DARE
DIGITAL LIFELONG PREVENTION
CODE NO. PNC0000002

Spoke 1 Deliverable

S1.D7.2 IPR Management and Exploitation Services

This research is co-funded by the Ministry of University and Research
within the Complementary National Plan
PNC-I.1 "Research initiatives for innovative technologies
and pathways in the health and welfare sector"
D.D. 931 of 06/06/2022, PNC0000002 DARE - Digital Lifelong Prevention

S1.D7.1 IPR Management and Exploitation Services

Deliverable information	
Spoke number and title	Spoke 1
WP number and title	WP7
Related task(s)	Task7.2
Lead beneficiary	UNIPA
Contributing beneficiaries	BI-REX
Dissemination level	Public, fully open
Due date	31.12.2023
Actual date of delivery	04/03/2024
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Document history

Version	Date	Author(s) /Reviewer(s) (Beneficiary)	Description
0.1	20/10/2023	Alessandro Chiarini (BI-REX)	Outline
0.2	28/01/2024	Giosuè Lo Bosco (UNIPA), Luca Leonardi (UNIPA)	First Draft
0.3	06/02/2024	Alessandro Chiarini	Technology Transfer Section and Exec Summary
0.4	20/02/2024	Giuseppe Pirlo	Revision
0.5	27/02/2024	Giosuè Lo Bosco	Final document

Disclaimer

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1. Executive Summary

Management of intellectual property rights plays an important role in all research projects. Based on guidance by the European Commission as well as the applicable EU law framework, aim of this report is to map the intellectual property options and tools available to the DARE Initiative partners for protection of the IP created during the project execution. To this end the analysis includes a presentation of protection and exploitation methods of IP Rights (such as trademarks, patents, copyright and transfer and licensing agreements). This generic presentation is followed by a first approach of how DARE's results could be protected and exploited in the future. Given the early stage of project development, this report's main purpose is not to bring forward a final protection and exploitation plan but instead to provide project partners with timely and comprehensive guidance on efficient and competent protection of their project-related IP rights. This includes for instance advice on a dissemination policy, confidentiality and trade secret practices, as well as exploitation strategy. It is recommendable that these suggestions are finalized in the final Spoke Affiliates Agreement.

2. Objectives and Approach

The ambitious objective of DARE is to create and develop, through research, innovation, and participation of multiple stakeholders, a connected and distributed knowledge community that produces, collects, and systematizes multidisciplinary knowledge and solutions (technical, ethical-legal, and organizational) necessary to affirm Italy as a leading country in the field of digital prevention.

The primary objective of SPOKE 1 is to reduce and dismantle obstacles to the adoption of innovative, sustainable, high-quality, and efficient digitally enabled solutions for prevention. The primary goal is to collaboratively develop a customised plan for future healthcare, in partnership with stakeholders, that integrates digital solutions across the entire preventative process.

2.1.Spoke 1 Workplan

SPOKE 1 winds through 7 Work Packages (WPs) each specialized in a specific aspect of innovation and represents a sequential or synergistic step within the pipeline of implementing a competence centre on Digital Health applications in secondary and tertiary prevention, targeting patients.

In terms of timeline, the SPOKE 1 strategy is essential for phase I – IMPLEMENTING: inside the spoke all the required components and functional blocks will be designed, developed, and Deployed, and in phase II – PILOTING: solutions will be tested in real life setting in the other spokes and collected evidence and feedbacks will flow back to spoke 1 in as many iterations as needed.

WP1 will establish the standardised structure for gathering needs/requirements, evidence, process, outcome, and effect indicators. The WP1 will have the responsibility of conducting communication and dissemination initiatives targeted at all pertinent stakeholders, as well as initiating the innovation pipeline.

WP2, WP3, and WP4 have the objective of reducing or eliminating legal, organisational, and technological obstacles that hinder the acceptance of digital technologies. WP5 will offer pertinent insights to decision makers and policymakers through an analysis of the impact and effectiveness of the innovations implemented in spoke 2 and 3.

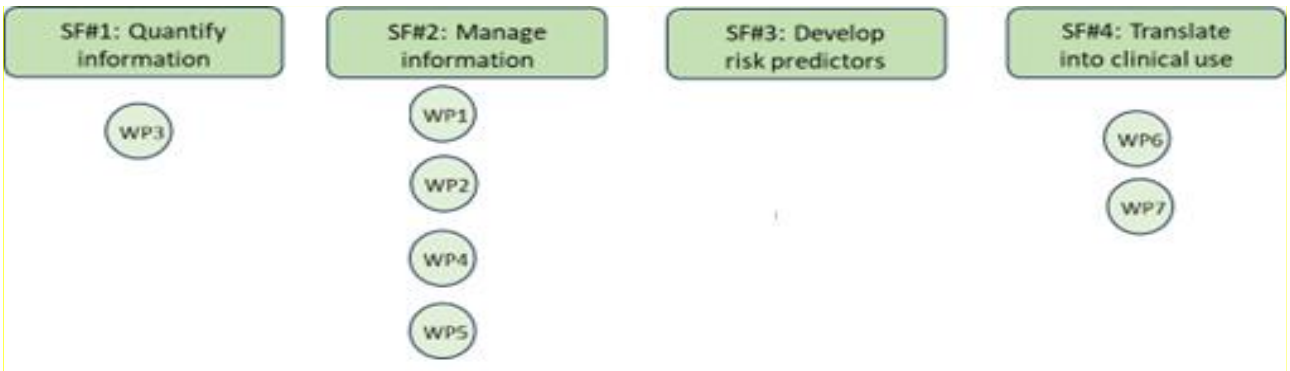
WP6 aims to resolve the issue of a deficient workforce by implementing comprehensive training and retraining initiatives focused on enhancing digital competencies for professionals in both technical and non-technical fields. Spoke 1 will primarily concentrate on managers and employees of technology and service providers, although it will not be limited to them solely. WP7 will tackle the issue of underdeveloped and long-lasting business models, oversee the intellectual property produced within the initiative's three branches, and handle the distribution of financing. Each entity will be assigned a specific budget for the cascade funding, which is intended for external providers and to promote the expansion or twinning of initiatives.

