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ThermoBreast

Project No. 101096329

**An innovative non-contact and harmless screening modality set
to change the course of breast cancer detection and patient monitoring**

Deliverable 9.2

Common work plan for scientific collaboration under the "Prevention, including Screening" cluster

WP 9 – OUTREACH – Communication, dissemination and exploitation

Version 1.0

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Executive summary

This deliverable D9.2 refers to the initial common work plan for scientific collaboration under the 'Prevention, Including Screening' cluster. It defines the strategy for the clustered projects over the next period. This deliverable is a joint deliverable agreed upon with the rest project coordinators participating in the cluster. The deliverable initially presents the Mission Cancer programme and the participating projects of the cluster. It showcases the way the cluster projects are currently organised to align their efforts by sharing best practices. Subsequently, the areas of potential collaboration are described. There are two main pillars discussed that there is maturity in regard to the concrete actions: a) data and their usage as defined from common data management plan strategies, EHDS alignment, secondary use as Open and FAIR for the benefit of the project and b) Joint Communication activities. Beyond that, a series of further ideas for collaboration are presented dealing with joint publications, living labs, joint end-user requirements, inequalities observation and financial mechanisms for reinforcing cancer screening programmes; however, a further re-evaluation is needed in the forthcoming cluster meetings. A pathway that defines these next has been created and discussed, which also includes a stronger engagement of project partners into joint working groups to increase the joint efforts. Finally, further enhancing the joint impact synergies with other cancer clusters shall be examined, with a particular view on joint policy recommendation. Overall, to ensure the success of the cluster, an active engagement of project partners and project coordinator is needed under the guidance and support of HaDEA.

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Abbreviations

Abbreviation	Term
EC	European Commission
EHDS	European Health Data Space
EU	European Union
HEU	Horizon Europe
HaDEA	European Health and Digital Executive Agency
DMP	Data Management Plan
WP	Work Package

1 Introduction

This deliverable aims to provide an initial plan for the projects that participate in the Mission Cancer cluster of projects called "Prevention, including screening", aligning the joint efforts and the cross-fertilisation of activities to create a more significant impact towards the Mission Cancer ambitious goal of improving the lives of more than 3 million people by 2030.

The cluster was built with the scope of supporting the Mission objectives, creating added value, and increasing the impact of EU funding. The areas to be addressed are:

- Data Management
- Research & Innovation
- Communication & Dissemination
- Citizen Engagement
- Addressing inequalities
- Research Capacity Building

The collaboration should reduce overlaps, harmonise research methods and models to enhance science and policy outcomes, and work together on research capacity building.

The projects should also organise exchanges with citizens, including patients, to engage them and address their views. This could also be achieved during the scheduled annual meetings, where the cluster components should exchange strategies, best practices, and results of organised workshops.

Finally, the projects must develop common ideas on how they can contribute to reducing inequalities of care and improving access to care.

The cluster work will be harmonised with the involvement of different joint activities, starting from the draw-up of a common work plan for scientific collaborations.

This deliverable provides an Initial common work plan for all the projects and aims to highlight which are the similarities and the approaches that this collaboration can further valorise.

2 Deliverable objectives

This deliverable aims to define the initial plan followed over the next years from the project coordinator and project partners participating in the 'Prevention, including screening' cluster. Secondly, it provides a methodology for how the partners communicate and work. Furthermore, it defines the next steps.

3 The EU Mission on Cancer

Unquestionably, fighting cancer remains one of the most significant challenges for society. The disease affects every individual regardless of sex, age, gender or social status, tremendously afflicting not only patients, survivors and caregivers but society at large. Many causes that trigger the onset of cancer are related to unhealthy lifestyles and unfavourable social, environmental, and working conditions. Looking at the local situation, Europe is even more affected by the burden of cancer than other countries. The annual incidence is strongly off-balanced, considering the global context. Indeed, the European population represents 25% of the cases registered worldwide, even if it is only one-tenth of the global one. According to [European Cancer Information System](#), in the last years, around 2.7 million people received a tumour diagnosis, and about 1.3 million died from this cause ([source](#)). Without any intervention, about 3.2 million new diagnoses are estimated by 2035 (F. J. S. I. e. a. Bray F, «Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries» CA: a cancer journal for clinicians, vol. 68, pp. 394-424, 2018). The lives lost to cancer in the EU are set to increase by more than 24% by 2035. But 40% of cancers can be prevented.

The concomitant Covid-19 pandemic worsened the health systems and delayed countless cancer diagnoses, and therefore countries are overburdened with higher organisational and financial

pressure. This situation imposes the necessity to undertake urgent actions at many levels, such as ambitious extra-EU collaborations and strong efforts of EU member states, improvement of basic, translational, clinical and interventional research, as well as support with tailored policies and legislation.

On these grounds, European Commission launched Mission on Cancer (hereafter referred to as Mission), (*Figure 1: Intervention areas of the Mission*) of [Europe's Beating Cancer Plan](#), as part of the [EU missions](#), an important novelty introduced with the Horizon Europe Research and Innovation programme for the 2021-2027 period. The aim is to develop concrete actions with the ambition of delivering tangible results by 2030, as stated in the Mission's slogan "By 2030, more than 3 million lives saved, living longer and better".

The European Commission is also building a strong European Health Union, in which all EU countries prepare and respond together to health crises, so that medical supplies are available, affordable and innovative, and countries work together to improve prevention, treatment and aftercare for diseases such as cancer. In this context, in September 2022, the European Health Union launched a new approach to support member states in increasing the uptake of cancer screening. Focusing on detection of cancers at an early stage, the objective of the proposed [recommendation](#) is to increase the number of screenings, covering more target groups and cancers.

This will impact by putting research and innovation into a new role, combined with new forms of governance and collaboration, as well as by engaging citizens. It will also generate evidence on factors limiting the effectiveness of policies and support actions to defeat cancer.

