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D8.1 ADLIFE Deployment Plans

Deliverable No.	D8.1	**Due Date**	30 June 2022
Description	This deliverable describes the process and interim outcomes of the development of the plans for the deployment of the ADLIFE pilot in all of the pilot sites. It delineates the objectives of the deployment plans, and the methodology used within the consortium for developing the plans for deployment at both the overall project level as well as the individual pilot site level.		
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Authors

Name and surname	Partner name	e-mail
Rachelle Kaye	AMCA	rachellek@assuta.co.il
Dolores Verdoy Berastegui	KRONIKGUNE	dverdoy@kronikgune.org
Bárbara López Perea	KRONIKGUNE	blopez@kronikgune.org
Ana Ortega	KRONIKGUNE	aortega@kronikgune.org
Esteban de Manuel Keenoy	KRONIKGUNE	edemanuel@kronikgune.org
Fritz Arndt	GWMK	f.arndt@gesunder-wmk.de
Anne Dichmann Sorknæs	OUH	anne.dichmann.sorknaes@rsyd.dk
Thea Damkjær Syse	OUH	thea.syse@rsyd.dk
Anna Hestner	RJH	anna.hestner@regionjh.se
Marie H. Sherman	RJH	marie.holm.sherman@regionjh.se
Lisa McCann	USTRATH	lisa.mccann@strath.ac.uk
Roma Maguire	USTRATH	roma.maguire@strath.ac.uk
Morven Miller	USTRATH	morven.miller@strath.ac.uk
Timothy Robbins	UHCW	timothy.robbins@uhcw.nhs.uk
Dipak Kalra	I~HD	dipak.kalra@i-hd.eu
Omar Khan	WARWICK	m.o.khan@warwick.ac.uk

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Abstract

The objective of the ADLIFE project is to improve the quality of life of senior people with Advanced Chronic Diseases, specifically advanced congestive heart failure and advanced chronic obstructive pulmonary disease, by providing innovative integrated intelligent personalized care. ADLIFE will conduct a large-scale deployment of digitally enabled holistic and integrated supportive care in seven healthcare systems in six countries. The purpose of Deliverable 8.1 is to describe the process and interim outcomes of the development of the plans for the deployment of the ADLIFE pilot in all of the pilot sites. This deliverable delineates the objectives of the deployment plans, and the methodology used within the consortium for developing the plans for deployment at both the overall project level as well as the individual pilot site level. The core instrument for guiding the deployment plans and preparation has been a Project level Standard Operations Manual (SOP) which has served as the basis for developing local operations manuals (MOPs) in each pilot site. These provide the guidelines for the preparation, implementation, monitoring, evaluation and termination of the pilots. Major issues and challenges identified by the pilot sites in preparing the plans for deployment are addressed. A monitoring process has been established for tracking and documenting every step of the process, identifying problems and how they are resolved that will support joint problem solving and will also serve as a basis for lessons learned to enable scaling and transferability.

Statement of originality

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1 Executive summary

The purpose of Deliverable 8.1 is to describe the process and interim outcomes of the development of the plans for the deployment of the ADLIFE pilot in all of the pilot sites. This deliverable delineates the objectives of the deployment plans, and the methodology used within the consortium for developing the plans for deployment at both the overall project level as well as the individual pilot site level. Major issues and challenges identified by the pilot sites in preparing the plans for deployment are also addressed.

The over-arching societal challenge addressed by ADLIFE is to improve the quality of life of senior people with Advanced Chronic Diseases, specifically advanced congestive heart failure and advanced chronic obstructive pulmonary disease, by providing innovative integrated intelligent personalized care. ADLIFE will conduct a large-scale deployment of digitally enabled holistic and integrated supportive care in seven healthcare systems in six countries. The ADLIFE ICT Toolbox solutions will be integrated and scaled in the actual ICT health systems participating in the intervention.

The 7 pilot sites are very diverse and include countries with centralized and decentralized Beveridgian healthcare systems as well as countries with Bismarkian healthcare systems. In some, physicians are employed by the healthcare system whereas in others, some or all of the clinicians are independent self-employed practitioners with a contract with some level of the healthcare system. The pilot sites are: Gesunder Werra-Meißner Kreis-(GWMK) In Germany, Odense University Hospital (OUH) in Denmark, Region Jämtland Härjedalen (RJH) in Sweden, Osakidetza, Basque Country in Spain, NHS Lanarkshire, Scotland UK, Assuta Ashdod Hospital and Maccabi Southern Region in Israel, and University Hospitals Coventry & Warwickshire NHS Trust, England UK.

The ADLIFE pilots will operate for 12 months during which time the ADLIFE processes, care pathways and digital solutions will be deployed in each of the pilot sites in caring for 126 patients in each site. The main objectives of the intervention are:

- To change the traditional care models for chronic patients with advanced chronic disease by integrating unconnected care tasks performed in different levels and settings
- To facilitate better communication and coordination among all of the professionals caring for each patient with particular emphasis on coordination between hospital staff and primary and community care
- To facilitate a more active role of patients and caregivers in managing their own health and symptoms
- To provide collaborative tools to create personalized care plans for multidisciplinary care team members
- To implement intelligent tools for clinical decision-making support
- To securely access, process, share and store patient’s data in electronic health records along with other patient generated data
- To deploy the new tools in hospitals and/or clinics and/or primary care centres in seven different European and associated regions.
- To assess the effectiveness of the intervention

Work Package 8, and particularly Task 8.1-Preparing the plans for Deployment of the ADLIFE intervention in the pilot sites - brings together the work of all of the other work packages which have been dedicated to the development of all of the tools and processes that will be deployed in the ADLIFE pilots. The objective of the task is to develop the plans and make all of the

preparations for implementing the ADLIFE pilots in all pilot sites including timelines and deadlines. The methodology used has been a joint collaborative process resulting in a common high level deployment approach while enabling each pilot site to adapt the approach to meet its unique needs, and constraints.

The core instrument for guiding the deployment plans and preparation has been a Project level Standard Operations Manual (SOP) which has served as the basis for developing local operations manuals (MOPs) in each pilot site. These provide the guidelines for the preparation, implementation, monitoring, evaluation and termination of the pilots.

The process of developing the MOPs has brought to light issues and challenges, particularly in a healthcare climate strongly influenced by the COVID pandemic, that have been discussed and jointly analysed. Examples include: obstacles to recruiting healthcare professionals, particularly in primary care, realistic expectations of healthcare professionals, incentives to participate in the pilot for both healthcare professionals and patients, defining who can realistically be responsible for case management and the role of nurses in facilitating integration of the care in the pilot intervention process. The final iteration of the MOPs will define how each pilot site is planning to deal with these issues.

Finally, a monitoring process has been established for tracking and documenting every step of the process, identifying problems and how they are resolved that will support joint problem solving and will also serve as a basis for lessons learned to enable scaling and transferability.

2 Purpose

The purpose of this deliverable is to describe the process and interim outcomes of the development of the plans for the deployment of the ADLIFE pilot in all of the pilot sites. As this deliverable is being submitted at the end of Month 30 and the intervention is not scheduled to begin until Month 36, final implementation plans are still being made.

This deliverable delineates the objectives of the deployment plans, and the methodology used within the consortium for developing the plans for deployment at both the overall project level as well as the individual pilot site level. In addition, the deliverable describes the main characteristics of each of the pilot sites and highlight those areas in which these characteristics require adaptation of the overall approach to the unique needs of each pilot site. Major issues and challenges identified by the pilot sites in preparing the plans for deployment will also be addressed.

3 Background and rationale

Due to population ageing and advances in medical science, people with chronic diseases – including advanced severe life-threatening chronic diseases- live longer. They are a special group who may face permanently or temporarily reduced functionality and capabilities. Challenges are how to sustain quality independent living for the patient; support caregivers facing an increasing burden; and create sustainable healthcare and social care systems with limited resources. Persons with progressive Advanced Chronic Diseases can greatly benefit from digitally supported interventions to improve or maintain their health, avoid unnecessary deterioration, extend their independence and optimize health resources utilization.

Integrated supportive care can be an effective approach to enhance independence and quality of life and may also positively influence the course of illness from early states. The digitalisation of health services is expected to lead a profound transformation and it is important to evaluate its impact. The coronavirus disease (COVID-19) pandemic has led to a paradigm shift towards a remote telecare highlighting the need for reinforcing the digitalisation of health services worldwide enabling and promoting digital care. ADLIFE aims to provide evidence -based guidance to adopt and use new digital health services supporting integrated care at different levels of the health care system.

The over-arching societal challenge addressed by ADLIFE is to improve the quality of life of senior people with Advanced Chronic Diseases by providing innovative integrated intelligent personalized care. As representative of this increasing group of diseases, we have selected two of the more prevalent ones, Chronic Obstructive Pulmonary Disease (COPD) and Congestive Heart Failure (CHF). Chronic obstructive pulmonary disease (COPD) is an important cause of morbidity and mortality with high social and economic costs[1]. The prevalence of COPD has been reported to vary between 6 and 26.1% worldwide. COPD has also been associated with a high prevalence of one or more comorbid conditions, which have an impact on health status and mortality. Heart failure (HF) is a major and growing medical and economic problem worldwide as 1-2% of the healthcare budget is spent for heart failure[2]. The global economic burden of HF is estimated at $108 billion per annum, with $65 billion attributed to direct and $43 billion to indirect costs. Europe accounts for 6.83% of total global HF costs.

ADLIFE will conduct a large-scale deployment of digitally enabled holistic and integrated supportive care in seven healthcare systems in six countries. The ADLIFE ICT Toolbox solutions will be integrated and scaled in the actual ICT health systems participating in the intervention. The toolbox comprises validated and trusted personalised digital solutions, most of them developed in previous FPVII and Horizon 2020 projects participated in by the consortium partners following international standards such as HL7 FHIR and PCHA device standards. Specifically, the ADLIFE ICT solution is comprised of 3 components: A Patient

[1] https://www.europeanlung.org/assets/files/publications/lung_health_in_europe_facts_and_figures_web.pdf

[2] Lesyuk W etal .Cost-of-illness studies in heart failure: a systematic review 2004–2016. BMC Cardiovasc Disord. 2018; 18: 74.

Care Plan Management Platform (PCPMP), a Clinical Decision Support System (CDSS) and a Patient Empowerment Platform (PEP)

The ambition of ADLIFE is to:

- Demonstrate that the ICT supported ADLIFE intelligent and outcome-based personalized care model of integrated care is flexible and can be deployed and replicated at large scale in different environments and can be trusted in regard to data access, protection and sharing.
- Achieve gains in patient health status, preventing suffering slowing down clinical and functional deterioration and improving patients' experience.
- Obtain improvements in efficiency by making a better use of resources, increasing the coordination among all the key stakeholders of care and improving working conditions of professionals.
- Protect functionality and enhance autonomy, empowering patients to participate in decisions making on their own health and adapting to their changing conditions and context.

4 Pilot sites description

The 7 pilot sites are very diverse and include countries with centralized and decentralized Bevedgerian healthcare systems as well as countries with Bismarkian healthcare systems. In some, physicians are employed by the healthcare system whereas in others, some or all of the clinicians are independent self-employed practitioners with a contract with some level of the healthcare system. The following is a description of all of the pilot sites.

