DARE

DIGITAL LIFELONG PREVENTION

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Spoke 2 Deliverable

SP2.D4.1 Concept of models and design of experimental protocols

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SP2.D4.1 Concept of models and design of experimental protocols

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1. Publishable Summary

The DARE project is a pioneering initiative in research, focusing on innovation and technological advancements, especially in the healthcare system. SPOKE 2 (SP2), a key component, is dedicated to instigating change and innovation in primary prevention through the integration of new technologies or repurposing existing ones with novel functionalities. Within SP2, Work Package 4 (WP4), titled "Digital tools for Primary Prevention," encompasses the design of eight pilot projects. These projects aim to promote primary prevention activities through technological innovation, grounded in scientific evidence, with the objective of developing strategies applicable to broader contexts.

WP4's goals include enhancing collaboration between primary health care and hospitals by deploying experimental protocols and digital tools for data acquisition, management, and analysis. The focus spans disease surveillance, vaccination programs, cardiovascular risk profiling, and fall prevention initiatives.

An operational architecture outlines tasks within WP4, such as predictive disease surveillance, digital support for vaccination programs, large-scale fall prevention, and innovative tools for personalized cardiovascular prevention. Various data sources, including hospital and territorial data, are employed while adhering to privacy regulations.

Efforts are concentrated on creating a logical data architecture using the Alma Health DB model[1], fostering collaboration between pilots, and establishing data warehouses for comprehensive accessibility. A detailed overview of pilot projects, their development phases, and potential synergies is provided, emphasizing the cross-applicability of technologies for cohesive implementation.

The Agile Framework[2] guides the iterative development phases, ensuring requirements are met for effective technology utilization. Individual pilot highlights include predictive disease surveillance models, vaccination program enhancements, and large-scale fall prevention strategies.

API Library Model[3] implementation is emphasized to facilitate data exchange, improve communication, and enhance security in the development of technologies across various pilots. The use of RESTful[4] tools and software development kits is planned to support the seamless integration of data from diverse sources.

In conclusion, the activities provided within WP4 in SP2 represent a comprehensive and collaborative effort to leverage digital tools and technologies for primary prevention, emphasizing innovation, scalability, and evidence-based strategies.

2. List of abbreviations

DARE – Digital Lifelong Prevention

WP – Working Package

VPDs - Vaccine preventable diseases

ER – Emergency Room

AVR – Anagrafe Vaccinale Regionale (Regional Vaccination Registry)

AOU BO – Azienda Ospedaliera Universitaria di Bologna (University Hospital of Bologna)

MRI – Magnetic Resonance Imaging

HDRs - Hospital Discharge records

PRS – Polygenic Risk Score

FPG – Fondazione Policlinico Gemelli (Gemelli Polyclinic Foundation)

UNIBO – Università di Bologna (University of Bologna)

IOR – Istituto Ortopedico Rizzoli (Rizzoli Orthopaedic Institute)

CVDs – cardiovascular disease

ETL - Extract/Transform/Load

ROMA1 – Azienda Sanitaria Locale Roma 1 (Rome 1 Local Health Authority)

UNIPA - Università di Palermo (Palermo University)

UNIPD - Università di Padova (Padova University)

AUSL ROMAGNA - Azienda Unità Sanitaria Locale Romagna

ROMA 2 - Azienda Sanitaria Locale Roma 2 (Rome 2 Local Health Authority)

APIs - Application Programming Interfaces

SDK - Software Development Kits

3. Introduction

The DARE project stands out in the research landscape as a beacon of innovation and technological advancement, particularly in its application within the Healthcare System. Specifically, Spoke2 is tasked with bringing about change and innovation in primary prevention through the implementation of new technologies or the repurposing of existing ones with novel functionalities.

Within the Spoke2 context, we find the Work Package 4 (WP4) titled "Digital tools for Primary Prevention," which involves the design of eight pilot projects. These pilot projects aim to promote primary prevention activities through technological innovation, grounded in scientific evidence, and aimed at defining strategies that can be exported and applied in broader contexts.

To accomplish this objective, we are implementing robust protocols in a systematic and methodologically rigorous manner, utilizing standardized procedures and models. The overarching objective is to foster primary prevention activities through the integration of cutting-edge technologies, ensuring the scalability and applicability of these innovations to broader settings based on sound scientific evidence.