2.2. Pilot Projects and Cascade Funding

38 pilots projects have been presented for SPOKE 1, as twin pilots of SPOKE 2 and SPOKE 3: 17 studies in the North, 6 in the Center and 15 in the South of Italy. In terms of medical specialties, the most frequent are Oncology, Orthopedics and Geriatrics, in some cases considering the effect of environmental factors.

2.3. Solution Framework

Four stages of the development of a digital prevention solution are represented by the four solution frameworks defined by SPOKE 1: we gather data on a subject, handle it appropriately, and use it to predict the likelihood that a clinically relevant event will occur for that individual. We then use these predictions in a clinical pathway for prevention. A more thorough description of the solution frameworks may be found in Deliverable 7.1 on Sustainability Plan. SPOKE 1 provided four solutions frameworks. The process of developing a digital solution for prevention can be summed up as follows: we gather data on a subject, handle it properly, and use it to predict the likelihood that an individual will experience a clinically relevant event. We then use these predictions to inform preventive clinical pathways. In the following, we report a schematic of the distribution of the Spoke 1 WPs among the solution frameworks:



Note that SF#4 is responsible for monitoring the progress of the pilot projects and their corresponding twins conducted by Spoke 1. This oversight includes commercial prospects, intellectual property management, and readiness growth, especially in the regulatory aspect. Various dimensions are managed by distinct solution frameworks.

3. IPR Management

3.1. Identification of Intellectual Property

Identify all potential intellectual property, including patents, copyrights, trademarks, trade secrets, and other intangible assets that may arise from the project.

Definitions

'Access rights' Rights to use results or background.

'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that is

(a) held by the beneficiaries before they acceded to the Agreement and

(b) needed to implement the action or exploit the results.

'Dissemination' The public disclosure of the results by appropriate means, other than resulting from protecting or exploiting the results, including by scientific publications in any medium.

'Exploit(ation)' The use of results in further research and innovation activities other than those covered by the action concerned, including among other things, commercial exploitation such as developing, creating, manufacturing and marketing a product or process, creating and providing a service, or in standardization activities.

'Fair and reasonable conditions' Appropriate conditions, including possible financial terms or royalty-free conditions, considering the specific circumstances of the request for access, for example, the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

'FAIR principles' 'findability', 'accessibility', 'interoperability' and 'reusability'.

'Open access' Online access to research outputs provided free of charge to the end-user.

'Open science' An approach to the scientific process based on open cooperative work, tools and diffusing knowledge.

'Research outputs' Results to which access can be given in the form of scientific publications, data or other engineered results and processes such as software, algorithms, protocols, models, workflows and electronic notebooks.

'Results' means any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether it can be protected, as well as any rights attached to it, including intellectual property rights.
'Partner' means an institution that is affiliated to the SPOKE within the DARE initiative and it is beneficiary of the MUR contribution.

Intellectual Property (IP)

Intellectual property (IP) is an important mechanism for protecting valuable research results, providing ownership of creators and the ability to control wide dissemination. IP management is one of the biggest challenges, especially for academic institutions. Therefore, creating an IP framework is crucial to ensure early disclosure of inventions, as well as to determine the institution's legal position on IP ownership, protection, conflict of interest, incentives, including benefit sharing, how to create a start-up based on technology developed in the laboratory, and so on.
IP refers to creations of the mind – everything from works of art to inventions, computer programs to trademarks and other commercial signs. IP is protected in law by, for example, patents, copyright and trademarks, which enable people to earn recognition or financial benefit from what they invent or create. By striking the right balance between the interests of innovators and the wider public interest, the IP system aims to foster an environment in which creativity and innovation can flourish.

Types of intellectual property

IP is often divided into two main categories:

- Industrial property includes patents for inventions, industrial designs, trademarks and geographical indications.
- Copyright and related rights cover literary, artistic and scientific works, including performances and broadcasts.

Patents

A patent is an exclusive right granted for an invention. A patent provides the patent owner with the right to decide how - or whether - the invention can be used by others. In exchange

for this right, the patent owner makes technical information about the invention publicly available in the published patent document.

Copyright

Copyright is a legal term used to describe the rights that creators have over their literary and artistic works. Works covered by copyright range from books to computer programs, databases, advertisements, maps and technical drawings.

