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**DARE**  
**DIGITAL LIFELONG PREVENTION**  
**CODE NO. PNC0000002**

Spoke 2  
**D1.2 Stakeholders' network and  
planned activities**

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## SP 2 D1.2 Stakeholders' network and planned activities

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## Disclaimer

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## Table of contents

|   |           |
|---|-----------|
| <b>Document history</b> .....                         | <b>3</b>  |
| <b>Disclaimer</b> .....                               | <b>3</b>  |
| <b>Table of contents</b> .....                        | <b>4</b>  |
| <b>1. Introduction</b> .....                          | <b>5</b>  |
| <b>2. Stakeholders' Network</b> .....                 | <b>6</b>  |
| <b>2.1. Stakeholder Definition</b> .....              | <b>6</b>  |
| <b>2.2. Stakeholder Participation</b> .....           | <b>6</b>  |
| <b>2.3. Stakeholder Engagement Strategies</b> .....   | <b>7</b>  |
| <b>2.4. Stakeholders engagement and GDPR</b> .....    | <b>8</b>  |
| <b>2.5. Stakeholders Platform</b> .....               | <b>9</b>  |
| <b>3. Planned Activities</b> .....                    | <b>12</b> |
| <b>3.1. Pilots List and Description</b> .....         | <b>12</b> |
| <b>4. Digital IT Infrastructure Description</b> ..... | <b>37</b> |

## 1. Introduction

The objective of Spoke 2 of the DARE project involves the execution of multiple pilot initiatives focused primarily on primary prevention. Each pilot project entails active participation from diverse stakeholders, each possessing specialized expertise in distinct roles such as health planning and management, epidemiology, data flow management, data acquisition, management and analysis, technology transfer, and more. Therefore, the creation of these pilot projects is closely linked to the collaborative efforts of multidisciplinary teams.

In the framework of a community-based ecosystem building a network of the institutions and stakeholders involved in the Spoke 2 activities will be established through dedicated agreements.

This deliverable serves the purpose of delineating these stakeholders, considering the varying degrees of their involvement, defining the communication channels that will facilitate interaction among them, and outlining strategies for engaging new participants. Furthermore, it will describe the platform designed to foster collaboration and interaction among the different components within each pilot, detailing the essential characteristics it must possess.

The document will also offer a comprehensive summary of the activities within Spoke 2, providing concise descriptions of the pilot projects and the respective stakeholders associated with each. Finally, it will underscore the underlying concept and necessity of the high-performance computing (HPC) infrastructure to be implemented.



## 2. Stakeholders' Network

This section focuses on the definition of stakeholders, their participation modes and engagement strategies. Finally it focus on the platform with which they will be able to interface. The next section (3 "Planned Activities") aims to provide a dynamic and non-exhaustive mapping of the stakholders currently involved for the implementation of the project pilots.

### 2.1. Stakeholder Definition

What is a Stakeholder? How can it be defined? A stakeholder is a party that has an interest in a project or activity and can affect or be affected by the business. The primary stakeholders in a typical project/activity/corporation are investors, employees, customers, and suppliers. However, with the increasing attention on health policy and planning and social responsibility, the concept has been extended to include governments, health agencies, hospitals, communities, schools, community pharmacies, scientific societies, patients' and citizens' associations.

Stakeholders can be internal or external to an organization. Internal stakeholders are people whose interest in a project/company comes through a direct relationship, such as employment, ownership, or investment. External stakeholders are those who do not directly work with a project/company but are affected somehow by the actions and outcomes of the business. Suppliers, creditors, and public groups are all considered external stakeholders. Stakeholders are important for a number of reasons. For internal stakeholders, they are important because the project's operations rely on their ability to work together toward the final's goals. External stakeholders on the other hand can affect the project indirectly. Ultimately, managing relationships with internal and external stakeholders is key to a business's long-term success.

### 2.2. Stakeholder Participation

Since the stakeholders have been defined and classified as internal and external, it is important to define and better describe their level of participation. As regards the DARE project, 4 levels of stakeholders' involvement have been proposed: a first level is the

**informative** one (making the project known), the second one, the intermediate level, is the **consultative** one for some reference topics, the third level is the collaborative one (i.e. the stakeholder actively collaborates in the giving activity), and, lastly, the fourth level is the **authorization** level (i.e. those who must provide authorizations for the processing of information functional to the execution of project activities without being involved in their implementation but potentially being able to benefit from them). All stakeholders currently included in the project and those already active in the various pilots are automatically considered in the level **collaborative**.

### 2.3. Stakeholder Engagement Strategies

In this project, as regards the stakeholder engagement strategy, several meetings have been held and precise decisions have been made. As an internal rule, except for institutional partners, with whom a signed agreement is necessary, it has been decided that signatures or specific forms are not required to undertake engagement activities with external stakeholders. The methods of engagement may be informative, consultative or collaborative. In each case, there is no need for signatures, contracts or anything else.

Regarding the channels through which the engagement can take place, 2 channels of involvement have been identified: **physical participation** (seminars, information activities and local workshops), and involvement via **digital channels** (webinars, surveys, email communications).

In addition, stakeholders can be engaged in different ways, including:

**Standard Invitation:** A uniform invitation letter, approved by all consortium members, will be prominently displayed on the project website. Additionally, a registration form will be provided to gather necessary information from participants.

**Private Information:** Confidential contact details of stakeholders will be handled by the DARE consortium partner, who will reach out to them. Upon receiving consent, their information will be incorporated into the unified communication system.



Registration Form: A platform for the registration of stakeholders, via the web, with an user-friendly interface and with a multiple access level was also planned by Spoke 1, to record all the activities carried out and with the aim of having information on them.

Informed Consent: During the registration process, participants must fill out an informed consent form, indicating their willingness to proceed. This measure is in place to uphold transparency and adhere to privacy regulations.

Finally, it was decided to carry out an in-person, digital presentation event for a meeting between DARE staff (WP leaders, Pilot leaders), and interested stakeholders, showing and describing the various proposed pilots, through small presentations and summary and information sheets. Interested stakeholders can be found directly in the appropriate section of the pilot sheet and must be contacted to participate in the event. This event is obviously open to all stakeholders who, interested in the aims and work of the project, wish to participate and continue the collaboration at one of the three levels previously described.

## 2.4. Stakeholders engagement and GDPR

The integration of GDPR principles into communication between stakeholders to a research project (in this case the pilots) is essential for ensuring the protection of individuals' privacy and the lawful processing of personal data. Stakeholder engagement, a crucial aspect of any research endeavor, demands a transparent and compliant approach. First and foremost, explicit consent mechanisms should be established, clearly outlining the purpose and scope of data processing activities. Information shared among stakeholders should adhere to the principles of data minimization, ensuring that only necessary and relevant data is exchanged. Additionally, robust data security measures should be implemented to safeguard sensitive information during transmission. Regular audits and assessments of data processing practices can further guarantee ongoing GDPR compliance. By incorporating these measures into communication protocols, research projects can foster trust, uphold privacy rights, and demonstrate a commitment to ethical data handling practices. The related WPs of the DARE project can be involved in those aspects.

## 2.5. Stakeholders Platform

The Stakeholder Platform, tailored as a dedicated web software tool, facilitates robust stakeholder engagement within the scope of the DARE project. Envisioned as a vibrant and interactive hub, it nurtures communication, collaboration, and the seamless exchange of information between stakeholders and diverse project members.

The platform will be designed and developed by Spoke 1 researchers in order to prioritize user experience and interaction, adapting to evolving project needs and technological advancements, ensuring continuous relevance and effectiveness. Its design fosters collaborative innovation and informed decision-making, making it a vital asset that could serve as a blueprint for future initiatives.

