



**DARE**  
DIGITAL LIFELONG PREVENTION

CODE NO. PNC0000002

**Spoke 3 Deliverable**

**S3.D7.3**

**Business-oriented services**

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## S3.D7.3 Business Oriented Services

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## Publishable summary

This deliverable describes the implementation of Task 7.3 for Spoke 3, which focuses on secondary and tertiary prevention through advanced clinical decision support, digital diagnostics, in-silico modelling and therapeutic or biomarker innovation. These projects operate in highly specialised medical domains such as oncology, orthopaedics, diabetes, transplantation and neurodegeneration, where exploitation depends not only on technical maturity but also on regulatory compliance, clinical workflow integration and evidence generation.

Within the WP7 framework, Spoke 3 teams participated in the ReActorPro entrepreneurial and translational programme, gaining a clearer understanding of feasible exploitation routes. The activities showed that startup formation is realistic only for a limited subset of solutions, particularly telemedicine platforms or data-driven decision support tools with lower regulatory constraints. Most innovations—especially AI-based diagnostics, digital biomarkers, in-silico models and therapeutic candidates—are instead more suited to institutional adoption, technology transfer or co-development with industrial or clinical partners. These pathways reflect the regulatory requirements of the MDR and the AI Act, as well as the need for clinical validation environments and strong stakeholder engagement.

The deliverable also recognises the functional value of the enabling frameworks developed in Spoke 1. While not universally adopted by all pilots, these interoperability, MLOps, data-processing and governance components provide optional but relevant capabilities that can support exploitation readiness and reduce the translational burden for many Spoke 3 innovations.

Overall, Spoke 3 contributes a set of clinically significant and scientifically advanced innovations to the DARE programme. Through the structured WP7 funnel—awareness, entrepreneurial training and exploitation pathway assessment—these projects have strengthened their translational positioning and identified realistic routes toward long-term adoption in healthcare and research ecosystems.

# 1. Introduction

The DARE initiative establishes an integrated ecosystem for developing, validating and translating digital-health innovations across prevention domains. Within this structure, the three Spokes operate with different degrees of clinical proximity, technical complexity and translational requirements. Spoke 3 covers digitally enabled secondary and tertiary prevention, producing outputs that interact directly with regulated clinical workflows, ranging from digital diagnostics and multimodal decision support to in-silico modelling and therapeutic or biomarker development. Because these innovations often require rigorous validation, regulatory alignment and structured clinical integration, their exploitation potential must be assessed using criteria different from those applied to community-level or infrastructural outputs.

Task 7.3 supports this assessment by providing a unified entrepreneurship and exploitation pathway that spans awareness building, structured training and acceleration. This pathway enables Spoke 3 teams to evaluate the feasibility of startup-based routes, identify alternative exploitation models, and understand regulatory and operational requirements that condition the translation of clinically intensive innovations. While the task does not aim to force homogeneous outcomes across Spokes, it applies a shared methodological framework that ensures comparability and provides a coherent basis for analysing exploitation readiness throughout the consortium.

Interaction with Spoke 1 plays an important functional role in this process. A subset of Spoke 3 innovations may benefit from enabling components developed within Spoke 1, such as interoperability mechanisms, wearable-signal processing pipelines, lifecycle management tools for AI systems and regulatory-governance frameworks. These assets reduce translational burden for those pilots that require them, although their adoption is not uniform across the Spoke and is not documented pilot-by-pilot in this deliverable. This functional alignment supports the Twin Pilot architecture and reinforces the overall coherence of the DARE solution frameworks.

Given this integrated structure, the deliverable includes methodological sections shared with S1.D7.4 and S2.D7.3—namely, the entrepreneurship pathway, the training and acceleration programmes, and the exploitation-pathway selection criteria—followed by Spoke-specific analyses.

## 2. WP7 Objectives and Purpose of the Deliverable

WP7 defines the set of activities required to ensure that the outcomes generated across the DARE consortium are assessed, protected, and prepared for exploitation in a form consistent with the sustainability direction of the initiative. Its general objectives include:

- protection and consolidation of intellectual property;
- identification and evaluation of exploitation models;
- assessment of technology transfer routes and conditions for industrial uptake;
- analysis of feasibility for potential startup or spin-off creation;
- alignment of project outputs with regulatory and operational requirements for real deployment.

*This deliverable evaluates the exploitation potential of Spoke 3 innovations using the WP7 methodology. It outlines the entrepreneurial framework, training activities and Spoke-specific patterns, and provides lessons and recommendations to guide the translation of clinically intensive digital-health solutions.*

Within this structure, Task 7.3 addresses the exploitation potential of the domain-facing innovations developed in Spoke 3. For Spoke 3, the WP7 methodology is applied to clinically intensive outputs—digital diagnostics, prognostic models, digital twins, transplant and oncology biomarkers, and telemedicine-based decision workflows—whose exploitation trajectories must account for regulatory constraints, evidence-generation requirements and their integration within specialist clinical environments. Despite these differences, WP7 adopts a unified methodological framework for all three tasks. The rationale is that exploitation activities (IPR assessment, TRL evaluation, regulatory checks, and pathway identification) rely on consistent criteria across Spokes. Moreover, Spoke 2 and Spoke 3 may functionally benefit from the enabling components produced in Spoke 1; these include interoperability architectures, compliance frameworks, and data governance principles. A unified framework ensures that S2 and S3 do not operate in isolation but benefit from a shared set of technical foundations, avoiding fragmentation and ensuring coherence across the translation process. SF#4, the Translational Framework, defines the methodological steps through which

project outputs progress from research prototypes to validated, interoperable and sustainable solutions according to the methodology agreed in Spoke 1<sup>1</sup>.

Within this structure, the goal of the present deliverable, S3.D7.3, is to document the implementation of WP7 activities for Spoke 3 and to assess the exploitation potential of its secondary- and tertiary-prevention innovations. The task focuses on evaluating how clinically intensive outputs—digital diagnostics, in-silico models, digital biomarkers, therapeutic candidates and telemedicine-based decision-support tools—can follow viable exploitation routes, including institutional adoption, licensing, co-development with industry, or in selected cases startup formation. While Spoke 3 may benefit from enabling technologies developed in Spoke 1, Task 7.3 applies the WP7 methodology directly to the innovations generated within its clinical pilots, assessing their maturity, regulatory feasibility and translational potential. Given this integrated approach, the deliverable includes common sections -namely the description of the entrepreneurship and exploitation methodology, the unified training and incubation framework, and the criteria used to evaluate assets. These sections appear, with appropriate contextual adaptations, also in Deliverables S1.D7.4 and S2.D7.3, ensuring consistency and comparability across the three Spokes.

