INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT IN CANCER-RELATED EUROPEAN PROJECTS









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INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT IN CANCER-RELATED EUROPEAN PROJECTS

EDITORS

Carina Dantas, *SHINE 2Europe* <u>carinadantas@shine2.eu</u>

AUTHORS

CONCEPT AND TRANSVERSAL SECTIONS

SHINE 2Europe Carina Dantas, Paola Bello, Natália Machado

LIVERATION

SHINE 2Europe Paola Bello, Carina Dantas

Fundación Avedis Donabedian Alexandra Dima, Helena Vall, Carola Orrego

4P-CAN

Center for Innovation in Medicine Ramona Popescu, Adriana Boată, Marius Geantă

INCISIVE

Kingston University Shereen El Nabhani, Lithin Zacharias

Maggioli SPA, Greek branch Gianna Tsakou

University of Novi Sad Tatjana Loncar-Turukalo

Czarkowska, Timelex Magdalena Kogut

CINDERELLA

Medical University of Gdansk Maciej Bobowicz

JANE

BIOSISTEMAK - Institute Health Systems Research Sarah Berrocoso Cascallana

SALVOVAR

PRISMA, Institut de Recerca Sant Joan de Déu Laura del Carpio

SalvOvar communication Susannah Carroll

Paola Bello, SHINE 2Europe

paolabello@shine2.eu

RESHAPE, INSERM, Université Lyon 1, & HCL Thibaut Reverdy, Julien Peron

Avedis Donabedian Research Institute Alexandra Dima

RadioVal

SHINE 2Europe Miriam Cabrita, Harm op den Aaker

University of Barcelona Oliver Diaz

ECHOS

Agência Investigação Clínica e Inovação Biomédica Hugo Soares

CCI4EU

Organisation of European Cancer Institutes Roxana Plesoianu

Sciensano Robbe Saesen

EUonQoL

Netherlands Institute for Health Services Research Merel Engelaar

GRAPHIC DESIGN

Joana Vieira, SHINE 2Europe





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INTRODUCTION

This publication aims to present creative approaches to involve stakeholders in EU-funded cancerrelated projects, by exploring innovative practices to engage individuals, organizations, and communities in a collaborative effort under this topic.

The main goal is to emphasise the critical importance of patient engagement and their empowerment at all phases of the projects, but also reinforce the need for effective communication, inclusive participation, and shared decision-making with other relevant stakeholders, such as policy makers, civil society actors, health and social care professionals, advocacy groups and industry partners among others, in driving progress and success in cancer research within the European context.

The LIVERATION project invited the projects hereby represented, with different typologies and supported under diverse funding lines, to an online workshop that was held on the 29th of April 2024, where each initiative was presented by their representatives, and a joint discussion was initiated.

By combining efforts, these projects can further work together to address the existing challenges from multiple angles, increasing the likelihood of finding comprehensive solutions and understanding the complexities of this topic at a deeper level, which may not be possible within the borders of individual initiatives.

This collaboration may facilitate the translation of our research findings into practical applications, ensuring that the produced outcomes have a more direct and meaningful impact on overall patient care and a higher societal relevance.

For each project, the following sections have been included:

- A synopsis, focused on the main project's objectives
- Innovative practices for stakeholder engagement
- Challenges and limitations, lessons learned, future works





LIVERATION

Stakeholder engagement methods: Social Innovation framework, ethical dialogue workshops, Living Labs

Key Challenges: Stakeholders with different interests and agendas; cultural and linguistic differences, Integration of new perspectives into the clinical trial

Key recommendations: Engage participants from various fields and areas of expertise; encourage the exchange of diverse perspectives and best practices to contribute to the project's development.

4P-CAN

Stakeholder engagement methods: Living labs, Personal Network Analysis (PNA)

Key Challenges: Engaging communities in rural areas; low awareness, stigma and scepticism

Key recommendations: Implement awareness campaigns to foster trust and engagement; develop context specific intervention; foster regional and national collaboration

INCISIVE

Stakeholder engagement methods: tailored meetings with selected stakeholders, trainings

Key Challenges: Ethics, legal and exploitation issues

Key recommendations: Achieve the right balance between patient privacy and data usability; support a strong involvement of stakeholders

CINDERELLA

Stakeholder engagement methods: Education and participation, collaboration and training

Key Challenges: Need for flexible and adaptive project management to address unforeseen challenges

Key recommendations: Early and continuous engagement with all stakeholders to ensure smooth project execution.

SALVOVAR

Stakeholder engagement methods: Creation of advisory groups, collaboration with external organisations, shared decision making

Key Challenges: Ensure diverse representation within stakeholder groups and involvement in activities

Key recommendations: Support involvement of stakeholders with tailored communication; adapt engagement strategies to account for evolving circumstances







JANE

Stakeholder engagement methods: Establishment of policy board and dialogues, stakeholder's forum Key Challenges: Language barriers, risks of duplication of efforts among organisations active in the same area Key recommendations: Establish key partnerships, maintain a strong coordination

RADIOVAL

Stakeholder engagement methods: Social innovation framework, multi stakeholders' sessions

Key Challenges: Planning in a very innovative and flexible context, changing nature of the societal landscape, including challenges, needs, regulations, political and economic priorities

Key recommendations: Involvement of all key stakeholders, flexibility in adapting to a fast-paced environment

ECHoS

Stakeholder engagement methods: Develop suitable impact models to adapt to national contexts and priorities; foster multi-stakeholder co-operation

Key Challenges: Long-term commitment from multiple stakeholders, including public and private entities

Key recommendations: Elaborate instruments to ensure stakeholders and citizens engagement; ensure governments' interest in mission-oriented projects' results.

CCIEU

Stakeholder engagement methods: Synergies with other EU research projects, forum for exchanges Key Challenges: Different healthcare systems and different standards, diverse priorities among stakeholders Key recommendations: Increase synergies and invest in long term collaborations

EUonQoL

Stakeholder engagement methods: Patient and Public Involvement (PPI); collaboration with patients and stakeholders

Key Challenges: Significant time and effort to ensure collaboration; paying attention to different levels of expertise

Key recommendations: Ensure trust in the process; maintain strong connections







PROJECT INFO •

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PROJECT ACRONYM:

PROJECT NAME: Unravelling the Impact of Radiofrequency in Liver Surgery

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COORDINATOR: Insitut Hopital del Mar (IMIM)

CONSORTIUM: 8 Partners

DURATION: June 2023 - June 2028

WEBSITE: liveration.eu

PROJECT PARTNERS

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Innovative solutions for a healthier life

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SYNOPSYS

Colorectal cancer (CRC) ranks fourth in cancer deaths worldwide, with between 20% to 30% of patients with advanced CRC having liver metastases (CRLM). Liver cancer ranks second in cancer deaths worldwide, including hepatocellular carcinoma (HCC), and despite recent advancements, liver resection offers the only chance of cure for patients with liver metastases. However, the recurrence rate of these tumours is high even after post-resection. The presence of positive margins in the remaining liver after resection correlates with increased local recurrence and decreased overall survival, being this the only factor where prognosis could be influenced by the performance of surgery. Still, the extent of an R-negative status remains debatable and varies widely between publications.

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Currently, there are radiofrequency ablation studies that, based on preliminary retrospective human clinical trials, are able to correlate an additional coagulation of tumour margins with a reduction on local recurrence. However, there is no prospective and pragmatic controlled study that accurately measures this additional margin and its impact on oncological outcomes.

The aim of LIVERATION is to conduct an ambitious, pragmatic multicentre clinical trial with 720 patients with CRLM and HCC at 24 clinical centres in different countries to determine whether additional ablated margin produced by radiofrequency can decrease the recurrence rate and improve patient survival. The project also aims to evaluate how the intervention is patient-centric, and its comparativeness with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings. To this end, the consortium has been formed by highly experienced, qualified and multidisciplinary entities that may ensure the results will not only have a major EU impact at social and scientific levels, but also on the economic perspective.

INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT

Stakeholders' engagement in cancer research: a multilevel approach

A crucial aspect of the LIVERATION project is the focus on translating research findings into tangible benefits for the patients, family and caregivers, health and care professionals and the health systems. This will be accomplished via comprehensive multi-stakeholder engagement enabled by social innovation methods, and the establishment of Living Labs in participating countries.

One of the primary components of LIVERATION is to conduct a thorough evaluation of the trial, assessing both social impact and comparative efficacy against other interventions. This will be achieved using a mixedmethods evaluation, incorporating perspectives from both patients and a plurality of stakeholders. To meet these goals, the project is:

- a) Developing a social innovation framework to enhance multi-stakeholder engagement.
- b) Comprehensively evaluating quality of life and the social perspective of patients.

Involvement of a diverse range of stakeholders at various levels is essential for the project's development. While the primary stakeholders are patients and their caregivers, other stakeholders include healthcare professionals, the scientific community, policymakers, industrial healthcare professionals, regulators, and key opinion leaders at local, regional, national, and EU levels. In LIVERATION, stakeholders will be involved in several initiatives and activities which take place at different levels and with different aims, interconnecting to create a flow of information that enables collaborative innovation across policy domains, disciplines and geographical locations.

European Level: multi-stakeholder engagement, ethical dialogue workshops and social innovation framework

Social innovation can be explained as a form of development and implementation of new ideas to meet social needs and create new social relationships or collaborations¹. It represents a way to provide new responses to a variety of challenges and demands, with a focus on societal impact. One of the tasks of the project is to involve a variety of stakeholders through a carefully designed *social innovation framework*, aimed at engaging participants from different fields and with different expertise to gather their perspectives, feedback and good practices, that will contribute to its development and adequacy. After the mapping of LIVERATION stakeholders, that required the identification and categorisation of the main stakeholder groups, a detailed stakeholder analysis has followed, based on their level of interest and capacity to influence the project. The stakeholder analysis resulted in the establishment of a multi-stakeholder group at European level, consisting of approximately 15 members. This group includes stakeholders from diverse sectors and areas of expertise.

The multi-stakeholder group is invited to participate in online iterative discussions and co-creation activities, defined as *Ethics Dialogue Workshops* (EDW), whose aim is to discuss the socio-ethical, clinical, legal and regulatory challenges that LIVERATION may face during the implementation phase and after its completion. The EDW will be held in three rounds over the course of the project, leading to the delivery of an action plan, guidelines, and recommendations to address the identified challenges



¹ European Commission, <u>https://single-market-economy.ec.europa.eu/industry/strategy/innovation/social_en</u>, accessed 15.10.2024

effectively. While the precise content and structure of each round will be agreed within the Consortium and may vary according to the selected stakeholders, the plan can be summarised as follows:

- In the first round, the challenges, needs, barriers identified by the consortium partners in a cocreation session will be introduced and discussed, and stakeholders will be asked to propose solutions, pathways or strategies to tackle them. During the session, new challenges and issues may be identified and will be then added to the follow-up discussion.
- In the second round, a summary of the main outcomes from round one will be presented and discussed with the stakeholders, that will aim to prioritise the challenges and corresponding strategies to tackle them in a matrix that should be achieved by consensus.
- In the **third round**, the matrix from the previous round will be updated and revised, and based on it, an agreement will be reached on the main areas for the action plan, guidelines, and recommendations, to be drafted as guidance documents for the Consortium.

By engaging multiple stakeholders, this approach will emphasize the project's multidisciplinary nature, shedding light on its various dimensions - scientific, medical, regulatory, legal, and social.

National level: Living Labs for collaborative innovation in care experience and quality of life in liver cancer surgery in participating countries

As a multi-country pragmatic clinical trial, LIVERATION aims to involve clinical sites in several countries, namely Spain, France, Switzerland, Italy, Poland, Slovenia, and Greece. In each country, implementing technologies for improving liver resection surgery outcomes, as all innovations in the care experience and quality of life of persons being treated for liver cancer, takes place within complex healthcare ecosystems that may be characterized by common features but also by cultural, social, and economical specificities that need to be considered. Each ecosystem has its own priorities and needs to self-determine and organise its own collaborations to pursue its agreed goals. The Living Labs are designed to facilitate this type of work. At the same time, national ecosystems benefit from coordinating with each other and the opportunity to input into shared goals and decisions at European level. By leveraging on the social innovation-based discussions previously described, the Living Labs will be able to take onboard findings of European multistakeholder activities and input into discussions at this level in an iterative manner.

