). This has in the past focused particularly on the detailing and measuring operational and financial value dimensions of IT (Melville, Kraemer, & Gurbaxani, 2004), often on a post-hoc basis, which contrary to the implementation science focus, to some extend introduces myopia regarding the contextual factors relevant to understand why an innovation was adopted or, indeed, why it failed. The literature from the IT field, however, also highlighted that value is not limited to a set of performance-related outcomes but that value can take a different form for different stakeholders, such as reputational, epistemic and platform value among others (Barrett et al., 2016) and puts a specific focus on human factors. All these foci are relevant for the exploitation planning of ADLIFE and will be integrated into an overarching framework. One well established model in the field is the HOT-fit model which addresses relationships between human, organizational and technological factors. The model and some of its variants are presented below.

HOT-Fit Model

The HOT-fit model (Human-Organization-Technology Fit) was published in 2008, based on multi-method approach, literature review and analysis of various use cases (primary care organization; digital Fundus Imaging System (FIS) for diabetic retinopathy, retrospective) (Yusof et al., 2008). It is based on the IS success model and IT organization Fit models and addresses the three dimensions: human, organization and technology. It is flexible in the sense that it can be applied to different settings at different times in the system life cycle.

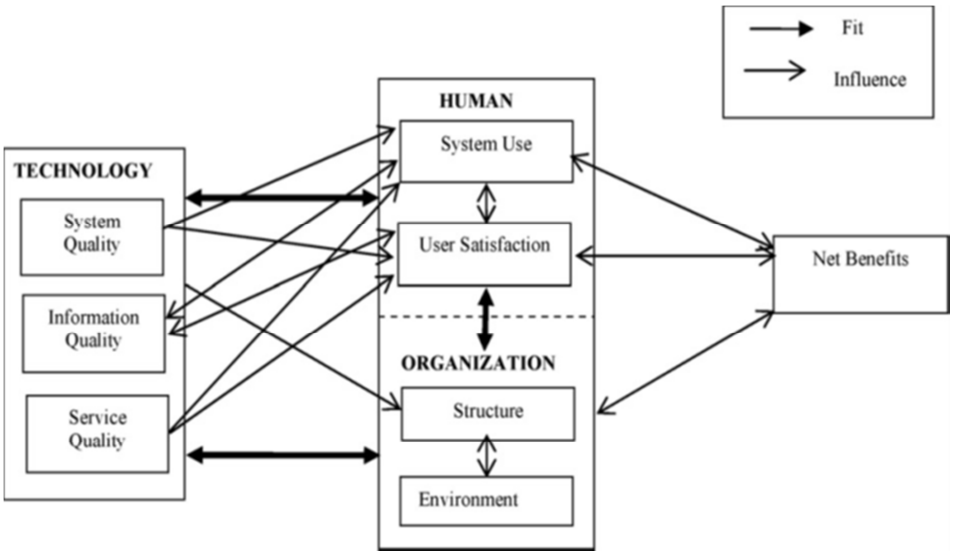

Figure 3. HOT-fit model

Model Fit between Individuals, Task and Technology (FITT Model)

The model "Fit between Individuals, Task and Technology" was published in 2006 based on work in Germany and Austria (Ammenwerth et al., 2006). It follows a similar development method (multi-method, literature review) and builds on a use case from the nursing documentation system at the University Hospital Heidelberg. It is based on the Technology Acceptance Model (TAM), the Task-Technology-Fit Model (TTF) and integrates the role of individuals (single persons or groups including attributes like ability, motivation, …), tasks (clinical tasks and processes, …) and technology. The model draws attention to the fit between two dimensions rather than a single dimension, can also be flexibly adapted to different settings and helps derive drivers and obstacles to IT adoption.

