DARE

DIGITAL LIFELONG PREVENTION

CODE NO. PNC0000002

Spoke 3 Deliverable

S3.D1.2
End-users and Stakeholders' Engagement

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

Ministero dell'Università e della Ricerca | Italiadomani | PNC Piano nazionale per gli investimenti complementari al PNRR | DARE DIGITAL LIFELONG PREVENTION

S3.D1.2 End-users and Stakeholders' Engagement

Deliverable information	
Spoke number and title	Spoke 3 - Digitally-enabled Secondary and Tertiary Prevention
WP number and title	WP 1 - Evidence, Outcome Indicators, and Stakeholders Engagement
Related task(s)	Task -1.3, 1.4.
Lead beneficiary	UNIPD
Contributing beneficiaries	UNIPD
Dissemination level	Public, fully open
Due date	14.12.2025
Actual date of delivery	TBD
Author(s)	Dario Gregori, Luca Vedovelli
Contributors	--
Quality Assurance	Alessandro Chiarini (BI-REX)

Document history

Version	Date	Author(s) /Reviewer(s) (Beneficiary)	Description
0.1	03/12/2025	Dario Gregori, Luca Vedovelli (UNPD)	Content drafting and consolidation
0.3	19/12/2025	Alessandro Chiarini (BI-REX)	Revision
0.4	19/12/2025	Luca Vedovelli (UNIPD)	Final document
1.0			

Disclaimer

Table of contents

Publishable summary

This deliverable reports on the stakeholder engagement activities conducted within DARE Spoke 3 pilot studies. The engagement process represents a cornerstone of the PNRR-funded Extended Partnership's commitment to developing patient-centered digital health solutions that address real clinical needs. Through systematic data collection via a dedicated REDCap survey, comprehensive information has been gathered from 32 respondents (31 pilot studies plus one Work Package) studies regarding their stakeholder engagement strategies, methods employed, and outcomes achieved.

The findings demonstrate a robust and multifaceted approach to stakeholder engagement across diverse clinical domains including oncology, diabetes and metabolism, orthopedics and biomechanics, neurology and psychiatry, organ transplantation, and cardiovascular diseases. Analysis of pilot studies with validated quantitative data (N≤10 stakeholders and specified stakeholder types) reveals 82 potential stakeholders identified across 16 pilots, 55 stakeholders already actively engaged across 14 pilots, and 61 planned for future involvement across 17 pilots.

Key engagement methods included focus groups (43.8% of pilots), workshops (34.4%), interviews (31.2%), co-design activities (28.1%), and surveys (28.1%). The perceived usefulness of engagement activities was rated as "High" or "Very High" by 59.3% of pilot leads, demonstrating the value attributed to stakeholder involvement in shaping research direction and clinical tool development.

1. Introduction

1.1. Background and context

The DARE (Digital lifelong prevention) project represents one of the one of the four so-called *Research Initiatives* co-funded by the Ministry of University and Research within the Complementary National Plan. Specifically, it falls under PNC-I.1 'Research initiatives for innovative technologies and pathways in the health and welfare sector' (D.D. 931 of 06/06/2022). This initiative aims to strengthen national research networks and promote participation in European and global strategic value chains through fundamental and applied research in digital health and precision medicine.

Spoke 3 of the DARE project focuses on the development and validation of digital biomarkers, artificial intelligence-based diagnostic tools, and innovative digital health solutions across multiple clinical domains. The spoke's activities are organized through a hub-and-spoke governance structure, with research activities distributed across multiple Italian research institutions including universities, IRCCS (Scientific Institutes for Research, Hospitalization and Healthcare), and collaborative partners from industry.

1.2. Importance of Stakeholder Engagement

Stakeholder engagement in clinical research and digital health development has evolved from a peripheral consideration to a central methodological imperative. Contemporary evidence strongly supports that involving end-users, patients, caregivers, clinicians, and other stakeholders throughout the research lifecycle enhances the relevance, quality, and ultimately the clinical impact of health interventions.