3.1. Objectives of the deliverable

WP4 aims to design, implement, and showcase the impactful integration of digital tools, enhancing collaboration between primary health care and hospital care. To this end, WP4 will deploy an original combination of experimental protocols for prospective studies and digital tools and protocols for data acquisition, management, and analysis. The focus is on extensive applications of digital technologies, addressing disease surveillance systems, vaccination programs, cardiovascular risk profiling, and initiatives to prevent falls and injuries.

The first objective of this deliverable is to summarize conceptual models and design experimental protocols for WP4.

The deployment strategy for the available computing solutions across all pilots is a vital component within the broader framework of our initiative. This strategy not only delineates how computing solutions will be introduced and integrated into each pilot project but is also a crucial aspect in ensuring the effective and cohesive execution of the entire program.

This implementation strategy carefully considers the specific needs of each pilot project, acknowledging differences in technological requirements, existing infrastructures, and operational dynamics. Through a thorough assessment, we aim to optimize the adoption of computing solutions while ensuring effective interoperability between various projects and maximizing the benefits derived from the utilization of advanced technologies.

Furthermore, the implementation strategy takes into consideration factors such as staff training, transition management, and adaptation to the specificities of each operational context. This holistic approach aims to ensure a smooth transition to the operational use of computing solutions, thereby contributing to the overall success of the pilot projects and the achievement of set objectives in terms of primary prevention and emergency response.

3.2.WP4 Operational Architecture

Here are brief the descriptions of the activities in the four tasks included in WP4.

Task 4.1 ("Predictive models for automatic disease surveillance system") aims to introduce monitoring methods and predictive models, integrated through data analysis techniques and extensive big data collection. The goal is to create a comprehensive set of statistical tools designed to identify turning points in daily hospitalization trends across various spatiotemporal scales, facilitating the monitoring of environmental exposures related to climate change.

Task 4.2 ("Use of Digital Technologies to Support Vaccination programs") focuses on devising innovative digital strategies to enhance collaboration between territorial and hospital realms in executing vaccination programs for specific vaccine-preventable diseases, with an emphasis on the most susceptible at-risk populationss, and with an integration with surveillance systems for vaccine preventable diseases (VPDs) Pioneering methodologies include data mining between Regional/National vaccination registry, hospital or ER discharge records and VPDs surveillance systems, implementing computerized reservation and, reporting systems (with reserved pathways for at-risk categories), disseminating correct information on vaccines safety and effectiveness through social media channels, and utilizing artificial intelligence tools to address and contrast determinants of vaccination hesitancy determinants.

Task 4.3 ("A sustainable and technological approach to large-scale prevention of falls and injuries") aims to address shortcomings in fall risk assessment and prevention attributed to small sample sizes and study heterogeneity by combining in-silico trial technologies with specialized prospective studies using cost-effective wearable sensor technologies for widespread prevention. A set of analyses, including machine learning-based tools, will formulate robust risk models, aiming for a more comprehensive influence on the prevention of falls and fall-related injuries.

Task 4.4 ("Innovative digital tools for personalized cardiovascular primary prevention") pursues a personalized prevention strategy, utilizing the polygenic risk score independently or in conjunction with digital technologies. This Task will be implemented through a community trial leveraging the digital platform from Task 3.2, with the goal of investigating the impact of pioneering primary interventions on lifestyle modifications. The approach involves employing individualized motivational strategies to encourage and study positive changes in individuals' lifestyles.

4. Data Source Modelling

During the design phase of the pilots, we identified the sources of data for their development and implementation. Each pilot started with a comprehensive literature review to inform its design, ensuring avoidance of redundancy with existing projects. Although data sources varied across tasks, they maintained a thematic connection.

Key data sources include databases from participating institutions, incorporating both hospital-related and territorial data, along with data from the technologies to be implemented.

For hospital-related data, the focus was primarily on clinically relevant information influencing patient participation and providing specific insights for actionable measures. Territorial data will encompass various types, drawn from local registries like the Italian AVR registries.