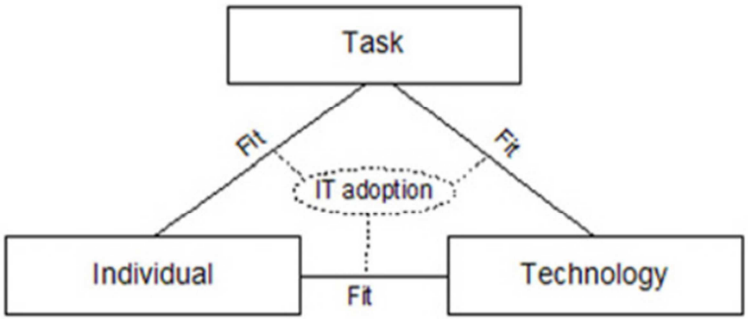

Figure 4. Fit between Individuals, Task and Technology Model

Fit between individuals, task, technology and environment model (FITTE Model)

An extension to above models is the "fit between individuals, task, technology and environment" model (Prgomet et al., 2019). The development process mimics the one of the models above, however, it integrates now the IS Success Model, the TAM (Technology Acceptance Model), the TTF (Task-Technology-Fit Model) and the FITT Model. Essentially, with the environment dimension it constitutes an extension to the FITT model and as such operationalizes environmental factors as temporal rhythms of a ward, infection control rooms, or space limitations as issues ultimately affected technology use. It also specifies a differentiation of "FIT" factors by groups (Doctor-Technology-Fit, Nurse-Technology-Fit).

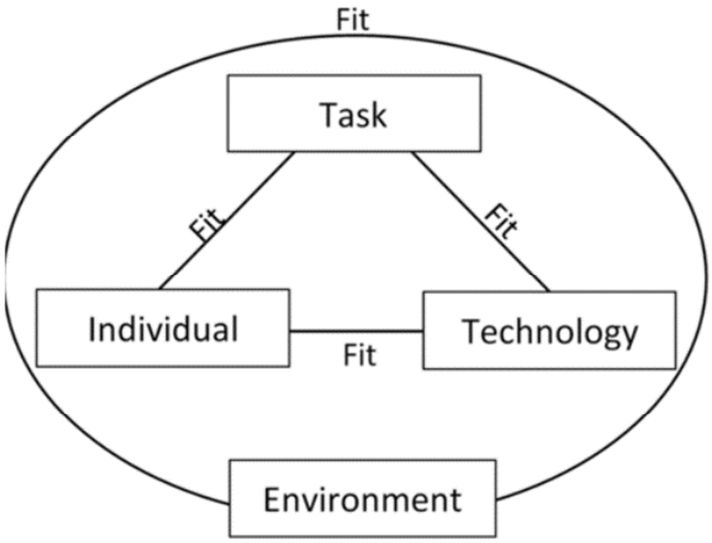

Figure 5. FITTE Model

Proposed conceptual model for ADLIFE exploitation framework

Based on the review of pertinent models, we propose a conceptual model for the ADLIFE exploitation that:

- is based on key findings from the adaption of innovations research as reflected in current implementation science frameworks
- recognizes key dimensions for successful adoption of innovations in the IT context, at least the human, technological and organizational factors and their fit to local contexts
- integrates the different benefits of innovation adoption as perceived by different stakeholders, such as reputational, epistemic and platform value
- considers for the commercial exploitation efforts the results from the implementation science and HOT-fit assessments
- enriches the above factors by broader policy dialogue and advocacy on the system benefits to be realized through the ADLIFE toolbox.

2.2 Tasks in the work package

The work package is based on five key tasks that build on each other and, augmented by the tasks of other work packages dissemination and evaluation provides the basis for both commercial and non-commercial exploitation.