4.1 Germany - Gesunder Werra-Meißner Kreis-(GWMK)

The goal of Gesunder Werra-Meißner Kreis Ltd. (GWMK) (https://gesunder-wmk.de/) is to reduce the projected cost rise of health insurances by improving health literacy, care coordination and offering guidance in the German health care system. To achieve its goal GWMK is building a “health network” with insurance members, who want to be part of the GWMK network, of partner insurances as well as health professionals of all kinds.

A core project is the establishment of “health guides” (deut. “Gesundheitslotsen”). E.g. physician/pharmacy assistants, therapists, midwifes are trained and supported by GWMK to be low threshold points of contact for insured persons. Health guides by means of motivational interviewing nudge the insured to form their individual health goals and to sign a goal agreement. Moreover, health guides are provided an extensive map of (ideally) all prevention offers and health care services in the region by the GWMK back office. The health guides time to consult the insured is reimbursed by GWMK.

Another part of GWMK is the establishment and management of local sector transcending treatment paths with health professional network partner → e.g. ADLIFE.

Table 1 - Characteristics of the healthcare system and Region, Germany – Gesunder Werra-Meißner Kreis-(GWMK)

Item	Description
Country/Region	Country (deut. “Land“) = Germany -> State („Bundesland“) = Hessia -> County („Landkreis“) = Werra-Meißner-Kreis
Geographical scale of the country/region	Regional (State, province, territory)
Geographical size and dispersion of the country/region (km ²)	1,024.55 km^2
Population size of the country/region (thousands)	100,965 (GWMK Target population ~21.000 based on health insurance contract)
Population density of country/region (inhabitants/km²)	99/km^2
Life expectancy of the country/region (years)	Germany (born 2015): Male = 77,7y; Female = 82,7y

Fertility rate of the country/region (births/woman)	1,4 (year 2015)
Mortality rate of the country/region (deaths/1,000 people)	5,7 / 1000 people (574 /100.000 people)
Top three causes of death of the country/region	1. Ischaemic heart disease 2. Acute myocardial infarction 3. Malignant neoplasm of the bronchi and lungs
Organisation and governance of healthcare services (Please describe how public and private healthcare services are organised and financed, including key organisations responsible for the delivery of those services – max 300 words)	Germany has a Bismarck type health care system based on individual insurances, e.g. health insurance. Up to a certain income threshold every person living in Germany must have (or is provided) a statutory health insurance. However, people are free to choose their provider (2019: 109) who are in competition. People with higher income than a certain threshold as well as civil servants have to take private insurances; ~10,7% of Germans are privately insured. Ambulatory physicians, who want to treat statutory insured people, need to be member of a "Kassenärztliche Vereinigung" (KV) (1 per state). Health insurances pay a lump-sum to the KV based on their members residence and comorbidities. The KV is then responsible to budget and manage ambulatory health care delivery. Hospitals are paid two ways. Building maintenance and long-term investment are paid by the state government. The running cost are paid directly by the health insurances to the hospital's management organisation.
Size of the workforce (thousands) and its distribution (%) in the country/region	No official all-encompassing overview of all sectors exists for the Region, except from our own analysis, simplified to practices: - 36 pharmacies - 67 general practitioners' practices - 2 general hospitals - 7 specialist clinics (mainly orthopedic rehabilitations, historic cluster of five clinics in the town Bad Sooden-Allendorf) - 59 outpatient specialists practices (2 anesthesia, 6 ophthalmology, 1 surgery, 9 gynecology, 4 ear, nose and throat medicine, 2 skin-and venereal diseases, 22 inner medicine, 2 neurology, 9 orthopedics, 2 urology) - 66 dentist practices - 65 physiotherapists' practices - 17 fitness centers - 13 ergo therapist practices - 14 logopedic practices - 21 psychological psychotherapist practices - 7 children & adolescent psychotherapist practices - 35 Ambulatory care service - 27 nursing homes

Healthcare policies in the country/region (Please describe max 3 key policy strategies that determines priorities for care delivery)	Werra-Meißner-Kreis key policies – view of the state/county administration[7,8]: 1. Keep and attract general practitioners (a not negligible proportion of general practitioners is over 60 years of age and are looking for young colleagues to take over) 2. Secure the existence of the two hospitals in the region (in Germany there is a movement to reduce the number of hospitals in general. Especially, the clinic in Witzenhausen could be subject to a closing, which was discussed in the past. However, the hospitals are owned by the county and is a major employer in the county. 3. Attract and secure more caregivers for ambulatory and stationary care (the county is aging, since young people do not find jobs and move away. The old stay and on average live longer. Now, the number one care givers are relatives. However, intergenerationally family structures are changing and it as assumed, more and more people will need professional care sooner.)

4.2 Denmark - Odense University Hospital (OUH)

Odense University Hospital (OUH) operates four academic and community hospitals located in the eastern part of the Region of Southern Denmark, including Svendborg Hospital, which has the largest medical department in Denmark.

A 1,000+ bed medical centre, OUH annually has more than 100,000 inpatient admissions and handles in excess of 1.1 million outpatient visits in 50 different clinical departments. The hospital has a budget of €870 million and employs more than 11,000 people. In Denmark, 16 specialised care pathways are offered only at OUH, and the hospital serves patients from across Denmark, as well as from abroad. The hospital has an organisation-wide, distinct patient-centred culture where the patients' and their relatives' benefit and experience are of the highest importance. At all times, this core value is reflected in every aspect of the work done at OUH by every member of staff. The patient groups involved from OUH in ADLIFE are patients with COPD and CHF. These patient groups are in less severe cases taken care of in primary care, while more severely ill patients are cared for by hospital specialists as out and inpatients. If patients with COPD and CHF also suffer from a different chronic disease, this disease will be treated by a specialist within this field. Whenever the patient is discharged from the hospital, the GP is informed about the different treatment, and is expected to have the general overview of the different diseases and treatments in the patient's journey.

The Danish healthcare system:

The Danish healthcare system is a universal coverage system financed via taxes, which provides free and equal access to healthcare for all citizens. The five Danish regions are responsible for hospitals and local general practitioners, while the 98 municipalities are responsible for out-patient care services such as rehabilitation, prevention, and elderly care.

In Denmark, all citizens have free access to a general practitioner (GP) who acts as the gateway to all healthcare services. The GP is the patient's primary contact point to the healthcare system, and 90 % of all medical cases are handled by the GP.

E-health in DK:

The Danish society in general is highly digitised including the healthcare sector. Every month 5.5 million digital messages are exchanged between 150 different systems.

The expansion of e-health in Denmark is based on public-private cooperation between the government, the regions, the municipalities, and the industry. This has brought innovation and implementation to a level where nearly all basic information from the various healthcare sectors has been digitised and made shareable.

One of the key elements for e-health in Denmark is the Danish Civil Registration System that allows for a unique digital identification of every citizen. All healthcare records e.g., in the hospital, at the GP or dentist are digital. Furthermore, Denmark has an extensive IT-infrastructure that allows for data sharing and supports collaborations across sectors.

Table 2 - Characteristics of the healthcare system and Region, Denmark - Odense University Hospital (OUH)

Item	Description
Country/Region	Denmark, Region of Southern Denmark (RSD)
Geographical scale of the country/region	Sweden is a country with big geographical differences. Most people live in the southern parts of the country, in or near the big cities Stockholm, Göteborg and Malmö. Sweden has a long coastline, many lakes, and forests. In the upper west part of the country there are large areas of mountains. RJH is a big region in the middle of the country, with vast areas of forests, mountains, and water.
Geographical size and dispersion of the country/region (km 2)	Denmark: 43.094 km2 RSD: 12.191 km²
Population size of the country/region (thousands)	Denmark: 5.840.045 RSD: 1,223 million
Population density of country/region (inhabitants/km2)	Denmark: 136,36/km2 (inhabitants/km2) RSD: 100 pr. km²

Life expectancy of the country/region (years)	females: 83,4 (years) (2020-2021) males: 79,6 (years) (2020-2021)
Fertility rate of the country/region (births/woman)	DK: 1.70 (births/woman) (2019)
Mortality rate of the country/region (deaths/1,000 people)	9 (deaths/ 1,000 people) (2020)
Top three causes of death of the country	1. Infectious or parasitic deseases 2. Cancer 3. Heart diseases https://www.dst.dk/en/Statistik/emner/borgere/befolkning/doedsfald (2020)
Organisation and governance of healthcare services (description of how public and private healthcare services are organised and financed, including key organisations responsible for the delivery of those services)	The Danish healthcare system is a universal coverage system financed via taxes, which provides free and equal access to healthcare for all citizens. The five Danish regions are responsible for hospitals and local general practitioners, while the 98 municipalities are responsible for out-patient care services such as rehabilitation, prevention, and elderly care. In Denmark, all citizens have free access to a general practitioner (GP) who acts as the gateway to all healthcare services. The GP is the patient's primary contact point to the healthcare system, and 90 % of all medical cases are handled by the GP.
Size of the workforce (thousands) and its distribution (%) in the country/region	DK: Labour force status: 3.073.000 https://www.dst.dk/en/Statistik/emner/arbejde-og-indkomst/befolkningens-arbejdsmarkedsstatus 77,7 (2020)
Healthcare policies in the country/region (Please describe max 3 key policy strategies that determines priorities for care delivery)	Denmark has an ongoing shift to "Near care", were focus is to give care as close to the patient as possible. Two of the focus areas in this work is person centred care and digitalisation. The Danish health system Is focused on keeping the patient at home in safe environment as long as possible. The expansion of e-health in Denmark is based on public-private cooperation between the government, the regions, the municipalities, and the industry. This has brought innovation and implementation to a level where nearly all basic information from

	the various healthcare sectors has been digitised and made shareable.

4.3 Sweden - Region Jämtland Härjedalen (RJH)

Region Jämtland Härjedalen (RJH) is a big, sparsely populated region (2,6 inhabitants/squarekm) situated in the middle of Sweden. The Region has one city, Östersund, where the only hospital is situated, so the specialized care is concentrated there. Primary care is taken care of by 29 different health care centres (HCCs) where the patients are free to choose where to be listed, often that is nearby their houses or workplaces. Municipal care teams are available for patients with high needs under specific conditions (see next section). There are 8 municipalities in the region, Östersund is the biggest, with half of the inhabitants on 5 precent of the area. Over 20 of the HCCs are run by the Region, but some are private or run by personnel or societal cooperatives or in a cooperation with a municipality. All HCCs are tax financed to >95%. The hospital and all HCCs have the same shared EHR “Cosmic”, while the municipalities have three different other systems. The social care in the municipalities also have separate systems. In Cosmic there is an integrated solution for web-based appointments.