Lastly, data from devices or procedures defined by individual pilots will inform each pilot with specific information collected from new technologies, sensors, algorithms, or technologies applied to the pilot. These data will be extracted from various platforms and sources, consolidated into purpose-built databases to comprehensively collect, process, and unify information, allowing different types of collected data to interconnect.

Data collection will adhere to current regulations, especially those related to privacy, and will be conducted with explicit consent. Access to the data will be defined for each pilot based on specific needs and prevailing regulations.

SPOKE	WP	TASK	PILOT	ID-PILOT	DataSource	From	Available	Structured
SPOKE 2	WP4	T4.1	Predictive models for automatic disease surveillance systems	S2-WP4-T4.1-P01	Emergency department data	IRCCS AOU BO	Y	Y
					Admission, discharge, hospitalization data	IRCCS AOU BO	Y	Y
					Electronic medical record data	IRCCS AOU BO	Y	Y
					Laboratory data	IRCCS AOU BO	Y	Y
					Radiology data	IRCCS AOU BO	Y	Y
					Outpatient activity data	IRCCS AOU BO	Y	Y
					Pathology data	IRCCS AOU BO	Y	Y
SPOKE 2	WP4	T4.2	Caring for frail patients through vaccination.	S2-WP4-T4.2-P02	Clinical data characterizing frail patients	TrakCare - 'IRCCS Policlinico Gemelli'	N	Y

						hospital departments		
					Vaccination coverage	AVR-Lazio Regional Vaccine Registry	Y	Y
SPOKE 2	WP4	T4.2	Empowerment for vaccinating Communities: Small world networks approach	S2-WP4-T4.2-P03	Hard-to-reach communities data	Social Media	N	Y
					Vaccination coverage data	AVR-Lazio Regional Vaccine Registry	Y	Y
SPOKE 2	WP4	T4.2	Digi-Vax: digitalization of vaccination processes and integration with surveillance systems	S2-WP4-T4.2-P04	Regional Vaccination registry for vaccination coverage rates	ONIT (for Sicilian Region) and other platforms	Y (on Provincia l Level)	Y
					Hospital Discharge records (HDRs) and Emergency Room (ER) discharge records	Regional HDRs and ERs Records	Y	Y
					RespiVirNet and Other VPDs surveillance systems	Regional surveillance systems of vaccine preventable diseases	Y	Y
SPOKE 2	WP4	T4.3	An in-silico trial technology to assess the efficacy of intervention strategies for the prevention of hip fractures.	S2-WP4-T4.3-P05	Cohort of >1000 virtual subjects (Ann Biomed Eng 2023;51:117–24).	UNIBO	Y	Y
SPOKE 2	WP4	T4.3	Muscle power and motor control degradation are better predictor of falls than muscle strength in the aging population.	S2-WP4-T4.3-P06	Clinical data to be obtained on a prospective cohort	IOR	N	y
					Motor tests	IOR	N	Y
					Electromyography	IOR	N	Y
					MRI	IOR	N	Y
					Muscle ultrasound	IOR	N	Y
						IOR	N	Y

					Acceleration and angular velocity (wearable sensor data focused on daily physical activity)			
SPOKE 2	WP4	T4.3	A multivariable model beyond the state of the art for predicting incident falls in community-dwelling older subjects.	S2-WP4-T4.3-P07	Clinical data to be obtained on prospective cohorts	AUSL Romagna, UNIBO, IRCCS	N	Y
					Motor tests	AOUBO AUSL Romagna, UNIBO,	N	Y
					Acceleration, angular velocity, heart rate (wearable sensor data, focused on daily activity and nighttime sleep)	IRCCS AOUBO AUSL Romagna, UNIBO, IRCCS AOUBO	N	Y
SPOKE 2	WP4	T4.4	Digital HeartCare: innovative approaches for personalized primary prevention of cardiovascular diseases (CVDs).	S2-WP4-T4.4-P08	Polygenic Risk Score (PRS)	Hospital departments	N	Y
					Lifestyle data	Wearable	N	Y

5. Logical Data Architecture

As previously discussed, Spoke2 involves the adoption of the Alma Health DB model for data management. Consequently, it will be necessary to establish a Logical Data Architecture for integrating data sources with AlmaHealthDB, utilizing tools like **ETL** (Extract/Transform/Load).