Trademarks

A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises.

Industrial designs

An industrial design constitutes the ornamental or aesthetic aspect of an article. A design may consist of three-dimensional features, such as the shape or surface of an article, or of two-dimensional features, such as patterns, lines or color.

Trade secrets

Trade secrets are IP rights on confidential information which may be sold or licensed. The unauthorized acquisition, use or disclosure of such secret information in a manner contrary to honest commercial practices by others is regarded as an unfair practice and a violation of the trade secret protection.

WIPO Diagnostics: IP Self-Assessment Tool

To help the spoke leader identify potential assets, DARE will make use of WIPO IP Diagnostics, a free, intellectual property (IP) self-assessment tool that helps businesses identify their IP assets. The tools will be usable and accessible from the web, and support for the use and the outcomes of the tool is foreseen. The IP assessment is in the form of two-level questionnaires. The first one is a "pre-assessment" which consists of ten questions about your company. The answers to these questions reveal the areas of relevance to the business and lead to a second-level assessment consisting of ten sections.

The system invites the user to respond to the more detailed questions in the different sections automatically generated based on the responses to the pre-assessment. Reports are automatically generated by the system depending on the responses provided to the

questions in the different sections of the second assessment, as well as to some of the questions in the pre-assessment (Annex 1.A).

The reports identify the IP issues that may be relevant to the business and offer useful information for managing those rights. The reports may be useful as a preliminary IP audit and constitute a useful basis for determining the IP strategy for the business.

https://www.wipo.int/ipdiagnostics-assessment/global/en

3.2. Institutional Policies

Ensure that your IPR management aligns with the policies and regulations of your institution or funding agency.

IP policies provide structure, predictability, and a beneficial environment, in which commercialization partners (industrial sponsors, consultants, non-profit organizations, SMEs, governments) and research stakeholders (researchers, technicians, students, visiting researchers, etc.) can access and share knowledge, technology and IP.

Each university or research institution has the autonomy to develop its own approach, taking into account the interests of all stakeholders.

Institutional IP policies are policies established by universities or research institutions to address IP issues typically encountered during collaboration with external parties and the commercialization of academic research. An institutional IP policy must comply with all relevant national policies and strategies.

National IP policies express the intent of a country to use the intellectual property system in a defined manner to achieve a stated goal. National IP strategies are measures taken by a government to realize its IP policy objectives. Many IP-related policies and strategies promote research and innovation and encourage the transfer and dissemination of technology.

3.3. Ownership and Access Rights

Clearly define the ownership of IP generated during the project, including contributions from team members, collaborators, and third parties.

Agreement to background

The beneficiaries must identify in a written agreement the background as needed for implementing the action or for exploiting its results. The format to be used to declare the background is proposed hereafter and should be identified before the submission of the Pilot and agreed upon for the Project.

Describe Background	**Specific restrictions and/or conditions for Implementation**	**Specific restrictions and/or conditions for Exploitation**

The partner must give each other, and the other participants, access to the background identified as needed for implementing the action, subject to any specific rules here reported. If background is subject to rights of a third party, the partner concerned must ensure that it is able to comply with its obligations under the underlying SPOKE – Affiliate Agreement (SAA) that at the moment of writing has not fully finalized.

Ownership of results

The granting authority (Ministry of University and Research) does not obtain ownership of the results produced under the DARE Project.

Results are owned by the partners that generate them. However, two or more partners' own results jointly if:

- they have jointly generated them and
- it is not possible to:
    - establish the respective contribution of each partner, or
    - separate them for the purpose of applying for, obtaining or maintaining their protection.

The joint owners must agree — in writing — on the allocation and terms of exercise of their joint ownership ('joint ownership agreement'), to ensure compliance with their obligations under the SAA. In the same manner as disciplined in the EC Grant Agreement and Consortium Agreement (DESCA), unless otherwise agreed in the joint ownership

agreement, each joint owner may grant non-exclusive licenses to third parties to exploit the jointly owned results (without any right to sub-license), if the other joint owners are given:

- at least 45 days advance notice and
- fair and reasonable compensation.

The joint owners may agree — in writing — to apply another regime than joint ownership. If third parties (including employees and other personnel) may claim rights to the results, the partner concerned must ensure that those rights can be exercised in a manner compatible with its obligations under the agreement.

Employment aspects – WIPO IP Diagnostics

- ❑ Do your employees invent any of your new products, processes or technical modifications? Yes/No
- ❑ Do your employees engage in the development of creative materials, designs or business signs that are subsequently used in your business? Yes/No
- ❑ Do you ensure that when you hire employees, they do not bring with them trade secrets from their former employers? Yes/No

3.4. IP Protection Strategies

Develop a strategy for protecting IP, which may involve patent applications, copyrights, or trade secret protection, depending on the nature of the innovation.

An IP strategy is a plan of action to manage and protect its intangible assets. An IP Strategy Checklist, realized by the World Intellectual Property Organization (WIPO), will be provided to each Spoke Leader to help them give a clearer picture of how IP portfolio is currently being managed and identify areas of improvement. It should be noticed that the IP strategy checklist is by no means all-inclusive. The IP Strategy Checklist will be revised at least every 12 months.