The care outside of the hospital is shared between the HCCs and the municipality care. If the patient needs help/assistance with either food intake, getting dressed, personal hygiene or to move, he has the right to get health care from the municipal care team. This care unit has nurses, physio therapists and occupational therapists, but no doctors. The latter come from the HCC. Municipality care works closely with the social services. At the HCCs there are doctors, nurses, psychologists and physiotherapists. Occupational therapists are few in the HCCs, and most of the HCCs do not have one. Municipality care takes place at the patient’s home, often on a regular basis, while for HCCs, the patient visits the unit when he has problems or for regular visits (with the exception for doctors, see above). All HCCs have laboratories with e.g. spirometry and ECG facilities. Home monitoring with devices and contact with caregivers (Imagine Care solution) of patients with heart failure, COPD and hypertension is now being widely implemented in primary care throughout the Region.

In the EHR there is a communication tool “Cosmic Link”, where both the primary, specialized, and municipal care (including social care) is active – but not the patient or relatives. Cosmic Link is used when patients are hospitalized to plan for the continued care at home, and for patients who has complex situation, where a SIP (SIP = samordnad individuell plan “coordinated individual plan”) is needed or asked for by the patient. The SIP is documented in Cosmic Link.

Mobile hospital-based care teams serving the entire county exist, within somatic care, for palliative care, for post stroke care, and one team for psychiatric health (the SPOT-team: Specialistpsykiatrins omvårdnadsteam, Specialized Psychiatry Care Team).

The patient groups ADLIFE is targeting, COPD and CHF, are in less severe cases taken care of in primary care, while more severely ill patients are cared for by hospital specialists as out

and inpatients. The most severely ill patients, especially with a psychiatric co-morbidity or in need of care in special housings, are again mostly taken care of by primary care doctors in collaboration with municipality care and potentially, also with hospital specialists.

Table 3 - Characteristics of the healthcare system and Region, Sweden - Region Jämtland Härjedalen (RJH)

Item	Description
Country/Region	Sweden, Region Jämtland Härjedalen (RJH)
Geographical scale of the country/region	Sweden is a country with big geographical differences. Most people live in the southern parts of the country, in or near the big cities Stockholm, Göteborg and Malmö. Sweden has a long coastline, many lakes, and forests. In the upper west part of the country there are large areas of mountains. RJH is a big region in the middle of the country, with vast areas of forests, mountains, and water.
Geographical size and dispersion of the country/region (km 2)	Sweden – 528 447 (km2) RJH- 49 341 km2)
Population size of the country/region (thousands)	Sweden 10,35 miljons RJH 132179
Population density of country/region (inhabitants/km2)	Sweden 25,7 (inhabitants/km2) RJH 2,6 (inhabitants/km2)
Life expectancy of the country/region (years)	females: 84,8 (years) males: 81,2 (years)
Fertility rate of the country/region (births/woman)	1.67 (births/woman)
Mortality rate of the country/region (deaths/1,000 people)	8,83 (deaths/ 1,000 people)
Top three causes of death of the country	1. Cardiovascular disese 2. Cancer 3. Covid-19 (Data from 2020)
Organisation and governance of healthcare services (description of how public and private healthcare services are organised and financed, including key organisations responsible for the	Heathcare is primarily founded through taxes in Sweden, with the regions responsible for most of the healthcare. In nursing homes and for some part (differs in different regions) in ordinary homes, the municipality is responsible for healthcare up to, but not on, the level of the physician. Healthcare is provided by both internal and external performers. The law of freedom of choice and the Public Procurement Act are regulating that. In RJH the primary care is provided according to the law of freedom of choice, ca 85% intern and 15% extern.

delivery of those services)	The secondary care is mostly internal.
Size of the workforce (thousands) and its distribution (%) in the country/region	Sweden, At the end of 2019: 4,9 doctors per thousand people and 13,7 nurses RJH 3,9 doctors per 1000 people, 13,1 nurses per 1000 people
Healthcare policies in the country/region (Please describe max 3 key policy strategies that determines priorities for care delivery)	Sweden has an ongoing shift to “Near care”, were focus is to give care as close to the patient as possible. Two of the focus areas in this work is person centred care and digitalisation.

4.4 Spain - Osakidetza, Basque Country

Osakidetza is the public healthcare service of the Basque Country, a region located in the north of Spain. Osakidetza was created by the Health Department of the Basque Government in 1983. All the public hospitals and primary care centers of the Basque Region are under this organization. Osakidetza has a target population of 2.19 million inhabitants, where in 2021 more than 23% of the total population was 65 or older.

The Basque Public Health Service is made up by 13 Integrated Care Organizations (IHOs) and includes 320 primary care centres, 12 medium-long stay hospitals (4,106 beds), 4 sub-acute hospitals (448 beds), 3 mental health network (505 beds) and 2 contracted long term mental health hospitals.

Osakidetza has in place processes and tools to promote integrated care, system capacity and patient empowerment focused to improve health outcomes and efficient use of resources. Some of the commitments of this strategy includes the creation of Integrated Care Organisations (IHOs) as Integrated governance bodies between primary care centers and hospital and a management model based on the identification through a risk stratification tool and adapted care plans based on needs for complex and chronic patients. The Ministry of Health of the Basque Government, through Osakidetza, has deployed a digitalization strategy to support the integrated care and health system transformation to deal with ageing, chronicity and dependency, with the support of the deployment of integrated communication systems: Electronic Health Record (EHR), e-prescription, intranets and other communication mechanisms. As a result, the unified system integrates all different clinical information and encourages continuity of care under the same process between the IHOs. The e-Health strategy provides non-face to face care focused on prevention, monitoring and health advice.

Table 4 - Characteristics of the healthcare system and Region, Spain – Osakidetza, Basque Country

Item	Description
Country/Region	Country = Spain -> State = Basque Country
Geographical scale of the country/region	Regional (State, province, territory)

Geographical size and dispersion of the country/region (km 2)	7.234 km^2
Population size of the country/region (thousands)	2.193.199 million
Population density of country/region (inhabitants/km2)	303,13/km^2
Life expectancy of the country/region (years)	Male = 80,27 and; Female = 85,97
Fertility rate of the country/region (births/woman)	1.25 (year 2020)
Mortality rate of the country/region (deaths/1,000 people)	11.08 / 1000 people (1108 /100.000 people)
Top three causes of death of the country/region	1. Certain infectious and parasitic diseases 2. Tumors (neoplasia) 3. Blood and hematopoietic organ diseases, and certain disorders that affect the inmunity mechanism
Organisation and governance of healthcare services (Please describe how public and private healthcare services are organised and financed, including key organisations responsible for the delivery of those services – max 300 words)	Basque Autonomous Community - Euskadi is configured by three constituent provinces. The Ministry for Health controls policy planning, financing and contracting of health services, the Ministry for Employment and Social Affairs defines the social policies, whilst the contracting of social services is done by the Provincial Councils and municipalities. The Public Basque Health System is a Beveridge type system working to improve the health status of the population. It is funded by taxes, and healthcare professionals are public employees. It governs and funds the public Healthcare provider (Servicio Vasco de Salud - Osakidetza) and other organizations in charge of biomedical research and innovation. All the public hospitals and primary care centers of the Basque Region are under this governmental organisation. The Framework Contract is the tool that the Ministry of Health of the Basque Government use for commissioning and funding the type and volume of activity to be performed and budget allocated to care providers. This relationship is based on Law 8/1997, 26 June on Health Regulation in the Basque Country. A minor part of the activity (elective surgery mainly) is outsourced to private providers.
Size of the workforce (thousands) and its distribution (%) in the country/region	More than 30.000 professionals work for Osakidetza, which could be considered the biggest organization of the Basque Country. There are 1,600 GPs, 4,416 specialists, 1,959 Primary care nurses and 6,324 hospital nurses. Activity indicators (2021) are: 21,731,721 primary care and 4,978,807 specialized care consultations, 246,095 hospital admissions, and 192,820 surgical interventions per year.

Healthcare policies in the country/region (Please describe max 3 key policy strategies that determines priorities for care delivery)	The Strategic Framework 2021-2024 (bit.ly/39WhX0a) guides the development of policies to transform citizen health and care system. It defines challenges for the Basque Government's health policies development. Health in all Policies is highlighted as an essential substrate for the health system, which considers people's health, well-being and quality of life as a human right and, therefore, an objective shared by the different public authorities and sectorial policies. Basque Country path line up with the European life-course approach: Health in all policies, Healthy Ageing, Child and Adolescent Health, digital transformation of Health and Care or Healthy Environments and Behaviors. PCTI Euskadi 2030 (bit.ly/3FCve9T) is the strategic commitment for promoting Research&Development&innovation (R&D&i) to accelerate the transition towards a digital, green and inclusive Basque Country. This strategy embeds the emerging health and care challenges in Europe, aligned with the Horizon Europe Programme, the European Green Paper on ageing or the Digital Europe Programme, as well as the “triple win” approach. It defines the bases of the new RIS3. The Socio-Health Care Strategy 2021-2024 (bit.ly/3PgK8a5) aims to improve people's health status and autonomy, integrating and coordinating health, social and community care key stakeholders. Main priorities are governance; coordination; interoperability, prevention, care and R&D&i.

4.5 United Kingdom - NHS Lanarkshire, Scotland

Lanarkshire is the most populated county in Scotland. NHS Lanarkshire is the third largest health board in Scotland and is responsible for improving the health of, and providing comprehensive health care to, a population of approximately 650,000 people living within the North and South Lanarkshire local authority areas.

Around 12,000 staff work within NHS Lanarkshire across community settings, health centres, clinics, day hospitals, offices and three district general hospitals: University Hospital Hairmyres, University Hospital Monklands and University Hospital Wishaw.

NHS Lanarkshire is committed to delivering high quality, innovative health and social care that is person-centred and aims to ensure that everyone can live longer, healthier lives at home or in a homely setting.