The Living Labs have been used successfully in many areas, including in oncology (e.g Project. 2 – 4P-CAN) and employ a variety of methods aiming to create spaces of collaboration and innovation on a given topic and a real-world context. While in practice Living Labs can take many forms, there are **five essential elements** that define this approach:





INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT IN CANCER-RELATED EUROPEAN PROJECTS

- a) The Living Labs involve activities that bring together different stakeholders to co-create specific outcomes or products. In LIVERATION, the care experience and quality of life of people being treated with surgery for liver cancer is impacted by contributions from many types of stakeholders. In each country, the ecosystem of care and innovation would benefit from this co-creation space to explore and prioritise challenges and subsequently develop solutions for addressing them in ways that best fit the social and cultural context.
- b) Living Labs combine methods flexibly depending on the needs of the creative process. In LIVERATION, we plan to combine individual interviews with online and in person group discussions, interactive surveys and synthesis of scientific and grey literature.
- c) Living Labs take place in real-life settings where the output is expected to be used. The LIVERATION Living Labs will be organised in each participating country, in the local language, and subsequently communication will be facilitated through a dedicated interactive platform in both local languages and in English for bringing common issues to discussion.
- d) Living Labs strive to involve all relevant actors in the specific area of innovation. The LIVERATION project aims to involve patients and their families, either directly or via their representatives, as well as members of multidisciplinary care teams and healthcare management teams at the hospitals providing liver surgery, and research and development professionals such as biomedical researchers, technology developers, medical manufacturers.
- e) Living Labs involve actors from the start and maintain their engagement throughout. In LIVERATION, this process itself will be the focus of study and experimentation, whereby in each country activities will be organised following a common protocol and interactions studied for the duration of the project to examine co-creation processes, barriers and facilitators in each country and commonalities and differences between them regarding needs, preferences, priorities, levels of engagement and recommendations for innovation.

By applying these five principles, the **LIVERATION Living Labs** will be developed using an exploratory mixedmethods design, consisting of **four stages**.

We will start by reviewing <u>literature</u> on patient experiences of liver cancer care pathways.

A lay language synthesis will complement data collected through <u>individual interviews</u> with stakeholders interested in participating in the Living Labs.

<u>Co-design sessions</u> will explore more in-depth the topics from interviews and literature synthesis and prioritise challenges in liver cancer care which participants agree on working together to develop solutions in co-design sessions moderated by the research team.



Finally, interactive asynchronous discussions will be organised through an online platform, in country languages and in English for collaboration across countries.

The research team will moderate these discussions for a period of 9 months, which will allow the exploration of interpersonal processes instrumental to collaborative action via a participative research approach. Moderation will also involve support for developing sustainability plans for the Living Labs within and across participating countries

Interactions between activities at European and national level

The Ethical Dialogue Workshops and Living Labs are planned to take place throughout the LIVERATION project and support each other by sharing relevant input from the different stakeholder groups (Figure 1).



Figure 1. Interaction between Ethical Dialogue Workshops and Living Labs activities at European and national levels.

After each EDW, a summary of issues relevant to liver surgery experiences and quality of life will be shared for input into the following Living Labs activities, highlighting challenges, solutions, or final recommendations.

The Living Labs activities will bring forward issues related to the LIVERATION trials as topics proposed for discussion and integration with EDW activities at key moments during the project. Local Living Labs teams will also be offered training in conducting EDW in each country, in order to broaden the toolbox of stakeholder engagement methods ready to be applied in the development of solutions generated by the local ecosystems. This interactive process ensures an effective exchange of experiences and solutions within and between the participating countries and at the European level.





CHALLENGES AND LIMITATIONS, LESSONS LEARNT, FUTURE WORKS

Challenges, limitations and future perspectives of the LIVERATION project

Due to the high level of complexity and interactivity and its multi-country context, the citizen engagement approach undertaken in LIVERATION may face some challenges and potential limitations that need to be carefully addressed during the project.

Firstly, the activities previously described require involving stakeholders with different profiles, and potentially different interests and agendas. The challenge is to engage different stakeholder groups and create a dynamic that brings value to each participant throughout the duration of the project and in the medium and long-term. To address this issue, particular attention will be given to developing materials that are informative to a diverse audience and explain the benefits of participation, to take the opportunity of individual interviews to understand individual motivations, respond to concerns and integrate feedback in future activities, ensuring they are appropriate and engaging. An important aspect is aligning engagement activities with the broader context of communication and dissemination in LIVERATION activities.

Secondly, the LIVERATION project takes place in different countries that speak different languages, and involves patients, carers, medical staff, researchers and clinical staff people of diverse backgrounds. Therefore, while participants involved in the EDW will necessarily communicate in English as common language, the Living Labs will be initiated in national languages, to ensure that all participants can fully express themselves. However, English will be used to discuss issues at cross-country level at a later stage on the online platform, which may confront some participants with a language barrier. This challenge will need to be addressed by preparing synthesis documents summarizing local activities and sharing them in English as input for crosscountry discussions. The use of automatic translation tools in the online platform will be explored as part of the solution. The training provided to research teams conducting the Living Labs activities in participating countries will be crucial to engaging stakeholders in similar ways across countries.

Finally, some challenges in the project are related to its implementation and sustainability. The outputs and information obtained from the EDW and the Living Labs will serve as inputs for the LIVERATION clinical trial but, to achieve this, clear pathways and communication channels need to be established between partners regarding their inputs in these activities and the integration of the EDW feedback in the main clinical trial processes during the project.

The initial steps of this process have already been taken with positive results. Furthermore, the lessons learned from the EDW and Living Labs will go beyond the LIVERATION project itself and serve as lessons learned for future initiatives and activities in a practical manner.







PROJECT INFO •

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PROJECT ACRONYM:

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4P-CAN

PROJECT NAME: Personalised Cancer Primary Prevention research through Citizen Participation and digitally enabled social innovationg

4PCAN

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COORDINATOR: Asociatia centrul Pentru Inovatie in Medicina (INOMED)

CONSORTIUM: 17 Partners

DURATION: May 2023 - April 2027

WEBSITE: 4p-can.eu



INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT IN CANCER-RELATED EUROPEAN PROJECTS

SYNOPSYS

4PCAN gathers national and European organisations, foundations, and universities, representing a broad range of stakeholders committed to combating major modifiable cancer risk factors. These factors include smoking, alcohol consumption, physical inactivity, excess body weight, preventable infections, and environmental pollution such as radon. **The overarching goal is to enhance primary cancer prevention and reduce health inequalities, particularly in Eastern European countries**.

Spanning four years, the 4P-CAN project investigates cancer risk at national (macro), community (meso), and individual (micro) levels. Adhering to the European Code Against Cancer, the project integrates implementation research, social and behavioural sciences, and advanced technology to develop personalised cancer prevention tools. These tools are created through collaborative knowledge and Living Labs, fostering innovation in prevention strategies.

The 4P-CAN project undertakes a comprehensive approach to cancer prevention through several key activities. Firstly, it evaluates existing legislation and policies related to cancer risk factors, assessing the effectiveness of current preventive measures and identifying barriers to policy implementation and individual adherence to healthy behaviours. This thorough assessment informs the development of personalised prevention algorithms designed to identify individuals at high risk of cancer. These algorithms are adapted to the cultural contexts of Central and Eastern European countries, ensuring relevance and effectiveness.

In addition, 4P-CAN aims to establish two Living Labs focused on primary cancer prevention, which serve as hubs for innovation. These labs actively involve citizens and stakeholders in the co-creation of novel prevention strategies. This participatory approach ensures that the developed measures are practical, culturally sensitive, and widely accepted. The project will also support decision-makers and health practitioners by providing them with tools and insights necessary for informed decision-making. By integrating social innovations into cancer prevention policies, 4P-CAN aims to address health inequalities and promote more equitable health outcomes.

The project will design and implement targeted communication campaigns aimed at changing attitudes, perceptions, and behaviours related to cancer risk factors. These campaigns are tailored to specific audiences and involve relevant stakeholders and influencers to effectively disseminate preventive messages. By fostering community engagement and leveraging the influence of key figures, these campaigns aim to enhance public awareness and encourage healthier lifestyles.

By conducting these activities, 4P-CAN aims to empower decision-makers and health practitioners with the knowledge and tools necessary to adopt personalised cancer prevention approaches. The project's efforts will culminate in evidence-based recommendations for policymakers, fostering social innovation and reducing





health disparities across Europe. Through targeted communication and community engagement, 4P-CAN will drive significant advancements in primary cancer prevention, ultimately improving public health outcomes across participating countries.

INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT

Enhancing stakeholder engagement through social innovation

The 4P-CAN project places a strong emphasis on social innovation as a core component of its mission. Engaging a diverse range of stakeholders at regional, national, and European levels, the project aims to provide tailored solutions for cancer prevention. Central to this mission is the innovative approach to enhance stakeholder engagement, particularly citizen involvement. Specifically, 4P-CAN has pioneered this by establishing the first Living Lab in a rural area of Romania. This Living Lab serves as a model for how local communities can actively participate in the co-creation of cancer prevention strategies, ensuring that solutions are relevant, culturally appropriate, and widely accepted. Through this innovative approach, 4P-CAN is able to deeply engage with citizens, fostering a more inclusive and effective primary cancer prevention effort.

Establishment of the Living Lab

In 2021, it was identified that the highest risk of poverty or social exclusion was among people living in rural areas, particularly in Eastern and Southern Europe. Access to healthcare in these rural areas remains a significant challenge. For instance, in Romania, almost 80% of the rural population must drive more than 15 minutes to reach a primary healthcare service. Given these factors, the South Muntenia region was selected to establish Romania's first Living Lab. This region has the highest number of rural inhabitants in the country, with 57% of its residents living in rural areas. Despite housing three universities, the region lacks a university hospital or public research institutes in the health or medical sectors, which could facilitate communication and healthcare services for its residents.

Rural areas often exhibit greater scepticism towards primary preventive measures, such as vaccination against hepatitis B virus (HBV) and human papillomavirus (HPV), reduction of alcohol consumption, and increasing physical activity. These attitudes are influenced by an individual's network of influence. By setting up the Living Lab in this region, 4P-CAN aims to directly address these disparities and foster greater engagement in



primary preventive measures among rural populations, spreading these measures across each individual's networks, with the aim to ultimately achieve high societal adoption of preventive measures.

Implementing Personal Network Analysis

The 4P-CAN Living Lab integrates the innovative approach of Personal Network Analysis (PNA). Once established, the Living Lab initiated several activities over the span of one year. The activities began with collecting the first wave of data for the PNAs through a series of interviews (320) to gather information on various attributes (e.g., obesity, physical activity, lifestyle, food habits), personal networks (e.g., social contacts, connectivity, ties to organisations), and medical records of participants. Through the collection of this data, a first iteration of citizen engagement was established to engage with the local community. This activity was necessary to better understand personal interactions among individuals and how these relationships affect each individual's decision-making and adoption of healthier lifestyles. Similarly, it helped to understand people's attitudes, preferences, needs, and perceptions about cancer risk factors and cancer prevention. In Romania, early analysis insights show that fatalism, stigma, low awareness of sedentarism, obesity, and poor diet as risk factors for cancer influence people's decisions on the preventive measures they adopt. Throughout the course of the 4P-CAN project, multiple waves of data collection will be conducted. This ongoing data gathering aims to analyse how attitudes and perceptions evolve over the years in response to the various activities implemented.

Stakeholder mapping and engagement

In parallel, a stakeholder mapping exercise was conducted. This activity is crucial to understanding the different levels of stakeholders involved in cancer primary prevention, measuring interactions across them in terms of funding, influence, collaboration, and authority, and ultimately grasping how information and innovation are disseminated to the individual. This exercise used advanced social sciences tools, such as the quadruple and pentagon helix models of stakeholder engagement and NetMap to map these different levels of influence, which encompass the European Commission, Ministries of Health, and local authorities.

This exercise has been critical in identifying where challenges are present. For instance, in Romania, the role of local and regional authorities seems to be underestimated in cancer primary prevention as most European initiatives do not reach such a granular level. This is significant as it indicates that more innovative and nonlinear methods are necessary for reaching local and regional populations and improving their health status.

Given the diminished role of local authorities, 4P-CAN emphasises the meso-level of engagement and the key role these authorities, together with informal community leaders, can play in influencing the adoption of positive behaviours. 4P-CAN aims to strongly encourage these communities to build supportive activities and





create innovative spaces. Several activities have already been conducted to bring the community together. A citizen's jury in the community was selected on a voluntary basis to help prepare the different citizen engagement activities that will be conducted throughout the four years. Additionally, activities promoting physical activity have been initiated. To further raise awareness of these campaigns, the local football team has decided to bear the logo of 4P-CAN, promoting the project and its activities.