The first task addresses the external environment and specific **policy and regulatory factors that govern the future introduction of the ADLIFE innovations**. For this task, policy and regulatory frameworks that influence the adoption of the ADLIFE tools will be monitored, including but not limited to frameworks and standards such as the European guidelines for cross-border exchange of patients´ health data (e.g. the European Electronic Health Record exchange format that recommends member states creating systems that enable EHRs to be securely accessed by citizens and securely shared within and between the different actors in the health system), Germanys national legislation on the introduction of patient portals in 2021, HTA standards on shared decision-making or PREMS, such as NICE QS15. Towards the exploitation phase of the project a comprehensive search of the scientific and grey literature will be conducted to identify relevant frameworks, including policies/frameworks and standards on patient empowerment, decision-support, eHealth/mHealth, health technology assessment. The search will cover the EU level but also specifically frameworks in the countries contributing clinical sites to this study: Spain, UK, Denmark, Poland, Germany, Sweden, Israel. We will analyse these frameworks and standards to gauge strengths, weaknesses, opportunities, and threats for the translation of the ADLIFE tools into routine practice.

The second task refers to factors below the regulatory factors at national level and addresses an **analysis of the contextual factors relevant for the translation of the innovation into routine practice**. We will also analyse and synthesise the contextual and implementation factors that influence the uptake and effectiveness of ADLIFE tools in different large-scale clinical pilot sites. We will explore adoption using the innovation framework described by Fisher et al (2016), which differentiates between external environmental factors, characteristics of the health organisation or health system, characteristics of the innovation or intervention, and the implementation process. Combined, these factors determine the adoption of innovations in healthcare and their effects on patient outcomes and the quality and costs of care. To gather the data re-quired, we will conduct interviews with the pilot site leaders and key staff, conduct documentary analysis and analyse health systems locally in terms of staffing, technology level, organization and

financing. This task is expected to provide a baseline assessment at the time of the start of the pilot test followed by a post assessment after the finalization of the pilot.

As a third task, we will turn to industry and SMEs to identify current status of digital health implementation and to **identify business opportunities resulting from the innovation findings, but also from industries and SME´s market assessment**. Workshops will be organized with industry, pharma, and SMEs to deepen understanding of how the ADLIFE tools could be embedded in the value chain and to assess commercial and non-commercial issues surrounding market exploitation, such as competition and procurement procedures. Three workshops will be conducted at EU project level with representatives from SMEs from all countries contributing clinical sites as well as participants representing the larger international eHealth industry environment.

A fourth task addresses **opportunities and barriers to exploitation through the organization of hackathons**. Two hackathons will be organized to address obstacles associated with research exploitation. A hackathon is an event in which software designers and developers come together and intensively work on a project. We will aim to draw young researchers and healthcare managers together to work on an interdisciplinary team to address very specific problems (resulting from the obstacles to implementation, as identified by experts and user groups, see tasks 10.1./10.2/10.3.) with the overall aim of developing solutions for the integration of ADLIFE tools into daily clinical practice.

A last task, which **integrates the assessment of regulatory, external, and context factors and which incorporates the findings from workshops with industry and the feedback from the hackathons will be the development of business plans for both commercial and non-commercial exploitation of the innovation findings**. Our business plans will address diverse market contexts and risks according to: Characteristics of national, regional, and local health systems (tax or insurance-based…), Characteristics of the market (open or highly regulated, extent of competition…), Purchasing arrangements (procurement and commissioning). Business plans will address national, regional and local health systems and provide a clear case for investment, specifying the prerequisites for implementation. To facilitate this process, we will use the Business Model Canvas, a lean management template for developing new business models that charts key elements of business proposals, such as key partners, key activities, value proposition, customer relationships, customer segments, key resources and channels. The aim is to generate a business case that demonstrates why a regional authority, health care provider or statutory health insurance company should invest in the technology as proposed in this project. Figure 6 (next page) shows a first working document for a business model. The final business canvas templates will be prepared after the analysis of regulatory frameworks and contextual factors and the workshops with the consortium members/members of industry, pharma and SMEs and will also incorporate output from the intellectual property assessment and hackathons. A business canvas template will be produced for each of the clinical sites/participating countries, supported by detailed documentation on the respective business proposals.

