

DARE

DIGITAL LIFELONG PREVENTION

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S3.D7.1 Sustainability Plan

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1 Executive Summary

This Deliverable Report is the sustainability plan related to the DARE initiative - Digital Lifelong Prevention, funded by the Ministry of University and Research as part of the National Complementary Plan PNC-I. The plan focuses on the sustainability of the National Health Service, prevention as a service, digital health technologies, and the financial framework of digital healthcare in Italy. Additionally, it presents the canvas methodology, the analysis of the stakeholders, and the organization of the DARE Foundation, as well as the vision and missions of the initiative. The document also examines the path towards sustainability, including monitoring of the pilot studies involved in the overall initiative, the financial sustainability, and the overall sustainability.

It is important to note that while the DARE initiative is functionally segmented into Hub and Spokes, the strategy and methodology were conceived from the outset to address the sustainability of the Foundation as a whole, rather than solely focusing on the sustainability of individual Spokes. This strategic approach acknowledges that the Foundation encompasses the professional and overarching vision regarding the role of digital health tools in prevention. Consequently, the sustainability plan is oriented towards ensuring the long-term viability, competence, and overall vision of the Foundation, which serves as the guiding force for the entire initiative, encompassing both Hub and Spokes. For this reason, it is essential to highlight that the vision, the backbone, and the framework for the three deliverables associated with each Spoke remain consistent. This uniformity ensures that despite the functional division into Spokes, the overarching vision and structural foundation guiding the deliverables are uniform across all components of the DARE initiative. This intentional consistency in vision and framework ensures cohesion and alignment with the Foundation's sustainability goals, enabling each Spoke to contribute cohesively towards the overarching objectives of the initiative.

The plan provides a detailed overview of the activities and objectives of the DARE initiative, along with strategies to ensure its sustainability. It also includes information on revenues, cost structure, and the overall sustainability of the project. The document is structured into various sections, including the state of the art, methodology, stakeholders and organization,

foundation vision and missions, the path towards sustainability, pilot study monitoring, financial sustainability, and overall sustainability.

The following document should be regarded as a living document, as outlined KPIs (Key Performance Indicators) in the overarching strategy need to be consistently monitored and updated on an annual basis. This dynamic approach ensures that the sustainability plan remains responsive to evolving circumstances, allowing for regular assessments and adaptations in alignment with the changing landscape of digital health, the evolving needs of stakeholders, and advancements in technology and healthcare practices. This iterative process of monitoring and updating KPIs annually serves as a mechanism to maintain relevance, effectiveness, and alignment with the evolving goals and objectives of the DARE initiative.

2 State of the art

2.1 Sustainability of the National Health Service

A deep analysis and a serious reflection on the sustainability of the Italian NHS were underway in Italy even before the pandemic emergency.

Already in 2018, 40 years after the establishment of the NHS (L.833 of December 23, 1978), institutional observers highlighted how factors such as:

- the progressive ageing of the population and the growing impact of chronic diseases,
- the increasing cost of innovations, particularly those in pharmacology and biomedicine,
- the increasing demand for health services and benefits from citizens and patients,
- the reduction of public investments in the healthcare,

have contributed to undermining the sustainability of the National Health System (NHS).

From 2010 to the present, the national health requirement has increased at an average rate of €1.94 billion per year, but with a strong acceleration in recent years:

- in the period before the COVID-19 emergency (2010-2019), the requirement was growing at an average rate of 0.9% per year;
- in the years 2020-2022, the growth of the requirement jumped to 3.4% per year.

It should be noted that the largest state allocations planned for the three years 2023, 2024 and 2025 are mainly intended to cover the higher energy costs, because of recent geopolitical crises, such as those in Ukraine and Israel.

Recent studies show that the total healthcare Italian spending for 2022 is about to €172 billions of which €130 billions of public spending, €37 billions of out-of-pocket spending (i.e. paid of families) and €4,7 billion of expenditure intermediated by health funds and insurance companies.

The Italian public healthcare spending in 2022 stands at 6.8% of GDP, 0.3 percentage points below to both the OECD average (7.1%) and the European average (7.1%).

Italy shares concerns about the sustainability of the NHS with most of the more industrialized states worldwide and also with those that have a public and universal NHS. The COVID-19 emergency has put a great deal of stress on the various NHSs, highlighting how a model predominantly based on the diagnosis and treatment of diseases is not sufficiently adequate to face current global challenges.

Many aspects need to be addressed to increase the sustainability of the Italian NHS. In particular, is important to emphasize that it is not enough to think only in economic terms (such as increasing state allocations, increasing medical and nursing staff, or a new balance between public and private health providers) but it is necessary to prepare a real paradigm shift.

There are several initiatives with which the Italian state intends to accelerate this paradigm shift through a series of structural interventions, now achievable thanks to Mission-6 of the RRNP:

- the National Health Prevention Center (M6C2, sub-investment 1.3.2.3.3),
- the National System of Health-Environment-Climate Prevention (art. 27, DL n. 36 of April 30, 2022)
- the National Prevention Plan 2020-2025 (PNP).



All these interventions aim to create a health system that shifts the focus from disease treatment to collective prevention.

The effort that all the most technologically advanced European nations are implementing thanks to the PNRR is in the direction of exploiting the digital revolution underway in recent years (due to technologies such as AI&ML, HPC, Big-Data, IoT and Wearable Devices, in addition to those in medical imaging, biomechanical modelling, personalized medicine etc.) to obtain significant impacts in many social areas, including those in public healthcare, finalized to increase the quality of life of citizens and patients, and to create truly sustainable NHS models.

On the other hand, the possibilities that these new technologies suggest must deal with a multitude of ethical issues among which the privacy of personal data (collection, storage, exploitation, sharing, ...) or the certification of AI-based or other algorithms.

However, a regulatory framework for these issues will likely be developed at the EU level, therefore, the scenario that is emerging in Italy, as in other industrialized nations, is that of a healthcare model in which "digital prevention" will quickly develop.

Thanks to new digital technologies it will be possible to enable technologies for:

- faster and more accurate diagnoses;
- continuous monitoring of chronic or at-risk medical conditions;
- accurate predictions on the potential outcomes of a disease.

All these possibilities will have very wide impacts on the sustainability of NHSs, limiting and reducing access to healthcare facilities and encouraging citizens to maintain a state of good health for as long as possible.

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2.2 Prevention as a Service

The modern lifestyle has a strong impact on widely spread diseases such as diabetes, obesity, or heart, intestinal and kidney diseases, as well as chronic inflammatory diseases such as arthritis - note that all these diseases are dramatically increasing in Western societies, even in Italy.

A healthcare system focused on care will naturally tend to concentrate its resources on the structures and tools dedicated to care, since the business model that characterizes it will guide decision-making processes in this direction.

In this case, the metrics to be used to measure the needs and the effects of investments are simple to understand and to implement.

On the contrary, a business model centered on prevention has more difficulty in demonstrating the extent of its effectiveness.

An intervention in prevention has a "degree of necessity" that is certainly lower than anyone else once justified by a full-blown disease.

Likewise, it is also difficult to measure the effects and the possible positive results of a preventive approach.

Therefore, on the one hand the more industrialized states are fully aware that healthcare models more focused on prevention are more sustainable over time, but on the other hand they know that to demonstrate their efficacy is a longer and more complex process.

To get out of this "impasse" it is necessary to have tools that can demonstrate and measure i) the very close relationship between people's behavior and their state of health (primary prevention), ii) the value of preventing the onset of illness, with screening and early detection and diagnosis (secondary prevention), and iii) the advantages of reducing the effects and the progression of the disease in a patient (tertiary prevention).

Only a detailed analysis enables us to precisely quantify the economic impact of prevention on NHSs.

Through continuous monitoring of the person's behavior and their living environment, it is possible to quantify and characterize the user's activity and their state of well-being, providing a measurable picture of how daily behaviors, in each living environment, influence a person's state of health.

The measurability of the effects allows the creation of scales and objective scores with which to evaluate the risk of a subject developing a specific pathology, allowing the activation of preventive measures which can anticipate the possible onset of symptoms.

Such a paradigm, therefore, does not have the objective of curing but aims to ensure that people remain healthy for as long as possible, delaying the need for medical care as much as possible and, therefore, decreasing the economic impact on healthcare systems.

Nowadays, a similar paradigm is made possible thanks to new digital technologies (mentioned in the previous section) which enable the so-called "digital prevention", with a Prevention-as-a-Service (PaaS) business model.

PaaS model inherits some strengths and weaknesses from the modern digital technologies that enable it.

Among the advantages we can include:

- cost-effectiveness - IoT and Wearable Devices allow continuous low-cost monitoring of both physiological and environmental parameters;
- customization - each user will be able to have solutions that are strongly in line with their specific situation and lifestyle habits;
- scalability - AI & ML facilitate the analysis and processing of a large amount of heterogeneous data;
- efficiency - modern and high-performance HPC infrastructures allow sophisticated, and complex analyses in a reasonable time and minimizing energy consumption.

Among the disadvantages:

- ethical issues relating to the management of personal data and the sharing of results;
- the creation of shared standards/methodologies for the processing and exchange of data.

However, the general framework (regulatory, technological, cultural etc.) already appears sufficiently mature and available to welcome the development of PaaS solutions.

The creation of precise and reliable tools for the preventive and dynamic assessments of the state of health in our citizens is potentially capable of producing value even now.

For all these reasons, the development of experiences of this type (such as those envisaged by the DARE pilot projects) are highly desirable.

Furthermore, it is essential to think about the creation of adequate platforms (both from a technical and legal point of view) for the sharing of data and the use of results, as well as for the dissemination of training and education activities, such as:

- the education/literacy of users in health's topics;
- Stakeholders' awareness of new opportunities;
- the dissemination of new technologies and analysis of methodologies for healthcare personnel.