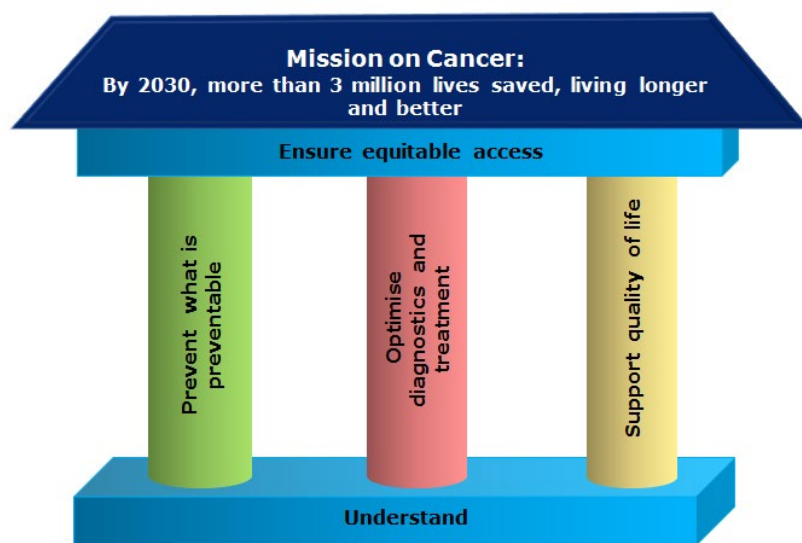


Figure 1: Intervention areas of the Mission

The Mission is articulated in 5 objectives, depicted in Figure 1:

1. Prevention,
2. Optimisation of diagnostics and treatment,
3. Support the quality of life of cancer patients, survivors, and their caregivers,
4. Equitable access to all the aforementioned areas,
5. Understand, as the basis of the four previous actions.

Transversal priorities such as addressing equity, innovation, childhood cancer and personalised medicine are also envisaged.

Thus, The Mission is focused on intensifying research and innovation efforts to understand cancer risk factors better and improve screening programmes, diagnosis, therapies, treatments, and prevention policies. It also aims to refine and strengthen cancer research and its infrastructure, optimising cancer therapies, creating a European digital centre for cancer patients, establishing national hubs for cancer missions and creating a network to support the EU Mission Against Cancer.

The Mission not only aims to improve patients' life but also aims to prevent and minimise the risk for those exposed to cancer. As stated in the previous list, one of the main actions regards "Prevention, including screening and early detection", which will be promoted for EU citizens by generating knowledge about current and potential risk factors for cancer, including interactions between multiple risk factors, by improving the performance of existing screening programmes and, through research, by developing new screening tools that can be integrated into new screening programmes and easily implemented at the national level.

4 Project members of the cluster

In late 2022, in response to the Horizon Europe call titled "Develop new methods and technologies for cancer screening and early detection", 12 research projects were selected for total funding of €125.6 million budget to support the EU Mission on Cancer. Seven projects have been included in a cluster oriented on "Prevention, including Screening". The group is composed of the following members:

4.1 LUCIA

Project title: **Understanding Lung Cancer related risk factors and their Impact**



Lung Cancer (LC) is the biggest cancer killer worldwide, with five-year survival following diagnosis varying between 5% to 25%. Though tobacco smoking has long been recognised as the major risk factor for LC, many cases (incl. LC patients that are non-smokers) cannot be explained by this reason. In this sense, LUCIA aims to establish a novel toolbox for discovering and understanding

new risk factors that contribute to LC development. The toolbox encompasses the analysis of three aspects: (i) personal risk factors, which include a person's exposure to chemical pollutants and behavioural and lifestyle factors; (ii) external risk factors, such as urban, built and transport environments, social aspects and climate; and (iii) biological responses to the personal and external risk factors, including changes in genetics, epigenetics, metabolism and ageing. Key components of the toolbox for analysing personal and external risk factors include retrospective and prospective cohort databases, AI models, wearable devices, novel non-invasive sensors, and multi-omics. Together, these tools will be used to identify the effects of a wide range of environmental, biological, demographic, community and individual-level risk factors associated with the formation of LC. Molecular changes associated with the risk factors identified by this set of tools will then be validated by cell and molecular biology methods and through in vivo analysis. The impact of the identified personal and external risk factors and the associated biological responses will be then validated in three clinical use cases: general population risk assessment and screening, precision screening of high-risk populations, and digital diagnostics. The resulting evidence within LUCIA will be translated into policymaking recommendations, with the aim to implement them in a screening program for LC. LUCIA is also part of action "Understanding of Risk Factors".

4.2 MAMMOSCREEN

Project title: **Innovative and safe microwave-based imaging technology to make breast cancer screening more accurate, inclusive and female-friendly**



MAMMOSCREEN

Breast cancer (BC) is the most common cancer in women worldwide, affecting 1 in 8 women. The figures from WHO's International Agency for Research on Cancer estimate that in 2020 worldwide cases of breast cancer accounted for 24% of all cancers in women (2.26 million women and 685,000 deaths globally). Mammography is the gold standard technology for breast screening, which

has been demonstrated through different randomised controlled trials to reduce breast cancer

mortality. However, it has limitations and potential harms, such as the use of ionising radiation, breast compression and performance restrictions due to the intrinsic nature of X-rays. In particular, breast density is a restrictive property that can prevent breast cancer detection in mammograms of women with radiographically dense breasts. Other existing techniques (MRI, Ultrasound, biopsy) also suffer from drawbacks. The overall aim of the MammoScreen proposal is to generate evidence about the use of MammoWave (a technology developed by UBT) as screening technique in population-based programs promoted by National or Regional Health Systems, to reach a revolution in breast screening. To do so, the consortium aims to confirm that MammoWave reaches sensitivity >90% and specificity >95% in BC detection on 10000 study participants undergoing regular screening programs. MammoWave uses safe non-invasive and non-ionising microwave signals, does not apply any compression to the breast and is very effective with dense breasts. Hence it can extend breast screening to younger women aged 20-49 (98 million women in Europe). This group accounts for ~30% of breast cancers in 2020. A comprehensive health economic assessment will be undertaken in this project and innovative way to implement patient engagement approaches is sought. An effective policy makers' engagement plan will be carried out to ensure that MammoWave is recommended as screening approach due to the benefits that it brings to women and healthcare systems.