Business Model Canvas – ADLIFE Project

Key Partners
- RTD-Innovation agent **(KRONIKGUNE)**
- Regional health care providers **(AMCA, FALKHOSP, OUH, OSAKIDETZA, Maccabi Healthcare Services, RJH, NHSL Lanarkshire, Werra-Meißner Kreis)**
- Distribution partners **(OptiMedis AG, STRAT)**
- **Data managment experts (I~HD)**
- ICT and E-health experts **(SRDC, CWARWICK, EVERIS)**
- Personalized care delivery experts **(RJH)**

Key Activities
- Provison of coordinated, anticipated and personalised integrated care
- Development and adaption of multi-morbidity care pathways
- Adaption and implementation of ICT components for collaborative and integrated care (ADLIFE toolbox)

Key Resources
- Partners' expertise in large-scale deployment in national/regional settings
- Background IP of University of Warwick, SRDC (C3 Cloud integrated care approach; CDSS, PCPMP, Intelligent Communication Engine)
- Experience in CRISP-DM (EVERIS)

Value Propositions
- Improved health outcomes and quality of life for elderly people with advanced chronic diseases (especially COPD and CHF) and reduction the socio-economic burden
- International implementation of integrated care with ICT support
- Improved cooperation and communication between health, social and informal care givers
- Support multi-morbid patients in active health self-management
- Provision of evidence for decision-making on stimulating, using and/or funding digital health strategies at various levels in the health care system as well as in supporting the sustainability of health systems by optimizing the available resources
- Increase product /service range for industry costumers

Customer Relationships
- Retentive relationship based on providing tailored information for each specific need through ADLIFE toolbox

Channels
- Social media
- Partner websites / portfolio
- Publication in scientific journals
- Presentation of project results at international conferences
- Knowledge transfer to healthcare professionals in training programs
- Multiprofessional health networks

Customer Segments
- Policy makers and healthcare payers
- Healthcare professionals
- Patients
- E-health industry
- Researchers / Research communities
- Guideline / pathways developers
- Regional / national bodies responsible for health and social care (pilot sites)

Cost Structure
- Personnel (Research & Development & Innovation)
- Exploitation and IPR Management
- Integration and Deployment of ADLIFE toolbox
- Communication/ Marketing experts
- Maintenance & indirect costs

Revenue Streams
- During project time: EU funding and partner resources
- Post project time:
  - Fees from payers for customisation, integration and deployment of the ADLIFE toolbox
  - Specific contracts with e-health solutions industry (different pricing models)

Figure 6. Business Model Canvas for ADLIFE Project (working document)

3 Impact to be realized through innovation exploitation

3.1 Non-commercial exploitation

For the non-commercial exploitation, the following key impacts will be pursued[2]:

Overall:

- change model of healthcare provision (integrated care), enhance integrated care educational offer

Specific:

- attaching added value to on-going digital health innovation, research and health ecosystem trans-formation
- create and maintain multi-professional health networks
- demonstrating that public-private collaboration for the creation of new solutions for healthcare services is possible and can generate new business opportunities for companies and optimizing re-sources
- improving quality and efficiency of healthcare, increasing sustainability and reducing opportunity costs
- create new direct collaboration with digital health industry.

For the predominantly non-commercial exploitation partners (KRON, STRAT, OUH, FALK) specific exploitation aims have been defined. KRONIKGUNE aims to transfer the know-how of the innovation findings directly to the training programs for Osakidetza healthcare professionals and include the ADLIFE toolbox potentially in the portfolio of Osakidetza´s healthcare services. STRAT has significant know-how in digital health, health analytics and health interventions as well as business analysis in health developments and will transfer the innovation findings to generate new publications, projects, collaborations, attract new students and bring pioneering ideas and knowledge to students that will impact their academic work (PhD dissertation, post- Doc, papers) along with the practical experience obtained. OUH, FALK, RJH, AMCA are experts in the management of chronic diseases in their corresponding regions and ADLIFE project will enhance their capabilities in changing the actual model of care into an integrated one.