Outlined below are the platform requirements, viewed through the lens of stakeholder engagement:

1. **User-friendly interface:** The platform will feature an intuitive, user-centered interface to encourage greater participation and engagement, thus ensuring effortless navigation and interaction for users with a diverse range of technical skills. It will feature an easily accessible dashboard with clear labeling and interactive tutorials, enabling a simplified experience for users accessing the platform.
2. **Multi-Level Access Control:** The platform will implement a stratified access framework, assigning differentiated access levels to users, stakeholders, and administrators. This structure ensures secure and appropriate access to various platform features and information, tailored to the roles and responsibilities of each user group.
3. **Interactive Forums & Discussion Boards:** The platform will incorporate interactive forums and discussion boards to foster a vibrant dialogue and exchange of ideas among stakeholders. These spaces will serve as a conduit for discussing project developments, addressing challenges, and exploring opportunities in a collaborative milieu.

4. **Document Repository:** The platform will house a secure and systematically organized repository to host all pertinent project documents, publications, and resources. This repository will serve as a centralized hub for knowledge management, enabling stakeholders to effortlessly access and share crucial information.
5. **Notification & Alert System:** The platform will feature an automated notification and alert system to keep stakeholders abreast of the latest updates, upcoming events, and key milestones related to the DARE project.
6. **Feedback Mechanism:** The platform will provide a conduit for stakeholders to voice their feedback on various project facets through an array of tools such as surveys, polls, and feedback forms.
7. **Data Visualization Tools:** The platform will incorporate advanced data visualization tools to present project data and progress in a comprehensible and accessible manner. It will be employed integrate interactive charts, graphs, and dashboards to visually articulate complex data sets, making it easier for stakeholders to grasp the project's status, trends, and key metrics briefly.
8. **Mobile Responsiveness:** The platform is engineered to boast full responsiveness, guaranteeing an optimal viewing and interaction experience across a diverse spectrum of devices including mobile phones, tablets, and desktop computers. The platform will have a fluid layout that will adapt to different screen sizes and orientations will ensure that users can access and navigate the platform with ease, irrespective of the device they are using.

## Technical Details & Development Goals

1. **Scalable Architecture:** The platform will be founded on a scalable architecture, poised to accommodate a burgeoning user base and escalating data volumes as the project advances.
2. **Security Protocols:** The platform will integrate robust security measures, including encryption and Secure Socket Layer (SSL) technology, to safeguard user data and thwart unauthorized access. The employing SSL technology will ensure that the data



transmitted between the user and the platform remains encrypted and secure, thereby significantly reducing the risk of data interception.

3. **Data Management:** The platform will implement efficient data management systems to adeptly handle the storage, retrieval, and analysis of extensive datasets generated throughout the DARE project. In such a context, a robust database management system (DBMS) could be employed to ensure data integrity, consistency, and accessibility by leveraging data indexing and optimized query processing techniques to significantly expedite data retrieval and analysis, facilitating timely insights.
4. **API Integrations:** The platform will integrate various Application Programming Interfaces (APIs) to foster interoperability with other software tools, thereby enabling the fluid exchange of data and augmenting the platform's functionality. So, integrating APIs from project management or data analytics tools will facilitate the automatic import/export of relevant data, ensuring a cohesive and updated view of project metrics.
5. **Continuous Improvement:** The platform is committed to a cycle of continuous improvement, with regular updates and enhancements being rolled out based on user feedback and technological advancements. This iterative approach will ensure that the platform remains aligned with the evolving needs of stakeholders and the project at large.
6. **Development Goals:** The main goals steering the development phase encompass ensuring the platform's reliability, usability, and adaptability. The design ethos is centered around nurturing meaningful engagement and collaboration among stakeholders, efficacious dissemination of project information, and substantially contributing towards realizing the DARE project's objectives.
7. **Sustainability:** A concerted effort will be directed towards ensuring the platform's sustainability beyond the tenure of the DARE project, envisaging it as a lasting resource for stakeholders and the extended community. A modular and scalable architecture will provide the groundwork for future expansions or adaptations, catering to the evolving needs of subsequent projects or initiatives.

### 3. Planned Activities

The implementation of Spoke 2 activities are guided by the implementation of pilots. Each pilot is primarily focused on primary prevention. The design and development of each pilot has included and involves the involvement of various stakeholders. The different stakeholders may represent the institutional levels or possess specialized expertise in distinct roles such as health planning and management, epidemiology, data flow management, data acquisition, management and analysis, technology transfer, and more.

For this reason, Section 3.1 provides a brief description of all the pilots proposed in spoke 2. For each pilot, the main purpose will be laid out, as well as the stakeholders involved for the design and future implementation phases. The pilots briefly outlined below are not exhaustive but dynamic and exemplary.

#### 3.1. Pilots List and Description

##### 1. Boostering population-based registries to improve multiple data linkage - LINK

**Brief Description:** The Pilot LINK aims to develop an advanced interoperable surveillance system on cancer, powered by an innovative digital infrastructure, integrating data from cancer registries with data from the primary healthcare level (general practitioner and pediatricians), allowing to implement innovative digital primary prevention strategies. To this end, a machine learning-aided online network will be deployed to interconnect Cancer Registries and new data sources like medical pathology services, general practitioners, and pediatricians. This approach will enhance the conventional cancer surveillance reporting process by connecting new data sources and implementing a machine learning algorithm to identify relevant documents and aiding operators with the automatic classification of oncology cases.

Moreover, a combined use of artificial intelligence and Lean Six Sigma will improve timeliness, appropriateness and quality of cancer surveillance, paving the way at the same time to study the epidemiology of cancer and the effectiveness of primary prevention strategies.

These digital functions will be developed in support of an Advanced Cancer Surveillance System and of a Digital Prevention Research Center conceived to support the local and the

national health authorities, in the upcoming framework of the National Prevention Hub and of the National System on Health, Environment and Climate protection.

**Leading Partner institution:**

- Azienda Ospedaliero Universitaria Policlinico "G.Rodolico - San Marco, Catania (AOUPCT)

**List of other Partners involved in the pilot design:**

- Università degli Studi di Palermo
- Università degli Studi di Enna Kore
- ARPA Sicilia

**List of other Partner institutions involved in the pilot implementation:**

- Azienda Ospedaliera Universitaria Policlinico "P. Giaccone", Palermo (AOUPPA)
- Local Health Agencies,
- Health Professional Organizations

**2. A population-based digital approach to interoperate cancer registries, specialized clinical/pathology networks and data flows, using suitable data mining solutions (focus on female cancers)**

**Brief Description:** To develop digital functions in support of an advanced interoperable cancer surveillance system to investigate the risk factors associated with cancer occurrence, to predict the risk of cancer development, to perform real world analyses and high resolution studies, while interoperating cancer registries with specialized pathology registries (including molecular data) from clinical specialized network, and data from the general population (lifestyles, occupational exposure, etc.), with the aim of implementing innovative community-based digital primary preventive interventions. The pilot will focus on the female cancers (breast, cervix, endometrial, ovarian, vulvar) because of different lifestyle behaviors and other social and health determinants that can influence the development of these tumors.

To these ends, the Sicilian Cancer Registries, accounting for 20000 new cancer cases per year since 2003, and databases provided by the Sicilian oncological network, including its molecular Tumor Board, will be interoperated to apply suitable data mining solutions.

These digital functions will be developed in support of an Advanced Cancer Surveillance System and of a Digital Prevention Research Center conceived to support the local and the national health authorities, in the upcoming framework of the National Prevention Hub and of the National System on Health, Environment and Climate protection.

