



MELCAYA

NOVEL HEALTH CARE STRATEGIES FOR MELANOMA IN CHILDREN,
ADOLESCENTS AND YOUNG ADULTS

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D8.9 Common work plan for scientific collaboration under the “Understanding” cluster



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Executive Summary

This report introduces the concept *EU Mission on Cancer* and its main objectives, which range from understanding the disease to the development of new strategies for prevention, treatment or improving the quality of life of the patients. MELCAYA belongs to a cluster of 5 projects financed by the *Horizon Europe* programme (*HORIZON-MISS-2021-CANCER-02-03*) aimed at better understanding the impact of risk factors and health determinants on the development and progression of cancer. In this report, the areas for scientific collaboration between the projects belonging to this cluster are presented, which include the following aspects:

- Sharing and agreeing on common practices for data/material management.
- Sharing and cross-comparison of risk factors and molecular features.
- Cross-comparison and integration of risk stratification/early diagnosis tool.
- Sharing of best practices on implementation of healthcare policies.

Finally, the particular actions for the practical implementation of collaborations between the projects in the cluster are presented, which include the organization of *Understanding* cancer cluster meetings and the creation of a data management board.

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Acronyms & Abbreviations

Term	Description
EU	European Union
HaDEA	European Health and Digital Executive Agency
AI	Artificial Intelligence
DMP	Data Management Plan
EHR	Electronic Health Records
KOM	Kick of Meeting

1 Introduction to EU Mission on Cancer

The European Union has put forward the *EU Missions* as a novelty of the *Horizon Europe* research and innovation programme for the years 2021-2027. Their aim is to bring concrete solutions to some of the greatest challenges of our time, having ambitious goals that will deliver tangible results by 2030. The *EU Mission on Cancer* [1] has the ambitious goal (in combination with *Europe’s Beating Cancer Plan*) of improving the lives of more than 2 million people by 2030 through prevention, cure and, for those affected by cancer (including their families), to live longer and better. The *Mission on Cancer* board estimates a reduction in the expected mortality rates between 2021 and 2030 with respect to the baseline scenario (resulting from the current efforts of Member States) from 14 % to 20 % for females and from 30 % to 40 % for males.

The specific objectives of the mission are the following [2]:

1. *Understanding*: despite the huge advancements in the field, much more research is still needed to understand why certain people, gender and age groups are at a higher risk of developing cancer, suffering from side-effects, etc. All these uncertainties limit the design of effective cancer prevention programmes as well as healthcare solutions adapted to each patient. Moreover, cancer research, healthcare providers, patient communities and industries are fragmented in the EU and do not benefit from patient engagement.
2. *Prevention, screening and early detection*: this is the most cost-efficient and long-term cancer control strategy. It is known that 40 % of cancers could be prevented, but a more personalized understanding of the disease is needed as well as improvements in the existing prevention programmes and general health literacy among EU citizens.
3. *Diagnosis and treatment*: the time to cancer diagnosis is generally too slow or early diagnostic tests do not exist. The currently existing best practices and standards of care are not consistently implemented across Europe, which results in unacceptable differences in standards of care and outcomes between Member States or socio-economic backgrounds. Many patients do not have access either to the latest personalized treatments across Europe (immunotherapy for instance) or are not empowered to make informed decisions on their treatment.
4. *Quality of life*: there is a clear lack of understanding or sufficient consideration of patient needs. Stigma affects patients and survivors of cancer and negatively impact their career and creates challenges to obtain health insurances or mortgages, generating a substantial burden for patients, their families and countries’ health systems.

2 Projects on the Understanding cluster

Our project (MELCAYA) is part of a group of 5 projects that received funding from the European Commission through the *Horizon Europe* programme (*HORIZON-MISS-2021-CANCER-02-03*) to work on the objective 1 of the *Mission on Cancer* programme, which is aimed at better understanding the impact of risk factors and health determinants on the development and progression of cancer:

- **GENIAL:** Understanding gene environment interaction in alcohol-related hepatocellular carcinoma [3].
- **LUCIA:** Understanding lung cancer related risk factors and their impact [4].
- **ELMUMY:** Elucidation of risk factors and health determinants associated with progression of monoclonal gammopathies to multiple myeloma [5].
- **DISCERN:** Discovering the causes of three poorly understood cancers in Europe (renal, pancreatic and colorectal) [6].
- **MELCAYA:** Novel health care strategies for melanoma in children, adolescents and young adults [7].

The main goal of this cluster is therefore to support the mission objective of *Understanding cancer*, create added value, establish a policy feedback loop and increase the impact of the EU funding.