[2] this section reports selected impacts relevant for the exploitation efforts, a full list of expected impacts is described in the grant agreement

3.2 Commercial exploitation

As it is described in WP10, exploitation of ADLIFE digital tools is a must for the project but also the creation of new opportunities for other companies in the digital health sector due to the nature/complexity of the health sector (interoperability, fragmentation, access, reimbursement). Business models for digital health solutions will be generated based in the experience of the consortium where industrial partners (EVERIS; SRDC and OPTIMEDIS) have previous experience and will establish an open dialogue (technical collaboration included) with healthcare systems from the seven participant regions including the project central IT supports team from the corresponding health systems. Given the heterogeneity of health systems in Europe, our business plans will address diverse market contexts and risks.

ADLIFE digital toolbox/platform is going to be the main exploitable result as well as their components thereof (Personalized Care Plan Management Platform, Patient Empowerment Platform, ADLIFE CDSS). For the exploitation of the complete solution EVERIS will reach exploitation agreements not only with the participating pilot sites for the future exploitation but also with SRDC to include its patient empowerment and chronic disease management platform in EVERIS´s portfolio.

Exploitable results

R1 ADLIFE Toolbox/Platform: will belong to all partners and EVERIS will lead the exploitation strategy and will reach the corresponding agreements with the participant partners (intellectual property rights (IPR) management, WP10). **EVERIS will exploit the results of the project across EVERIS´s presence at 16 countries** around the world, especially on health. **EVERIS has a wide experience in developing and commercializing Big Data and Artificial Intelligence solutions in different sectors but health is one of the most important**. Therefore, the important market capabilities of EVERIS will contribute to the exploitation activities. In addition, EVERIS will contribute to the business perspective of the health sector where **the company has a deep knowledge of** customers' requirements. The characteristics of ADLIFE platform **will take benefit of this expected increase ratios and EVERIS will use its network and partnerships agreements in Europe trying to translate this numbers to concrete sales** that will be included in the exploitation results of the project (WP10).

R2 ADLIFE CDSS: will belong to EVERIS, SRDC and WARWICK who will develop three different types of CDSS in collaboration (SRDC and WARWICK will focus on CDSSs for guideline suggestions while EVERIS will focus on CDSSs for early warning systems and scored assessments). EVERIS aims to include the three CDSS tools in their portfolio. **The exploitation actions will be focused on delivering ADLIFE CDSS to the market**. Basically, the expected impacts described at the beginning of this section will be accomplished if certain exploitation actions are also fulfilled. The relation between exploitation actions and their associated impacts can be depicted as it is shown in the following.

- Identification of related stakeholders and data sources
- Definition of the project's value proposition
- IP scouting, assessment and protection
- Presentation at specific venturing and industrial meetings, and other marketing activities
- Project's tests in relevant environment - data gathered and released

R3 ADLIFE PCMP and PEP will belong to SRDC that will extend their chronic disease platform. These chronic disease management services will include a variety of services, such as multidisciplinary care, guidelines for the self-management of the chronic disease condition, and guidance for healthy behavioural change, to in-crease patient empowerment. After these pilot studies in ADLIFE, SRDC will approach regional and national health services providers, public and private payers all over the Europe through the local partnerships it aims to establish (5-8 per year). Two of the first partnerships will be through EVERIS in Spain and OPTIMEDIS in Germany.

SRDC will initially utilize the extended dissemination channels of ADLIFE identified in Section 2.1.1.1 to reach potential customers. The **envisioned licensing strategy is yearly subscription fees**, which includes initial deployment, localization, integration with local systems. SRDC aims to cooperate with other technical partners of ADLIFE in this process (EVERIS and WARWICK) to propose an end-to-end solution. It is estimated that the cost of these initial deployment activities will be compensated after two years subscription, starting from third year we aim to obtain revenue from each deployment site. SRDC aims to provide these tools for the use of ADLIFE pilot partners without any license fee, will only ask for maintenance fees when technical support or extension is required by pilot sites.