Role of the Living Lab and other innovative approaches

Through its innovative approach and establishment of the Living Lab in South Muntenia, soon to be replicated in Plovdiv, Bulgaria, 4P-CAN addresses significant disparities in cancer prevention measures among rural populations. By integrating Personal Network Analysis, conducting comprehensive stakeholder mapping, and emphasising the role of local authorities and community leaders, the project fosters deeper citizen engagement and more effective primary cancer prevention strategies. This model not only enhances the relevance and acceptance of preventive measures but also sets a precedent for broader societal adoption and health improvement across Europe. The overall aim of this approach is to complement top-down initiatives from the European Commission with bottom-up strategies promoted at local and regional levels. This model seeks to create robust regional hubs at the national level that support informed behavioural decisions and the adoption of healthy habits.

Overall, the activities conducted in the Living Lab aim to develop personalised prevention algorithms that incorporate the specific data gathered through multiple waves of data collection. These algorithms will be tailored to the unique needs of rural Eastern European countries, providing regional and national decisionmakers, as well as local practitioners, with evidence-based and informed strategies for cancer prevention. Moreover, the insights gained from this data will facilitate the creation of targeted communication campaigns designed to increase the adoption of healthy behaviours and reduce disparities between Eastern and Western Europe.

It has become clear that this new innovative, comprehensive, and systemic bottom-up model seeks to revolutionise current paradigms and complement top-down national approaches. It is imperative that the EU Mission on Cancer may be recognised as a top priority for accessing funds and programs, especially those traditionally benefiting less developed Member States, such as the Horizon Europe Widening Program. Ensuring regional and national synergies with existing and emerging European initiatives and projects is crucial for the success and sustainability of these efforts.





CHALLENGES AND LIMITATIONS, LESSONS LEARNT, FUTURE WORKS

Challenges, limitations, and future directions of the 4P-CAN Project

4P-CAN faced some challenges in engaging the local community, particularly in rural areas where scepticism towards primary preventive measures is prevalent. Rural populations often exhibit distrust towards external initiatives, and this scepticism can be compounded by a lack of awareness and understanding of cancer prevention strategies. To address these challenges, the project had to implement a variety of incentives and awareness campaigns to foster trust and encourage involvement. This also included directly involving the local Mayor in the activities to attract increased citizen engagement. Despite these efforts, all actors involved are aware that maintaining sustained engagement from the community is difficult, especially spanning over the course of the project. For this, 4P-CAN has learned that continuous and adaptive communication strategies are essential for keeping the community informed and motivated. Leveraging local influencers and informal community leaders has been crucial in building trust and promoting participation. These leaders help bridge the gap between the project team and the residents, making the initiatives more relatable and accepted. However, this approach requires ongoing support and recognition of the contributions of these local figures, as well as a commitment to addressing their concerns and feedback. These insights from the pilot in South Muntenia are crucial for the efficient development of the future Living Lab in Plovdiv.

The establishment of the Living Lab in South Muntenia has also provided valuable lessons for future efforts. One key insight is the importance of personalised and context-specific interventions. The data collected through Personal Network Analysis (PNA) has highlighted the diverse factors influencing health behaviours in rural communities, such as fatalism, stigma, and low awareness of certain risk factors. By understanding these nuances, the project will be able to tailor its strategies more effectively. Additionally, the stakeholder mapping exercise has underscored the need for stronger collaboration with local and regional authorities, who play a critical role in disseminating information and supporting preventive measures.

Looking ahead, the 4P-CAN project aims to promote the establishment of Living Labs in other regions, reinforcing its bottom-up approach to cancer prevention and potentially extending this model to address other pressing health challenges. Future work shall focus on enhancing regional hubs that can sustain the momentum of the project's initiatives. This includes creating more robust support systems for local influencers and community leaders, ensuring they have the resources and training needed to advocate for healthy behaviours. Moreover, the project will continue to seek synergies with existing European initiatives and programs, to secure funding and support for its activities. By fostering regional and national collaborations, 4P-CAN hopes to create a sustainable model for cancer prevention that can be replicated across Europe, ultimately reducing health disparities and improving outcomes in underserved communities.







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WEBSITE: incisive-project.eu

DURATION: October 2020 - March 2024

CONSORTIUM: 27 partners

COORDINATOR: Maggioli SpA

PROJECT NAME: Improving cancer diagnosis and prediction with AI and big data

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INCISIVE

PROJECT ACRONYM:

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INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT IN CANCER-RELATED EUROPEAN PROJECTS

SYNOPSYS

INCISIVE is an EU-funded project that ran between October 2020 to March 2024, aiming at achieving two major objectives:

- the development of a reusable, pan-European, federated data repository of millions of FAIR medical images and clinical data that AI researchers can use for the development of INCISIVE's own AI tools, as well as other tools in the future.
- 2) the development of AI-powered tools that support the decision-making of HCPs in diagnosing and monitoring 4 types of cancer: breast, lung, prostate, and colorectal.

To fulfil Objective 1, the INCISIVE consortium delivered a federated repository of cancer images and GDPRcompliant supporting technical infrastructure for health data sharing. The repository allows interoperable health data sharing among registered stakeholders in compliance with legal, ethical, privacy and security requirements, for AI-related training, validation, and research experimentation.

To ensure data interoperability, INCISIVE delivered a data interoperability framework, including a methodology, tools and a Common Data Model that has been applied to all INCISIVE data. At the project's end, the repository aggregates more than 5.5 million anonymised cancer image data and accompanying clinical data from more than 11000 individuals. It relies on federated data storage abiding by the highest data privacy and security standards, allowing data sharing through a central node, or distributed federated nodes located at the data holders' site, depending on data holders' preferences. The repository is supported by tools for data preparation, such as data anonymisation, curation, annotation, quality checking, and more. The repository is also supported by data-sharing mechanisms, covering both technical and operational aspects of data sharing, and complying with legal and ethical norms before data is shared. Data users can search and reuse available data respecting the respective data access rights imposed by data holders. The data repository is now fully operational and integrates data from 9 distributed data providers.

The INCISIVE federated data repository has been used for the achievement of Objective 2, namely, the training and validation of an AI-based toolbox offering healthcare professionals' decision-support services for various cancer image modalities: CT, PET-CT, MR, mammography, Ultrasound, X-ray and histopathological images, for 4 types of cancer, i.e., lung, breast, colorectal and prostate cancer.

The toolbox consists of 28 novel AI models, combined into explainable AI-supported services that have been trained and validated using millions of cancer images and accompanying clinical data. The main decision-support services offered relate to the classification of abnormalities, patient prioritization, lesion segmentation and localization assistance, cancer diagnosis and staging and risk for metastasis prediction. The

Al toolbox is integrated with a set of intuitive and interactive visualisation and reporting tools that support the usability of the AI services, facilitating the delivery of the AI tools' outcomes to healthcare professionals.

INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT

As good quality data is an essential component towards the delivery of trustworthy and reliable AI services, within INCISIVE the focus has been placed towards supporting the data providers (DP) in the data collection process. INCISIVE gathered 9 DPs from 4 countries including different types of institutions and hospital levels, different data storage types and hospital information systems, and different healthcare pathways for four cancer types: lung, breast, colorectal and prostate cancer.

In the following paragraphs, the approach, and good practices in engaging with data providers/hospitals as our main stakeholders for their dual role, as both data providers and main users of INCISIVE AI Toolbox services for health care providers, are detailed. The efforts to facilitate privacy-preserving data collection with quality assurance, standard compliance and full technical support rely on the developed automated tools and data collection guidelines. INCISIVE Data Sharing portal relies on these innovative tools and practices to enable sustainable data sharing beyond the project lifetime. A significant facilitator in this complex process was the continuous communication and linking between the AI researchers and data providers.

The good and innovative practices to support and sustain data collection and data sharing, as an essential component for the development of AI services can be summarized as follows:

- Establishment of data collection and de-identification methods careful design of data collection methods with proactive Identification of Issues and standardization assurance to facilitate interoperability.
- Detailed and clear guidelines on data collection accompanied with video material for all technically advanced activities.
- Clear image annotation guidelines with no ambiguities reduce complexities and very ambitious annotation plans as these are the main sources of errors.
- Online training and continuous support to healthcare professionals and data providers

To impose and sustain quality, we have implemented automated data validation before upload, with the development of a Data Integration Quality Check Tool. The project has also ensured effective communication and collaboration, with seamless communication channels that were established with key stakeholders, facilitated by a central coordinating entity in the consortium.





Quarantine mechanisms for Non-Compliant Data were foreseen. Designating a temporary repository for noncompliant data allows for segregation and further validation, ensuring that only clean, validated data are integrated into the main repository. INCISIVE also did a clear investment on automation, developing robust scripts or tools for automated data validation and curation to minimise manual intervention and error propagation.

Quality assurance protocols were implemented and resources for manual intervention were also foreseen, as the project recognises the need for domain experts' involvement in complex data issues where resources need to be allocated accordingly. Finally, the project implemented and invested in continuous quality monitoring mechanisms to detect and address data anomalies in real time, minimising the need for postupload corrections.

Feasibility Study

The effective engagement of various stakeholders such as AI developers, data providers, clinical researchers, and legal partners was crucial in achieving the desired result in the feasibility study. This study was conducted to assess the user experience of INCISIVE by health care professionals (HCPs). The following strategies helped in achieving the desired outcomes:

- Biweekly partner meetings: one of the practices implemented in INCISIVE was conducting biweekly meetings with all partners involved to review progress on tasks. This approach ensured that everyone was on the same page, fostered a deeper understanding of progress, and provided crucial support to those who required assistance. These regular meetings served as a platform for collaboration and mutual support, ultimately enhancing our collective efficiency and effectiveness.
- Importance of ethics from the beginning and close collaboration with partners: obtaining ethical clearance and maintaining strong ethical practices were crucial components of this project. The project team demonstrated commitment to ethical research by proactively securing ethical approval from the very start of the project and complying with the GDPR. Close relationships and regular follow-up were crucial in achieving this target.
- Creation of a Brochure for accelerating patient recruitment: patients found it easier to get the information by placing the brochures at the entrance of the health care facilities when they visited. This facilitated patient recruitment.
- Training for healthcare professionals: to acquaint HCPs with the INCISIVE platform, interactive training sessions were held beforehand in cooperation with one of the partners involved in the study. When such programs were planned far in advance, HCPs were better able to do their jobs because they



were more prepared. By offering this kind of thorough training, we improved HCPs' capacity to successfully contribute to the success of the research.

- Development of handbooks: The feasibility study was greatly aided by the creation of handbooks for data providers and healthcare professionals. Providing HCPs with training manuals was very helpful in terms of providing step-by-step explanations for assessing usability in the INCISIVE platform and this could help in saving time and reducing errors. This also acted as a refreshing material where HCPs could refer to whatever they had learned in the training session. For data providers, this helped in guiding HCPs on what they had to do before and after the study.
- Monitoring HCP progress in the feasibility study through a Digital Diary approach enabled to ensure the timely completion of the study. Hence, a structured and organised approach was taken to monitor the HCPs' progress by creating an online form (Digital Diary) that was monitored by the study lead. This systematic follow-up helped in ensuring the smooth progress of the study.
- Adopting a mixed methodology helped in understanding the overall usability experience of healthcare professionals. The standardised tools as well as face-to-face interviews helped in providing a deeper comprehension of the HCPs' actual experiences and viewpoints.

CHALLENGES AND LIMITATIONS, LESSONS LEARNT, FUTURE WORKS

Several aspects will require attention in the future activities:

Decisions regarding medical data collection, storage methods, and use for project purposes, such as AI training, cannot be made in isolation from legal and exploitation considerations. Regular discussions, inperson meetings, workshops, and stakeholder questionnaires have proven effective in advancing discussions and aiding the decision-making process.

It is imperative to involve both ethics and legal teams in discussions about data collection, clinical studies, and technical design of data-sharing platforms. Their input is crucial for implementing GDPR requirements, particularly the principles of privacy-by-default and privacy-by-design, alongside ethical considerations. Collaboration among hospitals as data providers, to draft ethics applications and patient consent forms using a common template, has been beneficial.

Achieving the right balance between patient privacy and data usability for research is complex. Strict security measures can discourage data use, and overly redacting data will impact its usability for research. Yet GDPR compliance necessitates minimising data processed, requiring – among other measures - de-identification of



medical records. Misuse of terms like 'anonymised data' can have legal and usability implications, as advancements in technology may facilitate re-identification. Clarifying distinctions between 'anonymous information' and 'pseudonymised data' under the GDPR is crucial but lacks uniform understanding among privacy practitioners and the medical community. Developers of technical solutions and data providers, supported by their privacy advisors or DPOs, must openly discuss the limitations and consequences of chosen data de-identification methods.