Table 5 - Characteristics of the National Health Service and local NHS Board

Item	Description

Country/Region	Scotland, Lanarkshire
Geographical scale of the country/region	Lanarkshire can be broken down into North and South Lanarkshire
Geographical size and dispersion of the country/region (km ^{2})	North Lanarkshire: 469.8 km^2 South Lanarkshire: 1,772 km^2
Population size of the country/region (thousands)	Around 659,200
Population density of country/region (inhabitants/km^2)	North Lanarkshire: 724 people per km^2 South Lanarkshire: 180 people per km^2
Life expectancy of the country/region (years)	Scotland (2015-17): men 77 years, women 81.1 years North Lanarkshire (2015-2017): men 75.3 years, women 79.4 years South Lanarkshire (2015-2017): men 76.8 years, women 80.7 years
Fertility rate of the country/region (births/woman)	Scotland (2020) 1.29 births/woman
Mortality rate of the country/region (deaths/1,000 people)	Scotland: 11.7/1000 people North Lanarkshire: 12.1/1000 people South Lanarkshire: 13.2/1000 people
Top three causes of death of the country/region	Scotland: (not including corona virus) 1. Cancer 2. Ischaemic heart disease 3. Stroke
Organisation and governance of healthcare services (Please describe how public and private healthcare services are organised and financed, including key organisations responsible for the delivery of those services – max 300 words)	Responsibility for the National Health Services in Scotland is a devolved matter and therefore rests with the Scottish Government. The majority of NHS Scotland provision is paid for through taxation. healthcare is free at the point of access for anyone in Scotland via the NHS'.. The Scottish Government sets national objectives and priorities for the NHS, signs delivery plans with each NHS Board and Special NHS Board, monitors performance, and supports Boards to ensure achievement of these key objectives. NHS Boards in Scotland are all-purpose organisations: they plan, commission and deliver NHS services and take overall responsibility for the health of their populations. They therefore plan and commission hospital and community health services including services provided by GPs,

	dentists, community pharmacists and opticians, who are independent contractors. At local level, there are community health partnerships or community health and social care partnerships covering all areas of Scotland. These are committees of NHS Boards and have formal structures that ensure close involvement of local authorities, patients and the public. Private healthcare is also available throughout Scotland and is usually paid for through a private healthcare insurance scheme or individuals.
Size of the workforce (thousands) and its distribution (%) in the country/region	Scotland: just over 178,000 staff NHS Lanarkshire: just over 12,000 staff There are 100 GP Practices across NHS Lanarkshire.
Healthcare policies in the country/region (Please describe max 3 key policy strategies that determines priorities for care delivery)	Current priorities for health and social care are: Increasing frontline spending by 20% over the life of the current parliament Driving forward an NHS Recovery & Covid plan Establishing a National Care Service

4.6 Israel – Assuta Ashdod Hospital and Maccabi Healthcare Services Southern Region

Ashdod, the sixth largest city in Israel, has one hospital, Samson Assuta Ashdod University Hospital (AMCA) which is Israel's newest public hospital (began operation in June 2017). It is a 300-bed hospital with a potential for expansion to 650 beds. The unique mission of the new not-for-profit University Hospital is to create a fully integrated care system that links the hospital staff, community health care providers, social services, community support services, the patient and the patient's family by reengineering the care process supported by information and communication technologies. The hospital has departments, institutes, and clinics in every field of medicine, including cardiology and pulmonology departments and outpatient clinics. Many of its doctors also work as clinical consultants in Maccabi's community clinics in the area as a part of the strategy to integrate hospital and community-based care.

The Ashdod hospital is formally affiliated with the Ben Gurion University School of Medicine for training and research and has a clinical research unit that works closely with the hospital's innovation unit.

Maccabi Healthcare Services, the owner of the ASSUTA network (including AMCA), is the second largest health plan in Israel and provides comprehensive primary and secondary community healthcare services to over 2 million people. Maccabi's Southern Region has 33 community clinics and medical centers dispersed throughout the region, 5 of them in the city of Ashdod alone. All Maccabi clinics offer primary care services including laboratories, and many of them have other diagnostic institutes and consultants in a variety of different specialties. In addition, there are many independent physicians under contract caring for Maccabi patients in their private clinics. There are over 250 GPs, over 50 nurses, at least 50

other healthcare professionals including physical and occupational therapists, dieticians and social workers in the Southern Region.

Maccabi is AMCA's key partner in developing the model for integrating hospital and community care. The new Assuta Ashdod University Hospital's overall goal is the development of an integrated care system in collaboration with the Health Plans and the Municipality (social services). This is being developed by creating interfaces between the hospital and community EMRs predominantly with Maccabi Healthcare Services, and interfaces with Social Services of the Municipality.

Samson Assuta Ashdod Hospital's focus on integration with community services has already fostered unique innovations such as joint workshops between the Emergency Room staff and primary care doctors in the community, and the establishment of a unique home hospitalization unit. Maccabi has set up an Integration Unit in the hospital that fosters joint discharge planning for coordinated care in the community post-discharge and thus a seamless transition back to the community.

Table 6 - Characteristics of the healthcare system and Region, Israel – Assuta Ashdod Hospital and Maccabi Healthcare Services Southern Region

Item	Description
Country/Region	Israel, Middle East
Geographical scale of the country/region	Israel's geographical scale is very diverse, with desert conditions in south, and snow-capped mountains in the north. Israel is located at the eastern end of the mediterranean sea in western Asia. Ashdod- is located in the Southern District of the country, on the Mediterranean coast.
Geographical size and dispersion of the country/region (km 2)	Israel- 22,072 (km2) Ashdod- 60 (km2)
Population size of the country/region (thousands)	Israel- approximately 9,518,500 Ashdod- approximately 226,504 AMCA catchment area (Ashdod and surrounding towns) approximately 500,000
Population density of country/region (inhabitants/km2)	Israel- 431.25 (inhabitants/km2) Ashdod- 4,910 (inhabitants/km2)
Life expectancy of the country/region (years)	females: 83.3 (years)– 84.7 (years) males: 81 (years)
Fertility rate of the country/region (births/woman)	3.01 (births/woman)
Mortality rate of the country/region (deaths/1,000 people)	0.5 (deaths/ 1,000 people)
Top three causes of death of the country/region	1. Cancer 2. Cardiovascular diseases 3. Diabetes
Organisation and governance of healthcare services	A National Health Insurance Law in 1995 legislated a universal compulsory statutory health insurance for all citizens and centralized the collection of health insurance payments from the citizens as an

(description of how public and private healthcare services are organised and financed, including key organisations responsible for the delivery of those services)	earmarked health tax. This is supplemented by funding from the National Budget, thus resulting in a system financed by earmarked and general taxation. Under the Law, coverage for health care services is provided by the four competing nationwide health plans (HMOs): Clalit, Maccabi, Meuhedet and Leumit. The Health Plans are directly responsible for the provision of healthcare services, not only for their financing. Every citizen must join a health plan but is free to choose and move from one to another. Health Plans must provide a legally defined public basket of services to all their members (updated annually). The Health Plan budget covers all of the health care services in the public basket of services for all members. Health Plans are considered healthcare managers for their members and provide services themselves with either employed staff or through contracting with independent, private and public clinicians and providers, thus care is provided by public and private providers of services including physicians, hospitals, pharmacies and other health care professionals. Both primary care doctors (GPs) and specialists work in community clinics, either in solo or group practices. All of the Health Plans have contracts with all of the public hospitals. Payment to the hospital by the Health Plan requires Health Plan authorization.
Size of the workforce (thousands) and its distribution (%) in the country/region	Israel, At the end of 2018: 38,765 doctors (3.1 doctors per thousand people) and 68,543 nurses (5 nurses per thousand people). There is a big difference between the center of Israel and the North and South of Israel: Tel Aviv (center)- 5.3 doctors per thousand people, compared to the North/ South of Israel- 2.1 doctors per thousand people. Tel Aviv (center)- 6 nurses per thousand people, comparing to the North/ South of Israel- 3.3 nurses per thousand people.
Healthcare policies in the country/region (Please describe max 3 key policy strategies that determines priorities for care delivery)	1. Maintaining the Continuum of Treatment in transit between hospital and community (National Health Insurance Regulations), 5775-2015 – Defines the obligations of hospitals and health plans in assuring continuity of care in transitions between the hospital and the community 2. Director General of the Ministry of Health Circular on "Standards for operating a health service remotely"(2019). The purpose of the circular is to set standards for providing health services remotely, in order to ensure a high-quality, accessible and available health service to patients. 3. National Digital Health Strategy (2017) The vision of the Digital Health Program is to bring about a leap forward in the health system that will enable it to become "sustainable, advanced, innovative, renewed and constantly improving, by optimally leveraging the information and communication technologies available in order to improve health for the entire population of Israel. This involves the establishment of

	organizational infrastructures, processes and technologies and implementation of a policy of promoting systemic innovation .

4.7 United Kingdom - University Hospitals Coventry & Warwickshire NHS Trust

University Hospitals Coventry & Warwickshire NHS Trust is major tertiary referral centre hospital in the West Midlands region of the United Kingdom. The hospital has close links with primary care providers in the region, which are currently structured in primary care networks.

University Hospitals Coventry and Warwickshire NHS Trust is one of the UK's largest teaching Trusts responsible for managing two major hospitals in Coventry and Rugby, which between them serve a population of over a million people. We are the principal teaching hospital for Warwick Medical School with whom we work in close partnership to develop innovative medical education programmes and clinical research.

The hospitals are:

Hospital of St Cross, Rugby

University Hospital, Coventry

The Trust was first established in 1992 and expanded to include Rugby in 1998.

Every year we provide more than 800,000 episodes of care to patients from across Coventry, Warwickshire and beyond. The Trust's Vision is To be a National and International Leaders in Healthcare, with an ambition is to provide care for our patients that compares with the best, not only in the UK but also the rest of the world.

Table 7 - Characteristics of the healthcare system and Region, United Kingdom – University Hospitals Coventry & Warwickshire NHS Trust

Item	Description
Country/Region	Country (deut. "Land") = Warwickshire -> State („Bundesland") = West Midlands -> County („Landkreis") = **Coventry / Warwickshire**
Geographical scale of the country/region	Regional (State, province, territory)
Geographical size and dispersion of the country/region (km 2)	Coventry: 98.65 km^2 Warwickshire: 1.975k km^2
Population size of the country/region (thousands)	366,785 (Immediate area, but wider reach)
Population density of country/region (inhabitants/km2)	Coventry: 3,408 people per square km. Warwickshire: 296 residents per square kilometer
Life expectancy of the country/region (years)	(2019): 81.20

Fertility rate of the country/region (births/woman)	1.65 births/woman
Mortality rate of the country/region (deaths/1,000 people)	9.1 / 1000 people
Top three causes of death of the country/region	1. Dementia & Alzheimers Disease 2. Ischaemic heart disease 3. Cerebrovascular disease
Organisation and governance of healthcare services (Please describe how public and private healthcare services are organised and financed, including key organisations responsible for the delivery of those services – max 300 words)	"All English residents are automatically entitled to free public health care through the National Health Service, including hospital, physician, and mental health care. The National Health Service budget is funded primarily through general taxation. A government agency, NHS England, oversees and allocates funds to 191 Clinical Commissioning Groups, which govern and pay for care delivery at the local level. Approximately 10.5 percent of the United Kingdom's population carries voluntary supplemental insurance to gain more rapid access to elective care. Health coverage in England has been universal since the creation of the National Health Service (NHS) in 1948. The NHS was set up under the National Health Service Act of 1946, based on the recommendations of a report to Parliament by Sir William Beveridge in 1942. The Beveridge Report outlined free health care as one aspect of wider welfare reform designed to eliminate unemployment, poverty, and illness, and to improve education. Under the 1946 Act, the Minister of Health had a duty to provide a comprehensive, free health service, replacing voluntary insurance and out-of-pocket payments. Currently, all those "ordinarily resident" in England are automatically entitled to NHS care, still largely free at the point of use. **Role of government:** Responsibility for health legislation and general policy in England rests with Parliament, the Secretary of State for Health, and the Department of Health. Day-to-day responsibility for the NHS lies with NHS England, an arm's-length, government-funded body run separately from the Department of Health. Its responsibilities include: • managing the NHS budget • overseeing 191 local Clinical Commissioning Groups (CCGs), which are groups of local general practitioners (GPs) who plan, commission, and pay for most of the hospital and community care service in their areas • directly commissioning certain types of care, including primary care in some areas, dental care, treatments for rare conditions, and some public health services (such as immunizations)

	• working toward objectives in the annual mandate from the Secretary of State for Health, which include both efficiency and health goals • setting the strategic direction of health information technology, including the development of online services to book appointments and the setting of quality standards for electronic medical record-keeping and prescribing. The government owns the hospitals and providers of NHS care, including ambulance services, mental health services, district nursing, and other community services. These providers are called NHS trusts. Other important public agencies involved in health care governance include: • NHS Improvement, which licenses all providers of NHS-funded care and may investigate potential breaches of NHS cooperation and competition rules, as well as mergers involving NHS foundation trusts • the Care Quality Commission, which ensures basic standards of safety and quality by registering providers and monitoring the achievement of care standards • the National Institute for Health and Care Excellence, which sets guidelines for clinically effective treatments and appraises new health technologies for their efficacy and cost-effectiveness • Health Education England, which plans the NHS workforce." [Source: England | Commonwealth Fund]
Size of the workforce (thousands) and its distribution (%) in the country/region	No official all-encompassing overview over all sectors exists: UHCW NHS Trust employs 7320 WTE staff There are 123 GP Practices in the Coventry & Warwickshire region.
Healthcare policies in the country/region (Please describe max 3 key policy strategies that determines priorities for care delivery)	In addition to the structures described above, healthcare policy decisions are driven by the National Institute of Health & Clinical Excellence (NICE). NICE's role is to improve outcomes for people using the NHS and other public health and social care services. NICE's role is to: • Produce evidence-based guidance and advice for health, public health and social care practitioners

	• Developing quality standards and performance metrics for those providing and commissioning health, public health and social care services. • Providing a range of information services for commissioners, practitioners and mangers across health and social care.