The checklist is divided into four (4) parts that reflect the general stages of commercialization (Annex 1).

3.5. Disclosure and Record-Keeping

Establish procedures for documenting and disclosing potential IP, including a clear record-keeping system.

At least every 12 months, the Principal Investigator of the Pilot Study should fulfill the IP self-assessment tool accessible through the WIPO IP Diagnostics to document and disclose potential IP (https://www.wipo.int/ipdiagnostics-assessment/global/en). Furthermore, the pre-assessment questionnaire will be also useful to understand the ownership of results. At the beginning of the pilot study, the PI should also prepare the IP Strategy (1-3) to be communicated to the Spoke Leader.

The process is described in Figure 1.

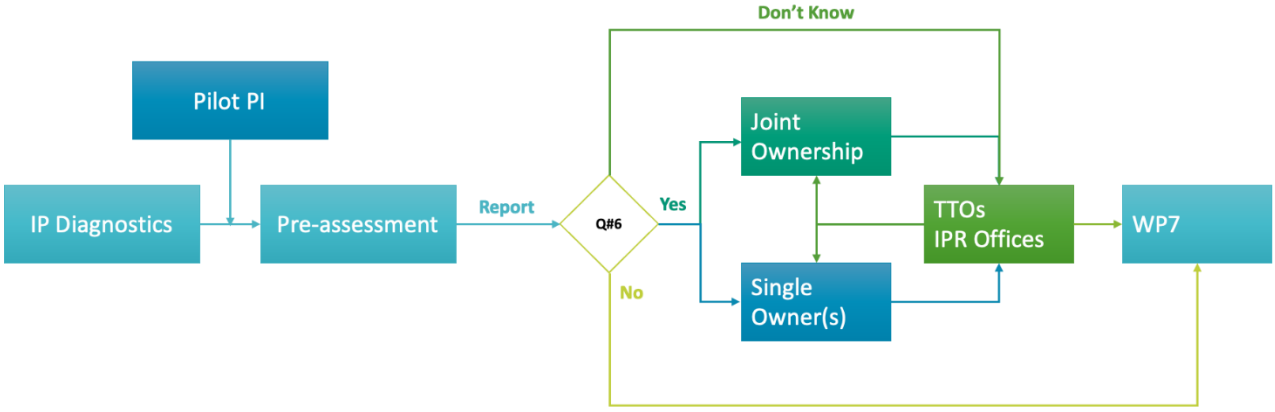


Figure 1: IP Self-Assessment process

Once the PI completes the pre-assessment questionnaire, a positive answer to question #6n #6 "*Do you rely on external suppliers, independent contractors or consultants for ensuring stocks, getting components, developing material, running advertising campaigns, etc.?*" might indicate the presence of joint ownership to be discussed with the Technology Transfer Offices (TTOs) or IPR Offices before being transmitted to the WP7 coordinator.

In any case, all the reports from the self-assessment tool should be sent to the WP7 coordinator to keep records and other supporting documents to prove the proper implementation of the action in line with the accepted standards in the respective field. A secure folder will be set on the DARE Sharepoint cloud repository.

The partners must keep the original documents. Digital and digitalised documents are considered originals if they are authorized by the applicable national law.

3.6. Education and Training

Provide training to project participants and collaborators on IPR issues to ensure awareness and compliance. – promote webinars to be organized

For each SPOKE, WP7 in synergies with WP6 will establish and consolidate a process of "*Awareness Raising*", by organizing events (remotely or in person) at least every 4 months for governments, universities and PRIs to explain how and why institutional IP policies can be of use. They will also promote the use of free tools, such as free WIPO publications, to educate policy makers and individuals.

4. IPR Monitoring

4.1. Collaboration and Licensing Agreements

The IP Strategy checklist and the background disclosure enable the Partner(s) and the Spoke Leader to monitor the collaboration and to regulate the procedure to be activated to protect potential IPR.

Exercise of access rights – Waiving of access rights – No sub-licensing

Requests to exercise access rights and the waiver of access rights must be in writing.

Unless agreed otherwise in writing with the beneficiary granting access, access rights do not include the right to sub-license.

If a beneficiary is no longer involved in the action, this does not affect its obligations to grant access.

If a beneficiary defaults on its obligations, the beneficiaries may agree that that beneficiary no longer has access rights.

Access rights for implementing the action

The beneficiaries must grant each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

- - informed the other beneficiaries that access to its background is subject to restrictions,

or

- - agreed with the other beneficiaries that access would not be on a royalty-free basis.

The beneficiaries must grant each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

Access rights for exploiting the results

The beneficiaries must grant each other access — under fair and reasonable conditions — to results needed for exploiting their results.

The beneficiaries must grant each other access — under fair and reasonable conditions — to background needed for exploiting their results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to restrictions.

Requests for access must be made — unless agreed otherwise in writing — up to one year after the end of the pilot.

4.2. Confidentiality and Non-Disclosure Agreements

Implement confidentiality agreements to protect sensitive project information and IP.

The partners must keep confidential any data, documents or other material (in any form) that is identified as sensitive in writing ('sensitive information') — during the implementation of the pilot and for at least until the time-limit set out in the specific agreement between the spoke and the affiliated entities.