**Leading Partner institution:**

- Università degli Studi di Enna Kore

**List of other Partners involved in the pilot design:**

- Università degli Studi di Palermo
- Azienda Ospedaliero Universitaria Policlinico "G.Rodolico -San Marco", Catania
- ARPA Sicilia

**List of other Partner institutions involved in the pilot implementation:**

- La Rete Oncologica Siciliana
- Rete siciliana Registri Tumori
- ASP Enna
- Azienda Ospedaliera Universitaria Policlinico "Paolo Giaccone", Palermo
- ARNAS Ospedali "Civico - Di Cristina -Benfratelli", Palermo
- ARNAS "Cannizzaro", Catania
- Local Health Agencies

**3. A population-based digital approach to interoperate cancer registries, specialized clinical/pathology networks and data flows, using suitable data mining solutions (focus on the digestive tract)**

**Brief Description:** To develop digital functions in support of an advanced interoperable cancer surveillance system to investigate the risk factors associated with cancer occurrence, to predict the risk of cancer development, to perform real world analyses, while interoperating cancer registries with specialized pathology registries (including data from biobanks) from clinical specialized network, and data from the general population (lifestyles, occupational exposure, etc.), with the aim of implementing innovative community-based digital primary preventive interventions. The pilot will focus on the six major digestive tract cancers (cancers of the esophagus, stomach, liver, biliary tract, pancreas and colorectal) because they currently account for approximately 25% of

diagnosed cancers and because different lifestyle behaviors and other social and health determinants can influence the development of these tumors.

To these ends, the Sicilian Cancer Registries, accounting for 20000 new cancer cases per year since 2003, and the SINTESI digital platform, which provides data of over 50,000 subjects with metabolic, autoimmune and virological diseases of the liver, and other databases provided by the Sicilian oncological network and its molecular Tumor Board, will be interoperated to apply suitable data mining solutions.

These digital functions will be developed in support of an Advanced Cancer Surveillance System and of a Digital Prevention Research Center conceived to support the local and the national health authorities, in the upcoming framework of the National Prevention Hub and of the National System on Health, Environment and Climate protection.

**Leading Partner institution:**

- Università degli Studi di Palermo

**List of other Partners involved in the pilot design:**

- Azienda Ospedaliero Universitaria Policlinico "G.Rodolico -San Marco", Catania
- Università degli Studi di Enna Kore
- ARPA Sicilia
- University of Pittsburgh Medical Center Italy

**List of other Partner institutions involved in the pilot implementation:**

- Rete siciliana Registri Tumori
- La Rete Oncologica Siciliana
- Rete multidisciplinare per la prevenzione, diagnosi e la terapia dei tumori primitivi del fegato in Sicilia
- Azienda Ospedaliera Universitaria Policlinico "Paolo Giaccone", Palermo
- ASP Enna
- Local Health Agencies

#### **4. Interoperating population-based registries and environment monitoring system**

**Brief Description:** To develop an advanced interoperable surveillance system on cancer powered by an innovative digital infrastructure integrating data from cancer registries with data from environment monitoring systems (integrated with data collected from individual



or community exposure measured by sensors), allowing to implement innovative community-based digital primary preventive strategies.

These digital functions will be developed within a Digital Prevention Research Center conceived to support the local and the national health authorities, in the upcoming framework of the National Prevention Hub and of the National System on Health, Environment and Climate protection.

**Leading Partner institution:**

- Università degli Studi di Palermo

**List of other Partners involved in the pilot design:**

- ARPA Sicilia
- Azienda Ospedaliero Universitaria Policlinico "G.Rodolico -San Marco", Catania
- Università degli Studi di Enna Kore

**List of other Partner institutions involved in the pilot implementation:**

- Azienda Ospedaliera Universitaria Policlinico "Paolo Giaccone",
- La Rete Oncologica Siciliana
- Rete siciliana Registri Tumori

## **5. Managing the effects of environmental exposures across the lifespan on health outcomes in different target populations using suitable data mining solutions**

**Brief Description:** To protect community health across the lifespan in different target populations (newborns, children, pregnant women, adults, elderly) from long-term exposure to environmental pollution, following a coordinated inter-institutional effort and using suitable data mining solutions.

The digital functions developed through this pilot will be implemented within a Digital Prevention Research Center, conceived to support the local and the national health authorities in the upcoming framework of the National Prevention Hub and of the National System on Health, Environment and Climate protection.

**Leading Partner institution:**

- ARPA Sicilia
- Università degli Studi di Palermo

**List of other Partners involved in the pilot design:**



- Università degli Studi di Enna Kore
- Azienda Ospedaliero Universitaria Policlinico "G.Rodolico -San Marco", Catania

**List of other Partner institutions involved in the pilot implementation:**

- Sicilian Health Regional Agencies,
- Sicilian Health Regional Authority

**6. Implementing an interoperable web-based platform to support health surveillance against latent tuberculosis infection in health care workers and students to define prevention strategies and interventions**

**Brief Description:** Tuberculosis (TB) prevention is a major goal in teaching hospital setting. Because of the possible progression or reactivation of latent disease, the screening of both health-care workers (HCWs) and students is an important issue in the TB control program. The aim of this Pilot will be to create an interoperable web-based platform to provide health surveillance against LTBI in teaching hospitals in Italy.

**Leading Partner institution:**

- Fondazione Policlinico Universitario "Agostino Gemelli" IRCCS, Roma

**List of other Partners involved in the pilot design:**

- Università degli Studi di Palermo
- Università degli Studi di Bologna

**List of other Partner institutions involved in the pilot implementation:**

- Azienda Ospedaliera Universitaria Policlinico "Paolo Giaccone", Palermo
- Azienda Ospedaliera Universitaria Policlinico "Giovanni XXIII", Bari

**7. An Assess, Warn & Response (AWARE) approach to monitor and prevent the effects on human health of high-intensity pollution generated by environmental emergencies or disasters, including the effects of climate change and natural hazards.**

**Brief Description:** To protect communities and the environment from high-intensity pollution generated by environmental emergencies or disasters, including the effects of climate change and natural hazards, adopting an 'Assess, Warn & Response' (AWARE) approach in a coordinated inter-institutional effort in support of preparedness.

The digital functions developed through this pilot will be implemented within a Digital Prevention Research Center, conceived to support the local and the national health authorities in the upcoming framework of the National Prevention Hub and of the National System on Health, Environment and Climate protection.

**Leading Partner institution:**

- ARPA Sicilia
- Università degli Studi di Palermo

**List of other Partners involved in the pilot design:**

- Università degli Studi di Enna Kore
- Azienda Ospedaliero Universitaria Policlinico "G.Rodolico -San Marco", Catania

**List of other Partner institutions involved in the pilot implementation:**

- Sicilian Local Health Agencies,
- Sicilian Health Regional Authority,
- ISS

**8. Model of diseAses related to environmental exposure to heavy meTals, nanopaRticles and emergent contaminants, using a dIgitAl platfOrm of clinical and bio-humoral data: the way to Susceptibility/RisK BiomArker [MATRIOSKA Study].**

**Brief Description:** Heavy metals, nanoparticles, and emergent contaminants are environmental factors able to impact on biological systems functioning and host human cells, potentially causing serious damage.

Both environmental exposures and individual susceptibility play an important role in the development of allergic contact dermatitis (ACD), a common occupational health problem with a significant incidence.

Furthermore, in about 20% of ACD patients, the ingestion of nickel-rich foods causes systemic skin disorders and extracutaneous multi-organ symptoms, expressed singularly or in variable association.

In the MATRIOSKA study, we aim to address primary prevention of allergic diseases related to heavy metals and nanoparticles exposure in at-risk populations.

We will collect environmental, biological, and clinical data from workers and subjects exposed to heavy metals and nanoparticles, patients with ACD, patients with systemic allergic syndromes, and general population.