The following tables provide a summary of the planned pilots and the data sources surveyed during the definition phase of each individual pilot.

LIST OF APPROVED PILOTS				
SPOKE	WP	TASK	PILOT	ID-PILOT
SPOKE2	WP4	T4.1	Predictive models for automatic disease surveillance system from the development of a Datalakehouse platform to clinical pathway classification, monitoring and forecasting disease evolution and the impact of climate changes on the hospitalization.	S2-WP4-T4.1-P01
SPOKE2	WP4	T4.2	Caring for frail patients through vaccination (Carevax).	S2-WP4-T4.2-P02
SPOKE2	WP4	T4.2	Empowerment for vaccinating Communities: Small world networks approach (EvACS).	S2-WP4-T4.2-P03
SPOKE2	WP4	T4.2	Digi-Vax: digitalization of vaccination processes and integration with surveillance systems.	S2-WP4-T4.2-P04
SPOKE2	WP4	T4.3	An in-silico trial technology to assess the efficacy of intervention strategies for the prevention of hip fractures.	S2-WP4-T4.3-P05
SPOKE2	WP4	T4.3	Muscle power and motor control degradation are better predictor of falls than muscle strength in the aging population	S2-WP4-T4.3-P06
SPOKE2	WP4	T4.3	A multivariable model beyond the state of the art for predicting incident falls in community-dwelling older subjects.	S2-WP4-T4.3-P07
SPOKE2	WP4	T4.4	Digital HeartCare: innovative approaches for personalized primary prevention of cardiovascular diseases (CVDs).	S2-WP4-T4.4-P08

LIST OF KNOWN DATA SOURCES	
ID-DATA SOURCE	DataSource
S2-WP4-DS-01	Emergency department data
S2-WP4-DS-02	Admission, discharge, hospitalization data
S2-WP4-DS-03	Electronic medical record data
S2-WP4-DS-04	Laboratory data
S2-WP4-DS-05	Radiology data

S2-WP4-DS-06	Outpatient activity data
S2-WP4-DS-07	Pathology data
S2-WP4-DS-08	Clinical data characterizing frail patients
S2-WP4-DS-09	Vaccination coverage
S2-WP4-DS-10	Hard-to-reach communities data from social media
S2-WP4-DS-11	Regional Vaccination registrie for vaccination coverage ratess
S2-WP4-DS-12	RespiVirNet and Other VPDs surveillance systems
S2-WP4-DS-13	Virtual subjects data
S2-WP4-DS-14	Motor tests
S2-WP4-DS-15	Electromyography
S2-WP4-DS-16	Muscle ultrasound
S2-WP4-DS-17	Acceleration from wearable sensors
S2-WP4-DS-18	Angular velocity from wearable sensors
S2-WP4-DS-19	Heart rate from wearable sensors
S2-WP4-DS-20	Lifestyle data from wearable sensors
S2-WP4-DS-21	Polygenic risk score

Efforts are underway through various activities and individual pilot projects to establish data warehouses, enhance accessibility, and provide a unified view of available data in accordance with the Alma Health DB architecture.

For instance, Task 4.1 involves creating a datalakehouse to manage data related to hospital facility access[5].
Similarly, Task 4.2 focuses on developing data warehouse systems to organize data from both hospital and territorial structures, ensuring proper arrangement across diverse platforms.

In the Carevax pilot, a platform is under development to match data from TrakCare at Policlinico Gemelli with information from the AVR system (Regional Vaccine Registry) in the Lazio Region[6]. Additionally, a framework is being established for more effective patient identification and rapid communication. Likewise, the EvACS pilot is creating a data warehouse system to match data from the regional AVR system with Small World[7] community data, identifying areas of interest and planning interventions[8].

In the Digi-Vax pilot, efforts are directed towards establishing communication between Sicilian AVR system (when will became available, actually is under construction and there are 9 different Provincial Vaccination Registry), aiming to match data of vaccines administration[9] with data of Regional surveillance systems for VPDs and HDRs and ERs records for VPDs, in order to evaluate vaccine effectiveness and safety[10]. Moreover, the project aims to optimize organizational aspects such as booking (with specific pathways for at high-risk categories) and contact, registration and reporting systems.