Unless otherwise agreed between the partners, they may use sensitive information only to implement the Agreement.

The partners may disclose sensitive information to their personnel or other participants involved in the action only if they:

(a) need to know it in order to implement the Agreement and

(b) are bound by an obligation of confidentiality.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party

(b) the information becomes publicly available, without breaching any confidentiality obligation

(c) the disclosure of sensitive information is required by EU, international or national law.

Specific confidentiality rules (if any) are set out in the specific Agreement between Spoke and Affiliated Entities.

4.3. Enforcement of Rights

Develop a strategy for enforcing IP rights and taking legal action if necessary to protect against infringement.

The strategy and the implementing processes, have to be updated once the specific agreement between the Spoke and the Affiliated Entities has been signed. Through the policies and the processes described the SPOKE intend to pursue the following strategy for enforcing IP rights:

Assessment and Documentation:

- Audit IP Portfolio: Evaluate and document all intellectual property assets including patents, trademarks, copyrights, and trade secrets.
- Identify Risks: Pinpoint potential infringement risks by monitoring markets, competitors, and online platforms.
- Documentation: Maintain thorough records of creation, registration, and use of IP assets to establish ownership.

Proactive Measures and Collaboration:

- Education and Training: Educate employees on IP rights, infringement risks, and procedures for reporting potential violations.
- Partnerships and Surveillance: Collaborate with legal experts, industry associations, and specialized agencies for surveillance and monitoring of potential infringement.
- Cease and Desist: Implement a strategy for issuing cease-and-desist letters to infringers, offering the opportunity for amicable resolution before escalating to legal action.

- Legal Action and Enforcement:
- Legal Counsel Engagement: Retain experienced legal counsel specializing in IP law to assess cases, send formal demand letters, and guide through litigation if required.

Litigation Strategy:

- Develop a robust litigation strategy, including the identification of appropriate jurisdictions, evidence collection, and potential settlement negotiations.
- Enforcement: Pursue legal action, seeking remedies like injunctions, damages, or licensing agreements to protect IP rights effectively.

4.4. Open Access and Publication

Determine how the project's research results will be published and whether any restrictions are necessary to protect IP.

Open science: open access to scientific publications

The beneficiaries must ensure open access to peer-reviewed scientific publications relating to their results. In particular, they must ensure that:

- at the latest at the time of publication, a machine-readable electronic copy of the published version or the final peer-reviewed manuscript accepted for publication, is deposited in a trusted repository for scientific publications
- immediate open access is provided to the deposited publication via the repository, under the latest available version of the Creative Commons Attribution International Public Licence (CC BY) or a licence with equivalent rights; for monographs and other long-text formats, the licence may exclude commercial uses and derivative works (e.g. CC BY-NC, CC BY-ND) and
- information is given via the repository about any research output, or any other tools and instruments needed to validate the conclusions of the scientific publication.

Beneficiaries (or authors) must retain sufficient intellectual property rights to comply with the open access requirements.

Metadata of deposited publications must be open under a Creative Common Public Domain Dedication (CC 0) or equivalent, in line with the FAIR principles (in particular machine-actionable) and provide information at least about the following: publication (author(s),

title, date of publication, publication venue); Horizon Europe or Euratom funding; grant project name, acronym and number; licensing terms; persistent identifiers for the publication, the authors involved in the action and, if possible, for their organisations and the grant. Where applicable, the metadata must include persistent identifiers for any research output, or any other tools and instruments needed to validate the conclusions of the publication.

Open science: research data management

The beneficiaries must manage the digital research data generated in the action ('data') responsibly, in line with the FAIR principles and by taking all of the following actions:

- establish a data management plan ('DMP') (and regularly update it)
- as soon as possible and within the deadlines set out in the DMP, deposit the data in a trusted repository;
- as soon as possible and within the deadlines set out in the DMP, ensure open access — via the repository — to the deposited data, under the latest available version of the Creative Commons Attribution International Public License (CC BY) or Creative Commons Public Domain Dedication (CC 0) or a license with equivalent rights, following the principle 'as open as possible as closed as necessary', unless providing open access would in particular:
    - be against the beneficiary's legitimate interests, including regarding commercial exploitation, or
    - be contrary to any other constraints, in particular the EU competitive interests or the beneficiary's obligations under the SAA, the Hub-SPOKE agreement and the DARE Initiative call regulations; if open access is not provided (to some or all data), this must be justified in the DMP
- provide information via the repository about any research output or any other tools and instruments needed to re-use or validate the data.

Metadata of deposited data must be open under a Creative Common Public Domain Dedication (CC 0) or equivalent (to the extent legitimate interests or constraints are safeguarded), in line with the FAIR principles (in particular machine-actionable) and provide information at least about the following: datasets (description, date of deposit,

author(s), venue and embargo); Horizon Europe or Euratom funding; grant project name, acronym and number; licensing terms; persistent identifiers for the dataset, the authors involved in the action, and, if possible, for their organisations and the grant. Where applicable, the metadata must include persistent identifiers for related publications and other research outputs.