5 Objectives of the Pilots (intervention)

The ADLIFE pilots will operate for 12 months during which time the ADLIFE processes, care pathways and digital solutions will be deployed in each of the pilot sites in caring for 126 patients in each site who have either Advanced Heart Failure, Advanced COPD or both, with or without other comorbidities. The objectives of the interventions in the pilots are:

- To change the traditional care models for patients with advanced chronic disease by integrating unconnected care tasks performed in different levels and settings addressing the multidimensional nature of their conditions and the secure and quality exchange of data and information.
- To facilitate better communication and coordination among all of the professionals caring for each patient with particular emphasis on coordination between hospital staff and primary and community care.
- To facilitate a more active role of patients and caregivers in managing their own health and symptoms encouraging shared decision making, deliver individualized adaptive interventions
- To provide collaborative tools to create personalized care plans for multidisciplinary care team members to efficiently manage the delivery of integrated care services improving working conditions of health care and social care providers, optimizing work time management and multi-disciplinary coordination.
- To implement intelligent tools for clinical decision-making support that enable them to seamlessly access and assess the patient's most recent clinical context (EHR and PROMs), by automating evidence-based guidelines and need assessments scales and risk prediction algorithms to early detect health changes or undesired events.
- To securely access, process, share and store patient's data in electronic health records and also other patient generated data (including sensor measurements, interactions with their environments, feedback about their care plans and PROMs) in line with the requirements of GDPR.
- To deploy the new tools in hospitals and/or clinics and/or primary care centres in seven different European and associated regions.
- To assess the effectiveness (in terms of gains of health outcomes and use of resources) and efficiency (in terms cost improvements) of the intervention

6 Preparing the plans for Deployment of the ADLIFE intervention in the pilot sites

Task 8.1 brings together, in a great many respects, the work of all of the other Work packages which have been dedicated to the development of all of the tools and processes that will be deployed in the ADLIFE pilots.

6.1 Objectives

The objectives of Task 8.1 Are as follows:

- To develop the plans, step by step, of preparing for and implementing the ADLIFE pilots in all pilot sites
- To develop a pre-pilot check list to assure that all of the necessary preparations have been made to enable the start of the pilots
- To develop the timeline and deadlines for each step
- To prepare a Standard Operating Procedures Manual (SOP) at project level to assure that all of the steps required for preparing for the intervention are made and to provide a uniform approach for all of the pilot sites
- To prepare operating manuals (MOPs) in each site that will be local adaptations of the SOP, taking into account the unique requirements of each pilot site
- To develop a monitoring process and a tracking tool to enable monitoring of the deployment plan preparation and the pilot implementation

6.2 Methodology

The methodology used for preparing the deployment plans for implementing the ADLIFE intervention in the pilot sites has been a very strongly collaborative methodology. As is apparent from the description of the pilot sites, there is a high degree of diversity among the pilot sites. Consequently, the challenge has been to develop a joint process resulting in a common high level deployment approach while enabling each pilot site to adapt the approach to meet its unique needs, and constraints.

Given the geographic distribution of the pilot sites, the collaborative process has been conducted virtually. Beginning in mid-January, the pilot sites and representatives of the other ADLIFE partners have met every 2 weeks using GOTOMEETING. The WP8 leader has been responsible for assuring that there is an agenda for each meeting, distributed in advance, as well as detailed summaries of each meeting. In addition, all of the meetings have been recorded. For each meeting, Power Point presentations have been prepared as a guide for discussion and decision- making. Decisions and action items are clearly detailed in the meeting summaries. The meeting discussions have been supplemented by a dynamic exchange of emails between meetings.

The following are the major steps agreed upon and followed by the pilot sites:

2. Appointment of the pilot site manager and management team.
3. Developing a pre-pilot checklist of all of the activities that need to be accomplished prior to deployment and their deadlines
4. Agreeing upon a pilot monitoring tool/tracker to assure that all activities have been performed as scheduled, to identify problems and resolve them in the process

5. Developing and implementing a Change Management Plan
6. Preparing Informational and training materials for all pilot participants) professionals, patients, carers and managers).

From Pre-Pilot Checklist to SOP

Once the pilot site management team was appointed and work was initiated on a pre-pilot check list, it became apparent that a Standard Operations Manual was required at project level to assure a common basis for preparing the deployment, deploying and monitoring the deployment. The Standard Operations Manual (SOP) that had been developed for ADLIFE's precursor project "C3Cloud" was used as a model for developing the ADLIFE SOP and this then became the core organizing mechanism for the deployment planning. The ADLIFE SOP is detailed in this document in Section 7.

From SOP to MOP

The initial version of the SOP was a detailed outline that was reviewed by all pilot sites as well as the technical partners to assure that all of the steps required for preparation for deployment were included. Technical partners were assigned the development of the pre-pilot checklist for all of the technology related aspects. Once consensus on the SOP outline was achieved, pilot sites began to work on their local manuals (MOPs) following the overall structure of the SOP. Initial MOP outlines were presented in the biweekly meetings that raised many very important issues that needed to be addressed in addition to identifying where local variations would need to be made. The development of the MOPs is an ongoing process that will be completed just prior to the actual implementation of the ADLIFE Pilots.

Ongoing coordination with other Work Packages

The preparation for pilot deployment is dependent on and driven by all of the other major processes in the project. There has been an ongoing close coordination with both Work Package 10 (Exploitation) that has implemented a systematic assessment of the contextual factors in each pilot site that has contributed to an assessment of the readiness for implementation, and Work Package 9 (Evaluation) that mandates the data to be collected at baseline, during the pilot intervention implementation, and post implementation. WP6 is key to the deployment plan, defining the change management strategy and the development of informational and training tools and processes. Needless to say, the development of the technology tools – the Patient Care Plan Management Platform (PCPMP), the Patient Empowerment Platform (PEP) and the Clinical Decision Support system (CDSS) are at the heart of the deployment. Thus, the preparation of the Deployment Plans has relied heavily on the work done and the outcomes of all of the other Work Packages in the project.

7 The ADLIFE Standard Operating Procedures Manual

7.1 Introduction

A standard operating procedure (SOP) is a document that provides clear-cut directions and instructions as to how teams and members within an organization must go about completing certain processes. SOPs provide an “on-the-ground” explanation of what needs to happen to ensure a given process goes as planned. A major objective of an SOP is to ensure the requisite level of uniformity and the quality of outcomes, and to reduce miscommunication and ambiguity among team members and project partners

The SOP formalises the tasks in an organisation, linking them to the people responsible for them and the resources used in each stage, specifying the identification of the data of "who," "what", and "when" for all phases of the operations to be carried out. The SOP defines the policies, processes and standards needed for the organisation to succeed.

7.2 Purpose of SOP in ADLIFE

In ADLIFE, we have created the Standard Operating Procedure to describe the procedures related to the study preparation, set-up, execution and evaluation of the ADLIFE pilot study.

The leading research question for evaluating the study of ADLIFE application is: When applied in real life settings, is the use of the ADLIFE toolbox able to deliver appropriate targeted and timely care for patients with Advanced Chronic Diseases?

In ADLIFE the SOP aims to define a standard way of implementing the study protocol across all of the pilot sites. It describes the processes and procedures for preparation of the deployment, and implementation of the pilot through study closure. Based upon the project-level SOP, each pilot site will develop its manual of operations and procedures (MOP) describing the application of the SOP to its local context, with specific attention to local variations while still following the SOP.

The rationale, content and methodology followed for the generation of ADLIFE SOP are based on the SOP developed in the C3-Cloud project (GA 689181) and have been adapted and contextualised as deemed appropriate.

7.3 Description of the current SOP in ADLIFE

The structure of this section reflects in an orderly manner the different phases of the study: preparation, implementation, realisation and closure. Preparation and implementation occur before the pilot study, the realisation includes the operation of the study and the evaluation, and the closure happens after the pilot ends.

This section describes all the activities grouped into broad topics. All subsections outline the specific actions to be accomplished. The content of the subsections varies. Some include descriptive text that provides relevant information related to the particular activities and context, while others are self-explanatory. The level of detail also varies between subsections. For example, some describe what is yet to be defined, while others describe the current concrete proposal. The following table shows the structure of ADLIFE SOP.

Table 8 Structure of ADLIFE SOP

ADLIFE PHASES	MAIN TOPICS
Preparation	*Approvals*
	Management

Implementation	*ICT related activities*
	Selection and recruitment
	Study preparation
	Change management
	Implementation of the pilot
Realisation	*Study operation*
	Conducting the evaluation
Closure	*End of pilot study/closure*

This document is an evolving draft based on the activities of the various tasks and outputs of the project. It will eventually become the standard operating procedure for the project. The complete SOP will contain all the procedures for the various preparation, study, and evaluation activities.

The SOP relies heavily on the ADLIFE Research Protocol that has been evolving since the beginning of the project and is currently in its 28th iteration. The SOP and all of the elements for preparation of the deployment and the implementation of the pilot has been based on solid project management and coordination among all of the work packages, including the tracking of deadlines and progress and the proactive management of the dependencies and problems/delays encountered.

The "pre-pilot checklist" referred to briefly in 5.1 will contain activities of the phases prior to the pilot (Preparation and Implementation phases), as described below. This document will be formulated as a checklist and be organised sequentially, with all of the events necessary in the pre-pilot phases to ensure the readiness of the pilot sites to start the pilot.