The pilot studies in Task 4.3 involve developing a data collection system linking information from devices and sensors with clinical data to create predictive tools.

Similarly, in Task 4.4, endeavors are focused on matching clinical data with information from devices to create predictive tools and specific interventions[11].

6. Concept of Digital Functions

Given the hierarchical organization of the project, structured into Spokes, Working Packages, Tasks, and pilots, the possible application of Digital Function models[12] has been investigated. The models considered are:

- Decentralized Model
- Federated Model
- Unified Model

During the design of individual pilots, consideration was given to potential areas of overlap and collaboration within WP4 or across the entire project. From this analysis, the possibility of collaboration between Task 4.1, "Predictive models for automatic disease surveillance system" (IRCCS AOU Bologna), and Task 2.2 of WP2 Spoke2, "Interoperable health and digital environmental data for primary prevention," became apparent.

In the context of Task 4.2 pilots, no synergies were identified initially for the development of the three different pilots, leading to the decision to proceed independently. However, upon analysing the structures of each pilot and studying them individually, points of contact emerged that could potentially be developed in subsequent stages.

In the Carevax pilot developed by FPG, points of convergence with the ROMA1 group surfaced, sparking discussions about potential collaboration and application of the project not only at the 'IRCCS Policlinico Gemelli' but also at hospital facilities under the jurisdiction of ROMA1. Similarly, the georeferencing model hypothesized by the Evacs pilot of ROMA1 could prove beneficial in informing the pilots of UNIPA and FPG.

For the Digi-Vax pilot, points of convergence with the pilots of FPG and ROMA1 have emerged, and the technology developed by this pilot could be adapted and applied to simplify, improve, and digitize some processes in the other two pilots. Additionally, for the pilot developed by UNIPA, a potential synergy with Task 3.2 of WP2 Spoke 2, 'Community trial platform,' has been identified.

For the pilot project titled 'A Multivariable Model Beyond the State of the Art for Predicting Incident Falls in Community-Dwelling Older Subjects,' managed by the UNIBO group, potential synergies have been identified with the other two pilots in the same Task. Similarly, synergies have been identified with two other tasks (3.1 and 3.3) belonging to WP3.

Regarding the pilot project 'An In-Silico Trial Technology to Assess the Efficacy of Intervention Strategies for the Prevention of Hip Fractures,' various points of contact and collaboration have been found. Primarily, synergy has been identified with Task 4.2 of WP4 in Spoke1, which examines the prediction of fall risk based on gait analysis. Similarly, synergy has been identified with Spoke3 concerning Task 2.1 of WP2, namely, the 'Clinical Validation of the Digital Twin BBCT,' believing that the application of this model could enhance the credibility of the overall model.

For the pilot project 'Muscle Power and Motor Control Degradation Are Better Predictors of Falls Than Muscle Strength in the Aging Population,' conceived by IOR, synergy has been hypothesized with Task 2.2 of WP2 in Spoke3 regarding 'Personalization and Risk Stratification Tools.'

Regarding the sole pilot project in Task 4.4, developed by UCSC, numerous synergies have been identified within the DARE project. Specifically, points of contact have been found with Tasks 1.3, 2.1, and 2.2 of Spoke2, focusing on digital implementation, surveillance, and data interoperability for primary prevention. Similarly, there are connections with Task 4.4 of Spoke1 concerning technology utilization, particularly wearables. Lastly, points of contact have been established with Tasks 1.2 ('Collecting Evidence and Indicators within the Pilots'), 3.3 ('Digital Tools in Cardiometabolic Diseases'), and 5.5 ('Non-Medical Wearable Devices for Monitoring Caloric Intake') within Spoke3.

7. Definition of Protocols

In accordance with the central coordination of the Spoke and other work packages, particularly WP2, we sought an architecture that could support various pilot projects, define the methodology within the WP, and establish relationships among tasks and pilots. The identified common procedure involves several phases to effectively manage the process. The identified phases are as follows:

- Collect
- Ingest
- Store
- Compute
- Consume

Each of these phases is considered *necessary* and fundamental for the development of individual pilots, especially for proper technological implementation and effective utilization and dissemination.