4.3 ThermoBreast

Project Title: **An innovative non-contact and harmless screening modality set to change the course of breast cancer detection and patient monitoring**

ThermoBreast

Female breast cancer is the most diagnosed cancer worldwide. In 2020, the International Agency for Research on Cancer estimated more than 2.26 million new cases of breast cancer. Early detection is crucial to survival; recovery rates approach 90% when detected in early stages. National population-

based cancer screening programmes in Europe currently implement 3 standard imaging modalities: mammography, ultrasound and MRI. The downsides of these screening methods include ionising radiation, high costs and high false positive rates in screening results.

The ThermoBreast multidisciplinary consortium of 16 partners from 10 countries aims to contribute to EU's Mission on Cancer and Beating Cancer Plan by drastically improving the prevention, diagnosis and monitoring of breast cancer while reducing the burden on women and female patients and their families, health care professionals and others who are directly or indirectly affected by breast cancer.

ThermoBreast proposes a new solution for accurate, harmless and non-contact screening, equally applicable for all age groups and breast densities and capable of detecting pre-cancerous states. This risk-free screening technology, recently patented by the project coordinator ThermoMind LTD, can detect vascular anomalies and asymmetry caused by cancerous growth. It combines innovative screening through multiple sensitive infrared sensors with advanced AI analysis of temporal dynamic thermal patterns. Through its patient-centred integrated diagnostics approach, this project converges intelligent computer vision, blood vessel extraction and tissue analysis with advanced information technology to deliver a medical class 1 device that will be validated in an international multi-centre clinical study. To enhance stakeholder participation, ThermoBreast involves end-users, SSH experts and a patient organisation in the co-creation of the new screening solution and assesses its health and socio-economic benefits as well as its cost-effectiveness.

4.4 ONCOSCREEN

Project Title: **A European "shield" against colorectal cancer based on novel, more precise and affordable risk-based screening methods and viable policy pathways**



With Colorectal Cancer (CRC) being accountable for 12.4% of all deaths due to cancer, and with only 14% of EU citizens participating in screening programmes, there is an urgent need for accurate,

non-invasive, cost-effective screening tests based on novel technologies and an increased awareness on the disease and its detection. Furthermore, personalised approaches for screening are needed, to consider genetic and other socio-economic variables and environmental stressors that lead to different onsets of the disease. ONCOSCREEEN responds to these challenges by developing a risk-based, population-level stratification methodology for CRC, to account for genetic prevalence, socio-economic status, and other factors. It complements this methodology by a) developing a set of novel, practical, and low-cost screening technologies with high sensitivity and specificity, b) leveraging AI to improve existing methodologies for CRC screening, allowing for the early detection of polyps and provision of a personalised risk status stratification, and c) providing a mobile app for self-monitoring and CRC awareness raising. Furthermore, ONCOSCREEEN develops an Intelligent Analytics dashboard for policymakers facilitating effective policy-making at regional and national levels. Through a multi-level campaign, the above-mentioned solutions are tested and validated. For the clinical solutions specifically, a clinical validation study has been planned with the participation of 4100 enrolled patients/citizens. To ensure the adoption of the developed solutions by the healthcare systems, their cost-effectiveness and financial viability will be assessed. The 48-months duration project will be implemented by a multidisciplinary consortium comprising of 38 partners, including technical solutions providers, hospitals, Ministries of Health as policymakers, legal and ethics experts, Insurance companies, actively involving end-users/citizens in all phases of implementation through targeted workshops.

4.5 SANGUINE

Project Title: **Early detection and screening of hematological malignancies**



SANGUINE

Project SANGUINE addresses the objectives raised by the Cancer Mission Call, which emerged from the growing societal challenge faced by European citizens. According to the

European Cancer Information System (ECIS), each year, 2.7 million people in the EU are diagnosed with cancer. The SANGUINE project focuses on haematological malignancies, which account for 10% of those cases, and aims to target the four objectives of the Cancer Mission: (1) understanding, (2) prevention, including screening and early detection, (3) diagnosis, and (4) quality of life improvement of the patients and their relatives. The project introduces a novel minimally invasive blood test that detects and classifies a set of haematological malignancies. The test is based on detecting a combination of epigenetic biomarkers in DNA from peripheral blood cells and in cell-free DNA. The SANGUINE test will provide superior sensitivity at low cost, which is ideal for screening purposes. This is enabled by direct fluorescent labelling of epigenetic marks in patient DNA and its analysis on a custom-designed microarray – the HemaChip. The SANGUINE team consists of a comprehensive and strong team of experts that will address medical, technological and social aspects of the developed diagnostic test. Expertise from the medical field includes clinical research, technology development and access to patients. This will enable optimisation of the test for haematological malignancies following a user-centric approach and experiencing its implementation in "real-life" clinical settings. The social part of the team includes researchers and patient organisation that will promote accessibility of the test to patients and individuals at-risk for screening, early detection and disease management, in combination with a study aiming to increase the screening rates. Ultimately, the project will provide validated reagents, HemaChips and data analysis software ready for large-scale screening and early-stage commercialisation.

4.6 PANCAID

Project Title: **PANcreatic CANcer Initial Detection via liquid biopsy**



Pancreatic cancer (PDAC) is usually detected at late stages, and most patients die within one year after diagnosis. In PANCAID we will therefore develop a blood test for early detection of PDAC. Despite tremendous technological advances in Liquid Biopsy Diagnostics

(LBx), this goal is very ambitious because small tumours release only minute amounts of cells or cellular products (e.g DNA, RNA, protein, metabolites) into the circulation. Thus, tests with a high sensitivity are required, but increases in sensitivity are usually achieved at the expense of reduced specificity, which can lead to significant overdiagnosis leading to unnecessary stress for individuals with a false-positive blood test and high costs for the health system. In PANCAID, we will therefore , analysing large cohorts of patients with PDAC and its precursor lesions, individuals at risk of developing PDAC and appropriate age-matched control groups (healthy and non-cancer diseases frequent in the targeted population).