The practice of stakeholder engagement in health research encompasses multiple dimensions, ranging from consultation to active collaboration in study design, data collection, and results interpretation. When implemented effectively, stakeholder engagement ensures that digital health solutions address genuine clinical needs, are acceptable to target users, and can be successfully integrated into existing healthcare workflows.

1.3. Objectives of this Deliverable

This deliverable aims to:

- Systematically document stakeholder engagement activities across all Spoke 3 pilot studies

- Characterize the types of stakeholders involved and methods of engagement employed
- Report quantitative and qualitative outcomes of engagement activities
- Assess the perceived utility of stakeholder engagement across different pilot contexts
- Identify best practices and lessons learned for future activities

2. Methodology

2.1. Data Collection Instrument

A structured electronic survey was developed using REDCap (Research Electronic Data Capture), a secure, web-based application designed to support data capture for research studies. The survey instrument was designed to capture comprehensive information about stakeholder engagement activities while minimizing respondent burden.

The survey comprised several key domains:

- **Pilot Identification:** Name of the pilot study and responsible investigator
- **Stakeholder Typology:** Classification of stakeholders as potential, already engaged, or planned for future engagement
- **Engagement Methods:** Specific approaches used (workshops, surveys, focus groups, interviews, co-design, other)
- **Engagement Outcomes:** Concrete results or modifications derived from stakeholder involvement
- **Perceived Usefulness:** 5-point Likert scale assessment of engagement utility
- **Supporting Documentation:** Upload capability for meeting minutes, agendas, presentations

2.2.Stakeholder Categories

The survey employed a standardized taxonomy of stakeholder types aligned with established frameworks in patient-centered outcomes research:

- **Patients:** Individuals directly affected by the conditions under study
- **Caregivers:** Family members and informal care providers
- **Clinicians:** Healthcare professionals including physicians, nurses, and allied health professionals

- **Policy makers:** Representatives from health authorities, regulatory bodies, and governmental institutions
- **Industry:** Partners from medical device, pharmaceutical, and digital health technology sectors
- **Associations:** Patient advocacy groups, professional societies, and civil society organizations
- **Other:** Additional stakeholders specific to individual pilot contexts

2.3.Survey Administration and Response

The survey was distributed to all Spoke 3 pilot study leads via the REDCap platform in October-November 2025. The data collection period extended from October 30, 2025, to December 6, 2025. A total of 32 complete responses were received, from 31 pilot studies plus one Work Pakage, representing comprehensive coverage of active pilot studies within Spoke 3.

2.4.Data Quality and Validation

Review of quantitative responses revealed heterogeneous interpretation of the stakeholder count questions. Some respondents reported aggregate population-level figures (e.g., total patients in a registry) rather than individually engaged stakeholders. To ensure accurate reporting, quantitative analyses of stakeholder numbers were restricted to responses meeting the following criteria: (1) reported stakeholder count between 1 and 10, representing plausible individual-level engagement; and (2) specification of at least one concrete stakeholder type (Patients, Caregivers, Clinicians, Policy makers, Industry, or Associations), excluding responses selecting only 'Other'. This validation approach identified 14-17 pilots (depending on engagement phase) with credible quantitative data. Qualitative analyses of stakeholder types and engagement methods utilized all 32 responses.

3. Results

3.1. Overview of Pilot Studies

The 33 responding pilot studies span multiple clinical domains and involve research teams from prestigious Italian institutions. The distribution of pilots by thematic area demonstrates the breadth of Spoke 3's research portfolio:

Thematic Area	N. Pilots	%
Diabetes, Metabolism and Nutrition	6	18.8%
Orthopedics and Biomechanics	7	21.9%
Oncology	6	18.8%
Neurology and Psychiatry	3	9.4%
Organ Transplantation	2	6.2%
Cardiovascular Diseases	1	3.1%
Other (Infectious diseases, education, etc.)	7	21.9%

Table 1. Distribution of pilot studies by thematic area

3.2.Stakeholder Engagement by Category

3.2.1. Potential stakeholders

The survey identified the types of stakeholders that each pilot considers potentially engageable. Clinicians emerge as the most frequently identified stakeholder category (84.4% of pilots), followed by patients (62.5%) and industry partners (50.0%). This distribution reflects the clinical nature of Spoke 3's research focus and the importance of healthcare professional involvement in digital health solution development. Analysis restricted to pilots with validated quantitative responses (1-10 stakeholders with specified types, N=16 pilots) reveals a total of 82 potential stakeholders with an average of 5.1 per pilot.