Dissemination of own (including jointly owned) Results

Prior notice of any planned publication shall be given to the other Partners at least 45 calendar days before the publication. Any objection to the planned publication shall be made by written notice to the Spoke Leader and to the Party or Parties proposing the dissemination within 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, publication is permitted.

An objection is justified if

- the protection of the objecting Partner's Results or Background would be adversely affected, or
- the objecting Partner's legitimate interests in relation to its Results or Background would be significantly harmed, or
- the proposed publication includes Confidential Information of the objecting Partner.

The objection has to include a precise request for necessary modifications.

If an objection has been raised the involved Partners shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Partner shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.

The objecting Partner can request a publication delay of not more than 90 calendar days from the time it raises such an objection. After 90 calendar days the publication is permitted, provided that the objections of the objecting Party have been addressed.

Dissemination of another Partner's unpublished Results or Background

A Partner shall not include in any dissemination activity another Partner's Results or Background without obtaining the owning Partner's prior written approval, unless they are already published.

Cooperation obligations

The Partners undertake to cooperate to allow the timely submission, examination, publication and defense of any dissertation or thesis for a degree that includes their Results or Background subject to the confidentiality and publication provisions agreed in the Spoke-Affiliates Agreement (SAA).

4.5. Compliance with Funding Requirements

Ensure that all IPR management activities comply with the terms and conditions of the research grant or funding source.

DARE will ensure that all IPR management activities will be compliant with article 3, comma nn), "Disciplinare di Concessione delle Agevolazioni" (D.Lgs. n. 59, 06/05/2021; D.D. n. 931, 06/06/2022).

4.6. Documentation and Reporting

Maintain thorough documentation of all IPR-related activities and provide regular reports to funding agencies, collaborators, and stakeholders.

The partners must continuously report on the progress of the action (e.g. deliverables, milestones, outputs/outcomes, critical risks, indicators, etc; if any), in the SharePoint tool and in accordance with the timing and conditions it sets out (as agreed with the granting authority).

Standardized deliverables (e.g. progress reports not linked to payments, reports on cumulative expenditure, special reports, etc; if any) must be submitted using the templates published on the site.

	Responsible	**Accountable**	**Consulted**	**Informed**

Background	Partners	Partners		Spoke Leader
Results	Partners	Partners		Spoke Leader
IP Strategy check list	PI(s) Pilot	PI(s) Pilot	Spoke Leader, TTO/IPRO	Spoke Leader SF#4
IP Self-assessment	PI(s) Pilot	PI(s) Pilot	TTO/IPRO WP7 Leader	Spoke Leader SF#4

4.7. Risk Management

Identify potential risks, such as legal challenges or changes in the market, and develop strategies to mitigate them.

Dispute Resolution Mechanisms: Establish procedures for resolving disputes related to IPR ownership or management.

The following critical risks with the level of likelihood (Likely, Possible, Unlikely) and severity (Low, Medium, High) have been identified along with mitigation measures.

Risk No	**Description of risk**	**Indicate level of (i) likelihood (Probable, Likely, Unlikely), and (ii) severity (High, Medium, Low)**	**Proposed risk-mitigation measures**
1	Disclose of sensible information	P, H	NDA in place in the Spoke/Affiliates agreement and internal policies defined
2	Missing commercial exploitation opportunities for Pilot projects	P, M	Awareness program with webinars periodic and training sessions for researchers involved in the pilots.

			Release and support on self-assessment questionnaires
3	Lack of participation/ Commitment from researchers	U, L	Periodic call-to-action related to the IPR assessment for research results.
4	No / Difficult market opportunities due to competition	P, M	Prior art research and market analysis /market opportunity screening to be done in the early stages of the Pilot
5	Conflict of ownership	L, H	Opt-in statement about background involved in the research program. Foreground: policies in place to require clear definition of ownership

At least every 12 months, the Spoke Leader will monitor and report the status of critical risks by completing the following checklist.

Risk No	**Risk Mitigation Measures**	**State of the Play**			
		Period	**Did you apply risk mitigation measures?**	**Did your risk materialise?**	**Comments**
1		1 – 2 - 3	Yes / No	Yes / No	
…					

5. IPR Exploitation Services

5.1. Ethical Considerations

Consider the ethical implications of IP management, such as ensuring that the benefits of the research are distributed fairly and do not harm society or the environment. – DNSH check list

Ethics

The project must be carried out in line with the highest ethical standards and the applicable EU, international and national law on ethical principles.

Values

The partner must commit to and ensure the respect of basic EU values (such as respect for human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities), and compliance with the Do No Significant Harm principle (DNSH) principle, which states that the actions outlined in Italian National Recovery and Resilience Plan may not cause any significant harm to the environment.

Consequences of non-compliance

If a partner breach any of its obligations under this Section, it will lead to specific measures set out in the Spoke-Affiliated Agreement.

5.2. Commercialization Plan

Create a plan for how the IP will be exploited, whether through licensing, partnerships, or the creation of a startup company. – link to the sustainability

Although IP protection is vital for prospective commercial or industrial exploitation, on the other hand it is not always mandatory. In fact, it goes without saying that the choice of the most suitable form of IP protection, as well as the duration and geographical coverage depends on the results at stake, but also the business plans for their exploitation and legitimate interests of Consortium partners. The overall strategy of the DARE Consortium is to pursing IP protection in cases where:

1. The Pilot project results are clearly capable of commercial application.

2. The rationale for protection is sound.
3. The potential economic benefits clearly outweigh the financial cost of seeking such protection.