**Leading Partner institution:**

- Fondazione Policlinico Universitario “Agostino Gemelli” IRCCS, Roma

**List of other Partners involved in the pilot design:**

- ARPA Sicilia
- Università degli Studi di Palermo

**9. Monitoring lifestyles and health determinants in different settings and population targets through novel technological approaches for digital primary prevention.**

**Brief Description:** The pilot project is aimed at: 1) creating a database (Lifestyle Platform) in which data collection system is based on digital technologies and 2) developing predictive models for the primary prevention of chronic non-communicable diseases.

Therefore, novel digital tools will be tested to collect information on physical activity, sedentary behavior, physical fitness, diet, smoke/alcohol/drug habits, sleeping, metabolic and weight status, psychological, neurological and socio-economic-cultural-environmental aspects in different settings and target populations

**Leading Partner institution:**

- Università degli Studi di Palermo

**List of other Partners involved in the pilot design:**

- Università degli Studi di Bologna
- University of Pittsburgh Medical Center Italy

**List of other Partner institutions involved in the pilot implementation:**

- Regional health authority
- Local health agencies (Prevention Departments, Health Districts, Health houses, Reference centers for diseases)
- USR - Regional School office
- Pharmacies (Federpharma)
- Municipalities

## 10. Interoperable community trial platform

**Brief Description:** A digital infrastructure will be deployed to conduct community trials to assess the effectiveness of preventive interventions, including digital tools for innovative primary prevention paths, and post marketing evaluations using a real world evidence approach.

This digital function will be implemented within a Digital Prevention Research Center, conceived to support the local and the national health authorities in the upcoming framework of the National Prevention Hub.

### Leading Partner institution:

- Università degli Studi di Palermo

### List of other Partners involved in the pilot design:

- Università degli Studi di Enna Kore
- Azienda Ospedaliero Universitaria Policlinico "G.Rodolico -San Marco", Catania

### List of other Partner institutions involved in the pilot implementation:

- Local Health Agencies,
- Hospital Agencies,
- IRCCS Policlinico di Sant'Orsola, Bologna,
- Clinical Trial center at AOUPPA,
- Federpharma,
- Farmaindustria,
- Regional School Office,
- Scientific society and healthcare integrated network,
- Private Partners

## 11. SHAPE program - Staying Healthy After a solid organ transplant: a digital Primary prEvention wellness program for non-communicable diseases (NCDs) and brain health

**Brief Description:** We aim to implement a global strategy for primary prevention of NCDs, including diabetes, cancers, chronic respiratory disease and cognitive impairment, based on a multi-domain lifestyle approach among selected solid organ recipients (heart, liver, kidney, lung, pancreas and combined) with sustained remission of end-organ dysfunction. The intervention will consist in a digitalized holistic approach including nutritional

guidance, physical exercise plan, cognitive training, social activities promotion ideas, sleep hygiene rules, alcohol/tobacco/substances abstinence campaigns and educational programs on vascular and metabolic risk factors.

All interventions will be tailored to the organ specific transplanted categories employing digital technology, as smartphones and web-based platforms, which represents a new paradigm for global health improving patient's adherence and compliance 1.

This Pilot will be complementary to the other T3.1 Pilot dealing with other targets groups selected from the general population. Both the mentioned Pilots will support of a Digital Prevention Research Center conceived to support the local and the national health authorities, in the upcoming framework of the National Prevention Hub.

**Leading Partner institution:**

- UPMCI

**List of other Partners involved in the pilot design:**

- Università degli Studi di Palermo

**List of other Partner institutions involved in the pilot implementation:**

- Digital solution company to build apps and software
- Primary care physician organizations
- Specialist scientific associations
- Pharmacies' networks
- patient's associations

## **12. Preventing psychological issues related to work and lifestyles in the digital transition era**

**Brief Description:** The aim of this pilot is to prevent workers' psychological issues generated or exacerbated by work, an unsustainable work-life balance, and problematic lifestyles.

In the first phase, the pilot study will include a systematic review, which will be performed according to the PRISMA guidelines, on the following topics:

- work-life balance and workers' well-being
- lifestyle measures and metabolic measures associated with workers' well-being

- psychological issues of workers in target workplaces (industry, construction, education, health, public administration, financial sector, clerks).

As concerns the experimental phase, the pilot will be organized into two data collection actions.

The first data collection will exploit data collected from self-reported questionnaires specifically designed for measuring lifestyles (with particular attention to sleep, nutrition, and physical activity), work-life balance, and psychological work-related issues (e.g., burnout, stress, depression) to identify the risk factors for the onset of psychological diseases.

The second data collection is aimed at exploiting physiological and behavioral data gathered from sensors and wearable devices, both during work and spare time, to predict the onset of psychological issues. Additional data will be collected through peripheral blood sampling for the quantification of systemic oxidative stress and inflammation, which are determined by lifestyle and play a key role in the pathogenesis of chronic diseases.

For both data collections, 2 follow-ups are envisaged (at 3 or 6 and 12 months), in order to monitor the worker's mental health and identify those cases that actually developed a psychological condition (e.g., stress, depression) which is worthy of attention.

All the data will be analyzed using machine learning techniques to build predictive models to identify people at risk of developing psychological diseases and to identify risk factors.

Finally, the last phase of the pilot will be dedicated to preventive action through the communication of the results obtained from the data collection and the distribution of informative material and guidelines in organizations, especially those operating in the working contexts that will be identified as the riskiest for the workers' mental health.

**Leading Partner institution:**

- Università degli Studi di Padova

**List of other Partners involved in the pilot design:**

- Università degli Studi di Bologna
- Università degli Studi di Palermo



### 13. Use large-scale cohort studies to identify lifetime, environmental and occupational determinants of healthy ageing

**Brief Description:** The aim of this proposal is to combine and integrate data from on-going cohort studies in order to produce evidence on ageing-related health characteristics and determinants, and their socio-economic implications.

The study will be based on pooled data from cohorts participating in the “Consortium on Health and Ageing: Network of Cohorts in Europe and the United States” (CHANCES) project, which was funded by the European Commission between 2010 and 2015 (Grant # HEALTH-F3-2010-242244). Fourteen cohort studies participated in CHANCES, including over 680,000 subjects, from 23 European and three non-European countries.

This will leverage previously carried out data harmonization within CHANCES, which included over 250 variables related to environmental and occupational exposures, behavioral factors, diet and nutrition, genetics and other biomarkers, outcomes and comorbidities. The main outcomes investigated in CHANCES were cancer, cardiovascular diseases (CVDs), cognitive decline, and bone health. The first three outcomes will be included in the proposed study.

The analysis will be carried out in two stages. Stage 1 will be focused on a multilevel assessment of diet-related factors, including micro/macronutrients, foods, food groups, food patterns. Stage 2 will be a parallel process based on the integration of additional variables aiding the identification of patterns of healthy aging, including data regarding imaging and pathomics, environmental pollutants, social and cultural habits, and other contextual information.

In both stages, machine learning techniques will be adopted for data analysis. Firstly, descriptive techniques will be used to identify novel patterns of risk factors associated with each of the main outcomes, thus allowing the identification of primary prevention actions potentially improving health among aging populations. Techniques such as clustering and association rule discovery, will be used to identify the most common patterns in terms of diet (stage 1) and in terms of exposures in general (stage 2), while subgroup discovery will be used to draw insight about the relation between such patterns and the onset of the diseases of interest.

Moreover, predictive techniques will be exploited to build models estimating the risk of disease occurrence for the individuals based on the discovered patterns.

**Leading Partner institution:**

- Università degli Studi di Bologna

**List of other Partners involved in the pilot design:**

- Università degli Studi di Palermo

#### **14. Multi-drug Resistant Organisms (MDRO) Analysis and Surveillance System through automatized elaboration of laboratory data**

**Brief Description:** We aim to acquire, clean, and analyse healthcare data on multi-drug resistant organisms (MDRO) in healthcare facilities. The analysed data will be showcased in an interactive dashboard, and performance benchmarks will be set for ongoing monitoring and improvement of MDRO health management and prevention. The project has already been successfully implemented and tested on MDRO surveillance data from AOUPPA (Azienda Ospedaliera Universitaria Policlinico of Palermo).