Stakeholder Type	N. Pilots	%	Total N.
Clinicians	27	84.4%	-
Patients	20	62.5%	-
Industry	16	50.0%	-
Caregivers	12	37.5%	-
Associations	8	25.0%	-
Policy makers	7	21.9%	-

Stakeholder Type	N. Pilots	%	Total N.
Other	5	15.2%	-
TOTAL POTENTIAL STAKEHOLDERS	**-**	**-**	**83***

Table 2. Potential stakeholders by category

**Total based on validated responses only (N=16 pilots with 1-10 stakeholders and specified types)*

3.2.2. Already Engaged Stakeholders

Analysis of stakeholders already actively engaged reveals that clinician involvement has been successfully achieved in 68.8% of pilots, confirming the central role of healthcare professionals in the development process. Patient engagement has been realized in 37.5% of pilots, while industry collaboration is active in 15.6%. Restricting analysis to pilots with validated quantitative data (1-10 stakeholders with specified types, N=14 pilots), the total number of already engaged stakeholders is 55, with a mean of 3.9 per pilot (range: 1-10).

Stakeholder Type	N. Pilots	%	Total N.
Clinicians	22	66.7%	-
Patients	12	36.4%	-
Other	9	27.3%	-
Caregivers	5	15.2%	-
Industry	5	15.2%	-
Associations	4	12.1%	-
Policy makers	0	0.0%	-
TOTAL ENGAGED STAKEHOLDERS	**-**	**-**	**55***

Table 3. Already engaged stakeholders by category

**Total based on validated responses only (N=14 pilots with 1-10 stakeholders and specified types)*

3.2.3. Planned Future Engagement

Looking forward, 65.6% of pilots plan to engage clinicians, 43.8% plan patient involvement, and 34.4% anticipate industry partnerships. Among pilots with validated quantitative data (1-10 stakeholders with specified types, N=17 pilots), the total number of stakeholders planned for future engagement is 61 (mean: 3.6 per pilot), indicating structured growth plans for stakeholder involvement as projects mature.

3.3. Engagement Methods

The survey captured diverse engagement methodologies employed across pilot studies. Focus groups emerged as the most commonly used approach (43.8% of pilots), followed by workshops (34.4%), interviews (31.2%), and co-design activities (28.1%). This methodological diversity reflects thoughtful adaptation to different stakeholder needs and research contexts.

Engagement Method	N. Pilots	%
Focus Groups	14	43.8%
Workshops	11	34.4%
Interviews	10	31.2%
Co-design Activities	9	28.1%
Surveys/Questionnaires	9	28.1%
Other (Seminars, conferences, web platforms)	8	25.0%

Table 4. Engagement methods employed across pilots

The total number of engagement occasions reported across all pilots was 241, with a mean of 7.5 occasions per pilot (median: 3, range: 0-120). This variation reflects the different stages of development and the specific engagement needs of individual projects.

3.4. Perceived Usefulness of Engagement

Pilot leads assessed the perceived usefulness of their stakeholder engagement activities using a 5-point Likert scale. The results demonstrate overall positive perceptions of engagement value:

Usefulness Rating	N. Pilots	%
Very High	2	6.1%
High	17	53.1%
Medium	11	34.4%
Low	0	0.0%
Very Low	2	6.2%

Table 5. Perceived usefulness of stakeholder engagement

Notably, 59.4% of pilots rated engagement usefulness as "High" or "Very High," while only 6.2% rated it as "Very Low." The latter cases represent pilots in early stages where engagement activities have not yet been fully implemented or where preliminary engagement has not yielded substantial results yet.