3 Areas for scientific collaboration within the Understanding cluster

The following areas of collaboration have been identified between MELCAYA and the different projects forming part of the *Understanding* cluster:

3.1 Sharing and agreeing on common practices for data/material management

All the projects within the *Understanding cancer* cluster work on the integration of retrospective information from European registries, biobanks and cohort studies on different types of cancer with prospective data to complement missing features. The processed information ranges from medical (clinical, epidemiological, histopathological, etc.) to environmental data (demographics, lifestyle, exposure to chemicals, etc.). A close collaboration will be established in this topic to address commonalities on data standards, data validation, as well as on the best practices regarding data privacy (anonymization/pseudo-anonymization techniques), storage and exchange protocols.

The overarching goal is to find common practices to share the information in pan-European research infrastructures, such as the European biobanking platform (BBMRI-ERIC) or the future UNCAN.eu platform, a federated cancer data hub platform currently under development [8]. This is a particularly

critical point, as at the present time patient health data networks in Europe show a high level of heterogeneity in terms of involvement of EU Member States as well as the types and interoperability of collected data, organisation and governance of data storage, security or the possibility to use this data for research purposes.

3.2 Collaborations in technology, tools, knowledge and best practices for data exploitation and computational (AI) modelling

Several ongoing initiative and programmes are highlighting the key role of information technologies for improving cancer understanding, prevention, diagnosis, treatment and quality of life. The ever-growing amount of information coming from last generation digital diagnostics, including radiological imaging, digital pathology, multiple omics technologies (e.g., genomics, proteomics, transcriptomics, epigenomics metabolomics, and volatilomics) and a new generation of biochemical and biophysical sensors, is able to provide information on cancer phenotypes to an unprecedented detail, helping to discover different biological mechanisms of disease onset, presentation and progression, both from research studies/cohorts and from real world data. Exploitation of this deep phenotype and complementary information across multiple layers and biological scales requires last generation computational techniques for data integration, pattern recognition, biomarker discovery and model development, aimed at providing unprecedented comprehensive information of the underlying biological mechanisms and paving the way for new diagnostic and prognostic approaches.

At the population level, electronic health records (EHR) provide a vast amount of information that can be exploited to discover common risk factors and to make accurate predictions of the risk of developing cancer in the following years as some prototype artificial intelligence models already promise [9]. Linking this information to the exposome, through open data sources and by capturing lifestyle information on individuals, may provide a better picture of the risk of developing some cancers providing the basis for developing public health policies and improving or enabling personalized cancer screening approaches (e.g., based on individual risk).

Such complexity demands the exchange of knowledge, technology, tools and good practices, among others, in the following areas:

- Information and knowledge models, which are semantically interoperable, allowing the consistent representation of information from individuals, digitally representing the domain knowledge and enabling integration and exploitation of data across different layers and data sources.

- Methodologies, technologies and tools for data integration, feature extraction and classification, adapted to the different data modalities, with emphasis on unstructured data sources such as imaging, molecular, signal or text data.
- Development of new statistical and/or computational (AI) models for personalized prediction of risk, that are unbiased and can be generalized to different populations.
- New technologies and tools for data analytics, hypothesis generation and discovery by researchers. This may include novel integrative models, that are able to link data-driven insights to biological models and biological/clinical knowledge.

3.3 Sharing and cross-comparison of risk factors and molecular features

In all the projects there is a common interest in analysing omics information (mainly from genomic sequencing but also proteomics in the case of DISCERN) to identify novel genetic factors that predispose to the development of a particular type of cancer and how the environmental factors can influence the onset of the disease. Three projects (LUCIA, MELCAYA and ELMUMY) also have a particular interest in characterizing the molecular features and biological pathways that drive the progression from healthy or precancerous lesions to cancer, such as for instance the change from monoclonal gammopathy of undetermined significance to multiple myeloma (ELMUMY). We plan to share results on the identified gene mutations, environmental factors and molecular characteristics between the different projects to perform a cross-comparison that could be potentially interesting from a number of aspects, including the definition of cross-cancer features, cancer-specific genetic risk factors or to guide therapeutic target identification so that subsequently developed drugs have the potential to be useful for treating multiple types of cancer.