The need for effective stakeholder engagement in cancer care has become increasingly vital, as the healthcare landscape continues to evolve. INCISIVE is a testimony of the strong involvement of stakeholders, including data providers, healthcare professionals, clinical researchers, AI developers, and legal partners to drive innovation and ensure the smooth operation of the project. It is evident from this project that innovative practices which advance meaningful collaboration between key stakeholders can lead to better outcomes. This has a direct effect on improving patient quality and making a sustainable healthcare system.





CINDERELLA

PROJECT INFO

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PROJECT ACRONYM:

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CINDERELLA

PROJECT NAME:

Clinical Validation of an artificial intelligence (AI)-based approach to improve the shared decision-making process and outcomes in Breast Cancer Patients proposed for Locoregional treatment

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COORDINATOR:

Fundação D. Anna de Sommer Champalimaud e Dr. Carlos Montez Champalimaud

CONSORTIUM: 9 Partners

DURATION: June 2022 - May 2026

WEBSITE: cinderellaproject.eu











PROJECT PARTNERS











SYNOPSYS

Breast cancer is the most commonly diagnosed cancer, with an estimated 2.3 million new cases per year globally. Approximately 90% of these patients will undergo breast surgery with or without radiation (locoregional treatment). Different surgical techniques can be offered to the patient, each leading to completely different aesthetic outcomes. Moreover, for different patients undergoing the same surgery, the aesthetic outcome could be completely different based on individual patient's factors (e.g., age, body habitus).

In the CINDERELLA project, we use the BreLO-AI system (an artificial intelligence-based tool for classification of aesthetic outcomes and matching data and photographs) integrated in CANKADO (a cloud-based healthcare platform) to create an easy-to-use application that can be used on any electronic device. The CINDERELLA APProach is unique as it uses a clinical database and performs biometric matching, to generate images that simulate the expected surgical outcomes for patients. In the CINDERELLA trial (running during the project) we compare if the application helped to fulfil patients' expectations and led to a better quality of life. By feeding new clinical and photographic information to the CINDERELLA APProach after surgery, the AI platform will be able to improve for the next cases. This trial will be practice-changing in the field of patient education and shared decision making.

CINDERELLA platform will help to overcome any miscommunication and potential boundaries in patient's or physician's understanding of the potential outcomes of locoregional treatment of breast cancer. We believe that the CINDERELLA APProach will be used in the future to other locoregional treatments that might change patients' aesthetic appearance, being thus a forerunner for new innovative tools supporting communication with our patients.

INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT

Patient Engagement and Empowerment

Patient engagement is at the core of the CINDERELLA Project. The BreLO-AI system integrated into the CANKADO platform allows patients to visualise realistic aesthetic outcomes based on their individual characteristics and treatment options, which empowers patients through:

• Visualisation Tools: enhancing understanding and expectations through interaction with images of similar cases.



INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT IN CANCER-RELATED EUROPEAN PROJECTS

- Educational Content: facilitating informed decision-making by providing comprehensive educational • content in six languages. Substantial effort was dedicated to the development and implementation of high-quality educational content. This multilingual approach allows patients to explore locoregional treatment options, weigh their advantages and disadvantages, and actively engage with previous images from similar patients treated with the same technique, matched with their data and photos. This immersive educational content addresses potential complications and, more importantly, provides insights into realistic aesthetic results associated with the proposed techniques.
- **Clinical Trial Participation:** enabling active participation in clinical trials via the CINDERELLA App, • which offers easy access to medical information, questionnaires, and personalised treatment insights.
- Al-friendly Digital Health Environment: by establishing a routine digital approach for patients proposed for locoregional treatment through a more home-based, less costly and environment friendly solution, the CINDERELLA APP will lead to more reproducible attitudes and decisions among different centres.

Collaboration with Healthcare Professionals

Effective communication and collaboration with healthcare professionals are pivotal. The project involves:

- Regular Meetings: biweekly virtual meetings and biannual face-to-face plenary events to ensure • continuous engagement and feedback.
- User-friendly Platform: development of a user-friendly interface for healthcare professionals to access and utilise AI tools seamlessly.
- Training and Support: comprehensive training and support sessions to integrate the AI system into • clinical workflows, ensuring the technology enhances rather than disrupts existing practices.
- Practical and Training Sessions: practical and training teleconference sessions were held to guarantee • all centres were on the same page using the CANKADO platforms properly.

Inclusive Participation of Policymakers and Advocacy Groups

The project actively involves policymakers and advocacy groups to ensure broader societal impact and alignment with public health goals. Its Advisory Board is composed of experts from international organisations to provide high-quality advice and operational guidance, which was formed through a combination of open calls and direct nominations to create a diverse and inclusive group. Moreover, regular updates and consultations with policymakers help to align project goals with national and European health and AI policies, enhancing the project's relevance and impact.



Engaging Civil Society and Industry Partners

The CINDERELLA Project fosters collaboration with civil society and industry partners to ensure comprehensive stakeholder engagement. Its educational outreach is based on the development of brochures, videos, and manuals in multiple languages to educate and engage a wide range of stakeholders. A detailed dissemination and communication plan complements the work, to share project findings widely through scientific publications, conferences, social media, and the website.

Active involvement of patient advocacy groups ensures that the project addresses real-world challenges and patient needs effectively. CINDERELLA project's societal impact aims to develop a data and AI-friendly culture in both medical professionals and patients by improving the understanding of the role of AI and good-quality data for better breast cancer treatment options, decisions and outcomes. The project's efforts to overcome socioeconomic barriers and provide accessible technology for all patients and care providers are expected to enhance the quality of information and care provided to all breast cancer patients.

Collaborations with industry players to explore potential commercialisation and broader adoption of the developed technologies is also key. Economically, the project's final product, the CINDERELLA APP, is expected to increase cost-effectiveness in breast cancer treatment by optimising decision-making processes. The implementation of the CINDERELLA approach, which combines educational content and artificial intelligence-generated predictions of aesthetic outcomes, into the cloud-based CANKADO healthcare platform is designed to improve breast cancer patients' decisions regarding locoregional treatment. This aims to lead to more efficient use of resources and potentially lower costs due to optimised treatment pathways and reduced need for additional consultations and surgeries.

CHALLENGES AND LIMITATIONS, LESSONS LEARNT, FUTURE WORKS

The CINDERELLA Project faced several challenges, including delays in the clinical trial recruitment due to changes in key personnel and geopolitical events; technical issues in integrating multi-language support, particularly for Hebrew; and managing the balance between high-quality image processing and maintaining patient data privacy and security.

Key lessons learned during the project include:

• The importance of early and continuous engagement with all stakeholders to ensure smooth project execution.



- The need for flexible and adaptive project management to address unforeseen challenges • promptly.
- The value of multilingual educational content in enhancing patient understanding and engagement.
- Future works looking ahead, the CINDERELLA project plans to:
- Include more diverse patient populations and additional breast units across Europe. •
- Development of a brochure gathering key technical information of the technologies developed. •
- Further refine the AI algorithms based on clinical trial feedback to improve accuracy and user experience.
- Continue fostering collaborations with stakeholders to translate research findings into practical • applications, enhancing patient care and societal impact.
- Webinars organized/co-organized by the project inviting experts, researchers, and industry audience. • Events where the project will be invited to present its work and vision. All events will be communicated via the website and social media accounts.
- Develop a comprehensive go-to-market strategy to commercialise the CINDERELLA APProach and ensure its widespread adoption. Moreover, a brokerage event will be organised targeting the industry, end-users and investors with the aim to connect and promote the outputs/results and uptake after the end of the CINDERELLA project. These activities will take place after the release of a stable application version and after patients' recruitment.

The CINDERELLA Project exemplifies how integrating AI into healthcare can enhance shared decision-making and treatment outcomes in breast cancer care. By engaging a broad range of stakeholders, including patients, healthcare professionals, policymakers, advocacy groups, and industry partners, the project addresses existing challenges from multiple angles. This collaborative approach not only increases the likelihood of finding comprehensive solutions but also ensures that research findings have a direct and meaningful impact on patient care and societal health.





PROJECT INFO •

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PROJECT ACRONYM:

SalvOvar

PROJECT NAME:

A European multi-disciplinary clinical project meant to improve the management of patients with poor prognostic ovarian cancer after neoadjuvant chemotherapy

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COORDINATOR: Lyon University Hospital (HCL)

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CONSORTIUM: 11 Partners

DURATION: May 2023 - April 2028

WEBSITE: salvovar.eu







Lyon Ingénierie







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PROJECT PARTNERS

European Cancer Patient Coalition





Mrs Susannah Carroll





Ovarian carcinoma represents the fifth most common cause of cancer-related death in women worldwide (Torre et al., 2018²), making the search for effective treatment strategies a priority. The standard first-line treatment typically includes systemic chemotherapy (carboplatin-paclitaxel), complete debulking surgery, and subsequent maintenance therapy with targeted agents (the anti-angiogenic monoclonal antibody bevacizumab, and/or the DNA repair interacting PARP inhibitor). However, a subset of patients face poor prognosis (<20% 5-year survival) due to poor chemosensitivity (indicated by a CA-125 KELIM[™] score of <1.0) and unresectable disease following 3-4 chemotherapy cycles. Uncertainty persists regarding the optimal treatment approaches for this patient group.

SalvOvar is a pragmatic phase III trial which aims to evaluate the effectiveness of adjusting the dose and dosing schedule of chemotherapy for ovarian cancer patients with poor prognosis. It is a multidisciplinary clinical project, which has the following objectives:

- Propose practical and cost-effective diagnostic tools for identifying ovarian cancer patients with poor prognosis due to refractory disease after initial treatment
- 2. Assess the effectiveness, acceptability, and cost-effectiveness of therapeutic interventions based on early adjustments to medical and surgical treatments designed to improve overall survival.

The trial involves multidisciplinary partner organizations from across Europe and takes place in several countries. These include France, the Netherlands, Italy, United Kingdom, Czech Republic, and Israel, as well as the more recent addition of Japan, with additional countries to be confirmed. SalvOvar consists of nine work packages carrying out the different project components, from the randomised phase III trial to statistical analyses, homogenization of surgery outcomes, economic evaluations, as well as quality of life and patient reported outcomes. One work package focuses specifically on assessing the determinants of the treatment decision-making process by both patients and physicians involved in the trial. As a result of these various components, numerous opportunities arise for the involvement of stakeholders to enhance the value of the project and its findings.





² Torre, L. A., Trabert, B., DeSantis, C. E., Miller, K. D., Samimi, G., Runowicz, C. D., Gaudet, M. M., Jemal, A. & Siegel, R. L. (2018). Ovarian cancer statistics, 2018. CA: A Cancer Journal for Clinicians, 68: 284-296. <u>https://doi.org/10.3322/caac.21456</u>

INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT

Research on shared decision-making

An important component of the SalvOvar project is its focus on measuring patient preferences and patientcentred decision-making in a dedicated work package (*WP 3- Determinants of the treatment decision-making process by physicians and patients in the context of therapeutic uncertainty*). This WP sets out to investigate the determinants of the treatment decision-making process faced by patients and clinicians within the trial, regarding multiple decisions: the addition of bevacizumab to chemotherapy, delayed cytoreduction surgery in patients considered initially not amenable to surgery, and maintenance treatment (bevacizumab and/or PARP inhibitors). Ultimately, this work aims to inform the development of a future tool for shared decisionmaking (SDM) in situations of therapeutic uncertainty. A mixed methods programme of investigation has been initiated, involving key stakeholders at several moments.

The integration of stakeholders' views has been considered fundamental from the project outset, acknowledging the numerous benefits of incorporating these perspectives – from enhancing the relevance, quality, and impact of study findings, to considering ethical issues and maintaining the focus on what matters most to those affected. The stakeholders involve primarily cancer patients, but also healthcare professionals, some participating in the clinical trial and some external to the study, family members and carers, patient advocates, and research experts. Several activities are planned, some of which have already commenced, while others are scheduled to begin over the duration of the project. These include:

- Establishment of a patient and clinician advisory group to advise on project design, implementation and findings.
- Engagement of researchers, patients, and clinicians in the formal translation of patient-reported outcome measures
- Collaboration with two cancer support organizations for expert advice and enhancement of the communication around the project
- Involvement of patients and clinicians to help design and provide feedback on a digital tool for SDM.