7.3.1 Preparation

Approvals

The following approvals, agreements and governance are required for the study:

- Local Ethical Committee Approval
- Local ICT and Data Security Approval
- Data Protection Impact Assessment (DPIA)
- Agreements with Local ICT department
- Governance Approval
- Data Processing Agreement (DPA)

The research protocol (RP) guides the conduct of the study and is the basis for information provided for approvals and agreements. Current agreements and approvals have referenced the latest version of the Research Protocol. Therefore, any updates to the RP will require assessing whether the changes require modifications/notification to relevant approvals and agencies.

Approvals and agreements often contain requirements for collecting research data or creating, retaining, and destroying documents. The overall project process is documented in the D1.1 Data Management Plan (DMP) and relevant parts in "Study Closure". The DMP, submitted in Month 8 of the project (August 2020), is a living document. An updated version is due by month 36.

Each pilot site will follow its own local ethics application procedure and provide feedback on any issues raised to the ethics committee. In addition, regulatory and ethical bodies may require audits and reports on the study.

GDPR compliance instruments (e.g. consent forms, transparency notices, other on site displayed information) will make clear to all patients that this pilot is taking place, and summarise how patients are being recruited, what information is being shared and with whom, for what purposes, who the responsible DPO is and how they may be contacted.

DPIA helps to systematically analyse, identify and minimise the data protection risks of a project or plan. The DPIA should be conducted by the data controller or the health service provider organisation on its behalf. In ADLIFE, each pilot site should complete its DPIA if deemed appropriate by its organisation's Data Protection Officer (DPO).

Aspects such as integration with the ADLIFE platform interface, hosting data, and keeping data for ADLIFE patients identifiable and trackable have to be clearly defined and agreed with the local ICT departments in the seven sites. They will be referenced within the site MOP.

All components of ADLIFE solution will be hosted on the healthcare provider's infrastructure and managed by the local ICT department unless issues arise that require intervention by the ADLIFE service provider. In the hypothetical case that the technical partners need access to the site to support and troubleshoot components in each site's production environment, a Data Processing Agreement (DPA) will permit access of technical partners to the site. DPA will be the legal agreement that relates each technical partner with each pilot site to protect both parties.

Any locally-relevant adaptations to the SOP to comply with local governance requirements will be documented within the MOP. In addition, MOPs should contain or refer to any relevant documentary evidence of approvals and agreements.

Management

The following tasks have to be defined in an early phase of preparation of the study:

- Appoint a pilot site manager
- Appoint a pilot site team
- Define pilot site team members' roles and responsibilities

The pilot site manager administers and takes care of all aspects of the pilot preparation and implementation, including assuring technical and process support to professionals, patients and carers, developing a local communication strategy and disseminating materials. In addition, the pilot site manager is responsible for ensuring all of the training manuals/materials are done, and everybody is doing their job.

It has been proposed that the pilot site team include the following roles: Clinical lead, Nurse lead, ICT lead, Training lead, Research lead and Communication lead. One person may have multiple roles. The research lead is responsible for those things directly related to the research itself. They include identifying the patients in the database that meet the inclusion criteria, monitoring the selection process of the intervention group and the matching of the control group, and the data collection and the evaluation process at the local level.

7.3.2Implementation checklist

ICT related activities - list and definition

ADLIFE will deploy developed and validated personalised digital solutions for integrated supportive care The ADLIFE Toolbox solutions include: a Personalised Care Plan Management Platform, Clinical Decision Support Services; Interoperability Solutions and Patient Empowerment Platform with Just-In Time Adaptive Intervention Delivery Engine. These have been developed during the first two and a half years of the project by the technical partnets in collaboration with the clinical partners. The implementation check-list for the ICT related activities identify all of the steps required in order to deploy the ADLIFE toolbox.

Infrastructure Design & Implementation

- Current IT infrastructure excel sheet filled, detailing the systems and processes in use
- Relevant API documentation forwarded to WARWICK which would allow TIS and SIS adapters to be built
- ADLIFE software components and component diagram on SharePoint, T8.2, reviewed. Approval from IT for this to be deployed at sites obtained

System Installation, Support & Maintenance

- Timescales for final testing and deployment of environments agreed
- Customisations to environments defined and agreed
- At least 2 servers/VMs which are able to support containers installed (for staging and live environments, more details are available in SOP document)
- SLA (Service Level Agreement) between pilot site IT and technical partners agreed for outlining level of support provided from site- outlining who is responsible for what.
- Processes have been defined and disseminated for patients, health and care professionals' members of the multidisciplinary team (MDT) and project staff to report issues with the system or the data. How they report back on issues with the system, with the local site or with the technical partners.
- Help Desk or equivalent contact point is in place for each site- we should consider having two separate help desks, one will deal with IT technical problems, and the other will deal with process questions.
- Processes defined and disseminated for reporting, assessing, escalating and resolving faults once identified.

All identifiable data and software services accessing the data will be deployed on physical servers installed at each pilot site. Therefore, no external access will be required for data or software services.

Remote access to the pilot site testing and live environments will be provided to technical partners for installation, updating, management, and troubleshooting purposes, including identifiable data within the system if unavoidable, e.g., fixing a bug. For troubleshooting purposes, the service level agreement made with the ADLIFE service provider will detail what technical support will be available, through what channels and with what response time in the event of a technical problem or system failure or a wider organisational ICT problem. The DPA signed between each pilot site with each technical partner will permit remote access to the live environment if needed. ADLIFE partners who provide technical support will retain no identifiable data on any repository outside the pilot site. Any data copied for error checking will be deleted as rapidly as possible.

System Testing

- User Acceptance Testing plans and protocol defined.
- Timing of tests agreed.
- Pilot site parties needed for testing have been informed.
- Technical tests detailed in WP3 T3.4, performed by technical partners and includes integration and system testing against requirements to ensure they are satisfied.

Data Management, Integration & Data Extracts

- EHR systems at sites that will be connected to ADLIFE via TIS have been defined, and necessary permissions provided.
- Strategy and frequency for updating the ADLIFE components with new clinical data on a regular basis has been agreed.
- Strategy for exporting any ADLIFE data to healthcare provider systems during or after the pilot study defined OR agreement that confirms none of that study-generated data is necessary for ongoing continuity of care.
- It has been documented which data are needed for intervention and control patients, including demographics, identifiers, clinical data, questionnaires, among others.
- There is an agreed approach to checking data accuracy and completeness.
- There is an agreed approach to addressing / rectifying inaccurate or incomplete data.
- There is an agreed location for storing paper health records/research data per site (e.g. study master file).
- There is an agreed process for transferring evaluation data between partners and there is an agreed long-term storage plan & how data will be transferred to this facility.
- Integration is covered under system testing, above
- Data management and extracts covered in WP1 (D1.1 DMP) and WP8 (SOP and local MOPs).

The ADLIFE solution will create a unified repository of relevant clinical data, the information needed to support care planning, but not all patient information. The relevant information according to the clinical decision support services will be imported from the local EHR and displayed on the clinical summary screen of the PCPMP. There will be a full import of agreed upon data from local systems into ADLIFE components for each patient in the intervention group at the beginning of the pilot (and after there is a signed consent form), and subsequently, only changes since the previous upload will be imported into the components. The technical Interoperability Suite will check all incremental updates automatically, and by using the Semantic Interoperability Suite transform the data into FHIR resources and push any update into the ADLIFE FHIR Repository.

In the pilot sites taking part in ADLIFE, the integration will be one-way integration, from the Electronic Health Record (EHR) to the PCPMP but not the reverse. Hence, the data documented in the ADLIFE platform will not necessarily or automatically be documented at the EHR local systems.

Business Continuity & Disaster Recovery

- Disaster recovery and business continuity needs agreed including frequency, criteria and authorisation for roll-back and are ready to implement at pilot sites
- VMs integrated with existing backup procedures

ADLIFE system will be run alongside existing systems.

The healthcare provider organisation should integrate the ADLIFE clinical data within its normal ICT backup schedules and infrastructure. For backup and business continuity purposes, a strategy will be developed to regularly export data from the ADLIFE clinical data repository, and a destination repository will be designated under the direct management of the local pilot's ICT department to maintain a copy of the data. The business continuity plan should be defined prior to live use to support healthcare professionals in collaboration and care planning.

System Security and User Access

- Pilot sites have obtained IT approval for hosting/running the project as well as IT signoff for remote access for the technical partners to administer the systems.
- Technical partners have applied for research passports/contracts and remote access to the host organization's network as required.
- Necessary access has been provided to technical partners to administer the ADLIFE components.
- The audit trails to be kept by ADLIFE components have been specified and agreed with pilot site data protection, information governance and ICT security leads if required
- Pilot sites have agreed how they will create user accounts, e.g. if the accounts will be set up by the technical partners or by local administrators.
- Pilot site administrators have been trained on how to create and manage user accounts.
- Security of systems is covered in WT3.4.

The site manager, in collaboration with the technical partners, will be responsible for coordinating all tasks in the ICT pre-pilot checklist and for assuring that all tasks are performed and accomplished on time, inside the site boundaries.

Procedures for approving, granting and revoking access to the ADLIFE system for patients, carers and healthcare professionals will be defined locally. A designated administrator in each pilot site will have the responsibility for maintaining records of which patients, caregivers and health professionals receive authorisation credentials and when, and whether they are revoked due to staff changes or other reasons.

Selection and recruitment of professionals and patients

Prior to the selection and recruitment of health and care professionals, patients and carers, the following activities must be performed:

- Preparation of material for recruitment of professionals
- Preparations for the recruitment of professionals
- Preparation of data base of potential patients for intervention and control group
- Preparation of information materials for recruitment of patients and informal caregivers

The methodology for selecting healthcare sites within each pilot environment will be determined and described in each pilot site. This will be documented to guide implementation and for future publications.

Managers of the health centres recruited for the study will invite health and care professionals to participate, considering their profiles (willingness and suitability to participate). The process for selecting the health and care professionals needs to be specified including defining the expectations of the professionals during the course pf the pilot and clearly identifying incentives for participating in the project for each type of professional.

Patients will be selected in accordance with the inclusion/exclusion criteria defined in the Research Protocol and each site will specify how patients will be identified and selected. Each site needs to specify the persons who will have permission to manually search/screen for patients or to conduct and know the identified patient details returned via the searches made of EHRs. Each site will describe in their MOP the process for identifying and selecting patients for recruitment to the intervention group.