3.5.Concrete Outcomes of Engagement

Qualitative analysis of reported outcomes reveals multiple categories of tangible impact from stakeholder engagement activities. The following themes emerged from the analysis:

3.5.1. Study Design Modifications

Several pilots reported significant modifications to their research designs based on stakeholder feedback. For example, the FITMATE pilot noted that engagement with nutritionists and sports medicine physicians allowed optimization of patient compliance strategies, resulting in cleaner, higher-quality data. Similarly, the IBD care pilot reported that regular meetings between clinicians and software developers enabled progressive refinement of software functionalities, improving usability and reliability.

3.5.2. Clinical Practice Translation

Multiple pilots demonstrated direct translation of engagement outcomes into clinical practice. The MARIO algorithm pilot reported routine clinical implementation for identifying patients at risk of inappropriate hospital resource utilization. The psychiatric disorders pilot noted that dissemination activities led schools to establish mental health counseling services, while clinicians began incorporating cognitive assessments for psychosis risk evaluation.

3.5.3. Technology Development Refinement

Stakeholder input directly influenced technology development trajectories. The diabetes management pilot (Task 5.4) reported comprehensive understanding of clinical visit routines and disease management practices, leading to algorithm design modifications compatible with existing workflows. The NICU at home pilot achieved improvements in technical solutions and adaptability to specific clinical contexts through stakeholder collaboration.

3.5.4. Enhanced Recruitment and Participation

Several pilots reported improved patient recruitment and participation rates following stakeholder engagement. The Digital Tools in Cancer pilot noted that clear project presentation to clinicians, caregivers, and patients increased patient enrollment in the research project. The ADPKD digital therapy pilot reported improved patient compliance following engagement activities.

4. Discussion

4.1. Key Findings and Implications

The findings from this deliverable demonstrate that Spoke 3 has successfully established a robust framework for stakeholder engagement across its diverse portfolio of pilot studies. The predominance of clinician engagement (66.7% of pilots actively involving clinicians) reflects the clinical orientation of the spoke's research focus and acknowledges the critical role of healthcare professionals as both implementers and gatekeepers of digital health innovations.

The substantial patient engagement pool (more than 19k potential stakeholders) indicates significant opportunities for expanding patient-centered research activities. The progression from potential (60.6% of pilots identifying patients) to actual engagement (36.4% actively involving patients) suggests a maturation pathway that should continue to develop as projects advance.

4.2.Comparison with Best Practices

The engagement approaches employed by Spoke 3 pilots align well with established frameworks for stakeholder involvement in health research. The use of multiple engagement methods, including co-design

activities, reflects contemporary understanding that effective engagement requires methodological flexibility adapted to specific stakeholder needs and research contexts.

The high perceived usefulness ratings (57.6% rating engagement as "High" or "Very High") compare favorably with published benchmarks and suggest that engagement activities are generating meaningful value for research teams.

4.3.Challenges and Limitations

Several challenges warrant acknowledgment. The absence of policy maker engagement across all pilots (0%) represents a gap that may limit translation of research findings into health policy. Additionally, the wide variation in engagement intensity (0-120 occasions) reflects heterogeneous implementation that may benefit from more standardized guidance.

The two pilots reporting "Very Low" usefulness were both in early stages where engagement activities had not yet been fully implemented, suggesting that ratings may improve as projects mature.

5. Conclusions and Recommendations

5.1. Summary of Achievements

Spoke 3 has successfully implemented comprehensive stakeholder engagement activities across 31 pilot studies plus one Work Package (education, training, and career pathways). Analysis of pilots with validated quantitative data reveals 55 stakeholders already actively engaged across 14 pilots (mean: 3.9) and 61 planned for future involvement across 17 pilots (mean: 3.6). The engagement has employed diverse methodologies including focus groups, workshops, co-design activities, and interviews, generating concrete outcomes including study design modifications, clinical practice translation, technology refinement, and enhanced patient recruitment.

5.2.Recommendations for Future Activities

Based on the findings, the following recommendations are proposed:

1. **Expand policy maker engagement:** Develop targeted strategies to involve health policy stakeholders in research activities to facilitate translation of findings into policy and practice.
2. **Standardize engagement documentation:** Encourage all pilots to maintain comprehensive documentation of engagement activities to facilitate cross-project learning and reporting
3. **Enhance patient and caregiver involvement:** Support pilots in progressing from potential to actual patient engagement through shared resources and best practice guidance.
4. **Foster cross-pilot collaboration:** Create opportunities for pilots to share engagement experiences and strategies through regular coordination meetings.
5. **Monitor engagement outcomes longitudinally:** Implement systematic tracking of engagement impact on research outcomes over the project duration.