Patient & Clinician Advisory Group

An initial task within the project was to set up an advisory group comprising of patients and clinicians to reflect the perspectives of those involved in the trial, i.e., ovarian cancer patients and treating physicians. The purpose of this group is to guide the development and execution of the work package. Best practice guidelines





were followed to help recruit and involve patients in the research (e.g., Arumugam et al., 2023³; Cancer Research UK, 2023⁴; Kaisler & Missbach, 2019⁵; NIHCR, 2024⁶; NIHR, 2010⁷). Recruitment took place through project social media platforms, local and international patient organizations (including a partner organization), healthcare centres, and personal networks. Thus far, the group has provided valuable feedback on a conceptual model of decision making that was developed for the project. The group also reviewed and tested the questionnaire and interview materials and provided comments on important ethical issues to be considered. At a later stage, involvement is planned to include practice interviews to facilitate interviewer training, interpreting the study results, and disseminating study findings to diverse audiences. In this way, the role of the group will extend throughout the project, helping to shape the study and ensure that stakeholders' perspectives are consistently considered.

Translation of patient-reported outcome measures

As part of data collection for WP 3, patient and clinician questionnaires are planned in at least four countries to collect experiences and perceptions surrounding treatment decision-making. These questionnaires, comprised of various self-report measures, require translating into the respective languages. The translation process used by the work package team adheres to international guidelines for translating patient-reported outcome measures (Beaton et al., 2000⁸; Muñiz et al., 2013⁹; Wild et al., 2005¹⁰), and involves forward-back translations, input from the original scale authors where possible, as well as testing the proposed translations with a group of users in the target languages.

¹⁰ Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A., Erikson, P., & ISPOR Task Force for Translation and Cultural Adaptation. (2005). Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value in health: The journal of the International Society for Pharmacoeconomics and Outcomes Research, 8(2), 94–104. https://doi.org/10.1111/j.1524-4733.2005.04054.x





³ Arumugam, A., Phillips, L. R., Moore, A., Kumaran, S. D., Sampath, K. K., Migliorini, F., Maffulli, N., Ranganadhababu, B. N., Hegazy, F., & Botto-van Bemden, A. (2023). Patient and public involvement in research: a review of practical resources for young investigators. BMC rheumatology, 7(1), 2. https://doi.org/10.1186/s41927-023-00327-w

⁴ Cancer Research UK. (n.d.). Patient involvement toolkit for researchers. Retrieved April 25, 2023, from <u>https://www.cancerresearchuk.org/funding-</u> for-researchers/patient-involvement-toolkit-for-researchers

⁵ Kaisler, R. E., & Missbach, B. (2019). Patient and Public Involvement and Engagement: A 'How To' Guide for Researchers. DOI: 10.5281/zenodo.3515811

⁶ National Institute for Health and Care Research. (2024). Resources and training for public involvement in research. Retrieved from https://www.learningforinvolvement.org.uk/

⁷ National Institute for Health Research. (2010). Patient and Public Involvement in Health and Social Care Research: A Handbook for Researchers by Research Design Service London. London, UK: The National Institute for Health Research.

⁸ Beaton, D. E., Bombardier, C., Guillemin, F., & Ferraz, M. B. (2000). Guidelines for the Process of Cross- Cultural Adaptation of Self-Report Measures. Spine, 25(24): 3186-3191.

⁹ Muñiz, J., Elosua, P., & Hambleton, R. K. (2013). Directrices para la traducción y adaptación de los tests: segunda edición. Psicothema, 25(2), 151-157. https://doi.org/10.7334/psicothema2013.24

The original scale authors of all proposed measures were contacted for permission to use the instruments, and additionally invited to participate in the translation process. This participation includes reviewing and providing feedback on the proposed translations, and if desired, taking part in the validation of the measures. Several scale authors expressed an interest in this process and have been participating throughout the process.

In addition, five cancer patients and five clinicians from each respective country, all native speakers of the target languages, are reviewing the translated measures. This involves checking the clarity, comprehensibility, and cultural appropriateness of the wording. An interviewer in each country conducts structured one-to-one interviews with participants to gather feedback on their understanding, difficulties, and suggestions for improvement.

Participation of two cancer support organizations for their expert input

Two cancer patient organizations have been involved since the project's original submission. A large Europelevel organization assisted in establishing the patient & clinician advisory group, providing feedback on the recruitment documents to ensure that the wording was appropriate and complied with legal and ethical standards, as well as helping to find participants. Another local ovarian cancer organization will be involved in SalvOvar throughout the trial and will serve as a point of contact for questions and feedback on practical or ethical issues. This ongoing involvement ensures that the patient perspectives and voices are consistently heard and integrated into the research.

Development and Testing of a Shared Decision-Making Tool

Drawing on the collective data from the mixed methods research in WP 3, a digital tool will be developed to enhance shared decision-making in clinical encounters. Patients will be invited to design, test and provide feedback on the tool, ensuring it is accessible, user friendly, and effective in addressing their needs and preferences. Similarly, the involvement of healthcare professionals will ensure the tool is practical and relevant for use in their own settings.











CHALLENGES AND LIMITATIONS, LESSONS LEARNT, FUTURE WORKS

In the context of a multinational clinical trial, several challenges and limitations may present when involving stakeholders. The reflections in this section pertain to the lessons learned thus far. As the project progresses and learning continues, these insights will undoubtedly expand.

Recruiting the advisory group of patients and clinicians posed a number of challenges. Many of the patient organizations and countries involved had specific guidelines and regulations for the relevant documentation. Consequently, documents such as information sheets and consent forms needed approval from multiple institutions and organizations. Confidentiality agreements were also required due to the trial being in its early stages and not yet approved. Finding patients with ovarian cancer who were willing and available to participate, along with clinicians with sufficient availability, was a further challenge. Logistical barriers further complicated recruitment, particularly when trying to schedule participation to accommodate multiple individuals' availabilities. Lessons learned from these challenges include leveraging patient organizations and social media channels to improve recruitment efforts and recognizing the value of personal contacts and referrals for identifying potential interested participants.

Ensuring diverse representation within stakeholder groups may also be challenging. In the case of SalvOvar, efforts were made to include a range of participants from various age groups, countries, and backgrounds, as well as professionals with various levels of experience, within the tight timelines of this initial stage. Despite these efforts, achieving representation from all countries and groups was challenging. The small group of patients and clinician ultimately recruited for the initial feedback tasks did not fully capture the intended diversity, highlighting the need for ongoing efforts to seek more representative viewpoints. This experience highlights the importance of targeting recruitment strategies more widely to ensure representative participation.

Sustained engagement with stakeholders presents additional challenges for various reasons. Patients' disease progression, the emotional burden of taking part in a heavy subject, or declining interest or availability over time may prevent sustained involvement of all participants. This highlights the importance of adapting engagement strategies to account for evolving circumstances and maintaining flexibility in the level of involvement of individuals.

A further point concerns the need to convey complex medical information about a clinical trial in an effective and appropriate way. When working with patient representatives from various backgrounds, it was important that written and verbal information was communicated clearly, and additional resources such as glossaries, further reading materials, and the contact details of a clinician from the work package were provided for any questions on complex medical topics. A contact person from the patient organization was also available



should patients have felt they could have benefited from this. Indeed, unease about language skills (given that group discussions were held in English) was a concern for some patients. Building rapport and having members on the research team who were able to communicate in the respective languages, or who could access translations easily, facilitated this process.

While the feedback provided by stakeholders across various activities was valuable and relevant, there were some cases where regulatory and technical constraints restricted the ability to implement all suggested changes. For example, certain sociodemographic details could not be captured in some countries, and some suggested modifications to the electronic Case Report Form layout and format were not technically possible. This reflects the delicate balance between accommodating feedback and adhering to regulatory requirements and the importance to inform stakeholders of the constraints applicable to research projects.

Finally, there is a lot of discussion around the issue of compensation of participation in stakeholder engagement activities such as Patient and Public Engagement (e.g., Arumugam et al., 2023; Cancer Research UK, 2023; Kaisler & Missbach, 2019; NIHCR, 2024; NIHR, 2010). Guidelines stress the need for consideration and clear communication about expectations from the outset. The discussion around appropriate remuneration for stakeholder involvement in research remains complex, particularly when navigating differing regulations across countries and institutions. The logistical issues of arranging (often relatively small) individual payments can be complex. Nevertheless, given the time and effort that stakeholders dedicate to enhancing a project, clear approaches for recognition are essential. Ultimately, the ongoing involvement of stakeholders at various levels has and will continue to be key in ensuring that the project findings are meaningful and impactful to all those involved.





PROJECT INFO •

PROJECT ACRONYM:

JANE

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PROJECT NAME: The Joint Action on Networks of Expertise

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COORDINATOR: La Fondazione IRCCS Istituto Nazionale dei Tumori

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EU JOINT ACTION

ON CANCER

NETWORKS OF EXPERTISE

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CONSORTIUM: Associations from 16 countries all around Europe

DURATION: October 2022 – September 2024

WEBSITE: jane-project.eu



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SYNOPSYS

The Joint Action on Networks of Expertise (JANE) arises from one of the proposals put forward by the European Union (EU) as part of its renewed commitment to address the needs for cancer prevention, treatment and care in response to the global challenges posed by cancer in Europe. In addition to the European Reference Networks for rare cancers, two new types of networks, the Comprehensive Cancer Centre Networks (CCCs) and these Networks of Expertise (NoEs), are envisaged to be established in Europe with the main objective of ensuring high standards of cancer care.

Specifically, the JANE Joint Action aimed to establish seven NoEs focusing on cancer-related issues in the areas of complex & poor prognosis cancers, palliative care, survivorship, personalised primary prevention, omics, high-tech medical resources, and adolescents & young adults with cancer. These areas are expected to benefit from cross-border cooperation and EU expertise, linking experts and bringing their expertise across Member States (MSs). In this sense, the NoEs will provide services to the European cancer community, aiming to contribute to the development of guidelines and best practices and to facilitate research and innovation, enhance education and training, and strengthen health policies at regional, national and European levels, supporting the concept of "network of networks" between the different Member States.

This Joint Action had a total of 24 months to critically evaluate existing models of current and future EU networks, research infrastructures and platforms in order to properly design these new networks, and also to prepare everything necessary for their definition. The follow-up Joint Action (JANE-2), which is expected to start in the last quarter of 2024, will enable the final launch of the seven NoEs and allow them to start fulfilling their mission.



INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT

The establishment, implementation and operation of this type of network requires the involvement of a variety of profiles with different levels of expertise from the very beginning. The collaboration and support of stakeholders in the oncology community will make it possible to identify the needs, challenges and opportunities that will allow these networks to have a significant impact on the European ecosystem in the future. The JANE consortium worked on the preparation of actions that foster collaboration and knowledge sharing between all EU Member States, leading to the delivery of different services and ultimately to the improvement of health policies at national and European level. Within the JANE work packages (WPs), the WP4 on sustainability supported the development of strategies to ensure the sustainability of networks and





their alignment with European and national policies. This WP included two tasks related to the involvement of different key external actors in JA, which are explained below.

Policy Board and Policy Dialogues

The **Policy Board of JANE** is an external board composed by policy-makers at different decision levels. The members of this panel were nominated and invited to participate by the Competent Authority of each MS. During the development of this JA, JANE has had the participation of 16 representatives for each of the MSs of the consortium, as well as the additional representation of a Policy Board representative for Slovenia on behalf of the coordination of the European Network of Comprehensive Cancer Centres Joint Action (CraNE).

The role of the Policy Board is to provide guidance and input on policy recommendations for European NoEs in JANE on the best knowledge, skills and facilities and on European and national policies for sustainability. This Board has been involved in several online events during the Joint Action. Initially, after nomination and formal invitation to be part of this Board, informal online coffee meetings were held with the different representatives of the Policy Board, with the main aim of introducing and contextualising JANE, gathering initial reactions to the JA approach and discussing the potential impact that NoEs can have on the cancer care ecosystem in Europe.

Two **policy dialogues** were then organised, inviting these representatives to engage in deliberative conversations on issues important to the sustainability of JANE JA.

The first JANE Policy Dialogue was held on 3 October 2023 with the participation of the Policy Board members from 7 countries (Germany, Croatia, France, Lithuania, Norway, Portugal and Spain) and a total of 75 online participants. The event featured two keynote speakers, Jean-Yves Blay, the ERN-EURACAN coordinator with the communication "Key aspects related to the strengthening of collaboration mechanisms in Europe - How could networking between different organisations (CCCs, ERNs, societies, patient advocacy) be promoted", and Matthias Schuppe, Deputy Head of Unit in DG SANTE B.1: Cancer, Health in all Policies, with the Communication "EC expected impact from the NoEs: alignment with European and national policies". The discussion highlighted the importance of creating a knowledge platform where challenges, legislation, success stories and strategies can be shared, and the need to organise such meetings, dialogues, between Member States in order to move forward in the fight against cancer in Europe, based on mutual learning.