These aspects can support the PaaS model to limit/delay the spread of chronic diseases, incentivize inclusiveness, equity as well as financial sustainability of the NHS, making it also less susceptible to territorial factors and disparities and inequalities.

2.3 Digital health technologies: barriers and opportunities

Although "digital prevention", based on a PreventionaaS model, has all the requirements to become a pillar of the sustainability of the NHSs of the future, there are some barriers that hinder the adoption of healthcare models predominantly focused on prevention rather than on care.

In the DARE initiative proposal (in section B.2 – Work plan - Overall Concepts, models, and assumptions) nine main obstacles were identified, briefly recalled below:

“ ...

1. **Lack of evidence** – *Much of the evidence that is available to support ICT-based health promotion and prevention comes from studies with low or very low-quality evidence, with small sample size, groups that are not representative of the target population, lack of sufficient consideration of the influence of different settings, and very fragmented definition of standard of care. Cost-effectiveness is not reported in most cases. In general, there is a need for more consistent guidance on how to report evidence.*
2. **Lack of mature solutions** – *The number of mature digital solutions applied in healthcare on a large scale is constantly growing, but their adoption in health promotion and primary, secondary, and tertiary prevention is still scarce and patchy.*
3. **Difficulty in accessing the data** – *Despite the great interest shown by universities, research centers, clinical research organizations, public health institutions, and epidemiology organizations to have access to the vast and rich amount of data available in clinical communities, there is a lack of basic knowledge on the secondary use of health data and on*

secure ways for accessing and processing the data in compliance with the patient's privacy and the General Data Protection Regulation (GDPR).

4. **Lack of interoperability** – Fragmentation is a consequence of the inability, or the unwillingness, of public and private healthcare organizations to communicate and coordinate with each other. There are many reasons behind this: from the lack of resources and skills to the spread of proprietary solutions in place of open standards. Fragmentation of health information systems dramatically impacts the care itself, leading to fragmented healthcare delivery, inefficiencies, and increased costs for the national health service and the families.
5. **Poorly informed stakeholders** – It is paramount to provide timely, clear, and correct information to all relevant stakeholders. Effective communication must be developed for all non-technical stakeholders: healthcare personnel, regulators, policymakers, patients, and the general public. We need a Responsible Research & Innovation framework: to conduct risk and cost-benefit analyses, monitor the perception of digital prevention in public opinion and promote trust in the digital services of the healthcare providers.
6. **No clear regulatory pathways** – Successful translation of innovative medical products, from the idea to the clinical practice, requires an understanding of norms specifications and the capacity to overcome many challenges. Unfortunately, regulatory pathways are poorly understood, not only by academia but also by industries. Therefore, there is a need to support innovators and companies in selecting and undertaking the proper regulatory pathway starting from the design phase. At the same time, there is the need to help and train healthcare providers in selecting the right digital products and services that comply with legal requirements.
7. **Poor scalability** – Making system design, models, and code reusable, scalable, and consistent is challenging. Scalability in digital health goes together with the capacity to integrate with legacy systems and third-party platforms. Scalability and reusability also refer to the legal and organizational levels, which are key for adopting new solutions.
8. **Lack of business models** – There is not yet a clear business model for digital prevention. Different companies/providers use different models, and the return of investment is uncertain, especially for products and services targeting primary prevention. Marketing innovative products without established business models exposes companies to very high risk, considerably slowing down investments.
9. **Lack of trained workforce** – All companies operating in the digital health sector confirm the lack of staff with adequate digital skills. The shortage of digital experts who can develop cutting-edge technologies is a problem at the global level, but the percentage in the Italian workforce is even below the EU average, and the outlook is not good because of the low enrolment and graduation rates in the ICT sector. To achieve digital transformation in healthcare and to support the growth of the digital health industry, there is a need for specialized professional figures and re-training for employees of public and private companies. Such a large and educated workforce requires a substantial investment in new training, re-training, and higher education programs for both technical and non-technical professionals.”



These issues are often interdependent and strongly contribute to the current slowing down of the change in NHS models, particularly in the direction of greater sustainability.

However, ten "core concepts" have been identified which, if appropriately developed, can transform the typical barriers of this sector into opportunities:

1. **Foster Innovation:** Encourage continuous research and development of innovative technologies to improve prevention, diagnosis, treatment, and rehabilitation in the social-health sector.
2. **Collaboration and Partnerships:** Establish and nurture partnerships with public and private stakeholders, civil society, the third sector, and the entrepreneurial system to promote active participation and collaboration in research and innovation initiatives.
3. **Knowledge Sharing:** Create a connected and distributed knowledge community to facilitate the growing? of innovative models and solutions for surveillance, prevention, health promotion, and health security across different populations, including workers, minors, pregnant women, chronic patients, fragile individuals, and vulnerable groups.
4. **Digital Health Leadership:** Focus on establishing Italy as a leading country in the field of Digital Health focused on prevention by producing, collecting, and systematizing multidisciplinary solutions and knowledge in technical, ethical-legal, and organizational domains.
5. **Bridge Inequalities:** Use digital technologies and big data to bridge social and territorial inequalities in providing integrated social and health services, ensuring equal access and outcomes for all reference communities, and filling the health digital gap and divide.
6. **Life-course Perspective:** Promote preventive actions enabled by digital technologies and big data to improve the readiness and accuracy of key public health tasks, including prediction, surveillance, preparedness, diagnosis, and response to acute and chronic diseases, considering health-related conditions from a life-course perspective.
7. **Sustainability:** Ensure that the Foundation's activities and initiatives are carried out in a sustainability framework, contributing to the cultural, economic, and social growth of the country and its local communities.
8. **Reputation and Policy Influence:** Advocate for policies and regulations that support the advancement and implementation of enabling technologies in the social-health sector,



emphasizing the protection of health, the value of health data for the common good, and the well-being of communities and ecosystems.

9. **Continuous Improvement:** Embrace a culture of continuous improvement by monitoring and evaluating the impact of research, innovation, and projects, and incorporating feedbacks to enhance the effectiveness and outcomes of the Foundation's activities.

10. **Public Health Standards:** Uphold and promote the highest levels of public health by drawing on the best evidence coming from scientific research and contributing to the dissemination of this knowledge to contribute to the implementation of Article 32 of the Constitution of the Italian Republic, first and second paragraph. This activity aims to safeguard the health of communities and ecosystems, which will also be implemented through interventions on health determinants and the interrelationships between health, environment, and climate.

If the DARE initiative will be able to develop according to these 10 "core concepts" it is possible that most of the barriers that hinder the implementation of "digital prevention" models in the context of the Italian NHS can be overcome.

2.4 The financial framework of digital health in Italy

Digital prevention is part of a broader concept, that of digital health, which overall can benefit from a notable acceleration in recent years.

Recent analyses quantify the funds, both public and private, potentially destined for the digitalization of healthcare in Italy at around €32 billion.

Among the public funds we can consider those envisaged by the PNRR, addressed through the "Missions" (Mission 4 and 6) and conveyed by the relevant Ministries or by public entities (CDP Venture Capital, ENEA Tech and Biomedical Foundation).

Among private funds we can consider Venture Capital as well as the business incubators/accelerators to support young innovative companies (Start-Up).

The PNRR alone allocates in Italy for the years 2022-2025 around €27 billion for investments in Research and Health (€11.73 billion for Mission 4 and €15.63 billion for Mission 6).

Mission 6 includes interventions regarding innovation and digitalization of the National Health Service, for a total fund capacity of €11.46 billion, or approximately 73% of the total amount of the Mission.

To these resources we can add those that will come from EU tenders, which is very sensitive to the issue of prevention and sustainability of NHSs in the long term.

It is reasonable to think that a part of these public investments dedicated to digital health could be allocated to the digital prevention sector: considering the total share of investments, we can expect investments of a few billion euros to fall on the digital prevention sector in the coming years.

3 Methodology

3.1 Business Model Canvas

The document is structured based on the content dictated by the business plan canvas, useful for creating a shared common foundation of assumptions and objectives. Upon framing and defining the results of the activities in the various pilots and work packages of the DARE initiative and their relevant milestones, a business plan is drafted. This methodology has been chosen for its iterative characteristic to comply with the nature of living document of the present Deliverable. It will be necessary to identify the sustainability of the system based on its characteristics once the initial set of deliverables to support is created.

The Business Model Canvas (BMC) is a strategic management tool that provides a visual framework for developing, describing, and analyzing a business model. BMC was introduced by Alexander Osterwalder and Yves Pigneur in their book "Business Model Generation." The canvas is a one-page template divided into nine building blocks, each representing a fundamental aspect of a business. These blocks help entrepreneurs and managers to understand, design, and communicate the key elements of their business model in a concise and structured way.

Here there are the nine building blocks of the Business Model Canvas:

1. Customer Segments:

Describes the different groups of people or organizations that the company aims to serve.

Helps in identifying and understanding the target customers.

2. Value Propositions:

Outlines the unique value that the product or service provides to the customers.

Describes why customers would choose the company's offering over that of competitors.

3. Channels:

Examines how the company delivers its value proposition to its customers.

Includes distribution channels, sales channels, and communication channels.

4. Customer Relationships:

Defines the type of relationship the company establishes with its customers.

Can include personal assistance, self-service, automated services, etc.

5. Revenue Streams:

Identifies the ways in which the company generates revenue from its customer segments.

Includes pricing models, sales, licensing, subscriptions, etc.

6. Key Resources:

Lists the critical assets and resources required to deliver the value proposition, reach customers, maintain relationships, and earn revenue.

7. Key Activities:

Describes the essential activities the company must undertake to make its business model work.

Involves production, problem-solving, platform/network maintenance, etc.