The subsequent sections of this document describe:

- the general exploitation and entrepreneurship framework used across WP7 (Section 3);
- the awareness, training, and incubation activities implemented for Spoke 3 (Sections 4–6);
- consolidated results and KPIs (Section 7);
- Spoke 3-specific patterns and exploitation opportunities (Section 8);
- lessons learned and recommendations for future cycles (Section 9);
- and final considerations on the contribution of Spoke 3 to the sustainability mechanisms of the DARE Foundation (Section 10).

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<sup>1</sup> See Deliverable S3.7.1 about Sustainability plan, where the Solution Framework concepts are introduced.

## 3. The DARE Entrepreneurship Pathway: General Structure

This section describes the framework adopted in WP7 to analyse and support the potential exploitation of project outputs across the consortium. The framework is shared across Spoke 1, Spoke 2 and Spoke 3, with adaptations reflecting the nature of the assets developed in each area. It provides a structured way to move from initial awareness, through training, to the identification of feasible exploitation pathways. The subsections below outline the overall structure, the limits of a startup-centric interpretation, alternative exploitation scenarios, and criteria for selecting an appropriate route.

### 3.1. Overall Framework

The WP7 entrepreneurship framework adopts a funnel-based structure derived from the training and incubation programmes developed with G-Factor. The starting point is the entrepreneurial mindset training delivered through the ReactorPro programme, which introduces research teams to the fundamentals of value creation, IPR, regulatory constraints, and early exploitation logic.

Following this initial stage, the framework narrows toward more targeted activities that prepare teams for practical exploitation. The subsequent G-Force acceleration programme provides methodological and operational support for teams that intend to pursue a startup-based exploitation route. It introduces tools for refining problem definition, validating assumptions, and preparing for early company formation.

This funnel structure ensures that all teams begin from the same conceptual foundation, but only those whose outputs align with startup requirements progress toward acceleration. Other outputs follow alternative exploitation routes, addressed in Section 4.3. Detailed descriptions of Phase 1, Phase 2, and Phase 3 appear in later sections of the deliverable.

### 3.2. Limitations of a Startup-Centric Approach

Not all pilot activities or innovations produced within DARE are suitable for startup-oriented exploitation. Several categories of outputs do not map naturally onto company creation. Examples include enabling technologies, infrastructural components, methodological frameworks, data governance tools, and regulatory alignment mechanisms. These components typically require institutional integration rather than market positioning.

In addition, some project outputs address systemic or cross-institutional challenges, such as interoperability or population-level prevention workflows, which depend on regulatory adoption, public infrastructure, or regional coordination rather than commercial dynamics. Other assets may be technically immature (low TRL), embedded in clinical or organisational workflows, or dependent on pre-existing systems that limit standalone viability.

For these reasons, WP7 explicitly recognises that startup creation is only one among several possible exploitation routes. A broader set of scenarios is required to capture the realistic potential of DARE outputs.

### 3.3. Alternative Exploitation Pathways (Beyond Startup Creation)

Several exploitation pathways are relevant for assets that do not align with a startup-centric model. These include:

#### a. Institutional service models

Some outputs can be incorporated into long-term services delivered by the DARE Foundation or partner institutions. Examples include interoperability support, governance frameworks, and compliance-related services. These routes focus on operational continuity rather than market creation.

#### b. Licensing or technology transfer

When a component is technically mature and suited for integration into existing products or infrastructures, licensing or joint development with industrial actors becomes a feasible route. This option avoids the overhead of company formation.

#### c. Open frameworks with controlled governance

For methodological or infrastructural components, an open but governed framework may support broad adoption. This pathway is relevant when value derives from widespread use rather than commercial differentiation.

#### d. Internal adoption as an operational capability

Some outputs serve as internal tools that strengthen the technological base of the Foundation or its partners. In these cases, exploitation corresponds to institutional integration rather than external dissemination.

#### e. Contribution to national or European standardisation

When an innovation addresses systemic issues such as interoperability, AI governance, data lifecycle methodology, its primary exploitation route may be inclusion in guidelines, standards, or policy frameworks rather than market mechanisms.

### 3.4. Pathway Selection Criteria

Selecting the most appropriate exploitation pathway for a given innovation requires a structured assessment aligned with recognised European Commission methodologies for Key Exploitable Results (KER). The decision process must ensure that each asset is mapped to a route consistent with its maturity, nature, regulatory conditions, and expected beneficiaries. The following criteria synthesise the KER logic with the specific characteristics of enabling technologies developed in Spoke 1.

#### 1. Maturity assessment (TRL / IRL / CRL)

The starting point is the combined evaluation of Technical Readiness Level (TRL) and Integration Readiness Level (IRL), with Commercialisation Readiness Level (CRL) used when relevant.

- TRL < 5: the asset is not yet suited for external exploitation; internal use or open methodological frameworks are typically appropriate.
- TRL 5-7: the asset may support licensing, institutional integration, or standardisation efforts.
- TRL ≥ 8: fully validated outputs may be compatible with service deployment or, in selected cases, startup formation.

This maturity screening mirrors EC practice for identifying which results qualify as preliminary or validated KERs.

#### 2. KER typology (nature and value logic of the result)

- Following the EC's KER categorisation, the nature of the result strongly influences the exploitation route:
- Methodological, governance, interoperability or infrastructural KERs → often align with institutional service models, standardisation pathways, or internal adoption.
- User-facing applications, analytical tools, or standalone software → can support licensing or, in certain cases, startup-based exploitation.

- Policy-oriented or training-related outputs → typically align with standardisation, educational dissemination, or institutional uptake.

Classifying the asset correctly ensures compatibility with established EU exploitation categories.