Study preparation

The first step in preparing for the study involves revisiting the storyboard developed initially by each pilot site and finalizing the process that will be followed in caring for the patients in the intervention group, step by step. This will serve as the basis for other aspects of the preparation, including the following:

- Preparation of training materials (manuals, slides, videos) for professionals and patients and informal caregivers.
- Translation of platforms, user manuals and questionnaires into the native language, if required.
- Set up a" help desk" for supporting both professionals and patients/careers both for ICT -related and process-related issues. Appoint the people, define what they will do, how they can be contacted

Change Management

Change management will be addressed in detail in Deliverable 6.2 including the overall strategy and focus of the change management process as agreed upon by the partners. Briefly, it has been agreed that ADLIFE will focus on bringing about change in the three major areas that are at the heart of the project:

- The communication, joint decision making and care planning between the hospital and primary care staffs
- The role of the Nurse Care Coordinator/Care manager
- Shared decision-making of professionals with the patient and his family

The changes that need to be made in each of the above areas are:

- Changes in roles and relationships among the various actors
- Changes in processes and changes in work-flow
- Changes in communication and exchange of information
- Using the ADLIFE toolkit to support the changes

The activities that will need to be undertaken in the preparation phase prior to deployment

- Preparation of the internal information and communication materials about the project
- Meetings with upper level management people to provide updates on the project. Identify of the support need from them and ask for it.
- Engagement activities with healthcare professionals, including clarifying what they will be expected to do in the pilot and identifying the benefits that they may realize from participating in the pilot.
- Assessing the readiness for change at the relevant levels of the organizations that will be involved in the ADLIFE pilots in each pilot site. This assessment has been carried out to a degree at an earlier point in the project in the Interviews for the analysis of contextual factors for ADLIFE scaling up in WP10. While the intent of WP10 was to develop a baseline for comparison of the situation in each pilot site prior to and following deployment of the intervention, the methodology used and the results of the interviews has also acted as a tool for assessing readiness for change and helping pilots focus their change management strategies and plans.

Initial steps of the Implementation of the pilot

The following are the initial steps for implementation of the pilot itself, prior to deployment of the ADLIFE intervention:

- Recruitment of Healthcare professionals
- Training of Healthcare professionals
- Providing professionals with their list of patients that meet inclusion criteria
- Selection of patients to be approached
- Definition of the Patient Recruitment process for each site
- Training of Patients and Caregivers

As agreed upon in the Research Protocol, Healthcare professionals will be selected by "convenience sampling". The exact process for doing this will be described in the MOP of each pilot site.

Each site needs to specify its process in its MOP for contacting suitable patients and informal caregivers, defining timelines, dealing with a slow response rate, non-responders. An authorised person needs to manually check that appropriate patients and informal caregivers have been identified and subsequently oversee the issuing of invitations. The MOPs in each pilot site will specify the process contacting and recruiting patients and informal caregivers to the study, and the documentation that will be will be used. The procedure and responsible persons for receiving and checking consent forms is specified in the MOP.

Training plans are being developed within Task 6.4. There will be an overarching training plan for the project with supporting materials, but each pilot site needs to confirm any local variations that will be applied for training and preparing trial participants, including methods, materials, timing etc. The timing of training for healthcare professionals, patients and caregivers and how this will be provided is specified in each MOP. The training plans will confirm which elements of the ADLIFE project participants need to be informed about and trained on, when, and what methods.

7.3.3 Realisation

Study Operation

- Document electronic systems: Inform healthcare professionals' staff about how the ICT systems will work and how they will use them.
- Definition and documentation of the Multi-Disciplinary Team members Interactions
- Initial and follow-up visits protocol: Process for scheduling clinical appointments for study patients and follow up visits.
- Patient self-management and empowerment: Patients and informal caregivers will be guided about which features of the PEP will be relevant to their personal health management, how the guidance resources can be accessed and what data they should enter into the application.
- Handling of patient queries: This includes the designation of contact points, the guidance for enquiries about the use of the system and the documentation of interactions with patients

- Handling of healthcare professionals' queries
- Dealing with Issues: If the system is not available, where to provide a suitable message and contact details.
- Withdrawal from the Study: Health Centers/Organisations; Healthcare professionals and patients and informal caregivers

Healthcare professionals will be informed about the concurrent use of existing EHR and ADLIFE applications, including the need to continue current documentation practices, and what their documentation workflow might now look like.

A nominated healthcare professional will initiate the personalised care planning once a patient has been set up in ADLIFE. An initial visit will be arranged with the patient and his/her caregiver to introduce ADLIFE and discuss the care plan. Personalised activities and goals will be assigned to care team members, as well as to the patient and informal caregiver, both via suggestions provided automatically by the CDS services and manually by the healthcare professionals based on their experience. Routine follow-up care for patients should follow the recommendations of the personalised care plan a patient is on. This will include how frequently a patient should be followed up and what monitoring assessments should be undertaken. When a patient has an unscheduled visit, a procedure will be described to inform other clinicians that the patient is in ADLIFE study and what other clinicians might be expected to document differently to support the study.

Patients and informal caregivers will use the PEP via a web browser on their device (computer, tablet) and via a mobile application. Patients will have complete access to all of their PEP data. Informal care givers nominated by the patients will be given their own login but will have the same level of access to the record in PEP as the patient.

For handling queries, patients and their caregivers will be given clear instructions and details for direct contact for different scenarios. Suitably skilled and trained staff within the healthcare provider organisation will be the responsible for responding to possible enquiries from patients.

Healthcare professionals will be advised on how to report and rectify data errors. In the event of the ADLIFE solution not being available, the normal working practices that were in operation prior to, and that will run alongside ADLIFE, will continue. A communication strategy is needed to inform staff of any system downtimes.

Agreements on how participants will be notified of issues and how they will be resolved will be made and informed.

Participants in the pilot project can withdraw their participation in the study at any time, implying that they will leave the study. The withdrawal is effective form the point where the patient notifies the study team of their decision to leave. In the event participants (healthcare professionals, patients and informal caregivers) withdraw the project, their previously collected data will be retained, unless otherwise stated, and analysed under the intention-to-treat principle. The patient is not obliged to explain their decision to withdraw. In case he/she accepts, the patient's decision to withdraw will be registered. (Research Protocol v0.28).

Conducting the pilot evaluation

- Nomination of a Data Manager
- Data Collection

- Local Data collection in accordance with the codebooks

The set of data required for effective care planning is defined according to the clinical concepts defined within clinical guidelines. The data aims to be adequate, relevant and necessary to satisfy the data minimization rules of the GDPR. The ADLIFE systems will collect and store personal information about the patient, e.g. name, address, carer details, contact numbers etc. and clinical information such as the conditions they have, tests, treatments given, among others. In addition, patients will be able to upload information and complete questionnaires as required in their care plan.

For evaluation purposes, the set of the indicators to be collected from the intervention to generate conclusions have been agreed (Research Protocol v0.28). Evaluation partners have developed and shared with the consortium Data Collection Guides (DCG) detailing the data required, the timeline and the data sources (EHR, questionnaires and the FHIR repository). (Research Protocol v0.28, ADLIFE Data collection guide for quantitative effectiveness v0.2, ADLIFE Data collection guide for economic assessment, ADLIFE interview manual and ADLIFE Technology Acceptance and Adoption Evaluation v0.6). Data managers in each site will be responsible for data collection. The specific implementation of data collection in each site will be described in the MOPs.

The data transferred from the pilot site to the ADLIFE evaluation team will be properly processed. Data from intervention participants will be pseudonymized by the local Data Manager to reduce risks from the perspective of the data subject. Data from control group will be extracted anonymously from administrative databases (Research Protocol v0.28).

7.3.4 Closure

End of Pilot Study/Closure

- Informing sites
- Informing regulatory and ethical bodies
- Data archival

The study closure process will specify how to phase out the patient interventions and healthcare professional collaboration support. It will lay out what to do with patients' personalised care plans and healthcare professionals' communication history. The procedures on how and when to archive or destroy the data and/or to create an anonymised extract to back up the evaluation will be defined in each pilot site, following national and /or regional data retention obligations. The study closure will describe the decommissioning process of the deployed components and local hardware/software in each site. Finally, any consideration of whether the site must maintain the data after the project's closure will be considered.

8 MOP – Some of the differences between pilot sites

8.1 Comparison of Pilot Sites

The seven pilot sites all have national healthcare systems but with some significant differences among them that will affect the processes of the deployment of the ADLIFE intervention, The two UK pilot sites are district health authorities within a central National Health System, the Basque Country is an autonomous region in Spain with an NHS -type system. Denmark and Sweden are decentralized national health systems, and Germany and Israel are Bismarkian systems- that is national health insurance systems with multiple health insurers.

Perhaps more relevant to the deployment of ADLIFE is the nature of the relationship between the healthcare professionals and the health system. In Scotland, England and Germany, Denmark and Israel, the primary care physicians are independent practitioners. In the Basque Country, all of the healthcare professionals are public employees and in Sweden, eighty per cent of GPs are employed by the County Councils and 20 per cent are private practitioners. However, in order to work as a private practitioner within the social security system, an agreement with the County Council is necessary. In both Germany and Israel, many healthcare professionals outside of doctors are independent practitioners whose services are reimbursed by the health insurers. In all of the pilot site countries, hospital doctors and staff are by and large, salaried employees.

There is also a difference among pilot sites as to the locus of responsibility for the ADLIFE population- advanced CHF and COPD patients. In most of the pilot sites, primary care clinics are responsible for the ongoing care and management of these patients. However, in Denmark and Sweden, these patients are generally cared for by hospital specialists as out and inpatients. However, even in pilot sites where traditionally primary care clinics have been managing patients with severe chronic disease, we are seeing difficulties as primary care has been significantly overburdened and stressed as a result of the COVID pandemic. The following is a comparison among the pilot sites by type of healthcare system.

Table 9 Comparison of PILOT SITES among type of healthcare system

Pilot Site/ Parameter	GWMK Germany	NHS Lanarkshire Scotland	UHCW, England	RJH Sweden	OUH Denmark	Osakidtetza Basque Country	AMCA Israel
Health system	Bismarck type health care system based on individual insurances, e.g. health insurance. People are free to choose their provider who are in competition	Beveridgian system - The 3rd largest health board in Scotland providing comprehensive health care to approximately 650,000 people	Beveridgian system - Tertiary referral centre in the West Midlands Region of the UK, Healthcare provided to approximately 1 million people, 2 Hospital Sites (Coventry & Rugby), out each and Hospital at Home, Close links with GP Practices and Networks including GP Practices	Regional healthcare system- part of the public health system. One hospital. The basis of Swedish healthcare is the primary care, which consist of a number of health care centres, with 1000-1300 listed patients each.	Universal coverage system financed via taxes, which provides free and equal access to healthcare for all citizens. The five Danish regions are responsible for hospitals and local general practitioners, while the 98 municipalities are responsible for out-patient care services such as rehabilitation, prevention, and elderly care	Beveridgian Public Health System made up by 13 Integrated Care Organizations (IHOs)	Bismarkian National Health Insurance system. Health care services coverage is provided by the four competing nationwide health plans (HMOs). Every citizen must join a health plan but is free to choose and move from one to another
GPs	General practitioners are independent contractors, responsible for running their own practices. Trend	1st point of contact for anyone with a healthcare need Independent ontractors, responsible for	1st point of contact for anyone with a healthcare need, independent contractors, responsible for	Ist point of contact Patients need a referral from their general practitioner in order to access	GPs are in private practices but have an agreement with the regions that describes the scope and details	All health professionals employed by Osakidetza are public employees	Health Plans Provide services with employed staff or through contracting with independent, clinicians. Both

	towards salaried employment in group practices	running their own practices whose services are contracted by the NHS	running their own practices whose services are contracted by the NHS, Increasingly grouped into networks, alliances and integrated care systems	specialized health care Most health professionals are salaried employees to the region with a monthly salary	of their work. All visits to GPs by the citizen are free		primary care doctors and specialists work in community clinics, either in solo or group practices. In Maccabi most doctors are independent practitioners with a personal contract with Maccabi

8.2 ADLIFE Deployment Issues- Variations among pilot Sites.

In the process of preparing their MOPS, a number of major deployment issues are being addressed in which there are significant challenges and variations among pilot sites .