8. Key Partnerships:

Highlights external organizations, suppliers, or partners that help the company in executing its key activities and delivering its value proposition.

9. Cost Structure:

Outlines all the costs incurred to operate the business model.

Includes fixed and variable costs, as well as economies of scale.

The canvas is dynamic and can be easily updated as the business evolves. It is widely used by startups and established businesses alike to brainstorm, to validate, and to iterate on their

business strategies. The simplicity and visual nature of the canvas make it an effective tool for fostering communication and collaboration within a team or with stakeholders.

In our representation we merged Customers and Partners in a Stakeholder concept because this reflects our integrated and collaborative approach; combining Customers and Partners can be a way to shift the focus from a linear value chain to a more interconnected value network. This is particularly relevant in our scenario where networks of collaborators contribute to overall value creation.

The sections of the present deliverable map into those blocks according to the following scheme:

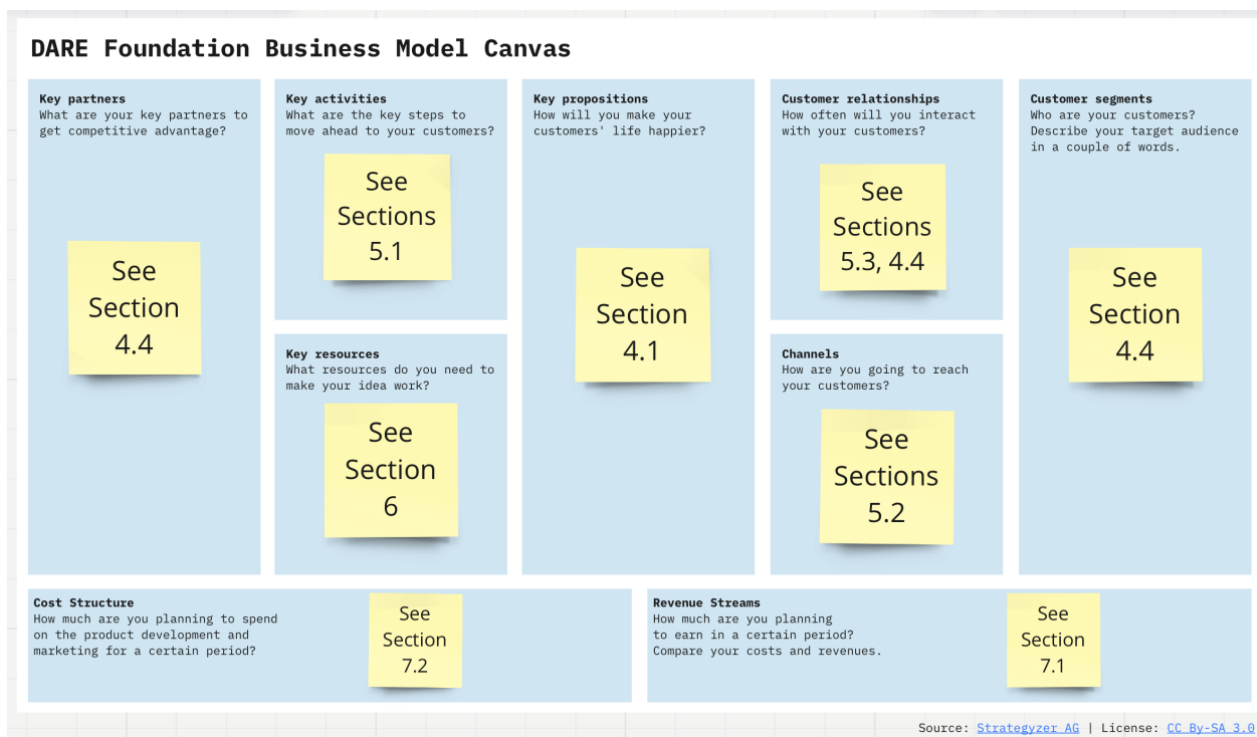


Figure 1

4 DARE foundation's stakeholders and organization

4.1 Objectives of the DARE initiative

The ambitious goal of DARE is to foster a connected and widespread knowledge community through research, innovation, and collaboration among diverse stakeholders.



This community aims to generate, gather, and structure a wealth of multidisciplinary knowledge and solutions encompassing technical, ethical-legal, and organizational aspects. The objective is to position Italy as a frontrunner in digital prevention. Here, digital prevention refers to health promotion and preventive measures facilitated by digital technologies. These technologies hold the potential to significantly enhance the speed and precision of crucial public health functions, including forecasting, surveillance, early identification, and response to acute, chronic, or complex diseases, as well as overall health management across different life stages.

4.2 Impacts of the DARE initiative

The expected impacts of the project DARE have been explained in section C of the project proposal and we are recalling here the main items.

1. **Health data exploitation:** DARE's ambition is to tackle this challenge directly. Spoke 1 will establish interoperability governance across real-world settings in Spokes 2 and 3. This includes managing diverse data types, not just structured information feeding national health systems but also unconventional data like environmental and behavioral insights. By embracing data curation, quality management, and widely recognized interoperability standards, DARE aims to handle these unstructured data sources effectively. All technologies within DARE, from computing solutions to big data analytics tools and pervasive sensing devices like wearables and mHealth apps, will adhere to interoperability governance and FAIR principles, ensuring scalable and reusable solutions. Ultimately, DARE aims to transform its spokes into highly specialized, interconnected, and self-sustaining centers of expertise, advancing Italy's digital transformation as a provider of digital solutions across primary, secondary, and tertiary prevention.
2. **Creation of evidences about digital prevention health systems:** DARE aims to build a robust digitally enabled health system through hands-on practices, consolidating experience into best practices and guidelines. In Spoke 1, standardized indicators and impact assessment models will be developed, linking various domains like social, economic, organizational, and environmental factors. Data from Spokes 2 and 3 pilots will validate these models. National and international initiatives emphasize

the importance of strengthening chronic care for an aging population, highlighting challenges in implementing digital solutions effectively due to overlooked micro-incentives among involved agents. DARE plans to address this by employing a large-scale experimental approach, drawing causal evidence on effective population health management strategies. By comparing outcomes across various healthcare settings and digital solutions, DARE aims to offer valuable insights into incentive structures and organizational models, aiding policymakers in refining healthcare institutions and policies.

3. **Creation of evidences about digital prevention programs and strategies:** aligned with the principles of the PNP 2020-2025, DARE focuses on Evidence-Based Prevention using life-course and settings-based approaches for primary and secondary prevention. Digital solutions are extensively deployed and validated in real-world settings across various pilots in Spokes 2 and 3. Additionally, DARE aims to standardize evidence collection to enable a comprehensive evaluation of personalized digital preventive approaches.
4. **Capability to scale digital health initiatives:** DARE embraces the "Health in all Policies" principle, recognizing that challenges in digital health infrastructure involve both technical and social aspects.
5. **Provision of training on digital skills:** during its funding period, DARE aims to bolster human resources tied to the initiative, fostering career prospects in academia and industry. In the short term, it targets the existing workforce involved in real-world data and applications, offering professional retraining and advanced training courses at individual and organizational levels. Looking ahead, DARE plans to enrich PhD programs and post-graduate courses, emphasizing crucial digital and computational skills for the future.
6. **Reduce socio-economic gaps in healthcare:** DARE orchestrates stakeholder engagement across all spokes, employing participatory approaches and co-creation in WP1 throughout Spokes 1, 2, and 3. A Stakeholder Platform acts as a link between Spokes, facilitating active engagement among various stakeholders including researchers, policymakers, health professionals, patients, citizens, insurance and tech companies, and innovators. Additionally, DARE's digital tools and infrastructures

serve as powerful assets for policymakers and decision-makers, enabling them to monitor population health, intervention effectiveness, and LEA delivery.

4.3 Organizational aspects (after the end of the projects)

4.3.1 Statute

The DARE - Digital Lifelong Prevention Hub is coordinated by University of Bologna (UNIBO) and will be set up in the form of a non-profit Foundation, with the initial involvement of 20 partners:

- Eight universities and public research bodies that are partners of DARE: six public universities, one public research center (INFN), and two private universities (UCSC¹, UKE²);
- Two local health authorities (ASL Bari and ASL Roma 1) and four research hospitals (IRCCS Istituto Tumori Bari Giovanni Paolo II, Istituto Ortopedico Rizzoli IRCCS, IRCCS Azienda Ospedaliero-Universitaria di Bologna Policlinico Sant'Orsola, Azienda USL di Bologna - IRCCS Istituto delle Scienze Neurologiche);
- Among the private partners: three private companies (UPMC³, EXP⁴ and ENG⁵), one private hospital (MCHGVM⁶), and one competence center BI-REX.

Additional partners of DARE can join the Foundation at any time, while external partners will be able to join the Foundation only after the end of the Initiative.

These are among the main actors of the public research and innovation system in Italy, guaranteeing excellence and quality of the technical-scientific competencies involved in the project and promoting the growth, enhancement, and integration of new research collaborations on a national and international level.

The statute foresees two types of memberships:

¹ UCSC: Università Cattolica del Sacro Cuore, Roma

² UKE: Università Kore Enna

³ UPMC: University of Pittsburgh Medical Center - Italy

⁴ EXP: Exprivia SPA

⁵ ENG: Engineering Ingegneria Informatica SPA

⁶ MCHGVM: Maria Cecilia Hospital, Gruppo Villa Maria

Founding Members: those who establish the initial endowment fund and contribute to the foundation's assets.

Supporters: public or private entities that contribute to the foundation's purposes through an annual monetary contribution or through non-financial contributions deemed suitable by the Board of Directors.

In line with the intentions and foundational values of the DARE initiative, it is important to increase the number of Foundation members. This expansion serves two main purposes: to achieve nationwide coverage of expertise, bolstering the consortium's national and international standing, and to increase the involvement of healthcare industry stakeholders. Their participation is essential for ensuring the translation of research outcomes into social and clinical practice.