3.4 Cross-comparison and integration risk stratification/early diagnosis tools

All the projects are planning to create a decision support tool based on AI-technology for patient risk stratification in different types of cancers. These tools will be based on the use of machine learning strategies on multidimensional, multicentric datasets including clinical, genetic, histological and radiological data among others. The results of this stratification will be shared between the different projects to assess if there are common patterns or signatures between cancer types that could be used for early diagnosis and prognosis. On top of that, two projects (LUCIA, MELCAYA) will explore the use of non-invasive devices based on the use of a wearable sensor for breath analysis and the detection of volatile compounds that could be used as cancer biomarkers. A close collaboration will take place between the institutions involved in these tasks to facilitate the ethical approval for the use of these

devices in the clinical studies and to determine if there are some breath compound signatures common to all cancers (that may also be useful to detect other types of cancer).

3.5 Sharing of best practices on implementation of healthcare policies

Three of the projects (LUCIA, DISCERN, MELCAYA) have an important focus on generating policymaking recommendations for the implementation of new prevention strategies for the early detection of different types of cancers (including lung, colorectal, renal, pancreatic and melanoma). In the particular case of the MELCAYA project, a lot of effort will be put on analysing the use of innovative healthcare technologies (particularly those based on AI-technology) on the prevention and diagnosis of melanoma in children and young adults. Similarly, in LUCIA project, AI-based technology will be used for screening and risk factor assessment (internal and external) of different populations for lung cancer. A framework to guide the life-cycle assessment of such innovations will be created, as well as an in-depth evaluation of the ethical, legal and social implications related to the use of these technologies to thoroughly consider the actual added value of incorporating them to the current standard of care. The sharing and extrapolation of these findings to the other Understanding cancer projects will greatly benefit them in the assessment and implementation of innovative technologies such as the AI-based risk stratification tools. Also, the mutual exchange of information on the main findings and policymaking suggestions between MELCAYA, LUCIA and DISCERN projects will be essential in finding commonalities in the new strategies and clinical guidelines for cancer prevention, and therefore make a stronger point when discussing screening programmes with EU stakeholders such as patient associations, government agents, etc.

4 Actions for collaboration within the Understanding cluster

In order to collaborate in the areas identified in the previous section, the following actions are envisioned:

4.1 Organization of cluster meetings

The organization of periodic meetings between representatives of the different projects in the *Understanding* cancer cluster is essential for knowledge exchange, development and adoption of best practices and creation of synergies to maximize impact. The main event will be an **annual cluster meeting** closely organized with the European Commission to address the common scientific challenges previously described. Each annual meeting will tackle different aspect of the Cancer mission in general and the cluster in particular. Relevant national ministries, agencies and policymakers will be invited to these annual meetings. The meeting agenda will include, for example, the following topics:

- *Research and innovation*: discussion on the identified areas of collaboration to reduce overlaps, harmonise research methods and models, enhance science and policy outcomes and build up research capacity at European level.
- *Citizen engagement*: the organization of exchanges with citizens at cluster level (including patients) will be discussed in order to ensure engagement and take their views into account when implementing future healthcare policies. Results and lessons learned in the workshops organized internally by each of the individual projects will be shared with the other members of the cluster.
- *Addressing inequalities in the access to quality care*: a forum to discuss ideas on how the different projects can contribute to reducing inequalities and improving the standard of care across Europe will be created.

Extra virtual meetings (including, the online kick-of-Meeting (KOM) of the cluster project and the HaDEA representative at the beginning of March 2023) and email communications will also take place on a regular basis in order to update all the people working on the different projects about relevant developments or to align on common work practices in aspects such as data management.

4.2 Creation of a data management board

The creation of a data management board including a representative person (or small group of persons) from each of the projects in the *Understanding* cluster is envisioned. The goal will be to establish a working group to discuss and agree on the common aspects related to the management of the data generated in each of the projects (standards, validation protocols, privacy, storage, etc.). The elements agreed upon by the board in the first meeting(s) will be added to the Data Management Plan (DMP) of each project. The monitoring and updating of the DMP for the duration of the actions will also be carried out by the board to ensure that the data produced by each project can be correctly integrated in the UNCAN.eu platform.

5 Conclusions

In this report we have presented the aim of the *EU Mission on Cancer* to reduce the cancer mortality rates between 2021 and 2030 and presented its main areas of focus. MELCAYA is part of a cluster of 5 projects granted in the area of understanding the impact of risk factors and health determinants on the development and progression of cancer (*HORIZON-MISS-2021-CANCER-02-03*). The main areas identified for scientific collaboration between the projects forming the *Understanding* cluster were also presented, including agreeing on common practices for data and material management, sharing and performing a cross-comparison of identified risk factors and molecular features for different types of cancer, comparing and integrating the different risk stratification tools based on artificial intelligence and sharing the best practices regarding the implementation of healthcare policies. Finally, the particular actions for collaboration have been presented, including the organization of cluster meetings and the creation of a data management board.

References

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