### 3. Regulatory and compliance readiness

For outputs interacting with regulated domains—data protection, medical devices, AI governance—the assessment must determine whether:

- regulatory compliance can be sustained by a small organisation or startup, or
- the asset requires the governance, oversight, and operational infrastructure of institutional adoption.

High regulatory complexity (e.g., MDR, GDPR-sensitive workflows, AI Act high-risk systems) generally directs the asset toward licensing, institutional service models, or integration into existing infrastructures.

### 4. Problem scale and stakeholder scope

The scale of the problem and the level of stakeholders required for adoption are central elements of KER logic.

- Local or niche-scale problems may justify startup-oriented exploitation.
- Regional, national, or cross-sectoral challenges typically require institutional models, public-sector integration, or standardisation.
- Cross-border or systemic issues (e.g. interoperability governance frameworks) are typically incompatible with startup formation and align instead with open frameworks or standard-setting routes.

### 5. Sustainability and maintenance requirements

KER classification requires assessing the effort needed for long-term maintenance, updates, monitoring and compliance:

- Assets requiring continuous regulatory alignment, security management, or updates are better suited for institutional exploitation or integration into long-standing infrastructures.
- Assets with stable functionality and limited maintenance needs can support licensing or venture-based scaling.

This ensures that the selected exploitation mode is feasible and sustainable beyond the project timeline.

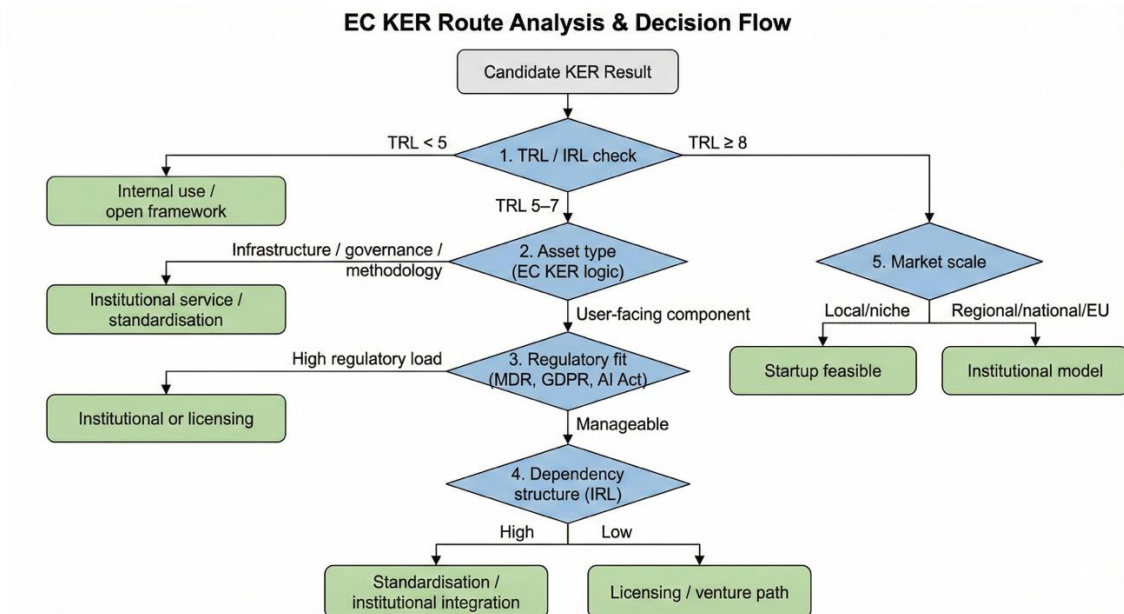
### 6. Dependency structure and system coupling

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Using IRL and dependency analysis, the decision process evaluates how tightly the asset is coupled with enabling technologies, legacy systems, or institutional infrastructures:

- High system dependency → startup routes are typically unsuitable; institutional adoption, integration, or standardisation are more consistent.
- Low dependency → the asset may be suitable for commercial exploitation, including licensing or startup formation.

This aligns with EC practice which requires each KER to identify its dependencies to ensure credible exploitation planning.



Some of the outputs produced in Spoke 1 are enabling or infrastructural in nature and do not naturally map onto a commercial product or a startup-driven business model. For these assets, the structured KER-based pathway selection process could be particularly valuable, as it helps identify the most appropriate exploitation trajectory—often institutional service models, licensing, or standardisation—instead of attempting to force a startup-based route that would not be technically or operationally viable.

## 4. Phase 1 — Entrepreneurial Mindset Activation and Internal Awareness

Phase 1 of T7.3 focused on establishing a baseline understanding of exploitation, technology transfer, and entrepreneurial pathways across the DARE consortium. This preparatory phase was necessary to ensure that research teams could evaluate realistic exploitation routes and understand the operational requirements associated with each option.

A first component of the phase was the co-design of the WP7 programme with G-Factor, integrating the entrepreneurial mindset programme (ReactorPro) and the subsequent acceleration phase (G-Force) into the DARE workflow. The co-design process aligned the training structure with the needs of digital health, data-intensive research, and enabling technologies. It defined the competence baseline expected from participants and delineated the topics relevant across Spokes, while allowing for differentiation in later stages.

In parallel, a structured internal communication effort was carried out throughout 2024. Information on WP7 objectives, participation requirements, and the structure of the entrepreneurship framework was disseminated via consortium mailing lists, targeted communications from WP and Spoke leadership, and direct interaction with the technical teams. The communication material included short technical notes, concise descriptions of the exploitation pathways, and clarification of the distinction between participation in WP7 and the eventual formation of a startup.

To complement internal communication, the consortium deployed external dissemination activities, including LinkedIn posts, press releases, short video explainers, and multimedia content produced in collaboration with institutional communication offices. These actions increased visibility of the whole DARE initiative and allowed teams across different partner institutions to access a consistent introduction to the exploitation framework.

A core element of Phase 1 was the organisation of DARE roadshow events hosted across several partner (Bologna, Roma, Bari and Palermo) sites in 2024. These sessions followed a structured agenda aimed at ensuring that all participants received a coherent introduction to WP7 while also establishing an interactive setting to evaluate interest and potential alignment with the programme. Each roadshow session included:

1. Presentation of DARE and WP7 — an overview of the project structure, the scope of WP7, and how exploitation is positioned within the Solution Framework (particularly SF#4–Translation).