To inform and monitor activities within a highly heterogeneous WP, we decided to apply a framework identified as the AGILE Framework[13].

The agile methodology follows an iterative structure based on the phases of:

1. Requirements
2. Design
3. Development
4. Testing
5. Deployment
6. Review

Most pilots within various tasks currently find themselves between phases 2 and 3. Some pilots are in more advanced stages, initiating the testing phase, while others are reviewing and completing the design phase of the study.

Within Task 4.1, a single pilot study was developed leveraging the collaboration between IRCCS AOUBO, UNIBO, and UNIPD with the aim to develop predictive models for automatic disease surveillance system from the development of a datalakehouse platform to clinical pathway classification, monitoring and forecasting disease evolution and the impact of climate changes on the hospitalization. To achieve this, the Task 4.1 pilot team developed technical specifications for the creation of a business intelligence system and corporate datalakehouse, to be implemented at AOUBO.

Regarding Task 4.2, three independent pilots were developed and coordinated by FPG, ROMA1, and UNIPA, respectively.

In the first pilot (FPG), the approach involved extracting data to characterize frail patients affiliated with IRCCS 'Policlinico Gemelli' and matching them with the regional vaccination registry [6](and eventually the national registry once completed and implemented). To achieve this, an algorithm was devised to identify relevant clinical characteristics, aiming to identify frail patients through a mask utilizing ICD9 codes[14] and Exemption Codes.

Concerning the pilot developed by ROMA1, its focus is on using data from the regional vaccination registry to analyse vaccine coverage in specific georeferenced areas of interest, particularly within certain communities. The goal is to initiate actions, especially through targeted social campaigns, to raise awareness on the subject. To monitor the impact of awareness initiatives, sentiment analysis will be conducted, with a georeferencing component to track information.

As for the pilot developed by the University of Palermo, the developed technologies could be readapted and utilized interchangeably across the three pilots, providing even greater strength and eliminating weaknesses in individual approaches. This cross-applicability allows for a more cohesive and robust implementation of the developed tools. By sharing and integrating technological solutions, the pilots can benefit from a synergistic effect, enhancing their overall effectiveness and potentially addressing any shortcomings identified in the individual approaches, especially for populations at high-risk of developing Vaccine Preventable diseases (VPDs). This collaborative and interchangeable use of technologies fosters a more comprehensive and integrated approach to achieving the common goals of the pilots.

The goal of the Digi-Vax pilot is to overcome challenges in data collection, partly dictated by current privacy laws, by implementing new surveillance systems and a novel data extraction methodology on platforms such as the Regional Hospital Discharge and Emergency Rooms records and the Vaccine Preventable Diseases (VPDs) Regional system. This integration could help in evaluating effectiveness and safety of vaccines included in the National and Regional Immunization Plans.

Task 4.3 has been developed to include three main pilot projects with the overarching goal of developing a sustainable and technological approach to large-scale prevention of falls and injuries. Synergies between pilot projects have been explored during Task meetings and have led to the identification of common approaches to wearable sensor selection and data acquisition.

In particular, one pilot study under Task 4.3 was started in collaboration between UNIBO and IOR to develop and implement an in-silico trial technology named *BoneStrength* to assess the efficacy of intervention strategies for the prevention of hip fractures. Virtual cohorts are generated using a statistical atlas, based on a dataset of CT scans of a physical cohort of postmenopausal women[15]. By the end of the project, the pilot plans to simulate at least two prevention strategies in a large cohort (approx. 1000 virtual subjects, typical sample size of phase III clinical trials) with long-term follow up (5-10 years).

Another pilot study under Task 4.3 was developed in collaboration between IOR and UNIBO to test whether muscle power and motor control degradation are better predictor of falls than muscle strength in the aging population. The pilot project team developed a study protocol to be submitted to the local Ethical Committee with the contribution of the departments and clinical units that will be actively involved in the enrollment phase and/or in the data collection (e.g., Radiology, Rehabilitation). The protocol foresees the recruitment of individuals older than 65 years diagnosed with knee osteoarthritis, who will be followed for 2 years. The prospective data gathered will be used to generate a digital twin (musculoskeletal model) for each participant and perform biomechanical simulations of common tasks.