**Leading Partner institution:**

- Università degli Studi di Palermo

**List of other Partner institutions involved in the pilot implementation:**

- Azienda Ospedaliera Universitaria Policlinico “Paolo Giaccone”, Palermo
- Hospital Fatebenefratelli Buccheri La Ferla of Palermo,
- Fondazione Istituto G.Giglio of Cefalù,
- I.R.C.C.S Associazione Oasi Maria SS. Of Troina

#### **15. 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**

**Brief Description:** Our aim is to combine monitoring methods and predictive models into a unique set of statistical and computational tools proposed to detect and forecast the short-term evolution and change points on the trend of daily hospitalizations and to evaluate the impact of mitigation policies targeting frailty populations considering different future scenarios. These methods will be used also to the surveillance and prediction of health

impact of environmental exposures. The proposed approach combines dynamical complex models, analytic and statistical techniques and big-data collection supported by the development of a datalakehouse infrastructure.

**Leading Partner institution:**

- IRCCS Policlinico di Sant'Orsola, Bologna

**List of other Partners involved in the pilot design:**

- Università degli Studi di Bologna
- Università degli Studi di Padova

## **16. Empowerment for vaccinating Communities: Small world networks approach**

**Brief Description:** The EVACS project aims to identify hard-to-reach communities and patients through the creation of an integrated flow system between the existing healthcare platforms and the territory, in order to increase the vaccination coverage of these target groups.

The new National Vaccine Prevention Plan 2023-2025 emphasises the need to identify individuals characterised by a greater social or economic vulnerability that result in greater difficulty in being reached by health services ('hard to reach, HRG') as recipients of vaccine prevention programs, with a view to reducing existing inequalities between different population groups.

The National Recovery and Resilience Plan (NRP) itself aims at combating health poverty and responding more precisely to the needs of the hard-to-reach hard-to-treat population.

The identification of hard-to-reach patients will be done through ICT systems that will allow the analysis of social media to assess sentiment about vaccinations and epidemic intelligence tools to identify coverage gaps.

This project would ultimately result in increased engagement and empowerment of these population groups.

**Leading Partner institution:**

- ASL Roma 1

**List of other Partners involved in the pilot design:**

- Università Cattolica del Sacro Cuore, Roma



## 17. Caring for frail patients through vaccination (CareVax)

**Brief Description:** The CareVax project aims to find frail patients at Fondazione Policlinico Universitario 'A. Gemelli' IRCCS (FPG) who could benefit from vaccinations against pneumococcal, Zoster, flu, HBV (hepatitis B) and SARS-CoV-2. This will reduce hospital stays, long-term effects, and deaths related to these diseases, as outlined in the PNPV 2017-2019 and Ministry of Health circulars from September, October, December 2022, and January 2023.

Eligible patients, upon consent, will be identified by applying an automated algorithm to the patient's electronic health record and vaccination history contained in the regional vaccination registry.

Identified patients will be contacted either directly if they are admitted to the inpatient wards of the FPG Hospital, or by messaging or e-mail in the case of access to the FPG for follow-up or routine visits or day hospital or day surgery service. Patients contacted, depending on their frail condition, will be booked for vaccination at a hospital vaccine clinic (extremely vulnerable patients) or an ASL Roma1 vaccine clinic respectively (frail patients). The CareVax Project will evaluate the feasibility of this integrated hospital-territory pathway in order to increase vaccination coverage.

The feasibility will be measured in terms of setting up the algorithm and its functioning in relation to the data present in the health register, ease of contact with patients, acceptability of the offer and possibility of carrying out the vaccination administration in the designated location (hospital / ASL Roma1).

The pilot will begin to test the feasibility of this new path in two specific contexts: the Nephrology departments and the Digestive System Disease Center (CEMAD) of the FPG Hospital with the involvement of haemodialysis patients, in peritoneal dialysis, waiting for a transplant or in post-kidney transplant hospitalization, with chronic renal insufficiency in pre-dialysis condition and of patients with inflammatory bowel disease treated with biological drugs.

The pathway will then be offered to other FPG departments after an initial test in these two selected contexts.

The project will envisage a validation phase of the algorithm, through the evaluation of its concordance with the judgement of a blinded clinician on a small group of patients.

The algorithm is inspired by the one already developed by the University of Florence for the 'Trova il mio vaccino' ('Find my vaccine') project ([www.trovailmiovaccino.it](http://www.trovailmiovaccino.it)) and consists of a decision tree requiring the following data from the patient's electronic health record: age, sex, cardiovascular diseases, diabetes type 1 or 2, lung diseases, renal insufficiency or dialysis, chronic liver diseases, splenectomy, complement factor deficiency, immunosuppressant drug therapy, chemotherapy or radiotherapy treatment, bone marrow or solid organ transplantation, malignant neoplasms, dysgammaglobulinemia hypogammaglobulinemia, cellular immunity deficiency, employment as a healthcare worker. These data from the Hospital Information System are cross-referenced with those of the regional vaccine registry, in order to obtain information on vaccination history and to exclude from the assessment all vaccines already received by patients. In the event that the information required by the algorithm is not directly available in the Hospital Information System (pregnancy status, type of diabetes, drug addiction, contact with new-born babies), it may be obtained by means of surrogate data (gynaecology-obstetrics service intake, recent birth, access for intoxication).

**Leading Partner institution:**

- Fondazione Policlinico Universitario "Agostino Gemelli" IRCCS, Roma

**List of other Partners involved in the pilot design:**

- ASL Roma 1

## **18. Digi-Vax: digitalization of vaccination processes and integration with surveillance systems**

**Brief Description:** The pilot aims to support with digital tools all the vaccination processes, from vaccination targeting to invitation and appointment reservation, and registration of vaccines' administration. Moreover, a digitalised function will be deployed to allow a post-vaccination follow-up. The vaccination databases and registries will be further interoperated with the institutional surveillance systems related to vaccine-preventable infectious diseases. Lastly, data mining techniques will be applied to monitor and analyse the impact of vaccination in accordance with data of the Surveillance System of Sicilian Region for respiratory diseases and other vaccine preventable diseases (VPDs) and to evaluate vaccine effectiveness.

**Leading Partner institution:**

- Università degli Studi di Palermo

**List of other Partners involved in the pilot design:**

- Sicilian Regional Reference Laboratory for the Epidemiological and Molecular Surveillance of Vaccine-Preventable Diseases at the AOUPPA

**List of other Partner institutions involved in the pilot implementation:**

- DASOE Sicilian Health Authority,
- Poste Italiane s.p.a.,
- Sicilian Network "Vaccinarsi",
- Local Health Unit/ Authority of Ragusa (for the development of the Regional Vaccine Registry)
- Epidemiology and Prevention of VPDs Unit of the Prevention Department of the Local Health Unit of
  - Agrigento
  - Caltanissetta
  - Catania
  - Enna
  - Messina
  - Palermo
  - Ragusa
  - Siracusa
  - Trapani

**19. An in-silico trial technology to assess the efficacy of intervention strategies for the prevention of hip fractures**

**Brief Description:** Ageing is associated with bone loss and increasing risk of fall, which may lead to hip fractures. Bone loss could be prevented with dietary, medication and/or exercise interventions. Falls can be prevented with environmental and/or exercise interventions. Bone loss is the most common target to prevent hip fractures, however there is some evidence that preventing falls could be a better strategy, at least for some populations of interest. Computational models (in-silico trials) can be applied to test the

effectiveness of different prevention strategies on virtual patients. The aim of the pilot is to apply and validate an in-silico trial technology (BoneStrength) to optimise and select appropriate strategies for the prevention of hip fractures.