2. Presentation of BI-REX and G-Factor — explanation of their roles within WP7, with BI-REX contributing technical and methodological support and G-Factor providing entrepreneurship training and acceleration expertise.
3. Presentation of the ReactorPro programme — detailed description of the expected commitment, training structure, technical content, and progression criteria for the mindset programme.
4. Participant pitches — each team presented a short, structured pitch outlining their research focus, the problem addressed, and the potential relevance for exploitation.
5. Inspirational pitches — one or two invited speakers presented short case studies describing their transition from academic research to startup creation. These interventions provided practical reference points and clarified the operational implications of entrepreneurial pathways.

The structure of these sessions had several functional impacts on meeting dynamics and the overall effectiveness of Phase 1. First, the joint presentation of DARE, WP7, BI-REX, and G-Factor established an integrated view of the ecosystem supporting exploitation. This avoided fragmented understanding across partners and ensured that technical teams recognised the complementarity of roles within the programme. Second, the presentation of ReactorPro with explicit discussion of the required commitment provided an accurate representation of the workload and expectations, allowing participants to self-assess their capacity to engage in later phases. This mitigated the risk of superficial enrolment or misaligned expectations during the training stage.

Third, the inclusion of participant pitches introduced an immediate interactive element. These pitches served as an informal diagnostic tool for WP7, enabling preliminary identification of assets with potential relevance for exploitation or assets requiring alternative routes. The pitches also created peer visibility across research groups, reinforcing the notion that exploitation requires cross-disciplinary interaction rather than siloed work. Finally, the inspirational pitch segment provided concrete examples of transition paths from research to entrepreneurship. This contributed to demystifying the startup process and clarified the distinction between scientific output and exploitable innovation. From an operational standpoint, these contributions helped reduce perceived barriers and allowed teams to contextualise their own work within realistic exploitation trajectories. In addition to in-person events, asynchronous materials (videos, interviews, and short explanatory modules) were distributed through institutional websites and social media channels. These supported participants who could not attend the roadshows and provided a consistent technical narrative for all partners.

## 5. Phase 2 — Entrepreneurial Training and Capability Building

Phase 2 (Jan 2025 - Dec 2025) of the WP7 framework consisted of structured entrepreneurial training delivered through the ReActorPro programme, developed and delivered by Fondazione Golinelli and G-Factor. ReActorPro is an established training model designed to introduce early-stage researchers and technical teams to the fundamental principles of entrepreneurship, technology transfer, and value creation, with a specific focus on the life sciences and digital health domains. ReActorPro is structured to address a common challenge in research environments: although many innovations arise from scientific activities, most teams have limited exposure to the requirements for translating a research output into an operational product, service, or business proposition. The programme is therefore designed to bridge this gap by introducing participants to the decision-making processes, constraints, and opportunities associated with exploitation and technology transfer. ReActorPro does not assume that participants must become entrepreneurs; rather, it aims to ensure that they understand the full spectrum of translational options and the implications of each path for technical, regulatory, and organisational planning.

The programme is delivered in a blended format, combining in-person sessions with remote webinars and one-to-one mentoring. Its curriculum is organised into four components: initial pitch and feedback, structured training modules, personalised mentoring, and a final Demo Day. In the first component, participants deliver a short pitch describing their research activity, which serves both as a baseline diagnostic and as a means to introduce them to the process of communicating research outputs in a translational context.

The structured training modules cover core topics required for evaluating and shaping an exploitation path: market assessment, competitor analysis, value proposition design, regulatory considerations (including specific modules on MDR and life science regulatory frameworks), intellectual property fundamentals, patent strategy, business model design, and financial planning. Across these modules, participants are introduced to the distinction between scientific claims and value claims, and to the factors determining whether an innovation is suited for licensing, internal adoption, a service-based institutional model, or startup creation. Personalised mentoring complements the training sessions and provides targeted feedback on the relevance and feasibility of each team's initial idea. These one-to-one sessions are used to clarify assumptions, identify gaps in regulatory or operational planning, and refine the definition of the problem addressed by the innovation.

The programme concludes with a Demo Day, held in person at G-Factor, where participating teams present their refined project pitch to a group of evaluators, industry partners, investors, and domain experts. Despite its name, the Demo Day is not intended to trigger immediate investment decisions; instead, it functions as a structured assessment point where teams demonstrate their ability to articulate a coherent exploitation concept, outline a credible development path, and recognise the technical and regulatory implications associated with translation.

ReActorPro is supported by a faculty with combined experience in entrepreneurship, venture investment, regulatory affairs, patent strategy, industrial development, and digital health. The expertise represented in the faculty provides participants with exposure to realistic decision-making contexts and constraints typically encountered during early-stage translation activities

## 6. Phase 3 — Incubation and Acceleration

Phase 3 of the T7.3 entrepreneurial path consists of targeted incubation and acceleration activities delivered through the G-Force programme, operated by G-Factor and it is planned to take place from January to April 2026. While Phase 1 established the entrepreneurial mindset and Phase 2 provided structured methodological training, Phase 3 is designed to support those teams whose outputs are suitable for startup-oriented exploitation or for advanced preparation of other exploitation routes. At the time of drafting this deliverable, Phase 3 has not yet begun.

G-Force is a four-month acceleration programme that includes an intensive two-month training and mentoring block, followed by a two-month follow-up period focused on execution and personalised one-to-one support. The programme is designed for early-stage ventures and research-driven teams with high-potential technological or scientific outputs. Its structure is based on a combination of plenary sessions, workshops, tailored mentoring, stakeholder engagement, and pitch sessions. While the programme is general enough to be applied across the three Spokes, its thematic content aligns strongly with the needs of digital health, medtech, and deep-tech innovations.

The G-Force programme follows a week-by-week thematic progression during the initial intensive phase. Each week focuses on a critical dimension of early-stage venture development, including market validation, positioning, product development, user experience, regulatory affairs, intellectual property, business model design, industrial scale-up considerations, financial planning, fundraising, negotiation, communication, and

investor-ready storytelling. This thematic structure is supported by a network of domain experts with backgrounds in life sciences, medtech, industrial development, regulatory strategy, and venture investment.