The model of the DARE initiative is to face those barriers and provide viable, evidence-based solutions. The structuring of the initiative with a hub-and-spoke model, where the Hub is represented by the Foundation and it is the interface between the initiative and the founding agency, and the operating parts, the Spokes. DARE will establish three highly specialized and highly interconnected Spokes:

Spoke 1 – Enabling Factors and Technologies for a Lifelong Digital Prevention – is the competence center that will act as a Solution Provider.

Spoke 2 – Community-based Digital Primary Prevention – is the competence center on Digital Health applications in primary prevention, targeting the general population.

Spoke 3 – Digitally-enabled Secondary and Tertiary Prevention – is the competence center on Digital Health applications in secondary and tertiary prevention, targeting patients.

4.3.2 Spoke 3 Role within the consortium

Spoke 3 is led by UNIROMA2 and focuses on implementing digital solutions for secondary and tertiary prevention, encompassing individuals of all age groups. This includes:

- a) Utilizing digital models of the human body;
- b) Employing AI and digital biomarkers to forecast complication risks and to assess treatment effectiveness;

- c) Integrating digital platforms that combine data registries, wearable sensors, IoT technologies, decision support systems, and home/mobile apps.

The main activities of the Spoke 3 are organized into pilot studies and address the following major aspects in secondary and tertiary prevention:

- Personalization and Risk Stratification Tools (WP2), to develop and test digital models of the human body. Mechanistic models such as Digital Twins will be applied as modern In-Silico Trials to replace In-Vitro, animal, and human experimentation in assessing the safety and efficacy of new treatments.
- Digital Tools for Screening and Early Diagnosis (WP3), to test the efficacy of AI to predict the risk of complications and treatment efficacy in a variety of non-communicable and communicable diseases in different ages.
- Digitally-enabled Biomarkers (WP4), to identify novel biomarkers for the early detection of pathological conditions by using innovative, multimodal, and personalized technologies on a large scale for patients.
- Continuity of care interventions for Secondary and Tertiary Prevention (WP5), to qualify and improve patient care pathways in various physio-pathological conditions and ages (new-borns to adults), leveraging platforms that integrate data registries, wearable sensors and IoT technologies, decision support systems, home/mobile apps.

4.4 Stakeholders

The stakeholder identification process will be guided by predefined questions focusing on relevance, responsibility, and institutional levels. The goal is to provide a comprehensive view of key stakeholders at the national, regional, and local levels, specifically in the realm of Personalized Prevention. This analysis is the objective of Task 1.2 of Spoke 1, an activity that has been carried out in parallel with the present sustainability analysis. Further details coming from the Deliverable D1.2 might be incorporated to improve the sustainability plan.

The stakeholder analysis differentiates between those involved in preventing communicable diseases and those addressing non-communicable diseases, considering levels of prevention (primary, secondary, tertiary) and target populations (citizens versus



patients, age ranges, gender, etc.). At the national level, engagement with institutional stakeholders such as the Italian Ministry of Health, the Istituto Superiore di Sanità, the Italian Drug Agency (AIFA), and the National Institute for Insurance against Accidents at Work (INAIL) is emphasized. Regionally, regulatory bodies and technical staff supporting preventive healthcare policies are identified, leveraging regional actors for communicable and non-communicable disease prevention. Local Health Units (LHUs), scientific associations of general practitioners and pediatricians, patient advocacy groups, and citizens' representatives are highlighted as crucial stakeholders at the local level.

In addition, also for-profit organizations specialized in digital and technological solutions are recognized as stakeholders, with potential public-to-private partnerships explored for their technical expertise. The stakeholder identification process concludes with an engagement plan, including workshops, Delphi consultations, and webinars to ensure continuous commitment and collaboration. Finally, stakeholders will be categorized based on an interest/influence matrix approach.

On the diagram below, we identified a number of potential stakeholder groups, clustered in six main categories (the color map on the right: Research, Healthcare Technology Providers, Health Practitioners, Insurance, Citizens & Patients, Opinion and Policy Makers) and mapped in an Interest/Influence diagram:

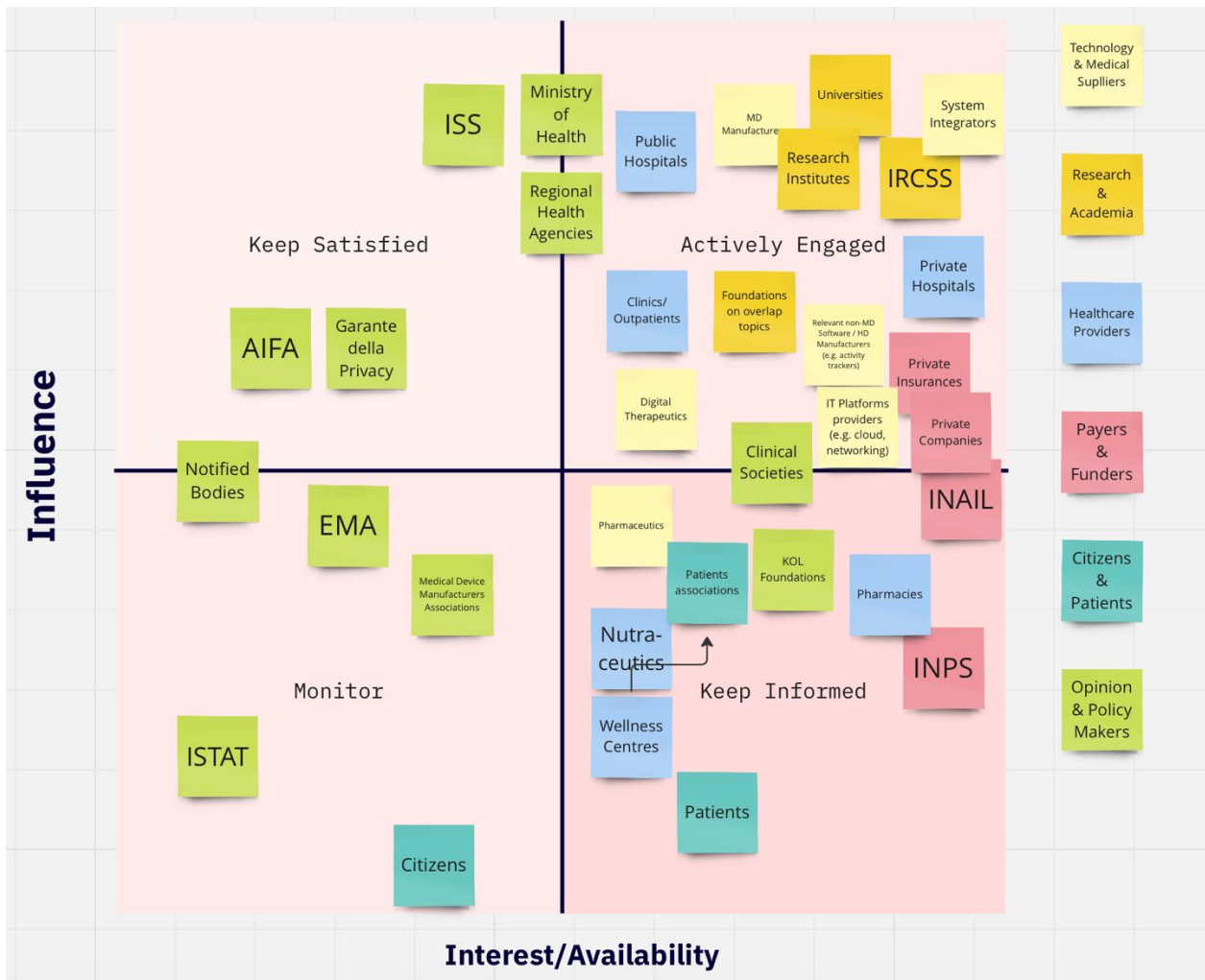


Figure 2.

4.4.1 SPOKE 3 Stakeholders

The diagram below represents a number of potential stakeholder categories, clustered in six main categories (Research, Healthcare Technology Providers, Health Practitioners, Insurance, Citizens & Patients, Opinion and Policy Makers) and mapped in an Interest/Influence diagram, as in the diagram above but specifically for Spoke 3 only:

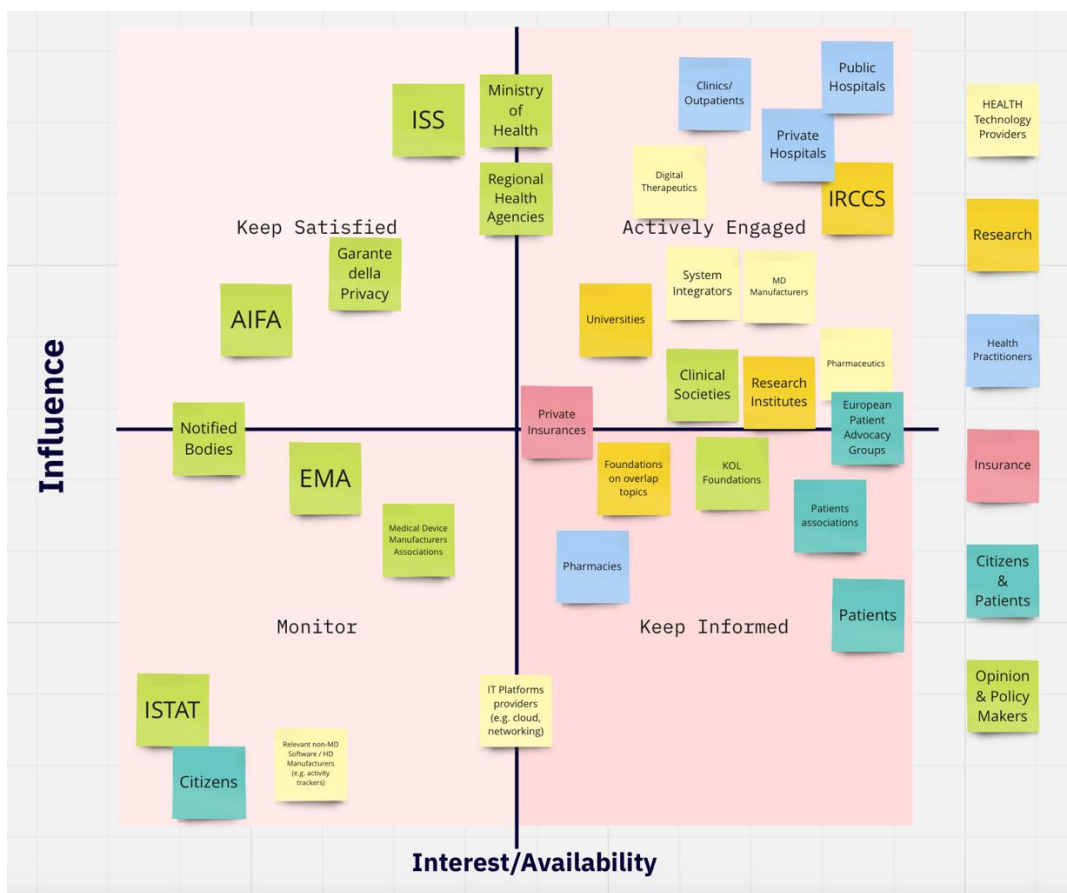


Figure 4.

5 Vision for the Foundation

5.1 INTRO: Digital Prevention Competence Center Model Definition

The DARE Foundation is a non-profit organization (in Italian: “Fondazione di Partecipazione”) that operates as a Hub for managing the "DARE - DIGITAL LIFELONG PREVENTION" initiative, funded by the Ministry of the University and Research.

The DARE Foundation involves 20 of the project’s initial partners as described above: additional partners of DARE can join the Foundation at any time, while external partners will be able to join the Foundation only after the end of the Initiative.

The mission of the DARE Foundation is to grow as an internationally recognized, connected and distributed knowledge community specialized in Digital Health.

The DARE Foundation aims to:



- prepare national and regional health ecosystems for future demands and support them in adopting the necessary innovation to transform;
- favor innovative research and set up tangible demonstrators to leverage enabling technologies for improving the social health sector;
- improve prevention, diagnosis, treatment, and rehabilitation pathways using evidence as a guiding star, a multi-project approach, and a One Health and Planetary Health vision.

Ultimate DARE Foundation goals are:

- to develop models and solutions for surveillance, prevention, and health promotion;
- to establish Italy as a leading country in Digital Health focused on prevention, utilizing digital technologies and big data to enhance public health tasks and to overcome social and territorial inequalities through a digital inclusion-informed strategy;
- to contribute, through multidisciplinary research, innovation, and stakeholder engagement, to the country's cultural, economic, and social growth and maintain public health standards to fully implement Article 32 of the Constitution of the Italian Republic.

The sustainability of the competence center model created for the DARE Foundation, to develop expertise and knowledge on Digital Prevention, is based on four different main activities, called "missions", described in the sections here below.

5.2 Mission 1: Applied Research in digital health tools for prevention

As already illustrated in section 2 (State of the Art), the sector of digital health tools for prevention represents a field of application of new technologies that all the most advanced nations want to develop.

These tools can not only have improving effects on the medical conditions of patients, allowing also a more careful monitoring by physicians, but they are also useful for research and prevention purposes, as they allow a preliminary collection of user data, involving large



segments of the population. In this way, they can also represent a reduction in costs for the NHS, as well as contributing to accelerating its digitalization.

However, the development of the Digital Prevention sector is not just a technological problem but is above all a topic of experimentation and validation in the field of technologies and their actual usefulness.

Only a very extensive applied research activity can generate the level of competence necessary to achieve the DARE's goals, i.e. the digital transformation of evidence-based actions and policies for health promotion and prevention.

The three DARE's Spokes were designed to be complementary but are structured also to be independent during and after the duration of the grant.

5.2.1 Secondary and Tertiary Prevention

Spoke 3 plays a fundamental role in advancing the state of the art in secondary and tertiary prevention. This spoke focuses on adopting digitally-enabled solutions for secondary and tertiary prevention, involving subjects of all ages. Its main areas of focus include:

- Designing, developing, and implementing digital models of the human body.
- Testing Artificial Intelligence and identifying digital biomarkers to predict the risk of complications and treatment effectiveness in various diseases.
- Utilizing digital platforms integrating data registries, wearable sensor technologies, IoT, decision support systems, and home/mobile applications.

These activities aim to improve early diagnosis and to address patients' health needs. Furthermore, Spoke 3 is structured to complement the other two spokes within the DARE initiative but is also designed to be independent during and after the project duration.

Moreover, Spoke 3 focuses on the application of technologies such as Artificial Intelligence, digital biomarkers, the Internet of Things (IoT), and mobile applications to enhance secondary and tertiary prevention. These technologies can help improving the speed and accuracy of key public health functions, including forecasting, surveillance, early detection, and response to acute and chronic/complex diseases.

5.3 Mission 2: Training on digital tools, regulatory, best practices on healthcare

Among the barriers that hinder the transformation of the Italian NHS towards the adoption of digital prevention models there is the lack of professionals with the right skills.

One of DARE's goals is to counteract this limitation by providing higher education and professional training in the activities of each SPOKE.

All universities in the consortium have a Faculty of Medicine and 7 out of 8 have departments of Information Engineering, Computer Science and/or Physics, all actively involved in the partnership.

This context is the best prerequisite for enriching training activities for future generations of healthcare professionals with the multidisciplinary skills, necessary to significantly advance the field of digital health promotion and prevention across the entire national territory.

The university training activities envisaged by DARE are mainly structured according to the activities summarized below.

- Activation of two new doctoral courses:

- UNIBA, (“Digital Innovation and e-Health”)
- UNIPA, (dedicated to the impact of health policies, health promotion and prevention and the complex interactions between health and the environment)

- Enrichment of existing doctoral courses with new courses closely linked to the skills developed in the DARE initiative:

- UNIBA, n.7 courses (ranging from Computer Science and Mathematics to Public Health and Aging and Social Medicine)
- UNIBO, n.3 courses (Health and Technologies; Data Science and Computation; Statistical Sciences)
- UNIPD, n.1 course (Information Engineering, with two curricula: ICT and Bioengineering)
- UNIPA, n.8 courses (ranging from Mathematics and Computational Sciences, ICT and System Dynamics to Biomedicine and Advanced Diagnostics, Health Promotion, Biomolecular Sciences, and Technologies for Human Health)

- UNIPR, n.1 courses (Information Technologies)
- UKE, n.1 courses (Intelligent Systems for Engineering Applications, with a curriculum on AI for Health)

- Activation of a new curriculum in the current M.Sc. degree:

- UNIBA, dept. of Computer Science, M.Sc. degree in Data Science focused on Healthcare Data with courses held by teachers and researchers involved in the project
- UNIBO, M.Sc. degree in Biomedical Engineering, focused on Digital Health and exploiting the results and methodologies of DARE
- UNIBO, update and expansion of the training contents of the M.Sc. degree in Statistical Sciences, with two relevant curricula: Data Science and Health and Population Analytics
- UNIPD, activation of two master's degrees (Bioengineering and Computer Engineering) and a second level master's degree (Machine Learning and Big Data)
- UNIPA, activation of a second level master's degree to train experts in the management of events of interest or concern for Public Health.

The professional education and training activities envisaged by DARE are structured as follows:

- Activation, with the contribution of the GIMBE Foundation, of training programs for healthcare professional as well patients and citizens based on DARE and its methodological and technological characteristics.
- Contribution, by BI-REX, of Industry 4.0 technologies available within its Pilot Plant for application, demonstration and practical activities to support professional and doctoral courses provided by universities and project partners.
- Enhancement of BI-REX's training offer with new training initiatives that make use of the skills present within the consortium and the network of technical partners.
- Updating and improvement, by INFN, of various post-graduate training programs (as part of the "Data Lab" project co-financed by the 2014-2020 FSE OP of the Emilia-Romagna Region, aimed at improving young people's big data skills graduates), taking advantage of the DARE results.

- Updating and improvement, by UNIBO, of the lifelong learning certification courses for professional operators in Data Science (developed within the UNA EUROPA consortium) and Medical Statistics, exploiting the results of DARE.
- Updating and improvement, by UNIBO, of the contributions provided to ASSINTER Academy (the training center of ASSINTER Italia, the Association of Internal Public Companies for Technological Innovation operating at Central, Regional and Local level) on innovation issues in digital healthcare, data-driven approaches and the new national Electronic Health Record.

5.4 Mission 3: Communication on prevention and digital technology related to prevention.

Effective communication of the activities carried out and the scientific results obtained by researchers is a fundamental part of the DARE initiative.

While the training activities have the specific aim of explaining and teaching healthcare professionals, the great possibilities offered by modern technologies and the adoption of a PaaS-type digital model, the communication activities have the aim of sharing what is done by the many Pilots of the project (implemented by Spoke 2 & 3), including twin projects (implement in Spoke 1, the concept of twin project is addressed in section 6).

To this end, there are many communication channels that can be used for disseminating the results of DARE Pilots, allowing different users (in terms of age, habits and interests) to easily understand the transformations that the world of healthcare is undergoing.

However, while on the one hand it is necessary to guarantee a level of complexity appropriate to the interlocutor and the means of communication adopted, on the other hand correct scientific rigor must be maintained.