**Leading Partner institution:**

- Università degli Studi di Bologna

**List of other Partners involved in the pilot design:**

- Medical Technology Lab, Istituto Ortopedico Rizzoli

## **20. A multivariable model beyond the state of the art for predicting incident falls in community-dwelling older subjects.**

**Brief Description:** This pilot study will test whether older people's fall risk may be predicted more effectively than the current state of the art by adding information on spontaneous activity, sleep, and heart rate derived from wearable sensors for five days every three months. A new time-variant fall risk prediction model will be developed and tested in 900+ subjects aged  $\geq 65$  years, recruited by hospitals and general practitioners in the Ravenna district and followed up for one year with prospective recording of fall incidence.

**Leading Partner institution:**

- Università degli Studi di Bologna

**List of other Partner institutions involved in the pilot implementation:**

- AUSL Romagna

## **21. Muscle power and motor control degradation are better predictor of falls than muscle strength in the aging population**

**Brief Description:** The pilot aims to define a set of measures and methods to identify subjects at high risk of falling.

Muscle power (measured during isometric/isokinetic dynamometry and dynamic tests) and motor control deficits (estimated using digital twins and in silico methods) will be compared to and/or combined with muscle strength measures to better characterize/assess elder individuals at risk of falling, to prevent future falls.

**Leading Partner institution:**

- Istituto Ortopedico Rizzoli

**List of other Partners involved in the pilot design:**

- IRCCS Istituto Ortopedico Rizzoli

**List of other Partner institutions involved in the pilot implementation:**

- Istituto Ortopedico Rizzoli
- Università degli Studi di Bologna

## **22. OCR (Optical Character Recognition) Model for Emergency Room certificates Digitalization**

**Brief Description:** The project aims to identify meaningful patterns from emergency rooms (E.R.) reports in order to find insights to prevent traumatic events and reduce aftermaths aggravation (e.g., road accidents, workers compensation injuries, home injuries, etc.). This objective will be implemented through the creation of an Optical Character Recognition (OCR) model. OCR is a computer technology that allows converting text from an image or scanned document into an editable electronic format readable by a computer. It detects characters present in the image, interprets them, and converts them into digital text, enabling processing and manipulation of the content like any other digital text. To this end, an algorithmical extraction of information from E.R. certified documents will be performed in order to extract risks factor.

Furthermore, this project place itself within the “Piano Nazionale Prevenzione 2020-2025”, specifically Goal MO5, which focuses on preventing injuries and reducing their severity. As a part of this alignment, the project is expected to evaluate the potential of creating synergies with health system entities, starting from three DARE’s partners, in different Italian Regions, to implement primary prevention initiatives and to highlight factors associated with injuries, in particular road injuries and accidents. This approach may involve sharing data and expertise, as well as coordinating efforts to address the underlying causes of traffic injuries and accidents.

**Leading Partner institution:**

- Leithà S.r.l. - Unipol Gruppo S.p.A.

**List of other Partners involved in the pilot design:**

- IRCCS AOUBO (Emilia-Romagna)
- ASLRMGN (Emilia-Romagna)
- ASL Roma 1 (Latium)
- AOUPCT (Sicily)

**List of other Partner institutions involved in the pilot implementation:**

- Azienda Ospedaliera Universitaria Policlinico “Paolo Giaccone”, Palermo

### **23. Digital HeartCare: innovative approaches for personalized primary prevention of cardiovascular diseases (CVDs).**

**Brief Description:** Non-communicable diseases (NCDs) account for 74% of global deaths, with cardiovascular diseases (CVDs) being the leading cause in terms of both mortality and morbidity.

The objective of our pilot study is to assess whether an innovative personalized approach, combining genetic information and digital devices, can effectively induce lifestyle changes in participants and consequently prevent diseases.

Our study will be a non-randomized interventional trial (pre-post design). We aim to determine whether the use of innovative digital tools for gathering information on lifestyle and genetic factors in a primary prevention setting can lead to behavioral changes in individuals. The primary goal is to evaluate the efficacy of providing Polygenic Risk Score (PRS) information for cardiovascular diseases, along with the use of a mobile app and wearable device, in promoting changes in lifestyle patterns compared to the baseline measurements.

In this pre-post trial, we will compare the participants' measurements taken at baseline with those obtained at the end of the study. Each participant will serve as their own control, and we will assess whether any changes occur as a result of our intervention.

We will enroll healthy participants without established cardiovascular disease, diabetes, or familial hypercholesterolemia, with no age restrictions. All differences will be considered during the analysis and results phases.

The baseline assessment will involve blood testing and physical examination. Participants will then complete a lifestyle questionnaire, which assesses factors such as smoking status, alcohol consumption, dietary patterns, sleep patterns, and physical activity. Participants



will be classified into three categories: favorable, intermediate, and unfavorable. These baseline measurements will serve as the reference for our study.

Subsequently, we will implement the intervention. Genetic information will be obtained through a salivary swab to analyse the genetic risk of developing CVDs using the Polygenic Risk Score (PRS). For the digital intervention, each participant will receive a wearable device and a corresponding app to monitor various health parameters, including physical activity, sleep patterns, and more. The app will be interactive, providing notifications and tips on how to improve the participant's lifestyle toward a healthier one.

At the end of the trial, we will compare the results with the baseline measurements and assess whether the proposed interventions have resulted in lifestyle modifications.

**Leading Partner institution:**

- Università Cattolica del Sacro Cuore, Roma

**List of other Partner institutions involved in the pilot implementation:**

- Fondazione Policlinico Universitario “Agostino Gemelli” IRCCS, Roma

**24. Development of innovative digital paths for primary prevention: digital advice for non-communicable diseases and personalized programs that reduce cardiovascular risk.**

**DIPPER study**

**Brief Description:** As is widely known, primary prevention is essential to minimize the burden of non-communicable diseases (NCDs) (mainly cardiovascular, cancer, diabetes, and chronic lung disease) and associated risk factors. Cardiovascular diseases in particular represent one of the main public health issues as they are still the first cause of morbidity, disability, and mortality in our Country. The present pilot, based on two interconnected activities, intends to carry out a Quality Improvement program through the introduction of a digitized process of large-scale primary prevention of NCDs (Activity 1) as well as a personalized primary cardiovascular prevention program supported by telemedicine systems (Activity 2). This digital function will be implemented within a Digital Prevention Research Center, conceived to support the local and the national health authorities in the upcoming framework of the National Prevention Hub. In line with the WHO recommending the use of a registered population to carry out “a good system of primary health care”, this pilot involves access to a large collection of data by means of an advanced

hospital IT system for the identification of population at risk of NCDs. Targeted recommendations based on currently available scientific evidence will be produced using artificial intelligence and will be visible to each recruited subject on a dedicated web portal (Activity 1). Furthermore, subjects identified as being at intermediate and high cardiovascular risk or those who do not lead a healthy lifestyle, will be offered an original personalized primary prevention programme supported by telemedicine systems. Such a programme will be structured to closely follow the subjects over time aiming at reducing their cardiovascular risk and modifying their lifestyle by means of personalized interventions (Activity 2).

The digital functions developed through this Pilot proposal will be interoperated with the Digital Prevention Research Center conceived to support the local and the national health authorities in the upcoming framework of the National Prevention Hub.