5.3.Final Remarks

This deliverable demonstrates that DARE Spoke 3 is making substantial progress in embedding stakeholder engagement as a core component of its research activities. The positive outcomes reported across multiple dimensions - from study design optimization to clinical practice translation - validate the investment in participatory approaches and provide a foundation for continued development of patient-centered digital health solutions within the PNRR Extended Partnership framework.

Appendix A: List of Pilot Studies

The following table provides a complete list of respondents included in this deliverable, 31 pilot studies, plus a Work Package focused on education and training, whose lead completed the form and considered it worthwhile to report in relation to stakeholder engagement in the areas of education, training, and career pathways.

1. SP3-T3.4a Digital Tools for psychiatric and cognitive disorders: identify subjects at risk for conversion from preclinical conditions to psychosis
2. SP3-T4.2 Biomechanical features for early detection of diabetic foot complications
3. SP3-T4.1 Accessible measurements of mobility and deformity as biomarkers for orthopaedic treatments
4. SP3-T2.3 Personalized functional models for pre-operative planning of High Tibial Osteotomy
5. SP3-T4.7 Neurotransmission enriched connectivity as a biomarker of healthy and accelerated ageing
6. SP3-T4.4a Bringing Medicine Digitalization into the Italian Solid Organ Transplant Network
7. SP3-T3.2d Radiogenomic approaches predicting neoadjuvant therapy in breast cancer patients
8. SP3-T4.3b Liquid-Biopsy and Liquid-based Cytology Biomarkers for Gynaecological Cancers
9. SP3-T5.4 Therapy optimization and prevention of adverse events in diabetes management
10. SP3-T3.1b Data mining approaches predict risk of infections in elderly frail frequent users of ED: OSTEOPOROSIS
11. SP3-T3.3a Digitally-Empowered Management of Type 2 Diabetes
12. SP3-T3.2a Generating AI-risk stratification strategies for improved colorectal cancer screening
13. SP3-T3.2c ML approaches for cancer subnetworks focusing on myeloma

14. SP3-T5.6 Developing social and health care integrated model for ER overcrowding reduction
15. SP3-T2.4 Predicting the risk of bone fracture in patients with metastatic carcinoma
16. SP3-T4.4c Non-Invasive Biomarkers For Early Diagnosis After Solid Organ Transplantation
17. SP3-T3.3c seCondary and tertiAry digitaL preventIon of non-alcoholic and dysmetaBolic liveR disEase (CALIBRE)
18. SP3-T2.1 A Digital Twin technology to monitor fragility bone fractures risk
19. SP3-T4.5 Digital biomarkers in Parkinson and Alzheimer diseases with Down Syndrome
20. SP3-T3.2b ML approaches for cancer subnetworks focusing on lung
21. SP3-T5.1 IBD care through hub&spoke infrastructure
22. SP3-T2.2b Sport Total joint arthroplasty-knee II
23. SP3-T2.2a Predicting the risks of Osteoarthritis and Joint Replacement failure
24. Spoke 3 WP6 (Education, Training and Career Pathways)
25. SP3-T5.5 FITMATE: Food Intake Tracker and Metabolic Evaluation
26. SP3-T4.6 ML-based approach for eubiosis/dysbiosis status through microbiome assessment
27. SP3-T5.2 Digital therapy and telemedicine for nutritional intervention in ADPKD
28. SP3-T4.3a Single oncological marker detection for early diagnosis
29. SP3-T3.3b Digital Tools in Cardiometabolic Diseases: Digital Predictors of NAFLD
30. SP3-T3.1c Data mining approaches to stratify response to vaccinations in children
31. SP3-T5.3 NICU at home: telemedicine for preterm and term infants
32. SP3-T2.5 Cardiovascular radiomics for coronary and carotid disease prediction