Ambitious objectives of PANCAID include (1) establishment of a unique resource of blood samples of early PDAC and risk groups (WP1); (2) establishment of a breakthrough blood test for early diagnosis of PDAC (WP2); (3) Identification of the best composite biomarker panel by integrating multimodal features in an AI-assisted computational analysis; (4) Analysis of the socio-economic impact of early PDAC diagnosis (WP4); and (5) Definition of the ethics parameters relevant to early PDAC detection (WP5). A robust multi-biomarker panel will be determined during the training period (year 1-3) and subsequently validated on bio-banked blood samples (year 4-5). Depending on the outcome of this comprehensive analysis, PANCAID will provide the design of a future prospective study for validation of the developed composite blood test in an international multi-centre setting required to introduce LBx into screening programs for high-risk individuals.

4.7 DIOPTRA

Project Title: **Early dynamic screening for colorectal cancer via novel protein biomarkers reflecting biological initiation mechanisms**



Colorectal cancer (CRC) is the third most common tumour in men and the second in women, accounting for 10% of all tumours worldwide and ranking second in cancer-related deaths with 9.4%. About 1.9 million new cases were diagnosed in 2020, translating into 0.9 million deaths, while incidence is projected to rise significantly over the next decade. Studies have showcased a difference of >30% in mortality rate favouring screening-detected vs symptom-detected CRC, so routine screening is key, especially since CRC is considered a highly preventable disease

with a wide temporal development window. In this context, western registry data show an increased incidence in the age group of 40-44, considerably lower than the current age threshold, attributed to modern lifestyle alterations, constituting a wide set of risk factors for CRC. Despite the available arsenal of screening practices, there exist a number of factors such as taxing procedures, citizen reluctance, poor awareness and screening accessibility that are hindering participation. In this vein, liquid biopsy appears as a promising new tool on non-invasive, quick, safe and cost-effective assessment. Therefore, DIOPTRA aims to introduce a front-line screening tool that will consider risk factors and protein biomarkers for pinpointing individuals at a high risk for CRC incidence. Tissue & blood samples will be examined towards a discriminative set of prognostic proteins that are detectable via standard bloodwork and can indicate a need for further evaluation (i.e., colonoscopy). Other data (e.g., medical, behavioural) will also be considered as potential risk factors. Artificial intelligence (AI) will be leveraged for assessing prognostic power, while personalised behavioural change will be promoted based on modifiable risk factors. Given the low citizen participation on CRC screening across EU, DIOPTRA seeks to broaden the evaluated population, boosting participation rates and bypassing age screening thresholds.

Common Workplan and Preparatory Activities

4.8 Joint agreement of common workplan

The workplan backbone was discussed with all the projects' coordinators and HADEA's members during the Cluster Kick-Off meeting held online on the 9th of February 2023. The joint actions included in the Grant Agreements outlined the work path and helped identify scientific collaboration inputs. The cluster unanimously agreed to create sub-clusters joining projects that share similarities (i.e, MammoScreen and ThermoBreast) and sub-groups to manage specific tasks such as Dissemination/Communication and Data management. These will be progressively defined as the cluster collaboration progress and consolidated at the first Annual Cluster meeting in September. A large part of the discussion focused on identifying common aspects of the projects, possible fields, and aspects to start synergic cooperation working together on research capacity building. A key aspect of collaboration concerns the identification of commonalities between the various member projects, which is useful to identify fields and activities to start synergic work.

4.9 Preparatory activities

4.9.1 Mapping single project activities

The mapping of the single project activities will help provide the members with an overview of each cluster project's overall activities, trying to identify those that can be implemented jointly by the cluster.

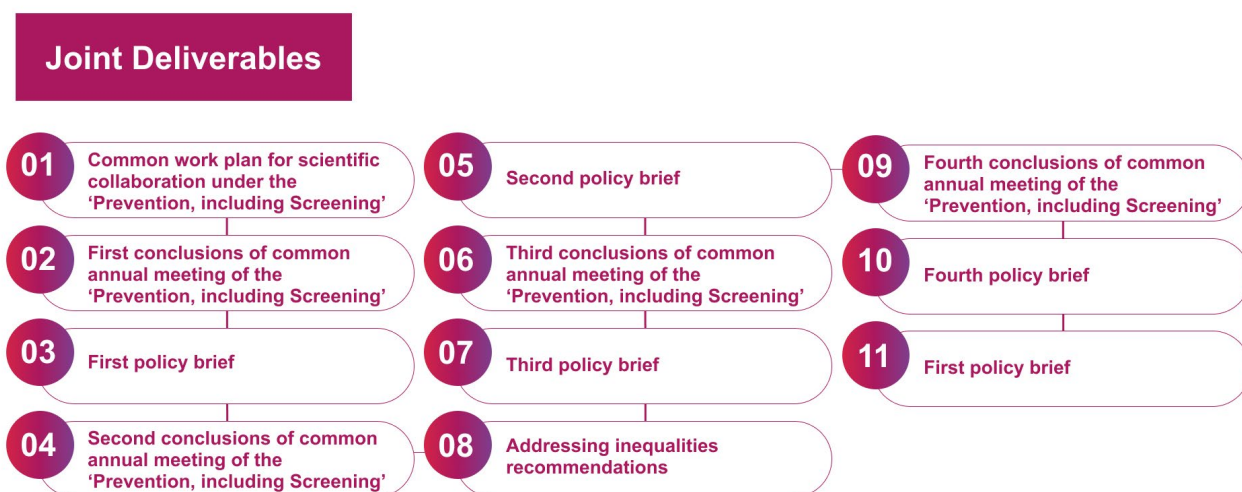


Figure 2: Cluster joint deliverables

4.9.2 Common Cluster Workspace

Additionally, ThermoBreast has shared a file to collect information about all the projects to facilitate communication and synergies. Each project has shared the details (including website, social media handles, logos, and responsibilities within a specific project in terms of defined cluster sub-groups). ThermoBreast has also set up the shared space for collaborative work by configuring a SharePoint platform that will help all cluster members share and store files and work on tasks efficiently. ThermoBreast is in charge of managing both the contact list and the SharePoint collaborative space.