4 Challenges for the work package that will be continuously addressed during project implementation

4.1 Rapidly changing landscapes for health care delivery and supply of digital tools

The exploitation efforts of the ADLIFE toolbox is heavily dependent on the rapidly changing landscape of EU health service delivery systems and market entry and implementation of digital tool sets. Whilst health care reforms have been in the past more characterized by incremental reforms, the COVID-19 crisis has and will have significant impact on the way services are provided in the future. Digital tools in particular have seen much higher degree of acceptance by health care providers and patients alike and will benefit from facilitated market entry.

For the non-commercial exploitation it will thus remain paramount to monitor relevant legislation and regulation at EU and national level to assess the extent to which ADLIFE tools may be incentivized and implementation in EU countries. For example, legislation to mandate a patient portal in countries participating in the ADLIFE pilots has direct implementation for the scope of the ADLIFE toolbox and efforts to ensure interoperability.

For the commercial exploitation, legislation as in the example above, would have direct implications for the entry of competitors in the target market and for the pricing model suggested for business exploitation. We will therefore continue to monitor regulation and the digital provider market as described under tasks in this work package to ensure maximum exploitability of ADLIFE findings.

For both commercial and non-commercial exploitation ADLIFE will need to be sensitive to different health system contexts where general financing policies (tax/insurance based, fee for service/capitation models), digital health maturity (low maturity: low level of digital health innovation and adoption, high maturity: cut-ting edge of digital health deployment), professional policies (supporting interdisciplinarity, supporting use of PROMs) have a considerable effect on the opportunities for ADLIFE exploitation.

4.2 Lack of value-based reimbursement and/or budgeting framework to incentivize ADLIFE implementation

Most health care systems in the EU still fund and/or reimburse health services based on history budgetary costs, diagnostic codes or procedures conducted in specific institutional settings. Such funding and reimbursement services are appropriate for the treatment of discrete episodes or therapeutic interventions for single diseases; however, they have been proven to be inappropriate to incentivize best care for patients with chronic diseases and multimorbid patients. Digital innovations such as the ADLIFE toolbox require an integrated

care implementation and reimbursement framework that incentivizes investments in community-oriented interventions and cross-institutional digital tools and work processes.

Value-based or population-based integrated care contracts facilitate funding and reimbursement and incentivization of the ADLIFE tools because they focus on overall health system impact, rather than micro-efficiency of institutional settings as clinics or hospitals. In tax-based or single insurance health systems the central purchaser may overcome this role. In competing health insurance contexts incentivization of population-based tools may be more challenging. In such contexts, population-based integrated care contracts can facilitate implementation and reimbursement of the ADLIFE tools. Such contracts are not restricted by an institutional perspective (costs to primary care, costs occurred in secondary care, social care costs etc.) and innovative technologies that improve outcomes while reducing overall health system expenditure might thus be implemented, even though a single institution might be disadvantaged. Given the overall direction for health systems development provided by OECD and WHO, population-based outcome and costs assessment is crucial to stimulating the uptake of innovations.

A business plan or pricing model ignoring health system reimbursement policies may therefore not be convincing for purchasers to invest in the ADLIFE toolbox. These issues should therefore be reflected on in the non-commercial exploitation and policy exploitation contexts of the project.

4.3 Ensuring appropriate definition of background and foreground IP to support exploitation

Since ADLIFE is based on IP used in the C3 Cloud Project, definitions on background and foreground IP are important. Especially for the exploitation of the results clear definitions of background IP are necessary. According to the consortium agreement Version 1.0, 2020/02/14 no background IP (data, know-how or information) of Asociación Instituto de Investigación en Servicios de Salud-Kronikgune (Party 1), Assuta Ashdod Ltd (Party 8) and EVERIS Spain SL (Party 10) is needed for implementation of the project or exploitation of the results.