**Leading Partner institution:**

- Maria Cecilia Hospital - Cotignola, Emilia-Romagna - GVM

**List of other Partners involved in the pilot design:**

- GVM

**List of other Partner institutions involved in the pilot implementation:**

- Azienda Ospedaliera Universitaria Policlinico "Paolo Giaccone", Palermo
- ARPA Sicilia
- Università degli Studi di Enna Kore

## **25. A multidimensional integrated digital prevention approach for healthy elder people**

**Brief Description:** In this pilot project, we will validate the ICOPE tool, a tool suggested by the World Health Organization for the loss of intrinsic capacity.

More in depth, we will assess health and social care needs to develop a personalised plan that will integrate ICOPE with other information (medical and non-medical) for the primary prevention of some conditions typical of older people. In particular, using a data miming approach, we will integrate the information derived from the ICOPE tool with other information available from medical and non-medical records for primary prevention of some conditions typical of older age that can interfere with a healthy aging.

The digital predictive tool developed in this pilot will support a Digital Prevention Research Center conceived to support the local and the national health authorities, in the upcoming framework of the National Prevention Hub.

**Leading Partner institution:**

- Università degli Studi di Palermo

**List of other Partner institutions involved in the pilot implementation:**

- AOUPPA

Specific agreements will be signed with these public and private partners:

- Pharmacies
- Nursing homes
- Local Health Agencies
- General practitioners' organizations

## **26. Clinical, cognitive and neuropsychological markers of healthy ageing**

**Brief Description:** The lifespan of the world's population is increasing, and the proportion of people over 60 years old is predicted to rise from 12% in 2015 to 22% in 2050 (World Health Organization, 2015). Staying healthy in a rapidly changing and increasingly digitalised society is a current global challenge. Existing methods for detecting cognitive decline are most effective in situations where symptoms have already materialised (for example, a referral after subjective cognitive impairment), but they are not useful for the monitoring of asymptomatic individuals.

Our work will contribute to the overarching goal of WP 5 (described in attached Appendix 1) by (1) individuating and integrating existing databases including potential sensible indices to detect early manifestation of cognitive decline (i.e., <https://healthsearch.it/>) and (2) integrating the existing material with psychological and physiological indices.

**Leading Partner institution:**

- Università degli Studi di Padova

**List of other Partner institutions involved in the pilot implementation:**

- Università degli Studi di Padova
- ARPA Sicilia
- Università degli Studi di Enna Kore



## 27. A multidimensional and multimodal analysis of visuospatial and socio-relational abilities in typical and atypical development

**Brief Description:** Based on the trans-diagnostic approach (Jaffee, 2022; Astle, et al. 2022), psychological development may be conceived as changes in dimensional variability between individuals. Among the psychological dimensions, this pilot will focus on cognitive processing (mainly visuospatial skills) and socio-relational skills in children and adolescents with typical and atypical development.

First, a digital battery will be devised to measure visuospatial and socio-relational domains and typical children (aged between 6 to 14) will be tested. The measures will be devised on the basis of the most recent findings (i.e., Hodgkiss et al., 2021; Prinstein & Giletta, 2020; Uttal et al., 2013), and shed light on the developmental changes of such domains in children with typical development.

Second, in order to increase our knowledge about the profile of different neurodevelopmental disorders, strengths and weaknesses in their neuropsychological profile will be assessed. The pilot will consider individuals with Autism Spectrum Disorder (ASD), Developmental Coordination Disorder (DCD), Nonverbal Learning Disability (NLD), as well as genetic syndromes, such as Down syndrome, characterized with peculiarities in visuospatial processing (APA, 2013; Semrud-Clikeman et al., 2010, 2014; Tsai et al., 2008), and socio-relational skills (Kwan et al., 2020; Musetti et al., 2019).

Our work will contribute to the overarching goal of WP 5 (described in attached Appendix 1) by identifying and integrating psychological health determinants to Pedianet and other data platforms as appropriate. The final goal is to understand how cognitive and socio-relational skills, viewed as changes in dimensional variability between children and adolescents, may help to increase our knowledge about risk factors of neurodevelopmental disorders.

**Leading Partner institution:** Università degli Studi di Padova

## 28. Early markers and correlates of learning disorders and ADHD

**Brief Description:** Learning and attention disorders represent the most frequent neurodevelopmental disorders, with a substantial impact on well-being throughout life. Many cognitive and environmental risk factors are known, but no single indicator is

sufficiently discriminative if taken alone. The identification of risk factors need large multi-method, multi-informant paediatric screenings that are currently unavailable. We aim to create a battery of instruments for screening of at-risk children in early-to-middle childhood, to link this data with the existing primary care paediatric health data platform (Pedianet) and other data sources, and possibly to contribute to establish a biobank for future inclusion of omics data.

Our work will contribute to the overarching goal of WP5 (described in attached Appendix 1) by identifying and integrating psychological health determinants to pedianet and other data platforms as appropriate

**Leading Partner institution:**

- Università degli Studi di Padova

**29. Unlocking the full potential for uniting, improving and using electronic health data: innovative pathways from health data research to better health care for all, from prenatal life into adulthood Use case: “The burden and risk factors of obesity in children and adolescents in Italy”**

**Brief Description:** Learning and attention disorders represent the most frequent neurodevelopmental disorders, with a substantial impact on well-being throughout life. Many cognitive and environmental risk factors are known, but no single indicator is sufficiently discriminative if taken alone. The identification of risk factors need large multi-method, multi-informant paediatric screenings that are currently unavailable. We aim to create a battery of instruments for screening of at-risk children in early-to-middle childhood, to link this data with the existing primary care paediatric health data platform (Pedianet) and other data sources, and possibly to contribute to establish a biobank for future inclusion of omics data.

Our work will contribute to the overarching goal of WP5 (described in attached Appendix 1) by identifying and integrating psychological health determinants to pedianet and other data platforms as appropriate

**Leading Partner institution:**

- Università degli Studi di Padova

**List of other Partners involved in the pilot design:**



- Università' Milano Bicocca

**List of other Partner institutions involved in the pilot implementation:**

- Università degli Studi di Palermo

## 4. Digital IT Infrastructure Description

High Performance Computing (HPC) has played an indispensable role in various scientific and technological fields for many decades. Its impact extends into research, technology transfer, and education. In the realm of research, HPC serves as a vital tool in Computer Science, Physics, Mathematics, Chemistry, Biology, Geology, Engineering, Statistical and Economic disciplines, and a significant portion of Medicine.

The widespread use of HPC in research necessitates a corresponding need for educational support. The tools and methodologies inherent to HPC are integral to curriculum, requiring robust computational resources for effective student learning and education.

Moreover, HPC tools are instrumental in technology transfer, particularly in areas of high relevance, such as Big Data Analytics, Artificial Intelligence, and Computer Vision. The European Union's relative lag in HPC compared to the global landscape has prompted its inclusion in the Next Generation EU program, recognizing its critical importance to the competitiveness of the European continent.

To address this gap, the EU is pursuing a two-pronged approach:

1. Supporting national champions, such as CINECA in Italy, to enhance their global competitiveness by providing state-of-the-art computing infrastructure.
2. Promoting the establishment of computing centers and computational facilities across the EU territory, following a federative model similar to that of cloud computing. This approach aims to decentralize expertise and skills within the HPC field, ensuring a more widespread and accessible distribution of HPC capabilities.