The second JANE Policy Dialogue was held on 27 June 2024 with representatives from 8 countries (Croatia, France, Germany, Hungary, Lithuania, Norway, Portugal and Spain) and 82 online participants. For this Policy Dialogue, the JANE consortium had the opportunity to count on keynote presentations by Markus Kalliola, coordinator in the EU Joint Action Towards the European Health Data Space - TEHDAS, with the presentation





'Interoperability: work towards JANE2'; and on the interactive workshop by Suszy Lessof and Yulia Litvinova from the European Observatory on Health Systems and Policies - OBS (Observatory Brussels hub and Observatory Technical University of Berlin hub) on building sustainable networks. Discussions focused on the challenges of the European Health Data Space (EDHS) and an open dialogue on the costs of health networking as an important tool for knowledge sharing between Member States.

Stakeholder Forum

The **Stakeholder Forum** is a space for discussion and collaboration between key actors in the cancer ecosystem, including Networks of Expertise, civil society, academia, the private sector and other relevant stakeholders. This space facilitated the exchange of expertise, experience and views and networking between Stakeholder Matrix members and JANE participating organisations, creating common understanding and building synergies and partnerships that support JANE and the current and future needs of NoEs, discussing issues of mutual interest.

The **JANE Stakeholder Matrix** is an external body composed of stakeholders who have an interest or a stake in the establishment of the NoEs, who are both impacted by them and who can have an impact on the JA itself. The role of the representatives in this matrix is related to provide input and establish links that could led to foster collaboration, share progress, and explore opportunities to strengthen the impact and sustainability of the future JANE Joint Action NoEs.

This stakeholder matrix was developed through a three-step iterative process with feedback from JANE partners (Figure 2). The first step was to identify relevant non-exclusive sectors/categories, secondly to list key organisations within these sectors/categories and finally to approach individuals as proposed members for the JANE Stakeholder Matrix. As a result of this process, the stakeholder matrix includes a total of 88 members from 54 organisations.



Figure 2. Definition of the Stakeholder Matrix of JANE



The JANE Stakeholder Forum was held on 16 November 2023 and brought together a total of 133 people in a hybrid format that included a face-to-face meeting in Barcelona and the opportunity to connect online. Eleven stakeholders from seven European countries (Spain, Malta, Portugal, Germany, Slovenia, Belgium and Luxemburg) attended the Forum and shared their impressions and knowledge.

Topics discussed among the experts included the added value that NoEs can bring to the European cancer health ecosystem and how external organisations can contribute to establishing and running these networks. There was also a roundtable discussion on patient involvement in NoEs. This session included a dialogue between two patient experts, Kristof Vanfraechem from Data for Patients and Wannes Van Hoof from Sciensano as JANE patient involvement leader.

Engagement of additional stakeholders

As mentioned above, strategic partnerships with existing organisations and stakeholders are essential to create synergies and increase the value of the network. Therefore, during JANE JA, additional stakeholder engagement strategies were developed to explore new opportunities and potential synergies.

Although all stakeholder contacts have the same purpose, we can differentiate these different actions according to how these key actors have been involved and the role they have played or will play for the NoEs. These three types of involvement can therefore be distinguished:

- Informative knowledge diffusion. Stakeholder target audience for communication and dissemination purposes (WP2 - Dissemination)
- Consultative. Representatives that are involved in the Policy Board, Stakeholder matrix (WP4 -Sustainability) or as members of the JANE Advisory Board (WP3 – Evaluation)
- **Collaborative participation**. Stakeholders that are being contacted for the different NoE leaders to be part of the networks in future or to stablish potential synergies (all NoEs)

It should be noted that in some cases the same stakeholder was able to participate in two or more of these roles and that some of them will be among the beneficiaries of the future JA JANE2.









CHALLENGES AND LIMITATIONS, LESSONS LEARNT, FUTURE WORKS

During the first two years of activity, JANE partners have had the opportunity to explore the current state of cancer care in the European ecosystem in different areas of interest to NoEs, as well as to explore the main challenges that this system of networks of collaboration could pose for the community. In this sense, the JANE Consortium has prepared a Green Paper "*Healthcare networking on cancer in the EU: a 'green paper' for open discussion*" which addressed some of the challenges and problems by posing a series of open questions to the community in order to promote dialogue on these issues.

With regard to the specific challenges encountered to date related to stakeholder collaboration, the following can be noted. Firstly, the use of English as a vehicle language in projects of this type sometimes makes it difficult to find profiles that can interact at certain levels and have a sufficient mastery of the language. Although this is something that can be solved at the project, meeting or communication level with the use of tools and support measures (e.g. translation of communication materials into different languages), it is a challenge to address in the future for implementation of the NoEs.

Secondly, we found that there are different types of organisations working on similar issues in the European cancer ecosystem. Identifying possible synergies with these actors to create alliances and collaborations, without leading to duplication of activities or efforts has been challenging. The NoE representatives have focused on a variety of actions to boost synergies and avoid overlaps such as the preparation of a scheme for the discussion about the alignment of the objectives of the seven NoEs and other networks as ERNs, CCCIs, scientific societies, research groups educational providers, in addition to other organisations at national level.

Finally, several partners performed stakeholder outreach activities, generating contacts with different stakeholders and inviting them to participate in different events. Clear indications on the contribution nature and level are key to avoid confusion of the external members about what to expect from them. JANE 2 will need to take these aspects into consideration to maximize the involvement in specific activities of the stakeholders and learning capacity. To this end, a matrix could be created, specifying the level of responsibility or function of certain stakeholders (informative, consultative or collaborative role) and the type of activities or networks in which they will be involved. Project stakeholder management would facilitate the coordination of interactions between project members and stakeholders in the different activities that may take place.

As a final remark, it is important to note that key partnerships will be crucial for NoEs, also to ensure the interplay with MSs, and other EU cancer networks and structures such as CCC (such as CraNE), CCN and ERNs. Formal integration of other entities such as scientific societies, patient advocacy groups, and research institutes are also highly encouraged. All these partnerships could help to ensure the sustainability of the networks over time.





Qradioval

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PROJECT INFO •

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PROJECT ACRONYM:

RADIOVAL

PROJECT NAME: International Clinical Validation of Radiomics Artificial Intelligence for Breast Cancer Treatment Planning

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COORDINATOR: University of Barcelona

CONSORTIUM: 16 partners from 13 countries

DURATION: September 2022 - August 2026

WEBSITE: radioval.eu

PROJECT PARTNERS



Nordic Healthcare Group



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INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT IN CANCER-RELATED EUROPEAN PROJECTS



SYNOPSYS

Breast cancer is now the most common cancer worldwide, surpassing lung cancer in 2020 for the first time. It is responsible for almost 30% of all cancers in women and current trends show its increasing incidence. Neoadjuvant chemotherapy (NAC) has shown promise in reducing mortality for advanced cases, but the therapy is associated with a high rate of over-treatment, as well as with significant side effects for the patients. For predicting NAC respondents and improving patient selection, Artificial Intelligence (AI) approaches based on radiomics have shown promising preclinical evidence, but existing studies have mostly focused on evaluating model accuracy, all-too-often in homogeneous populations.

RadioVal is the first **multi-centre**, **multi-continental and multi-faceted clinical validation of radiomics-driven estimation of NAC response in breast cancer**. The project builds on the repositories, tools and results of five EU-funded projects from the AI for Health Imaging (AI4HI) Network, including a large multi-centre cancer imaging dataset on NAC treatment in breast cancer. To test applicability as well as transferability, the validation takes place in eight clinical centres from three high-income EU countries (Sweden, Austria, Spain), two emerging EU countries (Poland, Croatia), and three countries from South America (Argentina), North Africa (Egypt) and Eurasia (Turkey). RadioVal is developing a comprehensive and standardised methodological framework for multi-faceted radiomics evaluation based on the FUTURE-AI Guidelines, to assess Fairness, Universality, Traceability, Usability, Robustness and Explainability. Furthermore, the project introduces new tools to enable transparent and continuous evaluation and monitoring of the radiomics tools over time. The RadioVal study is being implemented through a multi-stakeholder approach, considering clinical and healthcare needs, as well as socio-ethical and regulatory requirements from day one.

INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT

Stakeholder Engagement in RadioVal

One of RadioVal's objectives is to implement a multi-stakeholder approach to improve awareness, interest, and trust in radiomics-driven artificial intelligence in future breast cancer care. As such, the involvement of all key stakeholders of the RadioVal tool is of vital importance.





The Social Innovation Framework

In the RadioVal project, social innovation is decisive in providing practical insights into how the implementation of new technologies and services can be enhanced in specific societal systems pathways and practice: cancer imaging and its application for NAC prediction.

The RadioVal social innovation framework was designed mainly building on three methods: **Service ecosystems** – focused on the importance of social norms and common symbols for collaboration and creation of innovation¹¹, **Reflexive Interactive Design** – which focus the deliberation on the simultaneous design of technical and social features of systems¹², and **Design Thinking** – which centres on the study of the needs of users, built on how designers progress during the design process, with creative ideas and solutions designed to discover new opportunities¹³.



¹¹ Elliff, C. I., & Kikuchi, R. K. P. (2015). The ecosystem service approach and its application as a tool for integrated coastal management. *Natureza & Conservação*, 13(2), 105–111.



¹² http://actioncatalogue.eu/method/7437

¹³ Ferreira Martins, H., Carvalho de Oliveira Junior, A., Dias Canedo, E., Dias Kosloski, R. A., Ávila Paldês, R., & Costa Oliveira, E. (2019). Design Thinking: Challenges for Software Requirements Elicitation. *Information*, *10*(12), Article 12.

The overall Social Innovation Framework for RadioVal is depicted in Figure 3, guiding the procedures on how to optimally involve all relevant stakeholders, ensuring that their needs, wishes, fears and challenges are considered during the development of the RadioVal solutions.

Stakeholder Mapping

Stakeholder mapping is a well-recognized tool in the field of business and project management and policy making^{14,15}. Stakeholders can be defined as individuals, groups and organisations who have a "stake" (influence, interest, power, or another kind of relevance) in relation to an organisation, policy or project (adapted from Freeman R. E. , 1984)¹⁶. Mapping starts with outlining the scope or context of the object of interest, followed by the stakeholder analysis. The stakeholder analysis, as the central element of the stakeholder mapping, comprises identification of stakeholders, their visual categorization of stakeholders and exploration of inter-stakeholder relationships regarding the object of interest, after which the stakeholder engagement phase can begin (see Figure 4**Erro! A origem da referência não foi encontrada.**).



Figure 4. Key steps in the stakeholder mapping process.

Stakeholder mapping is a continuous exercise as the environment around the object of interest may dynamically change, the line-up of the stakeholders evolves, and the relationships between stakeholders fluctuate. Therefore, the stakeholder mapping may take several iterations over time within RadioVal, as it is considered a living process.



¹⁴ Brugha, R., & Varvasovszky, Z. (2000). Stakeholder analysis: A review. *Health Policy and Planning*, *15*(3), 239–246. <u>https://doi.org/10.1093/heapol/15.3.239</u>

¹⁵ Freeman, R. E. (1984). *Strategic Management: A Stakeholder Approach*. Pitman.

¹⁶ Freeman, R. (1984). Strategic Management: A Stakeholder Approach. Boston: Pitman.

This visualisation of the stakeholders' attributes, characteristics, and relationships can be performed through a variety of methods and techniques, from a power-interest matrix to a more complex Stakeholder Circle^{*} visualisation tool and 3-D modelling¹⁷. The attributes, which most commonly fall under investigation are stakeholders' influence, power, interest, attitude, and legitimacy¹⁸.

The process started with an initial set of stakeholders that were identified during the proposal preparation and that was further refined during an interactive brainstorming session with all project partners. Subsequently, an in-depth stakeholder expansion took place by finding answers to several questions like "Who else will be affected?", "Who else are the potential allies and opponents?", and "Who can contribute financial or technical resources?", which lead to the following set of stakeholders:

- Patients & Carers
- Healthcare Professionals
- Hospital Administration
- Ethicists & Regulators
- Policy Makers & Health Authorities
- Al Developers & Industry
- Payors

Based on these categories and on the co-creation exercises developed, the power and interest analysis showed that, for RadioVal, healthcare professionals have the highest levels of power and interest in terms of the successful deployment and clinical use of tool. The payors, ethicists and social scientists, and patients and carers have the least level of power, while regulators have the least level of interest.