4.9.3 Common Cluster Contact List

ThermoBreast will also explore the possibility of creating a mailing list.

4.9.4 Common Presentation Templates

A poster and a PowerPoint presentation will be created using the cluster's visual identity and branding guidelines, so the coordinators can present the cluster activities in the events they will attend.

4.10 Sharing Best practices

This activity plays a crucial role in optimising research processes, enhancing efficiency, and fostering mutual learning. This also represents an excellent opportunity to showcase and exchange valuable insights, strategies, and methodologies that can be effective within individual projects. The joint activities and the working cluster model "Prevention, including screening" under implementation can also become a good practice to be shared for implementation of the EC objectives of the Mission.

Each project will identify practices related to different aspects, from methodologies and experimental techniques, data analysis approaches, project management strategies or communication protocols, considering it may be necessary to shape some practices fitting the specific context, resources, and goals of each project.

5 Joint cluster workshops

This activity aims to share knowledge and insights among project partners and possibly extend them to the wider scientific community and citizens. The scope is to trigger awareness of the cluster goals and the strong EC commitment to the fight against the cancer burden. All projects will create educational resources based on the individual scope of each project to address specific topics or issues, and this can be achieved both with online activities and in-person events. The selection of opportune topics (research and innovation, socio-economic aspects, education, etc) and the content development could be distributed among the partners based on their expertise and experience. The possibility of involving people in face-to-face events should be facilitated, although it may not be easy since there is no dedicated budget.

Both scenarios can be facilitated using different online tools to implement interactive and engaging sessions incorporating Q&A sessions, panel discussions, polls and quizzes. This also makes a solid contribution to active learning. The topics could encompass fundamental aspects that valorise the single projects, such as cutting-edge technologies and methodologies adopted, theoretical frameworks, main barriers that need to be overcome, practical skills that are valuable to the scientific community. Dissemination events will be mainly dedicated to citizens, including patients, to engage them and address their views. Each individual project coordinator will notify their consortium members and encourage their participation in such events in order to foster interdisciplinary collaboration & knowledge sharing. It would also be pivotal to address the inequalities in access to quality care: projects will develop common ideas on how the cluster can contribute to reducing inequalities and improving access to care.

A general calendar with cluster-related events will be created (updated throughout the cluster activities) and shared with all member projects.

6 Joint dissemination actions

To manage joint dissemination and communication activities of the cluster, a dedicated working group was established and is comprised of the Dissemination Managers of the involved projects. The first sub-group meeting took place on the 15th of May and set out a working plan for collaborating on dissemination and communication activities. The Dissemination and Communication Working Group will hold a recurring monthly meeting to manage the task. At the same time, it was also agreed on chairing responsibilities of a certain project and the distribution of tasks within a defined time span.

Each project shared available communication materials in the common SharePoint folder, such as the project websites, social media channels, logos, and branding guidelines. Furthermore, the Dissemination Directory has been created for the cluster. It will help to identify specific events, training activities, and other opportunities for joint dissemination events.

In the next phase of close collaboration, the Dissemination and Communication Working Group will develop the branding guidelines for the cluster. The guidelines will be instrumental in establishing the identity of the cluster and raising awareness about the EU Mission Cancer. The branding will include a cluster logo, colour and font palettes and an explanatory infographic.

6.1 Joint video

A joint video presentation of the cluster and the EU Mission on cancer prevention will be prepared and published on multiple channels, including websites and social media of the cluster projects.

It was agreed that DIOPTRA will coordinate the activities on producing a joint video. DIOPTRA will collect the information from other projects and combine materials to produce a 3-minute video targeting the general public, such as cancer patients and citizens. DIOPTRA has prepared an initial idea for the video and requested individual contributions from each project. Based on the collected materials, DIOPTRA will draft and present the script and storyboard during the first cluster conference. Each project will have the time to provide feedback and comments before the video is finalised and published.

The joint video will be a narrative-driven animation with an explainer approach. The video will not explore every single project but present the strategies each project employs to develop new cancer screening methods and how these methods can improve cancer detection. It will focus on the complementarity of the technologies and solutions in all the projects rather than individual technologies and components.

The second iteration of the joint video will be discussed when the projects enter the development and result-oriented phase. The updated video will focus on the results, showcasing specific developments and achievements of the projects that promote the prevention and detection of cancer.

6.2 Joint brochure

In addition to the cluster video, the projects will develop a joint brochure. The brochure will present each project as well as common objectives and goals for increasing citizens' awareness of cancer technologies, methods, and screening programmes. It was agreed that PANCAID oversees all efforts of developing the brochure. The initial plan estimates that it will be an eight-page brochure presenting each project and a cover page with the main objectives and goals of the cluster. A ready-for-print version will be shared with all the projects. However, all the projects mainly aim for online distribution of the brochure on their websites and social media to reduce the environmental impact of printed documents.

6.3 Joint social media channel and newsletter

The cluster will create a joint social media platform. Based on the current social media trends, the dissemination managers agreed to create a dedicated LinkedIn group for the cluster. The page will include regular updates on each project, joint activities, and campaigns on cancer awareness and screening programmes, as well as develop specific content to facilitate social media engagement with different target audiences. The LinkedIn page will include a cluster newsletter, which will be issued every six months. The LinkedIn page and the cluster newsletter will be actively promoted via different online channels of the projects and projects' partners. Furthermore, each project will create a dedicated section on the cluster in their individual newsletters.