Regarding the University of Warwick (Party 3), the following background IP is identified and agreed for use in ADLIFE:

- Technical Interoperability Service (TIS) (from the C3 Could Project; shared IP)
- Terminology Server
- Structural mapping service (from the C3 Could Project; shared IP)
- Clinical Decision Support Service (from the C3 Could Project; shared IP)
- Coordinated Care and Cure Delivery Platform (from the C3 Could Project; shared IP)
- Comprehensive Unified Research framework (CURe)
- Query model from the TRANSFoRm project
- TRANSFoRm Query Workbench
- Extension of the CDISC SDM/ODM (as part of the TRANSFoRm project)

Regarding SRDC (Party 9), the following background IP is identified and agreed for use in ADLIFE:

- Coordinated Care and Cure Delivery Platform (C3DP)
- CDS Development Software Library and a set of CDS Services
- eSaglikKaydim Personal Health Record System
- Intelligent Just in time Adaptive Interventions (JITAI) Delivery Engine
- onFHIR HL7 FHIR® Based Secure Data Repository
- onAuth Security and Privacy Framework
- Terminology Server maintaining widely used terminology systems (e.g. SNOMED-CT, ICD-10, MedDRA)

All mentioned background IP may be subject to license and fee.

Together with EVERIS we will further assess IP issues and consider following models:

1. **Joint exploitation of ADLIFE:** An exploitation entity (a partner, a third party or even an external organization) tries to commercialize the solution and pays yearly royalties to the rest of the partners. In this sense payments were distributed depending on profit or non-profit organizations, giving a higher percentage to profit organizations due to the difference of payments received from the European Commission (100% for non-profit and 70% for profit organizations).
2. **Individual use of assets created by each partner:** Each partner can use or commercialize the components created by themselves.
3. **Safeguards** to use the system by pilot sites and non-profit partners to define the use of the global solution or some of its components and to regulate to access to the source code of foreground IP in order to facilitate maintenance.

In relation the IPR, the following will be considered:

4. **Joint exploitation of ADLIFE** - the agreement of the partners on how to use each assets resulted from the project;
5. **Individual project assets** - definition of each of the components and their owners that can be exploited at an individual level by its owner;
6. **Safeguards in relation to use of the system by clinical partners** - that define the right of use of the solution by the project clinical partners after the project termination;
7. **Safeguards on access to source code by clinical partners** - that regulates the right of access to the source code of foreground IP by the clinical partners.

Irrespective of the points above, the consortium will assess whether in case of commercial exploitation efforts license payments are required to NICE as it NICE guidelines were used to build algorithms underlying the ADLIFE toolbox[3].

4.4 Maximizing educational exploitation based on project findings

An important element of the non-commercial exploitation is the educational exploitation on the project findings. This includes to disseminate the project results among a wide range of scientific media including publications in high quality peer-reviewed journals in the area of digital health data, integrated care and clinical management of chronic diseases. Project results will also be presented at international high-impact fairs and technical/scientific conferences.

As for the academic partners (KRON, OUH, FALK, RJH, AMCA), the ADLIFE toolbox including its technologies and implementation-related factors will be used in the training of new healthcare professionals, to enhance knowledge about innovative digital health services in integrated care and to foster their use.