Multi-Stakeholder Sessions

Building on the framework and mapping, three rounds of social innovation sessions were designed, adapted to the maturity of the technological solution. The four areas of service ecosystems were explored in different questions towards the identification of challenges and needs: actors, technology, resources and the institutions – health systems. The sessions were prepared following a design thinking approach for the search of creative solutions and seeking discussion between the identified stakeholders that could overcome



¹⁷ Cenek, M., & Částek, O. (2015). A Survey of Stakeholder Visualization Approaches. *Central European Journal of Management*, 2(1,2), Article 1,2. https://doi.org/10.5817/CEJM2015-1-2-1

¹⁸ Chinyio, E., & Olomolaiye, P. (2009). *Construction Stakeholder Management*. John Wiley & Sons.

consensus and reach deliberation. Deliberation was not always possible, namely due to the early stage of the project technical solutions but will be further considered for the upcoming sessions as the project evolves.

The participants in the sessions consisted of representatives of the project partners, experts directly invited by consortium partners, and people who applied through an open call launched on the media channels of the project to take advantage of external expertise and diverse viewpoints. Seventeen experts external to the project consortium, including ethicists, health authorities' representatives, and clinicians, from 11 different countries, were invited to join the second and third rounds of the multi-stakeholder sessions.

The first social innovation session – the "science cafes" – was designed to lead to a set of requirements for the design and implementation of the RadioVal tools. In the second round – "ideation workshops" – different techniques were applied resulting in a framework for contextual implementation of the RadioVal tools. Additionally, in this second round, sessions with healthcare professionals and AI developers were conducted around the FUTURE-AI guidelines. The third and final round of sessions – Prototype deliberation – consisted of a presentation of low- and high-fidelity mock-ups to the stakeholders to evaluate, validate and comment the captured requirements.

Requirements Framework

In RadioVal, requirements are used as a framework for translating the needs, wishes and desires of stakeholders into a language that can be understood by the technical partners in the Consortium. The focus is on eliciting clinical, socio-ethical, legal, and regulatory requirements through a combination of the social innovation sessions described earlier, as well as desk research, and workshops with patients.

Analysis of the project's official documentation (Grant Agreement) and the social innovation sessions led to the definition of a set of 184 requirements, consisting of Business Requirements (describing high level project aims), Stakeholder Requirements (describing the needs and wishes of stakeholders), and Regulatory Requirements (describing legal and ethical boundaries).

The requirements elicitation and verification process are described in Figure 5 below, defining an end-to-end process from engaging stakeholders through delivering the RadioVal solution, making sure that no information is lost along the way. In terms of future work, it is of utmost importance that the generated list of requirements becomes the measuring stick on how well the project is performing. Tracking the progress on each requirement and making sure that appropriate responsibilities are assigned for each "must have" and "should have" requirement and reflecting on this process at key points during the remainder of the project's lifespan.





CHALLENGES AND LIMITATIONS, LESSONS LEARNT, FUTURE WORKS

When working through the process described above, we have encountered several challenges from which we can learn to improve methods in future projects. First of all, a Research and Innovation project of this scope has several moving parts, and the nature of innovation means that it is sometimes difficult to plan. While the project timeline sometimes dictates that certain activities should take place before a certain date (e.g. X stakeholder workshops before month Y), in reality a workshop may be better postponed while waiting for the completion of another project task. Thus, flexibility and close connection between partners, activities and outcomes are needed.

A second challenge relates to getting all crucial stakeholders at the table. In this project, healthcare professionals, AI specialists, ethicists, and technologist are all well represented, which has been instrumental in getting those stakeholders involved at the right place and the right time. However, others, such as payors and policy makers are less easy to engage on a constant manner. A flexible approach to other engagement strategies, such as interviews, policy events and roundtables are needed to engage such stakeholders. The work of the European Commission in gathering such actors in joint events between projects can be of enormous value.

The third key point is the changing nature of the societal landscape, which implies a constant change of the challenges, needs, regulations, political and economic priorities. Again flexibility in adapting to such change and seeking the best possible solutions at each time is key to ensure that the project's outcomes will be relevant, useful and impact the quality of life of cancer patients in the future.

WEBSITE: cancermissionhubs.eu

April 2023 – March 2026

DURATION:

CONSORTIUM: **61** Partners

COORDINATOR: Agência de Investigação Clínica e Inovação Biomédica (AICIB)

PROJECT NAME: Establishing of cancer mission hubs: networks and synergies

ECHoS

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PROJECT ACRONYM:

PROJECT INFO

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SYNOPSYS

Cancer is a major and growing societal challenge. The increasing incidence of cancer and the introduction of expensive innovative diagnostics, therapeutics, and care interventions makes it an everyday growing economic burden to European healthcare systems. To face this reality, the European Commission has set ambitious and innovative collaborative efforts, as part of the European Beating Cancer Plan (EBCP) and of Horizon Europe (HE), to integrate cancer control measures based on the outputs of fundamental, translational, and clinical research. Alongside this, the EU has invested in several innovation measures to foster R&I in the private sector, as well as to enable greater citizen participation, together with policy, and legislation support. While the organization of cancer awareness and control initiatives at various levels is laudable, there is a potential concern that a disconnected approach may dilute efforts and bring confusion to citizens, in addition to researchers and healthcare professionals.

Through Cancer Mission, EC appeals Member States and Associated Countries (MS/AC) to combine research, innovation, and policy development, in ways that cannot be achieved through individual and fragmented initiatives. The ambition of ECHoS is to further support the Cancer Mission by providing MS/AC with the capacity to gradually create National Cancer Mission Hubs (NCMHs) operating at national, regional and, where relevant, local levels. These NCMHs will have a key role in involving all relevant national, regional, and local stakeholders, including citizens, in cancer-related policy dialogues.

INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT

Multi-stakeholder identification, engagement and cooperation

Coordinated by Center for Innovation in Medicine (InoMed, Romania), the work package 3, *Multi-stakeholder Identification, Engagement, and Cooperation,* is dedicated to helping NCMHs identify, engage, connect, and enable traditional and non-traditional organized stakeholders to actively and impactfully contribute to the success of the Cancer Mission.

The objective is to establish connections and engage stakeholders to contribute to the success of cancer mission by (i) Develop suitable impact models for the Cancer Mission subareas that will contribute to the overall success of the Cancer Mission, by providing NCMHs with a blueprint to adapt to national context and priorities, allow them to rapidly engage relevant stakeholders and identify critical activities and necessary milestones. (ii) Based on impact models, systematically engage relevant stakeholder groups, and stimulate bottom-up cancer-mission activities, (iii) Foster multi-stakeholder co-operation by building a shared culture





around Cancer Mission. And (iv) Establish an interactive tool to map stakeholders across all groups in a way that enables new connections, and to encourage Mission activities among different stakeholders. More on Stakeholders identification will be available here: <u>https://cancermissionhubs.eu/</u>

CHALLENGES AND LIMITATIONS, LESSONS LEARNT, FUTURE WORKS

Mariana Mazzucato defined Mission-Oriented Research as a strategic approach to innovation centred around bold, ambitious and inspirational goals targeting relevant societal challenges. In Mazzucato's vision of Mission-Oriented Research, governments are not just funders of research, they are mission-setters and mission-partners – they define priority areas for investment and ambitious goals for missions, and they participate as a stakeholder. As a result, the interest of governments in mission-oriented projects' results increase significatively as they share missions' risks and successes. Unlike traditional research projects, mission-oriented research requires multisectoral collaboration between actors from policy & decision makers (representing governments and public interests) and academia (knowledge), industry (business) and civil society to deliver transformative and meaningful innovation results.

While Mission-Oriented research offers a promising approach to addressing societal challenges, it also faces significant challenges. One being the need for long-term commitment from multiple stakeholders, including public and private entities, and the promotion (and maintenance) of a collaborative environment which often tends to fade out in regular settings.

To address part of these challenges ECHoS is building up several tools such as the above-mentioned impact models, the interactive tool for stakeholders mapping, knowledge exchange events and a toolbox for citizens engagement. Moreover, ECHoS stakeholders' management initiatives are based on the Penta Helix model for multi-stakeholders' collaboration which extends the classical collaboration between state sector, private industry and academic institutions – commonly known as the triple helix model – to the non-profit sector, and citizens stressing the need for an environment of co-creation, co-design and co-implementation.

The Penta Helix framework adopted by ECHoS project was adapted to reflect the needs of the health and care sector, including research. Individual National Cancer Mission Hubs operating in each MS/AC should aim to incorporate representatives of i) Public administration, ii) Health and Care, iii) Knowledge and Academia, iv) Business sector and v) Citizens and Civil Society in their governance and operational structure. By understanding the interactions and dependencies between these stakeholders, organisations implementing Mission Driven innovation can engage more efficiently with the diversity of partners.



DURATION: May 2023 - April 2026

WEBSITE: cci4eu.eu

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CONSORTIUM: 26 Beneficiaries, 27 Affiliated Entities, 6 Third Parties

COORDINATOR: Organisation of European Cancer Institutes (OECI)

PROJECT NAME: Comprehensive Cancer Infrastructures for Europe

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EU

PROJECT ACRONYM: CCI4EU

PROJECT INFO

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INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT IN CANCER-RELATED EUROPEAN PROJECTS



The Comprehensive Cancer Infrastructures for Europe (CCI4EU) CSA is a European initiative aimed at strengthening the research capacities of Comprehensive Cancer Infrastructures (CCIs) across 27 Member States and 5 Associated Countries.

With a budget of approximately €9.98 million, the project, coordinated by the OECI, brings together 54 partners under a governance structure that fosters collaboration between major EU projects like UNCAN, CraNE, JANE, and ECHoS.

The core objectives of CCI4EU are to design and implement sequential steps that address the varying levels of CCI presence and maturity across Member States. Through these steps, CCI4EU seeks to:

- Define quality indicators and develop a Maturity Model to assess the strengths and weaknesses of CCIs.
- **Profile each country** based on their CCI presence and maturity levels, with an initial hypothesis suggesting wide disparities between Member States.
- **Design tailored capacity-building interventions**, prioritizing countries without established CCIs, and aligning these interventions with identified needs and maturity levels.
- **Deliver online training courses** to teams in Member States and Associated Countries, focusing on team-based learning to foster long-term impact.
- Implement onsite interventions, including deep dives in up to 9 CCIs in target Member States and regional conferences to encourage participation.
- Scale up and sustain development, evaluating the effectiveness of capacity-building programs and formulating recommendations for future EU-supported initiatives.
- **Disseminate results** widely through various formats to inform policymakers, professionals, and stakeholders, ensuring sustainability of the project's outcomes.

What is a CCI?

The Mission Board of the EU Mission on Cancer has defined Comprehensive Cancer Infrastructures as 'national or regional infrastructures that provide resources and services to support, improve and integrate cancer care, research, training of care professionals and education for cancer patients, survivors and families/carers.' The Horizon Europe Mission on Cancer will complement the set-up of an EU network of Comprehensive Cancer Centers across Member States that will be established through Europe's Beating Cancer Plan by 2025. The Mission aims to achieve the target of ensuring that 90% of eligible cancer patients have access to Comprehensive Cancer Infrastructures by 2030.







In that context, and in full complementarity and synergy with the actions foreseen under Europe's Beating Cancer Plan, this topic should set up capacity-building for Member States and Associated Countries to support them in improving or developing their existing or future Comprehensive Cancer Infrastructures, by helping develop their research & innovation-related capacities.



Figure 7. Comprehensive Cancer Network

Ultimately, CCI4EU envisions a Europe where every Member State benefits from strong, integrated cancer research and care infrastructures that work together to improve outcomes for cancer patients.



INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT IN CANCER-RELATED EUROPEAN PROJECTS

	Integrating Research with the Patient Pathway
	Citizens Screening Early detection Primary prevention - not covered in CCI4EU
Research and Innovation Themes for Capacity Building Discovery and translational research Clinical research Digital innovation Outcomes research	The Patient Pathway Diagnosis (pathology, radiology and molecular diagnostics) Surgery Radiotherapy Systematic therapies Patient-centered care
	Underpinning Infrastructures Human resources and education Clinical registries and real-world data Population registries Structures which ensure care continuity and equality of access

INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT

CCI4EU Stakeholder Engagement Practices

A crucial task of the CCI4EU project is **Task 8.2**, "Networking and bridging with other European initiatives and national authorities", which focuses on ensuring effective engagement and collaboration between the project and a wide range of relevant stakeholders, including other European projects and initiatives, national authorities, policymakers, health professionals, patient associations, and researchers. The engagement strategy used is designed to maximize the impact of the project and align its outputs with the needs and expectations of these key groups.