A key element of the programme is the emphasis on personalisation. Each participating team receives dedicated one-to-one mentoring aligned with its specific technical and organisational challenges. The personalisation component enables mentors to align the acceleration pathway with the real constraints of each asset, including regulatory dependencies, system integration requirements, or institutional adoption conditions.

Although startup creation is one exploitation route, G-Force also supports the analytical work required to determine whether a new venture is the appropriate mechanism for a given innovation. The structured evaluation across the 11 thematic weeks enables teams to test their assumptions, validate their problem-solution fit, assess market relevance, and determine whether the operational and regulatory conditions permit sustainable company formation. This structured testing is essential for preventing premature or misaligned startup attempts and for identifying cases where internal adoption, service-based institutional models, licensing, or standardisation may represent more viable exploitation pathways.

Each cycle of the programme concludes with a Demo Day, where participating teams present their projects to industrial partners, subject-matter experts, and investors. This event is designed to provide feedback and identify potential follow-up actions, but not to mandate a specific exploitation outcome. An Investor Day takes place at the end of the follow-up mentoring period and focuses on direct interaction with investors, where teams can present refined versions of their exploitation strategy and discuss potential collaborations or funding opportunities.

At the end of the G-Force programme, an Investor Day is planned to facilitate structured interaction between participating teams and selected investors. However, considering the expected maturity level of DARE teams by June—many of whom will not yet have established a formal company or validated a full business model—the event will be managed with caution. Venture capital firms and angel investors typically expect to evaluate already constituted and operational startups; presenting teams prematurely may generate misleading expectations within the investor network and expose participants to risks associated with premature visibility. For this reason, the selection of the Investor Day audience will be carried out with deliberate care, limiting participation to stakeholders capable of providing constructive feedback without imposing expectations inconsistent with the maturity level of the teams.

## 7. Outputs, KPIs and Consolidated Results

This section presents the measurable outputs of WP7 Phases 1 and 2 and the forward-looking indicators associated with Phase 3. The results combine participation metrics, training performance, satisfaction indicators, and early signals of readiness for the upcoming acceleration phase.

### 7.1 Outputs and Indicators from Phase 1 and Phase 2

Phase 1 (awareness and mindset activation) and Phase 2 (structured entrepreneurial training) generated a consistent set of quantitative and qualitative outputs across the consortium. A total of **37 project teams registered** for the initial call to participate in WP7 activities, representing 148 researchers from 14 universities, institutes, and research organisations across six Italian regions. Of these, **26 teams progressed into the structured training phase**, corresponding to a 70% conversion rate from expression of interest to active participation.

With the coordination and support of Spoke 1 and the Dare Foundation Communication Officer engagement during Phase 1 was reinforced by multiple roadshow sessions and dissemination events, which collectively attracted more than 50 external stakeholders in addition to internal participants. These activities provided the first mapping of exploitation interest, which indicated a broad spectrum of technological maturity and varying levels of readiness across Spokes.

Phase 2 delivered approximately 70 hours of formal training within a larger programme framework that foresees up to 140 hours across the full cycle. Training activities were supported by 12 expert mentors, providing both plenary instruction and one-to-one guidance.

Participant evaluations indicate strong engagement and perceived value:

- organisational and operational support received an average score of 9.1/10;
- overall training quality and plenary content were rated 8.6/10;
- the mentor network received 8.4/10;
- one-to-one mentoring sessions averaged 8.1/10;
- workload appropriateness was rated 7.8/10;
- the overall training experience received an average score of 8.6/10.

Across the consortium, teams—including those relying on Spoke 1 enabling technologies—developed a significantly clearer understanding of exploitation pathways and the constraints associated with interoperability, data governance, AI governance, and regulated digital workflows. Participation patterns show that these teams benefited from the structured introduction to exploitation logic and from the methodological alignment enforced across all training modules.

## 7.2 Forward-Looking Indicators for Phase 3 (G-Force Acceleration)

Phase 3, consisting of the G-Force acceleration programme, is scheduled to begin in January 2026. Based on participation trends, training performance, and self-assessment exercises completed during Phase 2, it is expected that six (6) teams will be ready to enter the acceleration phase.

The G-Force programme consists of:

- 2 months of intensive acceleration activities, including at least two residential weeks;
- 2 months of follow-up mentoring, focused on execution, planning, and refinement;
- multiple pitch sessions and structured feedback cycles;
- thematic weekly work covering market validation, positioning, product development, regulatory affairs, IPR consolidation, business modelling, industrial development, financial planning, fundraising, negotiation, communication, and investor readiness.

Outcomes from Phase 3 will be reported in subsequent project documentation once execution is completed.

## 7.3 Contribution to DARE's Long-Term Sustainability

Consolidated outputs from Phases 1 and 2 contribute to the long-term sustainability of DARE by:

- establishing a coherent exploitation framework applied uniformly across all Spokes;
- building a shared methodological foundation grounded in training, mentoring, and structured analysis;
- strengthening internal capacity in IPR assessment, regulatory awareness, and technology transfer;
- creating a pipeline of teams ready for Phase 3, with quantified expectations for acceleration;
- supporting the application of the Translation Framework (SF#4) to enabling technologies within Spoke 1.

## 8. Spoke 3 Specialisation

Spoke 3 operates in the domain of digitally enabled secondary and tertiary prevention, addressing clinical decision support, precision diagnostics, therapeutic optimisation, early detection of complications, and in-silico modelling. The innovations emerging from this Spoke typically involve AI, imaging, omics, physiological signals or mechanistic simulation, and interact directly with medical workflows. As a consequence, they exhibit higher regulatory complexity and stronger evidence requirements compared to the community-level tools in Spoke 2.

Spoke 3 provides one of the most diverse and technologically advanced portfolios within DARE. Many of its projects participated in the WP7 entrepreneurship and exploitation pathway and were evaluated for startup potential, institutional adoption, licensing opportunities and co-development with clinical or industrial partners. Given their clinical adjacency, most Spoke 3 innovations are better aligned with regulated exploitation routes rather than early-stage venture creation. However, several projects show credible value propositions for targeted startups or service-based models, particularly those integrating telemedicine, clinical decision support or digital biomarkers.

Below is the consolidated overview of Spoke 3 innovations assessed through the WP7 funnel.