6.4 Dedicated page for the cluster on the projects' website

All participating projects will create a dedicated section about the cluster on their project websites. The description of the cluster will include an overview of all projects, links to their websites and social media, as well as the cluster infographic, brochure, and video. The page will also include links to the LinkedIn cluster page and a subscription button that will lead to the cluster newsletter.

7 Joint scientific publications

By pooling together expertise and resources, it will be possible to collaborate on research efforts across the cluster's projects to produce high-quality publications in relevant academic journals. These possibilities will be proposed and assessed among the project coordinators. The publications could be based on shared research goals or methodologies or form specific reviews on the

overarching field of study. A list of recommendations to address the Mission's objective can also be published as a position paper. This becomes an essential activity to consolidate research efforts and maximise the impact of the cluster work creating a more robust body of knowledge and drawing up new proposals for work methodologies. An in-depth literature review could be conducted to build upon existing research and provide novel insights into the field, such as the strategy adopted to reach the Mission ambitions as tangible goals. Iterative internal peer reviews will clarify, organise and validate the manuscripts. The collaborative effort should be defined to reach the task aims. Three topics that have been identified as of high interest are:

- Early Onset Cancer
- Understanding inequalities between and within EU countries
- Risk-based factors contributing to cancer propagation

The first point underscores the crucial need to comprehend why an increasing number of young Europeans are being diagnosed with early-onset cancer. It paves the way for evaluating whether our current screening strategies and, by extension, screening policies need modifications to adapt to this new reality.

The second point seeks to achieve a shared understanding of the reasons behind the disparities among and within EU countries. The inquiry delves beyond mere budgetary differences or behavioural disparities, seeking a comprehensive, multi-faceted perspective.

The third point concerns any potential novel findings about the factors that contribute to various types of cancer, beyond what is already known.

8 Data management plan harmonisation

The DMP will be prepared using a template provided by ThermoBreast, which allows for completing the DMP in compliance with the European Commission's requests. The DMP will include a common chapter on the cluster's activities, addressing commonalities in data standards, validation, protection and data exchange possibilities. The data management task force has built the common chapter based on the draft provided by ONCOSCREEN.

A data management task force has been established (including a representative from each of the projects), which acts as a working group to discuss and agree on the common approach to the data management framework. The monitoring and update of the DMP (and/or recommendations for improvement) for the remainder of the duration of the actions will also be carried out by this task force to ensure that the data produced by each project can be correctly integrated into the UNCAN.eu platform.

Furthermore, the organisation of regular virtual meetings of the data management task force is foreseen. More specifically, during the first six months, the meetings have occurred on a bi-weekly or weekly (as needed) to discuss basic commonalities of the cluster projects to be addressed in the initial versions of the respective projects' DMPs. The task force will continue to meet once every quarter.

During the cluster projects' collaboration, the data management task force will further explore the possible shared commonalities and will provide more detailed versions of the common aspects of data management in the Prevention cluster in the upcoming versions of the DMPs.

9 Aligning end-user requirements

Although each project that participates in the cluster has different needs and addresses different types of cancer (in most cases), an effort will be made to align requirements among the end users (clinicians, patients/citizens and policymakers). ONCOSCREEN will undertake this initiative and more specifically, POLA, as an End User Coordinator, will be responsible for communicating with the other end-user coordinators and end users to facilitate potential common requirements for tools provided to the three main end-user types.

In ThermoBreast, partners CPE, TM, VUB, and clinical partners, are undertaking the initiative to collect end-users' needs. This will be done by collecting stakeholder requirements, recommendations, and policy expectations in workshops and surveys; gathering end-user perspectives from patients with surveys and focus groups; and collecting input from national cancer societies, hospitals' user organisations, and other patient advocacy groups. Furthermore, the ThermoBreast partners will be reviewing the scientific evidence base and recommended (inter-) national guidelines, as well as conducting an online survey and expert workshops with clinicians to collect end-user needs. The results of their effort will be shared as best practices for aligning the end-user requirements with common standards throughout the projects of the cluster.

It is noted that some projects have already defined a first set of end-user requirements. The above process is expected to feed the second round (and onwards) of requirements, enhancing the overall end-user participation in the co-designing activities. However, it should be noted that in each project, there may be technical limitations for dedicated solutions. A potential grouping of solutions across projects may occur to facilitate the common elicitation of requirements.

10 Promotion of secondary use of data under FAIR principles

The feasibility of sharing data is a tricky and sensible aspect necessary to be addressed, as the possibility of data sharing could be an added value among Cluster collaborations. However, this implies the need for mappings and comparability studies to understand how to share and which kind of data, under which data types.

Cluster members will consider the opportunity for data sharing depending on the context in which this will occur. Moreover, additional details, which may not be able to be incorporated early on, will be provided within the planned updates of the DMPs.

However, following the EU strategies for the promotion of FAIR and Open Data and given the fact that the clustered projects are conducting a series of clinical trials involving a significant number of patients, a special provision shall be included in the submission folder to the ethical committees for approval regarding the secondary use of data collected from citizens as Open/FAIR for the further continuation of research. Privacy preservation of citizens will be ensured by any means, following necessary guidelines for the protection of their data. It is noted that some projects have already designed the preparation folder and it is not feasible for all projects to alter the initial preparatory approval documents.

FAIR and Open Data strategies across the cluster can facilitate a further validation of components with more available data, enable the engagement of young innovators and start-ups to generate new innovative ideas and solutions and promote the newly derived knowledge from scientific publications in the future.