The key objectives of this task are:







- Maximizing Impact through synergies: by connecting with other ongoing EU cancer research • projects, the project aims to enhance its own contributions and ensure optimal use of shared deliverables. This includes identifying synergies across activities to avoid duplication and amplify the outcomes of the collective work.
- Aligning with stakeholder needs: through continuous dialogue and feedback, the project strives to • ensure that its results and milestones meet the expectations of its diverse target audience. This alignment is vital for translating research findings into practical, impactful solutions in cancer care.
- Providing a forum for exchange: task 8.2 creates platforms where stakeholders can engage in • discussions on the project's progress, milestones, and outputs. These platforms include the CCI4EU Project forum, the CCI4EU Stakeholder Forum and the CCI4EU Policy Forum, and are designed to enable the exchange of best practices, insights, and collaborative solutions that can advance the research capacities of CCIs across Europe.
- Strengthening national and EU collaboration: one of the overarching goals is to bring together • national cancer stakeholders and key EU counterparts, fostering a collaborative environment where challenges are addressed collectively and opportunities for improvement are identified.

The CCI4EU Stakeholder Forum was held on 30 September 2024, bringing together 219 participants from 34 countries, and providing a space for relevant stakeholders—such as researchers, patient associations, health professionals, and industry representatives—to receive updates on the project's progress, milestones, and outputs. The forum encouraged the sharing of experiences, results, and synergies between these stakeholders, ensuring they remained informed and involved. It also sought to bridge the gap between research and practice in cancer care.

For its Stakeholder Forum, CCI4EU leveraged the EU Health Policy Platform (EUHPP), a collaborative and interactive online tool moderated by DG SANTE that facilitates communication and discussion related to public health topics to enable stakeholders to exchange knowledge and good practices in a secure digital environment. Besides offering dedicated virtual spaces for people to communicate and discuss matters concerning European health policies, the EUHPP team can also host live webinars upon request.

By fostering ongoing communication and collaboration with a wide array of stakeholders, CCI4EU ensures that its objectives align with the real-world needs of cancer research and care communities across Europe.







INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT IN CANCER-RELATED EUROPEAN PROJECTS

CHALLENGES AND LIMITATIONS, LESSONS LEARNT, FUTURE WORKS

Due to the complexity and multi-national scope of CCI4EU, the stakeholder engagement efforts under WP8 face several challenges and potential limitations that require careful attention throughout the project. Its mission is to foster collaboration across countries with diverse healthcare systems and cancer care standards, supporting the development of robust cancer research infrastructures. WP8 involves a broad spectrum of stakeholders, including policymakers, healthcare professionals, researchers, patient associations, and industry representatives. Each group has its own priorities, which may lead to differing expectations, agendas, and levels of engagement. The challenge lies in building a collaborative environment that aligns these varied perspectives and keeps all parties meaningfully engaged over the course of the project.

The CCI4EU project spans 27 Member States and 5 Associated Countries, each with distinct languages, healthcare structures, and cultural approaches to cancer care. Communicating effectively across these cultural and linguistic divides is crucial for meaningful engagement but poses challenges, particularly when technical or specialized content is involved. To address potential language barriers, key project documents will be summarized in English and, where possible, in other major languages spoken within the consortium. Furthermore, local project activities will be conducted in national languages to maximize accessibility.

Collaborating with major EU projects such as UNCAN, CraNE, JANE, and ECHoS introduces opportunities for synergy but also potential challenges in maintaining a cohesive, non-overlapping framework. Aligning timelines, objectives, and activities across multiple initiatives requires careful planning and ongoing coordination. WP8 engages in cross-project meetings to identify and leverage synergies, prevent duplication, and streamline collaborative efforts. By keeping an open channel for communication, CCI4EU aims to maximize impact and ensure complementary work across all related initiatives.

A key challenge is establishing sustainable frameworks and practices that will continue to support CCIs and enhance cancer research capacity long after the project ends. Ensuring that the outcomes and recommendations from CCI4EU translate into lasting impact requires early planning and commitment from all stakeholders. The project team is committed to creating clear pathways for continued collaboration and setting up forums that can evolve into permanent platforms for cancer care and research dialogue. The CCI4EU Stakeholder Forum and Policy Forum will be essential in building long-term connections and preparing recommendations that align with future EU initiatives.

As CCI4EU continues, it will focus on refining and adapting its stakeholder engagement practices, prioritizing methods that are inclusive and sustainable. The lessons learned will guide future initiatives, setting a foundation for ongoing improvements in cancer care infrastructure across Europe. The establishment of these strong, interconnected infrastructures is envisioned to position Europe as a global leader in comprehensive cancer care and research, with equitable access to care and resources across all Member States.



PROJECT INFO

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PROJECT ACRONYM:

EUonQoL

PROJECT NAME:

Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe

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EUonQoL

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COORDINATOR: Fondazione IRCCS - Istituto Nazionale dei Tumori di Milano

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CONSORTIUM: 27 Partners

DURATION: January 2023 - December 2026

WEBSITE: euonqol.eu

PROJECT PARTNERS •

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SYNOPSYS

EUonQoL aims to develop, pilot and validate the EUonQoL-Kit, a patient-driven, unified system for the assessment of quality of life (QoL) based on evaluations and preferences of cancer patients and survivors. The EUonQoL-Kit is developed from a patient perspective, and will be administered digitally, available in the EU-27 and Associated Countries languages, and applicable in future, periodic surveys to contribute to the EU's Mission on Cancer. At the core of EUonQoL there is the adoption of a multistakeholder, co-design methodology, engaging patient representatives, healthcare professionals, administrators, policymakers, and citizens in all project related activities.

Existing QoL tools are being reviewed, scoping all relevant sources, aiming to be used in the context of the co-design consensus with stakeholders' and patients' preferences to identify gaps and establish all QoL dimensions that are relevant from the perspectives of patients, clinicians, and society. A multidisciplinary researcher panel, composed by talented experts is developing the EUonQoL-Kit that will be validated in a pilot survey using digital data collection within month 24 of the project. A total of 4,000 cancer patients and survivors will be enrolled through a network of EU cancer centres. An analysis of factors potentially impacting on cancer patients and survivors QoL, will also be performed. Implementation and exploitation strategies, as well as the linkage with other Cancer Mission projects and actions will be explored to develop future periodic surveys.

EUonQoL is composed by research institutions, cancer centres, as well as scientific, professional, and patient representative organisations involved in cancer research, all with extensive experience and robust scientific background in the development of self-report QoL measures. This partnership fuels the ambition of EUonQoL to translate QoL information into future changes in cancer care policy and clinical practice

INNOVATIVE PRACTICES FOR STAKEHOLDER ENGAGEMENT

The EUonQoL project is based on Patient and Public Involvement (PPI) research principles, which entails the active collaboration with patients and stakeholders throughout the research process. In this project, we do this by involving individuals with a current or past experience of cancer, either as a patient or as an informal caregiver, as 'co-researchers'.

In relation to the project aim, PPI in the EUonQoL project is employed to ensure that the toolkit that is being developed within the project, the EUonQoL-Kit, captures the aspects of quality of life that matter most to patients. Also, to safeguard that patient-facing materials in data collection and dissemination are tailored to needs and preferences of patients.



As a first step, a varied group of co-researchers was recruited to the project to ensure a range of perspectives. The criteria for the recruitment of co-researchers included: being eighteen years old or above; living in a European country; having experience of cancer as a patient or an informal caregiver; having a good command of English; having the ability, equipment, and willingness to participate in online meetings; and having the ability and willingness to travel to in-person meetings. Also, extra attention was given during recruitment to diversity in age, gender, country of origin, cancer type, disease stage, and treatment phase.

Recruitment of co-researchers took place via a call for action that circulated on social media (LinkedIn, X) and through the newsletter of the Organisation of European Cancer Institutes (OECI). Potential co-researchers who expressed their interest, first received additional information via e-mail and were then invited for a video call to meet and to discuss their potential involvement. Following these interviews, six co-researchers were selected to be involved in the project.

One co-researcher dropped out of the project shortly after being recruited, however, the remaining five coresearchers have continuously been involved in the project. The co-researcher group consists of people with (past experience of) cancer as well as informal caregivers, and they originate from different countries in Europe.

After receiving training on the process and content of the research project, co-researchers engaged in various activities within the project. These activities include, but are not limited to: participation in online and inperson meetings, providing input on research methods and preliminary findings, aiding with the interpretation of results, reviewing reports and scientific papers, and giving presentations to external researchers and other stakeholders.

The specific individual roles, tasks, and responsibilities of co-researchers for their work packages are defined together with the researchers, evaluated continuously, and adapted when necessary. Ideally, co-researchers take on roles with certain degrees of decision-making power. However, this depends on the preferences of co-researchers in which role they want to participate.

Support is provided to the co-researchers on a regular basis by the researchers who are responsible for coresearchers' involvement. These meetings are organised every two weeks and aim to get to know each other better and to relate and share experiences of working as co-researchers. We also reflect on their roles and contributions in the various work packages and discuss specific topics of interest in more depth. If needed, we take action to improve their involvement in specific work packages or in the overall project. These regular meetings create a strong foundation and a sense of community that is essential to be able to work together well.

We also use the regular meetings with the co-researchers for continuous evaluations while at the



same time making notes of these discussions, to be able to map the context and process of PPI within the project at a later stage. In addition, researchers and co-researchers are asked four times a year to fill in a digital evaluation form in order to reflect on their collaboration and what benefits it brings. If relevant, several researchers in the various work packages are invited for an informal conversation to help reflect, in more depth, on the participation, and also to guide any adaptations that need to be made in the collaboration.

There are several specific tools or working strategies that we use in our collaboration with co-researchers:

- A project-specific Handbook and checklist were developed in the early stages of the project, to guide researchers in their collaboration with co-researchers
- A training workshop on co-researcher involvement has been developed and organized for all researchers involved in the EUonQoL project
- The Involvement Matrix is used whenever a new task or activity starts, to collaboratively discuss roles and responsibilities with co-researchers
- The PPI impact log is used to evaluate the collaboration between researchers and co-researchers
- The GRIPP2 reporting checklist will be used to systematically report on PPI within the research project
- On several occasions, we used Mentimeter during the meetings with co-researchers to promote interactive discussion

Besides patients and informal caregivers, other external actors are involved in the project as members of the Stakeholder Board. The Stakeholder Board was constituted based on a stakeholder mapping exercise. As an initial step, relevant stakeholders working in topics related to quality of life and mental health of people with cancer, as well as data infrastructure systems, were identified. After the mapping was completed, the identified stakeholders were contacted and invited to join the EUonQoL Stakeholder Board. Currently, the Stakeholder Board is constituted of eleven experts from different geographic backgrounds and with a wide range of expertise. The Stakeholder Board meets several times a year and discusses specific topics of interest that are decided by the project researchers.

CHALLENGES AND LIMITATIONS, LESSONS LEARNT, FUTURE WORKS

We learned that PPI requires significant time, effort, and resources to develop effectively within a project. PPI is inevitably a somewhat messy and complex process that requires a lot of work from researchers and corresearchers. We learned that the difficulties we experienced in this process were important aspects of the learning process.



Another lesson learned is the critical difference between equal and equitable collaboration. Treating coresearchers exactly like researchers can be counterproductive. Co-researchers often lack familiarity with formal research structures, procedures, and terminology, and contribute from a vulnerable position, frequently as a minority sharing personal experiences. Therefore, their collaboration needs are different from those of researchers.

Researchers need training as well, particularly if they are new to PPI. One of the challenges we encountered in setting up co-researcher involvement in the EUonQoL project, was that most of the researchers in the other work packages were doing PPI for the first time. It turned out they needed training and practical tools, which we provided in the form of a training workshop.

Additionally, support for co-researchers is vital, such as having a designated, trusted contact person for concerns they might not feel comfortable raising with the wider team. In line with this, we learned not to underestimate the added value of informal contact. A personal connection is important to be able to create good conditions for collaboration. Without strong connections and a firm grounding, it is difficult to build actual participation practices. Informal moments such as social activities, but also coffee breaks and lunch breaks, help to break down social barriers and increase approachability, which is essential to feel comfortable working together and providing critical feedback.

Finally, we learned that collaborating with co-researchers in an international, large-scale context such as the EUonQoL project, is different than collaborating in national, smaller-scale contexts. For instance, language and cultural differences play a role. Also, events in the development process mainly took place online. While this has become increasingly common after the COVID-19 pandemic, we do recognize that within online meetings it is harder to connect on a more personal level.



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