Regulation of the IP rights consists of many coexisting and complementing layers, hence forms of result protections are manifold.

To delineate the best commercialization plan, the Spoke will refer to the definition of different types of IP and to the self-assessment carried out thanks to the WIPO IP Diagnostics defined in Section 3.1.

5.3. Market Research & Competitor Analysis

Conduct market research to identify potential market opportunities for the project's innovations.

According to what written in the Sustainability Plan, the role of SF#4 to support and to monitor the progress of the pilot projects and their corresponding twins implemented in Spoke 1. This oversight involves aspects related to market readiness and analysis of the 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. Accountable is the Pilot PI that has to appoint a person in the team, whereas SF#4 is consulted as support and informed, as well the Spoke Leader.
- **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.

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 Technology Transfer & Accelerators/Incubators might bring to the creation of specific topic dedicated to the digital prevention within Life Science specific calls 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.

5.4. Licensing and Technology Transfer

Define the terms and conditions under which the IP can be licensed or transferred to other parties.
Determine the value of the IP to guide negotiations and licensing agreements.
Revenue Sharing: Establish a clear revenue-sharing mechanism for project participants and contributors, which may include researchers, institutions, and investors.

IPR Licensing and technology transfer involve the legal transfer or licensing of IPR from one entity to another. This process delineates the terms and conditions for the use, ownership, and commercialization of innovative creations or discoveries generated within a project. It defines how the IP can be licensed or transferred to external parties, outlining the rights and limitations for utilization. Evaluating the value of the IP is crucial for negotiations and licensing agreements, determining fair compensation for stakeholders involved, such as researchers, institutions, and when involved investors. In the case of the DARE foundation, the aim is to gather IPR assets and leverage their value. Partners holding IPR or shared Joint IPR can negotiate licensing rights with the Foundation, establishing clear mechanisms for revenue sharing among contributors, aligning interests, and fostering sustainable collaborations.

DARE Foundation will implement a comprehensive range of services aimed at:

- defining and protecting the intellectual property made available by the partners at the start of the project through shared legal instruments;

- enhancing and exploiting the IPR developed by members through research and experimentation activities (pilot projects) during the project;

- facilitating the exploitation of IPR also with respect to activities collateral to the DARE project during the project and above all at the end of the project.

Technology transfer is a process that involves continuous monitoring of the various stages in the development process of a research idea, ensuring a continuous exchange of information between the research team and the relevant office staff within the DARE Foundation (this is the prediclosure phase where technology officers will assist researchers with respect to the disclosure, evaluation and protection process).

The partnership has set up a series of quantitative indicators (table below) related to monitoring the development and valorization of IPR, as well as subsequent updates linked to sampling within the Pilot Projects cohort.

KPIs Definition	Monitoring	Acceptance Criteria		
		M24	M36	M48
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

The above mentioned monitoring activity will pave the way to the IP disclosure step where the notice of the IP creation begins the formal TT process. The process of protecting the technology may take months or even years to complete. The length of time will depend on the development stage of the technology, the market for the technology, competing technologies, the amount of work needed to bring a new concept to market-ready status, and the resources and willingness of the licensees and the inventors.

The period in which the TT office reviews the IP Disclosure, is a crucial moment to conduct a patentability review, to analyze the market and competitive technologies to determine the IP's commercialization potential. This process will guide the strategy on whether to focus on licensing to an existing company or to a new business start-up.
The DARE Foundation will also set up a Revenue Sharing Agreements that sets forth how the revenues should be allocated (in an equitable and transparent way) between inventors, the Foundation and other stakeholders.

5.5. Exit Strategy

Consider an exit strategy for the project, which may involve selling the IP, shutting down the project, or transitioning it to another entity.

Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the General Assembly to terminate its participation in the consortium. A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Results developed until the date of the termination of its participation. It may request Access Rights within the period specified in Section 9.4.3. Any Party leaving the project shall continue to grant Access Rights pursuant to the Grant Agreement and this Consortium Agreement as if it had remained a Party for the whole duration of the Project.

6. Conclusions

This report aims at highlighting the main intellectual property rights issues that may arise during the DARE Initiative project lifetime. The analysis includes a presentation of protection and exploitation methods of IP Rights (such as trademarks, patents, copyright and transfer and licensing agreements respectively). A general presentation is followed by a first approach of how DARE Initiative, particularly the Pilots 'activities, results could be protected and exploited in the future. Given the early stage in project execution this report's main purpose is not yet to come up with a detailed protection and exploitation plan but instead to provide to project partners guidance regarding how they could efficiently manage their project-related IP. This includes advice on a dissemination policy that the partners could apply, confidentiality and trade secret practices, as well as preliminary guidance on Results' exploitation planning.

Annex 1.