### 8.1 Overview of Spoke 3 Innovations Participating in ReActorPro

#### ***Digital Twin and In-Silico Modelling***

- **Digital Twin for Fragility Fracture Risk (IOR)**

In-silico biomechanical modelling (BBCT-hip) to predict femoral fracture risk in osteoporotic patients, improving upon DXA-based risk stratification.

- **Digital Twin-enabled Decision Support for Type 1 Diabetes (Tor Vergata & UNIPD)**

Computational digital-twin platform supporting clinicians in optimising insulin therapy in paediatric diabetes.

- **BoneStrength – In-Silico Clinical Trial Simulation (UNIBO)**

Virtual population modelling for estimating hip-fracture incidence in specific cohorts to support drug/device development and health-economic analysis.

#### ***AI-based Diagnostics, Prognostics and Clinical Decision Support***

- **Radiogenomic Prediction of Neoadjuvant Therapy Response (IRCCS Bari)**

Multimodal AI combining radiomics and digital pathology to predict individualised tumour response in breast cancer.

- **SARA – AI-based CT Classification of Uterine LMS vs Leiomyoma (IRCCS AOU Bologna)**

Differential diagnostic model to distinguish malignant from benign uterine masses pre-operatively.

- **Digital Biomarkers for Parkinson's and Alzheimer's (IRCCS ISNB Bologna)**

Multimodal AI pipelines for predicting phenoconversion from prodromal syndromes to full neurodegenerative diseases.

- **Microbiome Dysbiosis Indicator via DNA Metabarcoding (UNIBA)**

ML-based diagnostic method assessing eubiosis/dysbiosis conditions through targeted sequencing.

- **ProBiOMICs – Omics-driven Diagnostic Analytics (Tor Vergata)**

Web-based bioinformatics service for multi-omics data interpretation, deployable as second-level diagnostic support for patients already positive to a clinical screening (e.g., post-screening stratification, adjunct tests, confirmatory or exploratory omics layers). The project team has already registered a new company.

### ***Therapeutics, Biomarkers and Pharmacological Innovation***

- **SEL-MA – Molecules for FLT3/ITD AML Treatment (UNIPA)**

Novel heterocyclic compounds targeting aggressive AML subtypes.

- **Non-Invasive Biomarkers for Transplant Function (Tor Vergata)**

Diagnostic biomarker panel (e.g., MR-proADM) for early identification of delayed graft function or rejection in kidney/liver transplant patients.

- **G&B Defence – Gut–Brain Axis Pharmacological Agents (UNIBO)**

Neuroprotective and antimicrobial drug candidates acting on gut–brain communication pathways for neurodegenerative disorders.

### ***Telemedicine, EHR and Risk Stratification Tools***

- **Promedion – AI-enhanced Telemedicine Platform (UNIPA)**

Integrated clinician–patient communication and decision support platform, expandable across medical specialities.

- **EHR-based Predictive Screening for Childhood Obesity (UNIPD)**

Early-risk modelling and trajectory prediction using structured EHR data from paediatric populations.

## 8.2 Exploitation Readiness and Thematic Patterns

The innovations developed within Spoke 3 can be grouped into four major thematic categories. Each category presents specific exploitation characteristics and different levels of feasibility for startup formation, institutional adoption, technology transfer or industry partnerships. The following subsections describe these patterns in a discursive manner, highlighting the maturity, constraints and realistic routes for exploitation.

### Digital Twins & In-Silico Models

Projects based on digital twins and in-silico simulation, such as the fracture-risk modelling platforms, the diabetes-treatment simulators and the BoneStrength virtual trial environment, exhibit a high level of scientific and methodological maturity. Their potential value in clinical practice is clear: these systems allow personalised modelling of disease progression or treatment response, offer decision support grounded in mechanistic understanding and provide a complementary layer to observational or trial-based evidence.

However, their exploitation readiness depends heavily on the ability to integrate these models within specialist clinical settings and comply with regulatory frameworks that govern medical devices and high-risk AI-based decision support tools. As a result, institutional adoption, licensing to med-tech developers or inclusion in emerging regulatory frameworks for in-silico testing represent the most realistic exploitation routes. Startup pathways remain possible but are generally suited to narrowly defined use cases where workflow integration is straightforward and clinical partners can co-develop or validate the system.

### AI-based Diagnostics, Prognostics and Clinical Decision Support

AI-driven diagnostic and prognostic tools, which include radiogenomic predictors, multimodal digital biomarkers and imaging-based differential diagnosis systems, represent a technically advanced and clinically promising cluster of innovations. Their exploitation potential is often constrained by the demanding regulatory requirements of the MDR and the AI Act, both of which classify most of these tools as high-risk technologies.

For this reason, the most feasible pathways involve structured collaboration with hospitals, technology transfer to industrial partners specialising in medical imaging or diagnostics or co-development within clinical-industrial consortia. These tools generally require extensive validation, curated datasets, reproducibility pipelines and clear clinical interpretability before they can be commercialised. Startup formation is not excluded but typically requires substantial investment, strong IP positioning and robust clinical partnerships.

### **Biomarkers and Therapeutics**

The projects related to pharmacological development, biomarker discovery and transplant-related diagnostic assays fall under innovation categories that traditionally follow long, regulated and capital-intensive translational pathways. Therapeutic compounds, neuroprotective agents and biomarker panels for transplant monitoring must go through preclinical experimentation, toxicological evaluation and staged clinical testing before exploitation is feasible.

Given these requirements, the exploitation routes that align most closely with their nature are licensing agreements, partnerships with pharmaceutical companies or structured collaborations with clinical-research networks. Startup creation is generally viable only when strong IP protection exists, supported by clear evidence of efficacy and a credible path through regulatory and preclinical development stages.

### **Telemedicine and Data-Driven Clinical Support**

Telemedicine platforms and predictive models based on structured EHR data represent the most accessible category of innovations for early exploitation. These solutions operate within the clinical workflow but rely on less stringent regulatory requirements compared to diagnostic or therapeutic tools. Their architecture—based on remote communication, workflow optimisation or risk stratification—can be adapted across multiple clinical areas, making them suitable for both institutional adoption and entrepreneurial exploitation.