8.2.1 Responsibility for Case management

Both the nature of the healthcare systems as well as the effects of COVID are influencing decisions of the pilot sites regarding primary responsibility for managing the care of ADLIFE Patients. COVID has had a particular impact on primary care. In Germany, while the GP practices will retain primary responsibility GWMK's heart and lung health team will lighten burden on GPs. In NHS Lanarkshire, primary responsibility will be in secondary care services (respiratory and cardiac services) and they anticipate very limited cooperation from primary care. In UHCW, similar to Lanarkshire, the "easiest" clinical fit for ADLIFE is in secondary care services, although they plan to reach out to academic GP partners to support, recognising the importance of primary care. In both RJH and OUH the hospital departments will be their primary clinical managers of ADLIFE patients. In Osakidetza - the Integrated Care Organizations (IHOs) will be responsible, but within them primary care will have the leading role. In AMCA, the Maccabi Integration staff together with the GP will have primary responsibility for managing ADLIFE patients in collaboration the Assuta Integration Nurse, and the Cardiology and Pulmonary department staffs.

8.2.2 Incentives

The approach to providing incentives, particularly to doctors, to participate in the ADLIFE project varies from pilot site to pilot site. In Germany, GWMK is framing ADLIFE as a research project, that will not lighten workload during the intervention, but will give insight into future care opportunities, that are time saving. They are also stressing the opportunity to contribute to the development of a new way of working. Nonetheless, they perceive the necessity for financial incentives and participating GP practices will receive payment as lump-sum for quarterly care per participating patient. In addition, time for training of GP practice staff in ADLIFE related topics will be reimbursed to the GP practice. In NHS Lanarkshire, it is unlikely that primary care will participate, and they do not anticipate the need for financial incentives for hospital staff. The incentive to participate will be opportunity to contribute to the development of a new way of working. In UHCW they will be involving academic GP partners who are on the faculty of the University who they believe will welcome the opportunity to contribute to the development of a new way of working, Academic and Innovation focused clinicians are increasingly interested in broadening their skills set. In RJH, there is no economic incentive, and many doctors feel that systems that they do not know will only take time and be a burden. The incentive must be for the doctor to feel that he either saves time or gets a better picture of the situation. In OUH, taking part in different projects is a part of clinicians' jobs as being employed by a university hospital. GPs are only tangentially involved so no specific incentives are planned. In Osakidetza, incentives will include awarding participating clinicians with Jakinsare Certificates of Participation (Osakidetza's training and knowledge management services) which are valued in the scoring system for applying for public positions. There will be monetary compensation for the participating Integrated Care Organizations (IHOs). Other possible incentives are being considered. In AMCA, financial Incentives for family doctors will be required for full collaboration in ADLIFE. The AMCA MOP will specify the exact nature of remuneration of the family doctors in ADLIFE that will be agreed upon with Maccabi

8.2.3 Recruitment

Germany plans to recruit GPs, and the GPs will recruit the patients. The Idea is to interest "GPs in training" as point of contact for each single GP practice who will then bridge the use for senior GP. The aim is to integrate ADLIFE as a trial for ambulatory physicians to integrate case management for one of their most vulnerable patient groups. At the same time, the county owned hospital is integrated via the political will to improve hospital stay prevention.
The intervention will be deployed at five physician practices and two locations of the hospital (Eschwege, Witzenhausen). NHS Lanarkshire patients and carers will be recruited through specialist nurse services and specialist review clinics. Health professionals will be recruited from respiratory and cardiac service teams, Recruitment and training will be undertaken by a Research Nurse employed specifically for ADLIFE. In UHCW, patients and carers will be recruited through dedicated R&D clinics (and clinic areas), specialist clinics, EHR screening and linkages. Health professionals will be recruited from existing academic staff. In RJH, recruiting patients will probably be via the hospital clinics since stage III and IV HF patients are seldom followed via primary care. COPD might be via hospital and/or primary care. Health care professional recruiting might be a challenge but interested persons could ideally be identified at an early stage. In OUH, clinicians will be recruited from the hospital, which means that it will be included in their daily job and not something that requires extra work. In Osakidetza – they will approach the OSIs. Once the OSIs decide to join the ADLIFE project, they will recruit their healthcare professionals. With regard to patients, their recruitment and training depend directly on the professionals. In AMCA the basic plan is to recruit the Maccabi GPs who will recruit the patients from among their patients who meet the inclusion criteria. Some consideration is being given to identifying appropriate patients from among those already being cared for in AMCA's cardiology and pulmonary departments.

8.2.4 The Role of Nurses in ADLIFE

The role of nurses, and particularly nurse care coordinators or case managers, has been the subject of much discussion among pilot sites. At this stage, there are some differences among the pilot sites although the inclination is to see an important role for nurse coordinators. In Germany, recruitment and training will be undertaken by the GWMK heart and lung health team that will provide group-based case management with a part-time coordinating nurse. In NHS Lanarkshire, the specialist Nurse Service for COPD and HF will lead the utilisation of the ADLIFE system – working across primary and secondary care. In UHCW, recruitment and training will likely be undertaken by Specialist Research Nurses with a track record in engaging across clinical departments. In RJH, nurses work with more systems than doctors and in general are more positive to change. It will be critical to make sure that nurses involved in the project feel that the system is actually helpful and ideally that they have sufficient time. This is particularly important as there is a shortage of nurses, particularly in the hospital. In OUH, the nurse specialist will work in close collaboration with the leading physician in the area (pulmonologists and cardiologist). OUH has selected a number of nurses with an interest in telemedicine that are in charge of working with this project in close collaboration with the coordinating nurses and other health professionals. The coordinating nurse in the project have research background. In Osakidetza, the role of the Nurse Care Coordinator is in the process of being defined with the local clinical team. In AMCA, the nurse care coordinator will have a central role in the project. There will be a 100% dedicated Maccabi community nurse care coordinator- (either one full time or two part time) who will have direct and continuous contact with the GPs and specialists. She will track the implementation of the patient care plan and will initiate proactive communication with patients. The Nurse coordinator will train patients in the use of the PEP and will support them in its use including assisting patients in filling out questionnaires. There will be close collaboration with the hospital nurse care coordinator.

The final iteration of the MOPs will define how each pilot site has decided to deal with these issues

8.3 Areas Requiring Local Adaptation in MOPs

The SOP has identified the main areas in which there are likely to be unique local processes and therefore indicated that these must be specified in each pilot site's MOP, as follows:

- Procedures for approving, granting and revoking access to the ADLIFE system for patients, carers and healthcare professionals including designating an administrator who will have the responsibility for maintaining records of which patients, caregivers and health professionals receive authorisation credentials and when, and whether they are revoked due to staff changes or other reasons.
- The methodology for selecting healthcare sites within each pilot environment (hospitals, clinics, integrated care organizations)
- The process for selecting the health and care professionals including defining the expectations of the professionals during the course pf the pilot and clearly identifying incentives for participating in the project for each type of professional.
- The process by which patients who meet the inclusion criteria will be identified and selected and recruited to the intervention group.
- Preparation of training materials (manuals, slides, videos) for professionals and patients and informal caregivers will be done by each site in their own language
- The process for translation of platforms, user manuals and questionnaires into the native language, if required will need to be described in the MOP
- Setting up a help desk – who, what hours, and availability will differ from site to site and needs to be done by each pilot site
- The process for contacting suitable patients and informal caregivers, defining timelines, dealing with a slow response rate, non-responders. Sites will need to designate an authorised person to manually check that appropriate patients and informal caregivers have been identified and subsequently oversee the issuing of invitations.
- The procedure and responsible persons for receiving and checking consent forms
- Training plans are being developed within Task 6.4. There will be an overarching training plan for the project with supporting materials, but each pilot site will be responsible for any local variations that will be applied for training and preparing trial participants, including methods, materials, timing etc.
- The timing of training for healthcare professionals, patients and caregivers and how this will be provided
- The establishment of Initial and follow-up visits protocol. The process for scheduling clinical appointments for study patients and the follow up protocol need to be specified
- Handling of patient queries including the set-up of clear contact points, and guidance for enquiries about the use of the system, including designation of suitably skilled and trained staff within the healthcare provider organisation who will be the responsible for responding to possible enquiries from patients.
- The process for how to deal with the situation when the ADLIFE system is not available, where to provide a suitable message and contact details.

- Designation of the healthcare professional who will initiate the personalised care planning once a patient has been set up in ADLIFE
- Appointment of Data managers who will be responsible for data collection.
- The specific implementation of data collection in each site will be described in the MOPs.
- The process for study closure including the decommissioning process of the deployed components and local hardware/software in each site.

As of the submission of this deliverable, the ADLIFE pilot sites are working intensively on completing their MOPs as well as other materials required for deployment such as defining how they will identify patients meeting ADLIFE inclusion criteria in their databases, preparing informational and training materials for professionals, patients and carers, and refining and implementing their change management plans and activities.

9 The monitoring/tracking tool

The consortium has developed a common strategy to ensure the oversight of the implementation and operation of the ADLIFE pilot and help to:

- Manage the preparations and plans for the pilot study at the sites (the procedures collated in the Standard Operating Procedures document and local MOPs)
- Assure that all agreements and approvals are in place (WP1, WP8, WP9 and WP11)
- Monitor the risks in the pilot study, identified in the areas such as ethics, data protection, confidentiality, study population, complexity of the intervention and recruitment (WP1, WP8 and WP9)
- Set up the pilot study (WP8)
- Run the pilot study (WP8)
- Evaluate the pilot study (WP9)
- Close the study (WP8 and WP9)

Having a monitoring tool in place will help the pilot sites to implement the research protocol and conduct the study consistently. ADLIFE is developing the “ADLIFE Pilot Activity Monitoring Tool” to ensure that the research protocol and corresponding project Standard Operating Procedure (SOP) and site-specific Manual of Operations and Procedures (MOP) are followed. The monitoring tool which is based on the one used in C3-Cloud project (GA 689181), will be a spreadsheet used for each site to track activities covering from pilot application preparation to after closure of the study. It will help ensure everything is in place and defined for each phase of the study, as stated previously. The following information will accompany each activity: a short description of the activity, an estimated date of achievement/completion, the person responsible for the task and a free text section to describe the problems encountered, if any, as well as the solutions/alternatives, implemented or the contingency plans developed.

Each pilot site will review it separately and also with other (technical and evaluation) partners, as required. Each pilot site will appoint a Study manager of the pilot who will (i) manage and monitor the deployment, (ii) ensure that everything is done (identifying problems and solving them), and (iii) be responsible for documenting in the tool. The tool will be reviewed on a regular basis, according to each phase of the intervention, in online meetings led by the WP8 leader and pilot sites Study managers, along with the required partners, depending on the issues that have been raised.

In addition to solving problems and making necessary changes in processes during the course of the pilots, the tool will contribute to the analysis at project’s end of lessons learned to enable scaling and transferability.