DARE is expected to transfer the results of its pilots both to stakeholders in healthcare and to manufacturing world, as well as to the general population.

Especially in the healthcare sector, no real transformation is possible if it is not understood and appreciated by the end users, i.e. the citizens.

5.5 Mission 4: Services to stakeholders

From a sustainability point of view, one of the most important activities that the DARE Foundation is called upon to carry out is the offer of appropriate services to stakeholders. Given the large number of partners involved and the complexity and multidisciplinary characteristics of the project, it is appropriate to divide these services into seven different thematic areas, as analyzed here below.

5.5.1 Clinical Studies

One of the main services that the DARE Foundation can provide is related to the organization and scale-up of clinical trials at a national and international level. There are two different study methods that DARE can manage:

- "for-profit" studies - in this case the funding for clinical studies will come mainly from private stakeholders.
- "non-profit" studies - are those studies financed mainly by public entities (Region, ASL, ...)

5.5.2 IPR Exploitation

In the management of Intellectual Property Rights (IPR) it is necessary to distinguish between four forms of intellectual property assets: 1.background, 2.foreground, 3.sideground and 4.postground. The services that the DARE Foundation can implement are:

- to define and protect IPR made available by the partners at the start of the project through shared legal instruments (1);
- to enhance and exploit the IPR developed by members through research and experimentation activities (pilot projects) during the project (2);
- to facilitate the exploitation of IPR also with respect to activities collateral to the DARE initiative during the project (3) and above all at the end of the project (4).

5.5.3 Technology Transfer

Among the services that can potentially have the greatest impact in terms of value generation and economic sustainability, there are those linked to technology transfer through the so-called "incubation" and "open innovation", in particular:



- the first service refers to the provision of spaces, structures, equipment, knowledge and experience suitable for hosting innovative startups; as well as to provide relationships and contacts with the universities and research centers? participating in the Foundation;
- the second service refers to the possibility of providing innovation-as-a-service, i.e. supporting new start-ups in the digital prevention sector through assistance in design, creation and management activities.

5.5.4 Assessment and support to certification, data management and AI governance

The skills offered by the DARE Foundation partners can be used to offer assessment and support services also to:

- MDR Certification (Medical Devices Regulation 2017/745). Already in 2017, the EU Commission adopted the European Regulation on Medical Devices 2017/74. To date, after a transition period ending in 2021, all medical devices placed on the market in EU must comply with the requirements of the MDR. Products that are already certified may still be marketed, provided that certain transitional provisions are respected, until the end of the validity of the respective certificates, but no later than May 26, 2024. Therefore, it is reasonable to expect an intense demand for skills for this certification in the coming years.
- Data Management compliant with the GDPR (General Data Protection Regulation), regulation (EU) no. 2016/679). This regulation also addresses the issue of the export of personal data outside EU and obliges all data controllers (including those with registered office outside EU) who process data of EU residents to observe and comply with the expected obligations.
- AI Governance (compliance with the upcoming European regulation called "AI Act"). At the moment there is no final regulation yet - the process of Parliament's "negotiating position" on the AI law began on 14 June 2023. Discussions are still underway with EU countries in the Council to arrive at a final form of the law, possibly by the end of 2023.

5.5.5 Test before Invest Services

Another service that the DARE Foundation will be able to offer to stakeholders is related to the valorization of the technologies developed in the pilots. The idea is to create a catalog of experiences (Demo-project, Proof of Concept, ...) generated within the pilot projects and twin projects. These technologies, at the end of the project, must have benefited from

extensive experimentation within the pilot experiences and must have been evaluated by highly competent researchers, from both technical and clinical points of view.

5.5.6 Pilot Data Licensing

A further service concerns the exploitation of data and results produced by the pilot projects, in full compatibility with the legal indications that will be produced during the DARE initiative (these activities are expected to be developed by WP2 in Spoke 1).

Certainly, the data will be subject to anonymization to allow their use for the purposes of scientific research activities.

The data will be differentiated according to the purpose for which they are intended: use for treatment or for the development of statistical purposes.

5.5.7 Consultancy Services

The last of the seven services that the DARE Foundation can offer to stakeholders interested in the topic of digital prevention consists of consultancy activities on the development of monitoring tools at a regional or national scale. Clearly, in this case we are thinking above all of public entities that might have an interest in commissioning the development of "ad hoc" projects on the topic of digital prevention.

In this table, a summary of these services, from the perspective of economic sustainability of the DARE Foundation, can be found, according to the Spokes.

Services	SP1	SP2	SP3
Clinical Studies		X	X
IPR Exploitation	X	X	X
Technology Transfer	X	X	X
Assess. and support to certification, data management and AI governance	X		
Test before Invest Services	X	X	X
Pilot Data Licensing		X	X
Consultancy Services	X		

6 Path Towards Sustainability

During the Project, N=66 pilot projects have been defined so far, each aimed at addressing a specific aspect of primary prevention (in Spoke 2) or secondary/tertiary prevention (in Spoke 3). The Pilot projects have been presented to Spoke 1 in two review rounds, with the goal of harmonizing and standardizing their contents regarding the assessment of clinical impact and healthcare system impact, and for a consistent definition and evaluation of clinical outcomes, data access, and, more broadly, interoperability. Additionally, the Pilot's skill requirements have been assessed from the perspective of the competencies provided by Spoke 1. The emergence of work plans in Spoke 1 to meet the needs expressed in the pilots of Spokes 2 and 3 led to the definition of twin projects: the twin project of a pilot is the set of support activities that Spoke 1 provides during the project to the corresponding in Spoke 2 or 3.

A review of the pilots has also been conducted by WP7, highlighting the main enabling technologies (AI, HPC/Cloud Computing, IoT, or more generally, Wearable Sensor, Additive Manufacturing, Simulation/CAE and Digital Twin). This involved a qualitative assessment of readiness compared to what was only partially presented in the description of the pilots, along with the types of data addressed by each pilot.

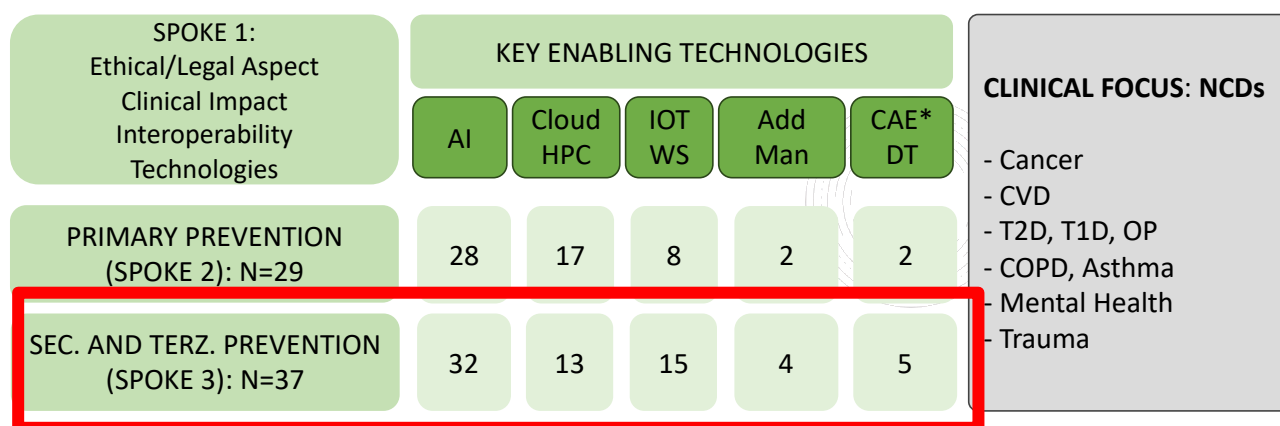


Figure 5.

6.1 THE SOLUTION FRAMEWORK FOR PILOT STUDIES MONITORING

SPOKE 1 will work to provide development to more than 60 pilot projects proposed by Spokes 2 and 3. About two-thirds of these explicitly requested Spoke 1 support, which involves so many twin projects. The Spoke management can't oversee every detail in numerous pilots. It's essential to establish broader criteria linked to project goals and outcomes instead of focusing solely on specific targets. Also, following the description of Objective ID 3, Spoke 1 defined four solution frameworks (SF in the diagram here below). These can be represented as four stages of the development of a digital solution for health prevention: we collect information on a subject (#1), manage this information appropriately (#2), and use it to make predictions on the probability for that individual that a clinically relevant event may occur (#3), and in case use such predictions in prevention clinical pathway (#4). Schematically:



6.1.1 SF#1: Quantification framework

This includes all methodologies aimed at quantifying patient data necessary to prevent specific conditions. These include questionnaires, scores, wearable sensor signals, medical imaging, biological and biomechanical data, etc. Success metrics revolve around accuracy and precision, followed by usability and acceptability. Core interoperability requirements are primarily related to the delivery of the quantifications to the data management framework with formats and metadata annotations required by the modelling framework.

6.1.2 SF#2: Data management framework

This solution framework should enable the collection, ingestion (the process of importing large, assorted data files from multiple sources into a single storage medium), storage,

analysis, and cleaning of the information generated by the quantification framework or extracted from primary data sources (e.g., electronic health record database). SF#2 will be dominated by legal and security considerations first and efficiency second. In particular, the framework must enable the management of sensitive, i.e. personal, patients' data complying with Italian law. Core interoperability requirements are, on the one hand, linked to the sources (SF#1 and primary sources) and the ability to present all information available in ways that are required by the development network.

6.1.3 SF#3: Risk prediction framework

The concept of prevention is intimately linked to that of prediction. The ability to estimate the probability that an individual's health status may change in the future in a given (assumed negative) direction, under certain conditions, is a valuable predictor, to be implemented in a software tool that, when provided with specific information on an individual, can estimate the probability of that individual experiencing a specific change in health status. SF#3 will be dominated by feasibility and technological soundness considerations and, to a lesser extent, by computational efficiency. SF#3 must interoperate with SF#2 without breaking the cybersecurity it provides. It is also necessary to produce several exemplary tools with the content and the form necessary for the following SF#4 to start possibly the clinical translation process.