In this area, startup formation is more likely, particularly when the solution provides a horizontal value proposition such as workflow coordination, communication optimisation or population-wide risk modelling. Nonetheless, successful exploitation depends on interoperability with clinical information systems, compliance with data-protection regulations and the capacity to scale within healthcare organisations.

### 8.3 Contribution of Spoke 1 Enabling Components

Several Spoke 3 innovations may benefit from the technological and methodological frameworks developed in Spoke 1. These frameworks provide functionalities—such as interoperability, signal processing, MLOps and regulatory governance—that are relevant to many Spoke 3 use cases, although the degree of effective adoption varies across individual pilots and its description is not in the scope of this deliverable.

- Salus Ratio interoperability layer → Integrates imaging, pathology, clinical and omics data.
- Wearable-signal processing pipelines (UNIBO Mobility Kit) → Relevant for neurodegeneration and frailty analytics.
- DARE App & data-collection infrastructure → Enables questionnaire, sensor and patient-reported data acquisition.
- UNIBA MLOps lifecycle management → Ensures reproducibility, auditability and regulatory compliance for high-risk AI systems.
- Regulatory & data governance frameworks → Essential for GDPR, MDR and AI Act-classified clinical tools.
- BI-REX Translation Framework (SF#4) → Supports IP positioning, exploitation route mapping, regulatory planning, rapid prototyping and HPC/AI workflows.

This dependency confirms the importance of the Twin Pilot approach: Spoke 3 pilots require robust enabling layers from Spoke 1 to reach exploitation-readiness.

### 8.4 Take Home Message

The set of innovations emerging from Spoke 3 represents some of the most clinically complex and scientifically advanced contributions within DARE. These projects operate in domains such as oncology, orthopaedics, diabetes, transplantation and neurodegeneration, where secondary and tertiary prevention depend on accurate diagnostics, personalised therapeutic strategies and robust prognostic modelling. The portfolio demonstrates a high level of scientific maturity and technological sophistication; however, the feasibility of exploitation is strongly shaped by regulatory constraints, clinical validation requirements and the operational realities of specialist healthcare environments. While a subset of projects—particularly those involving telemedicine and data-driven decision support—shows credible potential for startup formation, the majority of Spoke 3 innovations align more naturally with institutional adoption, co-development with clinical

or industrial partners or structured technology transfer pathways. Their translation depends on rigorous evidence generation, integration into existing clinical workflows and compliance with the MDR and the AI Act. A defining feature of this Spoke is its strong functional dependency on the enabling frameworks developed in Spoke 1, including interoperability infrastructures, MLOps pipelines, regulatory governance, wearable-signal processing tools and the BI-REX translation framework. These components are essential to ensure that Spoke 3 outputs can progress towards exploitation readiness, highlighting the importance of the broader WP7 governance model. Overall, the WP7 process—spanning awareness, structured training and acceleration—offers an effective mechanism to guide these clinically intensive innovations through an early assessment of exploitation routes, while recognising that their translation will require tailored strategies and longer-term collaboration with healthcare and industry stakeholders.

## 9. Lessons Learned and Recommendations

### 9.1 Lessons Learned

The experience gained from supporting Spoke 3 through the WP7 entrepreneurial and exploitation framework highlights several characteristics that distinguish secondary and tertiary prevention innovations from those observed in the other Spokes. Many of these projects operate within highly specialised clinical domains (e.g. oncology, orthopaedics, diabetes, transplantation and neurodegeneration) where the regulatory environment, evidence requirements and workflow integration challenges are significantly more stringent. As a consequence, teams often discovered early in the WP7 pathway that the feasibility of a startup route is constrained not by lack of scientific interest, but by the structural nature of the clinical context in which their innovations must operate.

One of the clearest lessons is that exploitation for Spoke 3 cannot be approached with a uniform entrepreneurial mindset. While several projects initially considered startup formation, discussions during ReActorPro revealed that the majority require alignment with institutional infrastructures, formal validation studies, or partnerships with med-tech or pharmaceutical companies. This is particularly evident for digital diagnostics, predictive models and therapeutic innovations, where compliance with the MDR and the AI Act imposes obligations that exceed the capabilities of early-stage venture teams. The WP7 training phases helped teams recognise these constraints, leading most of them to reposition their exploitation expectations

toward more realistic pathways, such as technology transfer, co-development agreements or integration into specialist centres.

Another lesson concerns the role of enabling components developed in Spoke 1. Contrary to initial assumptions that all pilots would directly rely on these frameworks due to complexity and resources allocation limits (e.g. pilots definition has been closed within the first year of the project, for some of them support has been provided by Spoke 1 team as twin project, while for the rest, competences have been found in internal research groups within Spoke 3), it became clear during the WP7 activities that dependency is functional rather than universal. Some Spoke 3 innovations actively use interoperability layers, MLOps pipelines and regulatory-governance tools; others could benefit from them conceptually but do not require direct integration at their current stage of maturity. This distinction proved important, as it helped clarify which teams could accelerate their development by aligning with Spoke 1 assets, and which instead needed bespoke clinical or laboratory infrastructures.

A further pattern concerns the diversity of maturity levels across Spoke 3 innovations. Digital twin and in-silico models tend to be scientifically mature but require careful workflow integration. Diagnostic AI models are robust in methodology but face substantial dataset, validation and regulatory barriers. Therapeutic and biomarker innovations follow long translational timelines and depend heavily on IP, preclinical evidence and partnerships. Telemedicine or EHR-based tools, on the other hand, showed more immediate applicability but nonetheless require rigorous attention to data governance. This heterogeneity confirmed the importance of the WP7 approach based on differentiated exploitation pathways rather than a single model.

Finally, the WP7 activities showed that Spoke 3 teams benefit significantly from early exposure to exploitation concepts, regulatory considerations and translational methodology. Many researchers approached ReActorPro with a scientific mindset primarily focused on accuracy, novelty or mechanistic insight. Through the training and coaching process, they learned to articulate value propositions, understand stakeholder landscapes and evaluate exploitation feasibility beyond the laboratory setting. This shift did not necessarily produce more startups, but it did create more realistic and better-informed exploitation plans.