4.5 Ensuring leverage on ongoing policy debates on digital agenda in Europe

To ensure leverage on ongoing policy debates on digital agenda in Europe, workshops with partners involved in relevant high level national and EU level committees of the industry, pharma, and SMEs will be conducted to deepen understanding of how the ADLIFE tools could be embedded in the value chain and to assess commercial and non-commercial issues surrounding market exploitation, such as competition and procurement procedures. Furthermore, hackathons will be held to address opportunities and barriers to ADLIFE exploitation and a final conference will be organized to communicate and disseminate the study findings, targeting key stakeholders including patients, clinicians, business and policy makers. To demonstrate the value and impact of ADLIFE from a policy perspective, policy briefs will be composed to enhance the communication with policy makers. After formal closure of the ADLIFE project, further plans will be made to ensure the use and sustainability of the project results.

[3] NICE – using our content outside the UK: https://www.nice.org.uk/about/what-we-do/international-services/using-our-content-outside-the-uk

5 References

Ammenwerth, E., Iller, C., Mahler, C. IT-adoption and the interaction of task, technology and individuals: a fit framework and a case study. BMC Medical Informatics and Decision Making. 2006; 6(3).

Barker, P.M., Reid, A., Schall, M.W. A framework for scaling up health interventions: lessons from large-scale improvement initiatives in Africa. Implementation Science. 2015; 11(12).

Damschroder, L.J., Aron, D.C., Keith, R.E., Kirsh, S.R., Alexander, J.A., Lowery, J. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implementation Science. 2009; 4(50)

Ferlie, E.B, Shortell, S.M. Improving the quality of health care in the United Kingdom and the United States: a framework for change. The Milbank Quarterly. 2001; 79(2):281-315.

Fisher, E.S., Shortell, S.M., Savitz, L.A. Implementation Science: A Potential Catalyst for Delivery System Reform. JAMA. 2016; 315(4):339-340.

Klein, K.J., Conn, A.B., Sorra, J.S. Implementing computerized technology: An organizational analysis. Journal of Applied Psychology. 2001; 86:811–824.

Kohli, R. & Grover, V. Business Value of IT: An Essay on Expanding Research Directions to Keep up with the Times. Journal of the Association for Information Systems. 2008; 9(1).

Melville, N., Kraemer, K., Gurbaxani, V. Review: Information technology and organizational performance: An integrative model of IT business value. MIS quarterly. 2004; 28(2): 283-322.

Pettigrew, A., Whipp, R. (1993). The Dimensions of Strategic Change. Managing Change for Competitive Success. Blackwell Publishing.

Polykarpou S, Barret M, Oborn E et al. Justifying health IT investments: A process model of framing practices and reputational value. Information and Organization 2018: 28(4):153-169

Prgomet, M., Georgiou, A., Callen, J., Westbrook, J. Fit Between Individuals, Tasks, Technology, and Environment (FITTE) Framework: A Proposed Extension of FITT to Evaluate and Optimise Health Information Technology Use. Studies in Health Technology and Informatics. 2019; 264:744-748.

Quinn K. The 8 basic payment methods in health care. Annals of internal medicine 2015; 163:300-6

Simpson, D.D. A conceptual framework for transferring research to practice. Journal of Substance Abuse Treatment. 2002; 22(4):171-182.

Stokes J, Struckmann V, Kristensen SR, Fuchs S, van Ginneken E, Tsiachristas A, Rutten van Mölken M, Sutton M. Towards incentivising integration: A typology of payments for integrated care. Health Policy. 2018 Sep;122(9):963-969.

Walker, A.E., Grimshaw, J., Johnston, M., Pitts, N., Steen, N., Eccles, M. PRIME--PRocess modelling in ImpleMEntation research: selecting a theoretical basis for interventions to change clinical practice. BMC Health Service Research. 2003;3(1):22.

Yusof, M.M, Kuljis, J., Papazafeiropoulou A., Stergioulas L.K. An evaluation framework for Health Information Systems: human, organization and technology-fit factors (HOT-fit). Journal of Medical Informatics. 2008; 77(6):386-398.

Vagnani G, Gatti C, Proietti L. A conceptual framework of the adoption of innovations in organizations: a meta-analytical review of the literature. Journal of Management and Governance 2019; 23: 1023–1062