The third pilot study under Task 4.3 was started at UNIBO with the aim of achieving a multivariable model beyond the state of the art for predicting incident falls in community-dwelling older subjects. The approach is based on combining the FRAT-UP scale, a state-of-the-art tool for fall risk estimation validated on different European cohorts [16] with information on physical activity, sleep, and heart rate from wearable sensors. The protocol foresees the recruitment of individuals older than 65 years, who will be followed for 1 year. Information on direct costs associated with falling will be gathered in collaboration with ROMA2 under Spoke 1. The pilot study deployment is foreseen to include as a main clinical study involving UNIBO and AUSL Romagna and recruiting frail and non-frail elderly subjects, as well as three smaller studies involving UNIBO, AUSL Romagna and IRCCS AOUBO to explore the scalability to different contexts, including hospital inpatients and the general population).

In task 4.4, the final definition of the pilot is still in progress. The UCSC group is actively engaged in delineating the pathway, specifying the target population, and refining the ultimate study design. In brief, the pilot aims to evaluate the efficacy of combining genetic[17] and digital interventions in inducing lifestyle modifications among participants and preventing the potential development of cardiovascular diseases (CVDs)[18]. During the development of the pilot, UCSC will collect data regarding polygenic risk score profile of cardiovascular risk of the participants, lifestyle of the participants (including socioeconomic status, area of residence, smoking status, alcohol consumption, dietary pattern, sleep pattern and physical activity), and biometric data of the participants (weight, height, etc.)[19]. The data will be integrated with the systems operating at Policlinico Gemelli.

8. API Library Model

The Application Programming Interfaces (APIs)[4] will constitute a fundamental phase in the development of technologies utilized in various pilots. The use of API technology will ensure easier management of applications, data, and technologies, both from a practical and innovative standpoint, as well as from a security perspective.

To achieve this, we will implement the API Library Model, enhancing programming, development, and functionality. APIs will facilitate seamless communication with components like databases, applications, and other systems in the various pilot projects described earlier.

The use of tools like RESTful[3] provides a fundamental instrument for data integration in the pilots. One of the fundamental aspects that emerged in the drafting, design, and implementation of pilots is the need for a tool that rapidly integrates data from various sources, often belonging to third parties.

The components that will be implemented in the WP4 pilot projects, with the support of Spoke2 and Spoke1, are:

- Data Model: would enable a rapid and accurate exchange of data between organizations and API servers. This would ensure a high degree of flexibility and continuous improvement in communication between various sources and APIs.

- Endpoints: would ensure a faster communication system through a direct process between parties and the API architecture.

- Authentication and Authorization: increased security in data management and access.

- SDK: Software Development Kits would provide significant support for creating applications useful for pilot implementation.

- Versioning: would allow continuous updating of technologies developed to support the pilots, avoiding interruptions and malfunctions.

During the pilot implementation process, it will be defined how and which components of the API library to leverage, specifying technical aspects with the support of experts within individual organizations or with the support of Spoke1 experts. Furthermore, the use of the API platform and its libraries will make it easier to make the data collected by individual pilots available to all participants in the DARE project.

9. Conclusions

The present document outlines the design and organizational models applied within WP4 of Spoke2, aimed at implementing technological innovations in primary prevention. To achieve this, it was necessary to precisely define the digital functions to be adopted, the protocols, and the theoretical and technological models to be applied.

The process began with the collection of data sources identified by various organizations within the individual pilots to inform their respective projects. Subsequently, consideration was given to how these data could be extracted, structured, and harmonized, defining the Logical Data Architecture to be incorporated into the Alma Health DB and made available. This step is crucial for the future implementation of the created models by both project partners and external entities involved in the DARE project.

During the work, the possibility of implementing federated or decentralized models emerged due to the numerous connections identified within the various pilots, although the initially hypothesized models tended towards a Unified Model.

Furthermore, concerning protocols, based on Spoke2's suggestion, it was decided to monitor and coordinate the work using the AGILE model.

Finally, efforts are underway to apply the API model in the implementation of the pilots, ensuring better project management, easier attainment of endpoints, and the utilization of services by end-users or third parties.

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