## 9.2 Recommendations

The findings from Task 7.3 for Spoke 3 suggest that future exploitation efforts should adopt a more differentiated, domain-aware approach. Clinical innovations would benefit from earlier and more systematic regulatory guidance, ensuring that teams understand the implications of the MDR, the AI Act and data-

protection obligations from the outset. This helps avoid unrealistic expectations regarding startup formation and directs researchers toward exploitation pathways compatible with their category of innovation.

It is also advisable to strengthen mechanisms for connecting Spoke 3 teams with clinical partners, industry stakeholders and specialised infrastructures. For digital diagnostics and prognostics, partnerships with hospitals, imaging departments or pathology units are crucial for obtaining the datasets and validation environments needed for regulatory progression. For therapeutic or biomarker innovations, early interaction with translational research offices, pharmaceutical companies or clinical-trial networks can accelerate the identification of suitable exploitation routes.

A further recommendation concerns the need to adapt the entrepreneurial training pathway for highly regulated innovations. While the WP7 funnel is effective, Spoke 3 teams would benefit from tailored modules addressing clinical evidence generation, protocol design, regulatory pathways, risk-classification, and industrial partnership models. This would improve alignment between the scientific objectives of the teams and the technical, operational and compliance realities of clinical exploitation.

Finally, the overall experience suggests supporting longer-term exploitation trajectories beyond the immediate project timeline. Secondary and tertiary prevention innovations often require years of validation and multiple stages of iteration before reaching a deployable or licensable state. Ensuring continuity of advisory support, connections to external accelerators, and access to infrastructures such as HPC, MLOps tools and regulatory expertise will be essential to maximise the impact of Spoke 3 outputs.

## 10. Conclusions

The activities conducted under Task 7.3 for Spoke 3 show that innovation in secondary and tertiary prevention presents a distinct exploitation profile compared to the other areas of DARE. The solutions developed within this Spoke, ranging from digital twins and in-silico modelling to multimodal diagnostics, transplant biomarkers, neurodegenerative digital biomarkers, telemedicine platforms and advanced therapeutic candidates, operate at the intersection of clinical care, data-driven analytics and regulated medical technologies. As a result, their exploitation potential depends not solely on scientific merit, but on a complex combination of regulatory requirements, evidence generation, workflow integration and the ability to engage specialised clinical partners.

Throughout the WP7 activities, Spoke 3 teams engaged with the entrepreneurial and translational framework in a way that highlighted both the opportunities and the constraints specific to clinical innovation. Many

teams refined their initial expectations after recognising that startup formation is feasible only for a limited subset of solutions, particularly those with horizontal applicability or reduced regulatory burden, such as telemedicine and structured decision-support platforms. For the majority of projects, exploitation is more realistically achieved through institutional adoption, structured technology transfer, or collaborative co-development with med-tech, diagnostics or biopharma companies. These routes reflect the maturity levels, clinical dependencies and validation needs of the innovations.

A key insight emerging from Task 7.3 is that the enabling frameworks developed in Spoke 1 play a functional and cross-cutting role in supporting exploitation readiness—whether directly used by a given pilot or simply available as an infrastructure that reduces the translational burden. Interoperability mechanisms, MLOps lifecycle management, signal-processing pipelines and regulatory-governance tools constitute a shared foundation that can facilitate compliance, reproducibility and integration for Spoke 3 innovations. Their relevance confirms the coherence of the DARE architecture and the importance of an ecosystem approach to exploitation planning.

The WP7 process itself proved beneficial for Spoke 3 teams. ReActorPro enabled researchers to articulate clearer value propositions, understand stakeholder landscapes and distinguish scientific advancement from feasible exploitation routes. The translational mindset fostered through WP7—focusing on differentiation between startup, licensing and institutional pathways—helped teams identify the specific actions needed to move closer to adoption, whether through regulatory engagement, clinical partnerships, dataset consolidation or iterative prototyping. Even where venture creation was not the ultimate outcome, the process increased translational awareness and improved the long-term sustainability prospects of these innovations.

Overall, the contribution of Spoke 3 to DARE's objectives is significant. The innovations assessed through Task 7.3 represent a substantive set of clinically oriented outputs with long-term potential to transform diagnostic, prognostic and therapeutic processes across multiple disease areas. While their exploitation trajectories may require extended timelines and specialised infrastructures, the structured approach implemented in WP7 provides a foundation for guiding these technologies toward regulated, evidence-based and sustainable translation. The combination of domain-specific innovation in Spoke 3, enabling frameworks in Spoke 1 and a unified exploitation methodology across DARE reinforces the internal coherence of the programme and supports its overarching mission of advancing digital health for secondary and tertiary prevention.

# 11. Appendix – Communication Material from Phase 1





Il Progetto DARE, finanziato dal Ministero dell'Università e della Ricerca (MUR) nell'ambito del Piano Nazionale per gli Investimenti Complementari al PNRR, mira a migliorare la promozione della salute e la prevenzione per tutta la vita utilizzando dati e tecnologie digitali avanzate. L'obiettivo è supportare il sistema sanitario nazionale con un monitoraggio continuo della salute, con un impatto significativo a livello sociale, culturale, economico ed etico.

DARE intende creare una rete di conoscenza integrata e diffusa, alimentata dalla ricerca, dall'innovazione e dalla partecipazione attiva di vari stakeholder, consolidando così il ruolo dell'Italia nella prevenzione digitale.

Il progetto aspira a diventare il centro di riferimento nazionale per le tecnologie digitali nella prevenzione, promuovendo una comunità orientata alla prevenzione digitale e favorendo la collaborazione tra sanità, accademia, industria e decisori.



## Accelerazione e Innovazione: il percorso di DARE per Imprenditori Emergenti

All'interno del progetto DARE, il programma di accelerazione promosso dal Competence Center BI-REX e sviluppato dall'acceleratore G-Factor della Fondazione Golinelli, offre un approccio unico per trasformare idee innovative in imprese di successo e sostenibili.

L'approccio sinergico di G-Factor mira a creare modelli d'affari replicabili e scalabili, assicurando che le imprese emergenti siano ben posizionate per prosperare. In questo modo, il progetto contribuisce al progresso e all'innovazione su scala internazionale, supportando lo sviluppo di soluzioni che possono avere un impatto significativo nel mondo del business.



Per maggiori informazioni scrivere a:  
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