### **Description of the intervention:**

Within the scope of this project, UNIPA, UKE, ARPA Sicily and AOUPCT, will realize a Digital Prevention Research Center, the first in Italy to provide technical and scientific support to national, regional and local health and environment authorities, in a shared vision coherent with the National Prevention HUB and the National health-environment-climate prevention system. To this end, an interinstitutional multidisciplinary framework dealing with health prevention and environment and climatic protection will be developed. The Digital Prevention Research Center will be supported by an interinstitutional advanced interoperable digital infrastructure. The Digital Prevention Research Center has been designed to be polycentric and spread over the target communities, allowing interoperability of the data among different bodies and institutions (local health agencies, hospitals, environment protection agencies, health professionals, citizens' associations, market operators, etc.). The Center will derive the greatest possible value from individual and aggregated data, while ensuring both on a regional and interregional level an easy integration of services and solutions in respect of the highest level of privacy and data protection, with the aim to improve disease prevention in specific territories and local communities, directly involving citizens as actors in the promotion of their own health and wellbeing. In line with the National Preventive Plan (NPP 2020-2025), aiming at improving the preventive approach by priority setting and identification of individuals and groups at risk, the Centre will allow to implement innovative prevention models and programs, including digital tools for primary prevention and risk profiling methods using disease-independent determinants and lifestyles, both in daily-life and occupational environments. Following a health and environment community-based interoperative digital approach, advanced functions will be developed in support of cancer surveillance system in place (Advanced Cancer Surveillance System), the effects of environmental exposures on health outcomes across lifespan in different target populations (communities living in the proximity of high-impact polluted sites) will be investigated, an Assess, WArn & REsponse (AWARE) approach will be implemented to insure a coordinated interinstitutional effort for timely responses in the management of environmental emergencies or disasters and in the preparedness against emergent and re-emergent infectious diseases, as well as in the antibiotic resistance surveillance, while providing clear communications to the

communities. A dedicated function will be implemented to collect individual data on lifestyles, health determinants, and genomic data for systematic and longitudinal surveillance of communities and specific target populations. Descriptive and predictive models on complex diseases will be developed to study relationships between health outcomes and lifestyles (dietary patterns, physical activity, behaviours, and psychological traits). A further function will be implemented to conduct community intervention trials to assess effectiveness of digital tools, used alone or in combination with genomic data, for innovative primary prevention paths including personalized approaches. These initiatives, taken together, will help to fill the existing the digital divide in the healthcare industry and sectors, overwhelming a part of the existing socio-economic distance and health inequalities, while improving access to prevention and care paths of citizens. The Digital Prevention Research Center will support regional policy makers and regional health authorities and other different stakeholders in evidence-based policy and decision making.

In brief, it is intended to create an HPC computational infrastructure model that can be, in a transversal way, at the service of:

- the research of the various groups in the Universities and Institutions that already make use of relevant computational resources or could make use of such resources if they become available;
- various teaching activities (academic and professional) on topic related to the use of HPC systems;
- technology transfer activities and services to the territory based precisely on the HPC infrastructure in question.

In other words, this project aspires to create an interinstitutional infrastructure, usable across the board by a wide range of stakeholders (institutions, researchers, faculty, students, professionals, third parties), that can be likened to a true computing center, capable of providing not only computational support to those who request it but also professional support to optimize its use and extend the currently existing expertise.

Regarding the configuration of the HPC infrastructure that is to be implemented, the following is a summary description of it that meets a good part of the research, teaching and

technology transfer needs currently present within the University and at least for the next 4 years.

The infrastructure comprises a primary node located at the University of Palermo, housing the entire high-performance computing (HPC) system. Additionally, is planned to create a backup node at the Enna Kore hub. The second node is fundamental to manage Disaster Recovery Scenarios. Figure 1 provides a high-level overview of the infrastructure. The University of Palermo (Unipa) will serve as the primary data center, housing all the HPC computational resources. In addition, recovery nodes are set to be deployed at the University of Enna Kore, guaranteeing resource accessibility even in the event of a disaster affecting one of the two centers.

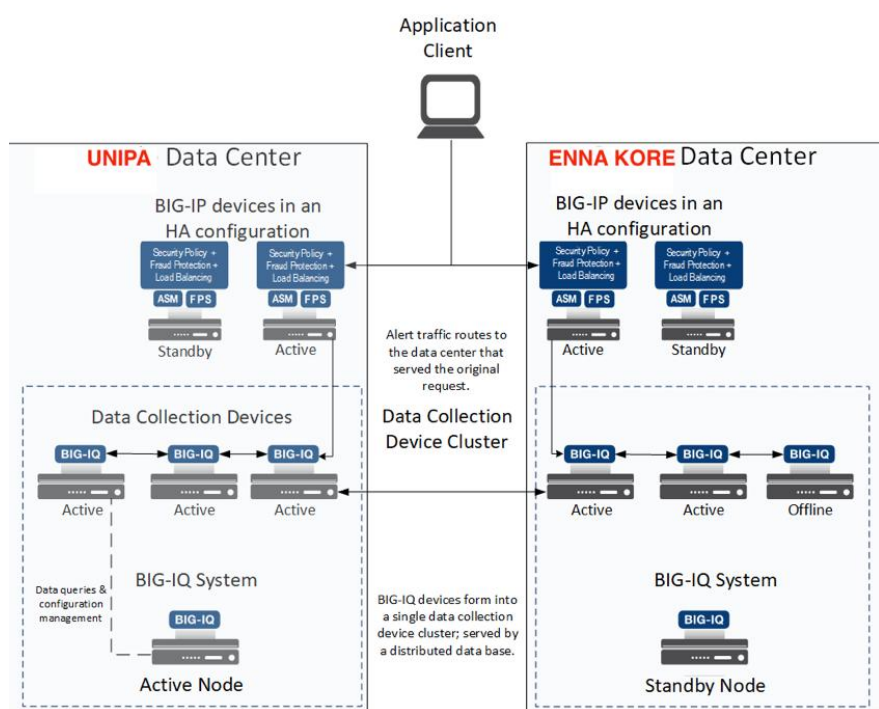


Figure 1- Data Centre HPC overview.

Both the Unipa and ENNA Kore data centers will be interconnected to the ARPA Sicily datacenter in order to integrate the data sources relating to the environmental information produced by ARPA and relating to the entire regional territory. This interconnection will proceed via secure network infrastructures equipped with an adequate level of IP encryption, and via an application collaboration architecture based on market software standards.

### **AlmaHealthDB:**

UNIPA will adopt the AlmaHealthDB to support all pilot activities related to the DARE project.

AlmaHealthDB is an organizational and technology framework that facilitates the ethical, organizational, legal, and regulatory compliance of the gathering and processing of substantial amounts of private clinical data for research purposes.

The Rizzoli Orthopaedic Institute, the Institute of Neurological Sciences of Bologna, and the S. Orsola-Malpighi Polyclinic are the three Scientific Institutes for Research, Hospitalization and Healthcare (IRCCSs) in Bologna that have contributed funds and shared the infrastructure of AlmaHealthDB.

In reality, it functions as a subnetwork of the regional healthcare system, which is overseen by the Emilia Romagna region's internal business, Lepida S.c.p.A.

AlmaHealthDB was designed to operate in both federated and centralized models, utilizing a shared infrastructure to provide optimal interoperability, enhanced control, and cost-effectiveness – particularly in the context of multi-center studies.

A method of assessment is applied to input data sources in order to determine their provenance, authorized uses, validity of consents and authorizations, and processing requirements.

It is based on several technologies, such as REdCap, Xnat, i2b2, ElasticSearch.

The platform requires that clinical data relating to a specific study be managed via the open-source RedCap platform. All non-textual data is loaded into a data lake and linked to the subject record. The data present in the primary systems are pseudo-anonymized, replicated, and made available for study in a transient loading zone. All data is pseudo-anonymized; only the research team can resolve the PID with the patient's demographic data. The algorithms to be developed on the data are implemented in special virtual machines, which can also be instantiated in other infrastructures (e.g., Cineca, INFN).

The types of data that the platform will be able to host may be medical images, data from biomedical instruments, data from in vitro diagnostics, data from molecular analyses,

clinical data from an electronic medical record, environmental data, and also detected data from wearable sensors and mobile health.

AlmaHealthDB will be integrated with the support of UNIBO, in order to be able to manage the environmental data produced by ARPA Sicilia.