11 Collaborating with a view to the European Health Data Space (EHDS)

The EHDS is an initiative and legislation currently under discussion at the European Parliament. It aims to promote an efficient and secure exchange of healthcare data. This presents a significant shift from a regulatory perspective, as it sets the standards for data accessibility across and beyond the borders of Europe. By collaborating in line with the EHDS, scientific projects can leverage shared data resources, enhance research capabilities and contribute to the broader goals of improving health and healthcare in Europe. Working towards EHDS is useful not only to exploit its resources but also to contribute to its improvement. It is thus fundamental to familiarise ourselves with the legal framework and guidelines, understanding where the EHDS can support and enhance the cluster goals. Dedicated events can be implemented to train cluster members on EHDS policy and roundtables for discussions could be dedicated to this.

In addition, with drafting the Data Management Plan (DMP) deliverable and the expected cluster common chapter, it will be easier to identify objectives and the potential contribution to this task and understand how to align with the EHDS. The identified processes and models for data definition,

treatment and collection will be harmonised with a view to the EHDS framework. Finally, the ethical and social implications of EHDS will not be neglected but addressed and valorised to ensure the safeguarding of privacy and confidentiality with robust protocols compliant with data protection.

12 Joint working groups

The project coordinators of the "Prevention, including screening" cluster will continue to facilitate discussions among project partners updating the existing set of common contact lists to promote the alignment of efforts. Already, two joint working groups have been established across the cluster: a) a Data Management Plan task force and b) a Dissemination & Communication working group. As the familiarisation across the projects of the technical solution progress possibly more, technical work could be created that can focus on the three main end-user groups as defined by the call (citizens, clinicians, policymakers) or based on the solution since there already different diagnostic devices with similar technologies like the CTCs (Circulating Tumour Cells). The exact groups shall be defined over the next cluster meeting, given that the project partners are familiar with the different solutions across the projects.

13 Cross-cluster activities

While in the "Prevention, including screening" the projects belonging to the HORIZON-MISS-2021-CANCER-02-01 referred in this document (ONCOSCREEN, MAMMOSCREEN, ThermoBreast, SANGUINE, PANCAID, DIOPTRA) are collaborating in joint efforts, further synergies with more clusters will be sought. More specifically, LUCIA project through TECHNION (project coordinator, project partner in ONCOSCREEN), handles the efforts of communication between the HORIZON-MISS-2021-CANCER-02-03 cluster of projects (LUCIA, ELMUMY, DISCERN, MELCAYA, GENIAL). Furthermore, ONCOSCREEN project through EXUS (project coordinator, project partner in ONCODIR) will handle the efforts of communication with the "Prevention and early detection" cluster of projects (CO-CAPTAIN, CPW, ONCODIR, PIECES, PREVENT and 4P-CAN) with the support of CERTH (ONCODIR project coordinator, project partner in ONCOSCREEN). The discussions with the other projects would aim to align the policy recommendations for change that, however, will take place towards the end of the project so that concrete recommendations have the highest possible approval and insights from multiple projects. Over the next 1-2 cluster meetings, it will be decided whether a dedicated event will be implemented for the participation of the projects across different clusters.

14 Joint recommendations for policy change

During the second half, where preliminary results of cluster project solutions will be made available, along with a series of supporting deliverables and potential scientific publications, a series of policy recommendations will be made available. Over the next cluster meetings, whether a white paper with key policy recommendations or a more extended policy brief should be created will be examined. To create a synergistic impact, cluster projects should align some common recommendations that may overlap and provide specific measures for change for the cancer types of the involved projects. The thought behind this is that it is easier for policymakers to accommodate one document with recommendations that refer to several types of cancer, rather than scattered policy documents deriving from different projects.

ONCOSCREEN, which has two Ministries of Health (in Greece and in Lithuania), will facilitate the discussions with feedback towards the corresponding partners that will draft policy documents. ThermoBreast will produce a white paper on the prevention and monitoring of breast cancer.

The "Prevention, including screening" cluster counts on the support of HaDEA for identifying a group of high-level contacts from other Ministries of Health from the EU Member states (that relate potentially to the drafting of National Cancer Plans) to receive recommendations and potentially adopt the suggestions of the cluster creating a long-term impact on the lives of EU citizens.

15 Next steps

This deliverable represents the first set of common actions determined by the "Prevention, including screening" cluster after spending the necessary time identifying those among projects. Furthermore, a set of internal organising activities took place (contact lists, web-based collaborative space

SharePoint etc.) that, along with regular meetings and hybrid cluster meet-up events, will ensure the execution of the commonly agreed actions. These activities shall be further enhanced by aligning the efforts among similar components through dedicated joint working groups for themes of common interest that may be decided over the next period.

More specifically, over the next period, it is foreseen that joint dissemination activities and joint cluster workshops will take place to familiarise the project partners across all projects regarding the activities taking place and enhance the sense of collaboration with the outer world and external stakeholders. The familiarisation of the technologies among the end users as well shall lead to a potential co-sharing of end-user requirements aligning their voices towards common needs.

Furthermore, most data management plans are finalised, and any updates will be monitored and discussed periodically. Specific provisions for Open, FAIR data re-use will be analysed by the corresponding partners along with EHDS strategies.

Depending on the cluster project results, a series of other activities that include publications, identification of inequalities and financial mechanisms for wide-population screening. An effort will be made to establish open innovation activities through hackathons and living labs.

Finally, a series of cross-cluster meetings shall take place to lead to potential joint recommendations for policy change towards the second half of the project period to create a more significant impact.

All the above shall be reported in progress report deliverables of cluster activities along with updates in the corresponding joint strategy of the cluster.