A. WIPO IP Diagnostics

- ❑ Have you developed a product, process, service or a technical modification that you consider new, innovative or unique? Yes/No
- ❑ Do you generate materials like manuals, pamphlets, labels, or produce videos, software, newsletters, music clips, etc.? Yes/No
- ❑ Do you use features like patterns, lines, colors or shapes to make the external appearance or the packaging of your product attractive? Yes/No
- ❑ Does your business rely on information that you consider commercially valuable and that you do not want your competitors to have access to? Yes/No
- ❑ Do you use a logo or other sign to distinguish your products or services from those of others? Yes/No
- ❑ Do you rely on external suppliers, independent contractors or consultants for ensuring stocks, getting components, developing material, running advertising campaigns, etc.? Yes/No/Don't know
- ❑ Do you have or intend to create a website? Yes/No/Don't know
- ❑ Do you manufacture or sell products outside the country where your business is based? Yes/No
- ❑ Do you have employees? Yes/No
- ❑ Do you have access to intellectual property services or expertise? Yes/No

B. WIPO IP Strategy Check List

1. Ideation process – Generating and developing ideas
    1.1. Commercial application
        - Does the idea/concept have commercial application?
    1.2. Identifying intellectual property assets

- Does the business have processes and/or procedures for identifying IP assets within the business? (IP Audits, due diligences and utilizing IP checklists)

1.3. Capturing intellectual property assets

- Does the business have processes and/or procedures for capturing IP assets?

1.4. Confidential information

- Does the business have processes and/or procedures for preventing disclosure of the idea/concept? (NDAs, trade secrets, restricted access, other agreements)

1.5. Likelihood of intellectual property protection

- Does the business have processes and/or procedures to identify the likelihood of obtaining IP protection (preliminary patent, design, trademark, copyright, domain name, plant breeders' rights searches)?

1.6. Partnerships

- Does the business have potential partners to collaborate with in the development and commercialization of the idea/concept?
- When collaborating with third parties, has/will the business secure ownership or access to the IP?

1.7. Identifying competitors

- Does the business have processes and/or procedures to identify competitors or the likelihood of infringing third party rights by applying the idea/concept?

2. Product and service development – Commercial and market analysis

2.1. Freedom-to-operate search

- Does the business conduct IP landscape, Freedom to Operate (FTO) searches or competitor analysis to identify any potential competing IP rights or technologies?

2.2. Intellectual property searches

- Does the business conduct regular IP and technology searches to determine the likelihood of obtaining IP protection for incremental innovations or improvements?

2.3.Third party rights

- Does the business have processes and/or procedures for addressing IP ownership considerations when collaborating with third parties to develop its product and services? (marketing, employer, R&D, licensing agreements)
- When collaborating with third parties, has the business secured the rights to use the results of the IP developed during the collaboration?
- Does the business use IP of third parties? If so, has the business acquired the rights to use the IP?

2.4.Intellectual property strategy implementation

- Does the business have technical or an IP review committee to decide on product or service development, taking into account the overall business and IP strategy?

3. IP protection – Securing assets

3.1.IP protection strategy

- Has the right protection strategy been identified? (i.e., patent, trade secret, design, trademark, open source, plant breeder's rights, copyright IP)

3.2.Prioritization of IP protection

- Does the business have processes and/or procedures for prioritizing IP protection? (I.e. the order in which IP rights and protection are prioritized)

3.3.Technology landscaping

- Does the business conduct IP searchers and/or technology landscape studies for patent, design, trademark, plant breeders rights searchers conducted before seeking protection?

3.4.IP Strategy Development

- Does the business have processes and/or procedures for developing an IP strategy including market, cost or timing considerations?

3.5.Monitoring ownership

- Does the business have processes and/or procedures for monitoring inventorship, authorship and ownership considerations?

3.6.Non-registerable IP Protection

- Does the business have processes and/or procedures for protecting non-registerable forms of IP know-how, trade secrets, goodwill etc.

3.7.Intellectual Property advice

- Is advice sought from IP professionals before seeking IP protection?

3.8.IP Strategy alignment

- Is the IP strategy aligned with the commercialization strategy?

4. IP commercialization – Market entry

4.1.Commercialization vehicle

- Does the business have processes and/or procedures to identify the appropriate commercialization vehicle? (manufacture, sale, license, etc.)

4.2.IP asset valuation

- Does the business have processes and/or procedures valuation of IP assets, especially for those to be licensed as part of business model / pricing strategy for products? (e.g., claim charting vis-à-vis competitor products/services)

4.3.Freedom to Operate

- Has a Freedom to Operate search been conducted to determine the potential to infringe third party rights?

4.4.Competition monitoring

- Does the business have processes and/or procedures for monitoring competitor activities, potential commercialization partners or enforcement of IP rights?

4.5.Branding

- Is the product and/or service appropriately branded (trademark, packaging, websites, domain names)? Is descriptive or distinctive branding considered?

4.6.IP review

- Does the business have an IP & innovation review board within company to periodically review IP assets, portfolio structure, new innovations & disclosures, competitive landscape, IP budget, etc.?

4.7.IP audit

- Does the business have processes and/or procedures for periodic audits of all IP assets and portfolio optimization, portfolio pruning, possible divestitures?

4.8.IP policy and education

- Does the business have processes and/or procedures for periodic IPR and IP policy and education trainings for employees?