6.1.4 SF#4: Translation Framework

Any clinical translation starts with a clear definition of the unmet needs that the innovation is expected to address and its translation into a clear Context of Use for the innovation. In the DARE initiative, we have seen two major families of unmet needs so far: those where the predictor informs the decision about an individual and those where the prediction informs decisions about populations. The first has the more complex translation pathway; thus, we will focus on it, handling the latter as a particular case.

When a software tool contributes to the clinical decision, it is considered a medical device (Software as Medical Device, SaMD). But when the development of SaMD with predictive capacity represents a radical innovation, the traditional product cycle for medical devices gets more complex (see diagram here below). Between identifying the unmet need and the

usual cycle from identifying the business opportunity to the commercialization, there is a phase which involves research, prototyping and a first part of validation activities, sometimes called *technical*. A second part, sometimes called *clinical*, requires a final design of the product. While the R&D activities are part of SF#3, SF#4 covers from the identification of the business opportunity (and its prospective? exploiter) to the commercialization.

This has an important implication: while in SF#3, Machine Learning Operations (MLOps) for healthcare aims to produce research prototypes, the product design and development part of SF#4 needs a development environment oriented to quality assurance and certification. This means there is a need to rewrite the prototype software in most cases, even in a clean room setting, if there are IPR concerns. While this is a waste of time and resources, establishing a MLOps for Healthcare able to cover all quality assurance and certification requirements seems impossible.

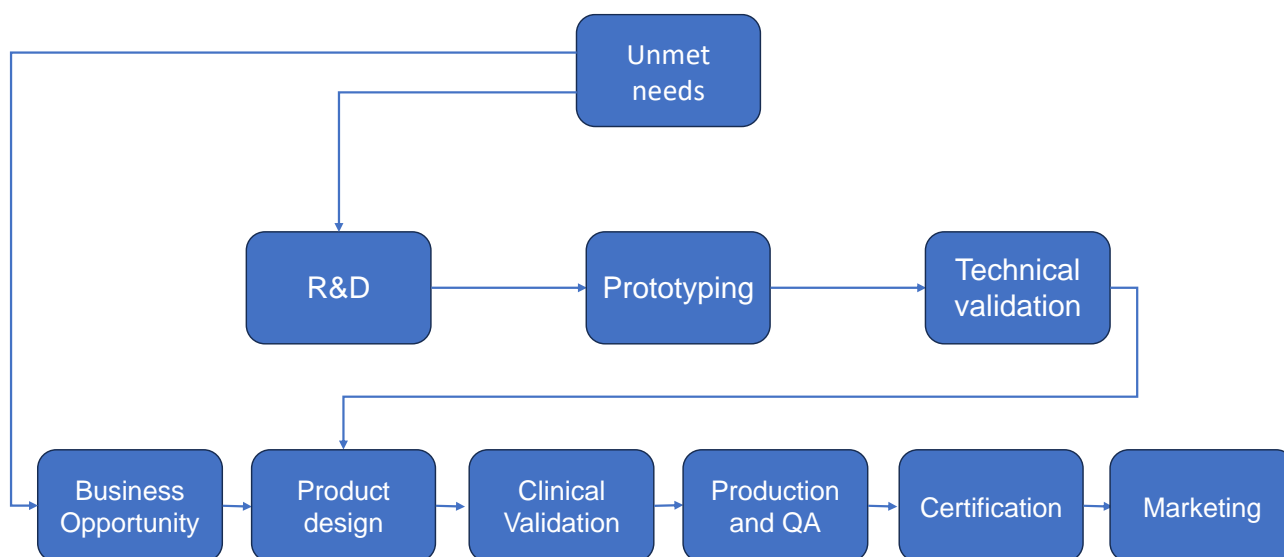


Figure 6.

SF#4 covers the complete medical device product cycle, except that the design starts from a research prototype. In terms of interoperability, attention should be given in SF#3 to develop the MLOps for Healthcare pipeline to minimize the software re-writing effort in SF#4.

6.2 Pilot Studies Monitoring

It is the responsibility of SF#4 to monitor the progress of the pilot projects and their corresponding twins implemented in Spoke 1. This oversight encompasses aspects related to business opportunities, IPR management, and the advancement of readiness, particularly in the regulatory dimension. Other dimensions fall under the responsibility of different solution frameworks.

6.2.1 Business Opportunity

Monitoring the business or market opportunity for a cohort of pilot projects in digital prevention involves several key steps:

- **Pilot Project Progress Tracking:** Continuously track and evaluate the progress of each pilot project. Assess their performance, the milestones achieved, the challenges faced, and the lessons learned. Due to the huge scale of the DARE initiative, it is necessary to establish efficient communication mechanisms.
- **Market Analysis:** Conduct an analysis of the market landscape to understand current trends, market size, potential competitors and emerging opportunities. This includes examining the demand for the specific solution, identifying target audiences (in terms of both end users and buyer personas) and assessing the competitive landscape.
- **Partnership and Collaborations:** explore potential partnerships or collaborations with industrial? players, healthcare providers or technology firms to leverage market expertise, to expand, to enreach and to enhance the market viability of the pilot project in an “open innovation” way.

6.2.2 IPR Management

IPR protection is crucial for ensuring that the outcomes of R&D endeavours are properly safeguarded, valued, and leveraged in the market. IPR incentivize innovation, attract investment, and supports the successful exploitation of R&D efforts for commercial, clinical and societal benefits. In any Spoke, including Spoke 3, IPR management is covered by WP7 - Task 7.2 activities, in particular IPR management is described in Deliverable D7.2.

It is important to emphasize that correct and timely auditing of background, foreground and also side-ground IPR is crucial, particularly in the context of collaborative R&D where partners come from different academic and research institutions.

6.2.3 Readiness Monitoring

Monitoring the readiness for a cohort of pilot projects in digital prevention involves several key steps:

- **Regulatory and Compliance Considerations:** We -as a consortium- need to stay updated on regulatory requirements and compliance standards in the digital prevention space. Ensure that the pilot projects align with regulations and standards now to facilitate market entry then.
- **Adaptation and Iteration:** Use the insights gathered from monitoring and feedback mechanisms to adapt and to iterate the pilot projects. This might involve pivoting strategies, refining features, or scaling up successful elements based on market responses.
- **Stakeholder Engagement:** Engage with stakeholders, including potential users, industry experts, healthcare professionals, and relevant organizations. Gather insights, feedback, and market needs to align the pilot projects with real market demands.

KPIs Definition	Monitoring	Acceptance Criteria		
		M24	M36	M48
Number of market pre-assessment carried out in pilot projects (per Spoke)	Yearly	>20	ALL	NA
Number of IPR disclosures tracked (per Spoke)	Yearly	>10	>15	NA
Number of IPR self-assessment questionnaire answered (per Spoke)	Yearly	>20	ALL	NA
Number of TTO contacted	Yearly	>20	ALL	>200
Number of Regulatory On-boarding sessions	Yearly	>10	>15	>25

Table 2.

6.3 Training Catalogue

In close collaboration with Spoke 3 - WP6, an extensive assessment of potential sources for training content is conducted. This involves identifying various organizations, educational institutions, and industry experts capable of delivering high-quality training material. Understanding the specific needs of the intended audience forms a critical aspect. This includes conducting thorough research and engagement sessions to comprehend the knowledge gaps and learning requirements of the end users. To keep the catalogue relevant and valuable, continuous updates are made based on evolving industry standards, emerging technologies, and advancements in the field. This ensures that the content remains current and aligned with the latest trends and practices. Lastly, considering different channels and formats for delivering the learning content is essential. By exploring various mediums such as online platforms, workshops, interactive modules, or live sessions, the DARE initiative aims to provide a diverse and engaging learning experience that accommodates different learning preferences.

KPIs Definition	Monitoring	Acceptance Criteria		
		M24	M36	M48
Number of training courses in the DARE portfolio	Yearly	>6	>9	>12
Number of training sessions	Yearly	>9	>20	>40
Training provided (hours)	Yearly	>30	>60	>150
Number of Participants	Yearly	>50	>100	>200
Number of External Participants	Yearly	NA	>25	>100

Table 3.

6.4 Services Catalogue

During the DARE initiative, alongside the previously described market analysis on the potential outcomes of pilot projects and their corresponding twins, a gap analysis will be conducted. This analysis aims to compare the market needs and requirements in the digital health technology sector with the expertise within the consortium and the project outputs. The objective of this analysis is to identify strategic areas to propose highly specialized



consultancy services that can be delivered through the expertise of the Foundation's partners. Some strategic areas (privacy and safety regulations, AI governance, data management and harmonization, data interoperability ... etc. just to name a few) have already been identified and discussed in the previous sections of this deliverable. On the other hand, the pilots themselves, when considered together with the adopted technologies, the protocol, and the robustness of the clinical evidence found, each constitute a potential element of an innovative portfolio in the field of primary, secondary, and tertiary prevention. Each of those should be correctly monitored and curated to populate such showcase of cutting-edge demos.

KPIs Definition	Monitoring	Acceptance Criteria		
		M24	M36	M48
Assessment of digital health technologies market needs (list of needs and related competencies/demonstrators present in the Foundation)	Yearly	>5	>10	>12
List of stakeholders for digital health technologies market needs (number of actual contacts)	Yearly	>50	>100	>250
Assessment of primary prevention market needs (list of needs and related competencies/demonstrators present in the Foundation)	Yearly	>3	>5	>8
List of stakeholders for primary prevention market needs (number of contacts)	Yearly	>15	>25	>75
Assessment of secondary and tertiary market needs (list of needs and related competencies/demonstrators present in the Foundation)	Yearly	>3	>7	>12
List of stakeholders for secondary and tertiary market needs (number of contacts)	Yearly	>50	>75	>150

Table 4.

6.5 Technology Transfer

Technology Transfer and startup/spinoff incubation is an activity covered in Task 7.3 in Spoke 1, 2 and 3. BI-REX, WP 7 leader in Spoke 2 and 3 is a consortium where one of the

members (Fondazione Golinelli) is leading one of the most relevant acceleration programs in the area of Life Science (G-Factor). Fondazione Golinelli screened more than 800 startups, providing more than 3000 hours in training and mentorships for 32 startups in their acceleration program. Their experience, expertise and network are a vital support for the success of this activity. Partner BI-REX collaborate with its Pilot Plant infrastructure to the acceleration program and it is planned that they play the same role within the DARE initiative with further investments in the Pilot Plant and by providing its expertise.

In order to address the project objective to accelerate two startups for each Spoke, the plan is to start with onboarding and entrepreneurship training. A close collaboration with Fondazione Golinelli might bring to the creation of specific topic dedicated to the digital prevention within their Life Science call and this would help to extend the funnel of potential entrepreneurial ideas/early stage startup to participate in to the acceleration program. On the other side, the DARE foundation, with its multifaceted expertise, can provide value added services to the acceleration program.

KPIs Definition	Monitoring	Acceptance Criteria		
		M24	M36	M48
Number of incubation programs activated	Once	NA	NA	>2
Number of on-boarding sessions	Yearly	NA	>2	>2
Percentage of Pilot covered by session (50)	Yearly	NA	>60	>150
Number of Participants evaluated	Once	NA	NA	>50
Number of startup/spin-off incubated	Once	NA	NA	>=4

Table 5.

6.6 Increase in the members of the Foundation

Monitoring the membership uptake or interest of potential affiliates in the DARE Foundation is crucial for several reasons. Firstly, aspiring to become the national reference center for digital technologies in prevention necessitates broad participation and representation from experts, institutions, and stakeholders in the field. This solidifies the Foundation's reputation and credibility as a leader in the field. Secondly, since the

sustainability model also relies on membership fees, a consistent increase in members directly contributes to the Foundation's financial stability. Membership fees constitute a vital source of funding to support activities and to ensure continuity of research and development programs. To implement and monitor this goal over the next three years, it is essential to:

1. **Promotion Strategy:** Develop a targeted promotion strategy to attract new members. This might involve awareness campaigns, networking events, partnerships with institutions, and targeted communications.
2. **Membership Selection Process:** Clearly define membership criteria and the benefits offered to members. This could include access to exclusive resources, collaboration opportunities, and participation in research projects.
3. **Online Membership Platform:** Create an intuitive and accessible online platform for membership and expression of interest. This streamlines and simplifies the affiliation process.
4. **Monitoring Metrics:** Establish key metrics to track the increase in members or expressions of interest over time. These metrics might include the number of new members, their sources, involved professional categories, and the growth rate over time.
5. **Feedback and Analysis:** Gather ongoing feedback from current members and potential affiliates to evaluate the effectiveness of promotion strategies and continuously improve the Foundation's attractiveness.
6. **Periodic Evaluation:** Conduct periodic assessments to analyze the effectiveness of strategies and make necessary adjustments based on the results obtained.

By consistently monitoring new member uptake or the interest of potential affiliates through these measures, the Foundation will be able to maintain and expand its membership base, solidifying its position as a reference in the industry and ensuring a robust financial footing for its future activities.

KPIs Definition	Monitoring	Acceptance Criteria		
		M24	M36	M48
Number of membership's endorsement letters	Yearly	>6	>9	>12
Number of new founding members	Yearly	>3	>6	>6
Number of new supporter members	Yearly	>2	>4	>8
Number of membership's endorsement letters in the private sector (healthcare industry)	Yearly	>3	>4	>6
Number of members in the private sector (healthcare industry)	Yearly	>2	>3	>3

Table 6.

7 Financial Sustainability

7.1 Revenues Streams

The revenue structure of the DARE Foundation is designed to ensure sustained capabilities and a leading role in the digital prevention domain without competing with its member institutions. To achieve an annual funding range of €20M-€30M within five years post-project, the foundation plans to source income from various channels while redistributing the majority of this revenue to its member institutions. Maintaining an efficient organization, the foundation's overhead aims to remain below 10% of the total funding, excluding specific activities deemed more suitable for execution directly by the foundation rather than its members.

Membership subscription fees, adjustable based on different membership levels, form a primary revenue source, inclusive of both Founders and Supporters.

Notably, specialized service sales in areas like regulatory compliance, data management, wearable sensors, AI governance, clinical trial networking, and training are expected to generate substantial income.

IPR licensing, collaboration with affiliated research entities, and direct public funding for digital prevention services development in regional and central health authorities are additional revenue streams envisaged by the foundation.

This multifaceted revenue strategy ensures financial sustainability while allowing the foundation to focus on specialized services and collaborations without conflicting with its member institutions.

7.2 Costs structure

7.2.1 Operating Structure: Personnel

The DARE Foundation anticipates personnel costs associated with a workforce ranging from 25 to 30 individuals within three years, distributed across several key sub-teams vital for the foundation's operations and growth.

1. **Administrative / Legal / IPR Team:** This team oversees administrative functions, legal compliance, and the management of IPR. It ensures the foundation's adherence to regulatory frameworks, handles legal matters, and safeguards the foundation's innovations through IPR management.
2. **Marketing & Communications Team:** Responsible for devising and executing marketing strategies, this team focuses on building the Foundation's brand, communication with stakeholders, and promoting its initiatives and achievements.
3. **Business Development and Operations Team:**
 - a. *Shareholders Engagement:* Engages with stakeholders, shareholders (i.e. Members), and partners to foster collaboration and alignment with the Foundation's goals.
 - b. *Public Funding:* Focuses on securing funding from public sources by identifying grants, subsidies, or other funding opportunities that align with the foundation's objectives.
 - c. *Consultancy & Training Services:* Develops and offers specialized consultancy and training services leveraging the foundation's expertise to external entities.
 - d. *Health Digital Technologies Atelier:* Manages and drives the development of digital health technologies within a dedicated workshop or lab environment.
 - e. *AI Governance & Ethics:* Concentrates on defining and implementing ethical frameworks and governance structures for AI initiatives within the foundation's scope.

These sub-teams collectively contribute to the foundation's multifaceted operations, ensuring legal compliance, amplifying the foundation's presence through strategic communications, driving growth through business development endeavors, and advancing cutting-edge technologies while adhering to ethical guidelines.

Personnel costs encompass salaries, benefits, training, and professional development initiatives tailored to attract and to retain top talent across these specialized domains. The allocation of resources to these sub-teams reflects the foundation's commitment to creating a comprehensive ecosystem that thrives on innovation, compliance, strategic partnerships, and ethical practices.

1.1.0. Other cost

The operational costs for the DARE Foundation encompass various essential components critical for its functioning and growth:

1. **IT Services (IaaS/PaaS and IT Software):** Covering expenses related to Infrastructure as a Service (IaaS), Platform as a Service (PaaS), and IT software licensing, ensuring a robust technological backbone for the foundation's operations, data management, and digital infrastructure.
2. **Marketing and Communication (Events, Social):** Includes costs associated with organizing events, both physical and virtual, social media campaigns, content creation, and other communication initiatives aimed at promoting the foundation's activities and engaging stakeholders.
3. **Participation in Conferences:** Budget allocated for attending industry-specific or scientific conferences, seminars, and events. These activities facilitate networking, knowledge sharing, and staying updated with the latest trends and developments in the field.
4. **Affiliation Fees to Networks, Clusters, Associations:** Membership fees and affiliations to networks, clusters, and professional associations relevant to the foundation's objectives, enabling access to collaborative opportunities and staying connected with industry peers.
5. **General Costs:** Miscellaneous operational expenses including office supplies, utilities, insurance, and other administrative costs essential for day-to-day operations.

Notably, in the initial years, the DARE Foundation does not foresee significant investments in infrastructure or machinery, as the majority of these assets are already part of original

partners and ongoing pilot projects, and are expected to be contributed in-kind by the founder members. This in-kind contribution will form a substantial part of the foundation's infrastructure, reducing the immediate need for substantial financial investments in this area.

By leveraging existing infrastructure and machinery contributed by the founder members, the foundation aims to manage and optimize operational costs efficiently. However, the operational budget will be dedicated to maintaining, upgrading, and optimizing these assets to ensure they align with evolving technological and operational needs. This approach allows the foundation to allocate resources towards other critical operational areas while maximizing the use of existing infrastructure.

8 Overall Sustainability

The DARE initiative, a significant endeavor focused on digital health tools for prevention, aims to contribute substantially to the sustainable development of the society, aligning with the Sustainable Development Goals outlined in the 2030 Agenda of UN.



Figure 7.

By fostering entrepreneurship, supporting spin-offs, and nurturing start-ups, the initiative seeks to boost economic development and advance the cause of decent work (Goals 8 and 9). Emphasis on addressing vulnerable groups and promoting gender equity lays the groundwork for mitigating inequalities across various sectors and social groups (Goals 3, 1,

5, and 10). Attention to ethical considerations ensures the creation of just and secure measures and technologies, especially for more vulnerable groups (Goal 16). The initiative and its associated technologies prioritize energy efficiency and minimize their impact on the environment, aligning with Goals 7, 11, 13, 14, and 15. Consequently, the components within the DARE initiative possess the essential attributes to sustain their operations beyond the project's timeline, evolving into enduring sources of innovation accessible to territories and reference communities.