Cluster Synergies

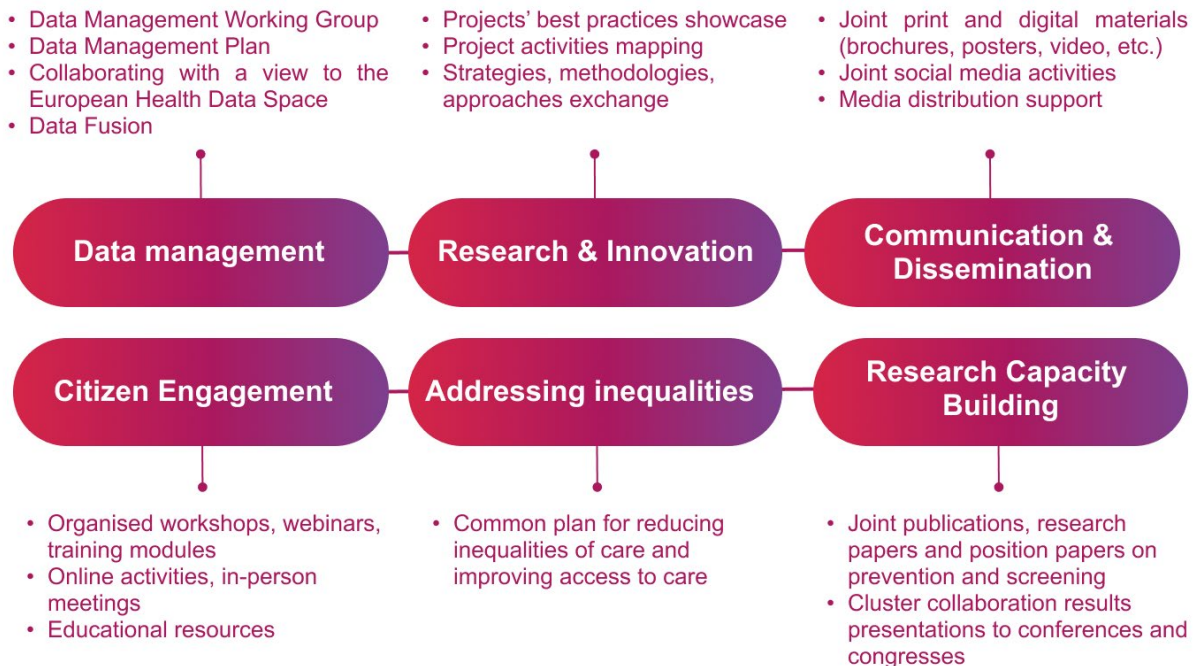


Figure 3: Identified common activities under cluster working groups

Annex A: "Prevention, including Screening" Cluster KoM

The conclusions of the "Prevention, including Screening" Cluster KoM that was held on Feb. 9th virtually were the following:

Tour the Table

All the project coordinator provided a tour the table, stressing the project objectives, the start date (all the projects started on Jan. 1st, 2023, except MammoScreen which started on Dec. 1st 2022).

Initial work plan of Mission cluster prevention Project

This deliverable will provide an Initial common work plan for scientific collaboration under the 'Prevention, including Screening' cluster for all the projects. This deliverable is due to Month 6 for all the projects. Since the MammoScreen Project has started one month earlier, only for this project the due date will be on M7, which according to the HaDEA is justifiable as change in the due date of the deliverable.

Laura Garcia Ibanez from the European Health and Digital Executive Agency [HaDEA], stated that this deliverable should highlight which are the similarities of the different projects and the approaches that can be further valorised by joint collaboration.

Marianne Da Silva from HaDEA, highlighted how this Cluster should reflect on what may be feasible in terms of collaboration finding the right balance in the context of the various projects. The participant agreed that the Deliverable should have a rationale, a list of activities that can jointly be implemented. The sub-cluster (i.e. MammoScreen and ThermoBreast) collaboration is also supported and should be sought. It also agreed that an initial mapping should be carried out, to understand from each project the specific tasks, events and activities within which the collaboration could happen.

Initial inputs for scientific collaboration are:

- Developing Joint publications in peer reviewed journals – Klaus Pantel (PANCAID) will provide some tailored journals;
- Sharing Best Practices among project partners – about the main regulatory, clinical hurdles the projects are facing and learning from each other;
- Develop Joint webinars and training modules;
- Fusion of data, when possible;
- Collaborate with a view to the European Health Data Space (EHDS);
- It was also suggested to share data among the partners, but since clinical protocols have already been approved in certain cases, there are ethical barriers to do so.

It is also agreed that TLS will lead the elaboration of this deliverable. It will be the same deliverable that will be submitted by all the partners.

Data Management Plan

The preparation of the Data Management Plan will include a common chapter on the 'Prevention, including Screening' cluster. The aim is to address commonalities in data standards, data validation, data protection and foster data exchange. Larisa Adamyan (ThermoBreast) will align with LUCIA members for a homogeneous Data Management plan (CMP). The proposal is to harmonise each project plan providing support to the members from different aspects. ThermoBreast project is going to schedule meetings/training and create an outline for the DMP. During these meeting Larisa Adamyan will collect information about the DPM of each project (especially for data standard and

data validation) and will draft the common chapter that each project will include in their own DMP and submit to the EC.

Annual Cluster Meeting

It is agreed that the 1st in hybrid Annual Cluster Meeting will be hosted by LUCIA, responsible for Year 1. The additional cluster meeting will be hosted by ONCOSCREEN (Year 2); PANCAID (Year 3); ThermoBreast (Year 4). The next meeting is likely to take place in early September 2023, in parallel with the Lucia consortium meeting. The LUCIA project will also be in charge of the Deliverable.

Joint Video and Brochure

It was agreed to develop a joint video by November 30th, 2023, focused on the general description of each project and, especially, on the potential benefit for the patients since all the projects won't have any significant result by the proposed deadline. The Patient organisations from all the projects will be involved to fine tune the message. All the Cluster members will use a very small part of their budget for the joint video. HADEA will check how each project can claim their part of the costs. In parallel, a brochure to showcase the Cluster members to the various stakeholders will be produced. PANCAID and DIOPTRA have offered to lead this task, liaise with all the other cluster projects and be in charge of the final outcome and deliverable.

Miscellaneous and conclusion

Specific project members involved in special tasks, such as dissemination, should be in contact creating "sub-groups" of collaboration. A more focused joint meeting is predicted by the end of May, close to the deadline for the Initial work plan Deliverable.