Appendix B: Survey form

Data Dictionary Codebook

DARE Spoke 3 - Stakeholder Engagement (PID: 156)

12-19-2025 12:40

Instruments	
Instrument	Form Name
Engagement Form	engagement_form

	#	Variable / Field Name	Field Label *Field Note*	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: **Engagement Form** (engagement_form)				Enabled as survey
	1	[record_id]	Record ID	text, Required
	2	[pilot_name]	Nome del Pilot	text, Required
	3	[referent]	Referente (nome e istituzione)	text, Required
	4	[stakeholder_type]	Section Header: *Stakeholder* Tipologia principale di stakeholder COINVOLGIBILI (potenziali)	checkbox, Required 1, stakeholder_type___1, Pazienti 2, stakeholder_type___2, Caregiver 3, stakeholder_type___3, Clinici 4, stakeholder_type___4, Policy maker 5, stakeholder_type___5, Industria 6, stakeholder_type___6, Associazioni 7, stakeholder_type___7, Altro
	5	[stakeholder_n]	Numero totale di stakeholder COINVOLGIBILI	text (integer), Required
	6	[stakeholder_type_2]	Tipologia principale di stakeholder GIÀ COINVOLTI	checkbox, Required 1, stakeholder_type_2___1, Pazienti 2, stakeholder_type_2___2, Caregiver 3, stakeholder_type_2___3, Clinici 4, stakeholder_type_2___4, Policy maker 5, stakeholder_type_2___5, Industria 6, stakeholder_type_2___6, Associazion 7, stakeholder_type_2___7, Altro
	7	[stakeholder_n_2]	Numero totale di stakeholder GIÀ COINVOLTI	text (integer), Required
	8	[stakeholder_type_3]	Tipologia principale di stakeholder CHE SI VORRANNO SICURAMENTE COINVOLGERE (che sicuramente veranno coinvolti in futuro)	checkbox, Required 1, stakeholder_type_3___1, Pazienti 2, stakeholder_type_3___2, Caregiver 3, stakeholder_type_3___3, Clinici 4, stakeholder_type_3___4, Policy maker

				5 stakeholder_type_3___5 Industria 6 stakeholder_type_3___6 Associazion 7 stakeholder_type_3___7 Altro
	9	[stakeholder_n_3]	Numero totale di stakeholder CHE SI VORRANNO SICURAMENTE COINVOLGERE	text (integer), Required
	10	[stakeholder_type_other] Show the field ONLY if: [stakeholder_type(7)] = '1'	Specificare la tipologia	text, Required
	11	[stakeholder_type_other_2] Show the field ONLY if: [stakeholder_type_2(7)] = '1'	Specificare la tipologia	text, Required
	12	[stakeholder_type_other_3] Show the field ONLY if: [stakeholder_type_3(7)] = '1'	Specificare la tipologia	text, Required
	13	[engagement_mode]	Section Header: *Modalità di coinvolgimento* Modalità utilizzata	checkbox, Required 1 engagement_mode___1 Workshop 2 engagement_mode___2 Survey 3 engagement_mode___3 Focus group 4 engagement_mode___4 Interviste 5 engagement_mode___5 Co-design 6 engagement_mode___6 Altro
	14	[engagement_mode_other] Show the field ONLY if: [engagement_mode(6)] = '1'	Specificare la/le modalità utilizzate	text, Required
	15	[engagement_n]	Numero totale di occasioni di coinvolgimento	text (integer), Required
	16	[engagement_outcome]	Section Header: *Risultati del coinvolgimento* Un risultato o modifica concreta derivata dal coinvolgimento *è possibile indicarne più di una*	notes, Required
	17	[usefulness]	Grado di utilità percepita	radio, Required 1 Molto bassa 2 Bassa

				3 Media 4 Alta 5 Molto alta
	18	[documentation]	Section Header: *Documentazione* Carica un file di supporto (verbale, agenda, slide, IMPORTANTE soprattutto per i già coinvolti e sicuramente coinvolgibili) *creare un file .zip unico se si vogliono caricare più file*	file
	19	[engagement_form_complete]	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete