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DEVELOPING THE FUTURE IN COMPREHENSIVE CANCER CARE

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Welcome of the OECI President

The European actions for the years 2021-2027 have brought about an unprecedented coordination effort between the activities planned by the Directorate General of Research and Innovation and those of the Directorate General for Health and Consumer Protection.

While several cancer related initiatives had also taken place in the years preceding the 2021-2027 EU framework of activities, this time round, the public institutions have had to face serious obstacles in trying to define the needed convergences among Programmes belonging from different EC Directions General.

As a consequence, the European cancer community is called to coordinate all its catalysing elements and have them interact in unison to find the needed balance to deliver the expected results.

There are many challenges ahead which do not solely involve the hard work of healthcare professionals, but also organisational skills and financial competences. In addition, they also require interactions with the political systems, which must be open to a multinational coordination, while guaranteeing that European alignment is not hindered by a single country's ambition to prevail over others. At the same time, it is understandable that every country will try to use the opportunities offered by the European actions to internationalise home-developed programmes, which are not always adaptable to the reality of the EU, due to a variety of differences, including financial resources, technological maturity, cultural approaches, etc.

The activities launched within the framework of the Cancer Mission and Europe's Beating Cancer Plan have shown that the European cancer community has made an enormous effort of analysis and coordination resulting from a transnational collaborative effort of numerous stakeholders. We hope these efforts will help overcome the many obstacles arising from a complex European Cancer Plan that also requires the right interpretation of the EC's ambitious objectives.

OECI understands the reasons driving the Cancer Mission and Europe's Beating Cancer Plan, which deeply resonate with our mission. This is the reason why we have aligned our network and the valuable expertise within our membership in order to translate the vision of the EC into concrete impartial actions. We sincerely hope this effort will be understood by the European and National authorities and that the largest worldwide network of cancer centres/institutes may receive the recognition it deserves.

This issue of the OECI Magazine collects some of the main ongoing activities within the framework of Horizon Europe, and in particular the Cancer Mission, and Europe's Beating Cancer Plan.

The Issue opens with an article outlining the future collaboration with Ukraine in the hope that it will find a concrete recognition by the EC Cancer Programme.

The adventure is only just beginning and we are aware that great revolutions entail fundamental changes and significant responsibilities. As we cooperate to achieve the impactful results expected by the EC, we bear in mind that OECI is not embarking in this venture to "discover unexplored lands", but to use available resources and collaborate effectively to find the right balance in the complexity of today's cancer landscape and deliver our patients the answers they expect.

Thierry Philip
OECI President

Oncology in Ukraine: On the Way to Quality and Excellence

Vasyl Chekhun[1], ***Lubov Buchynska***[1], ***Valeriy Zub***[2], ***Olha Rossylna***[3]

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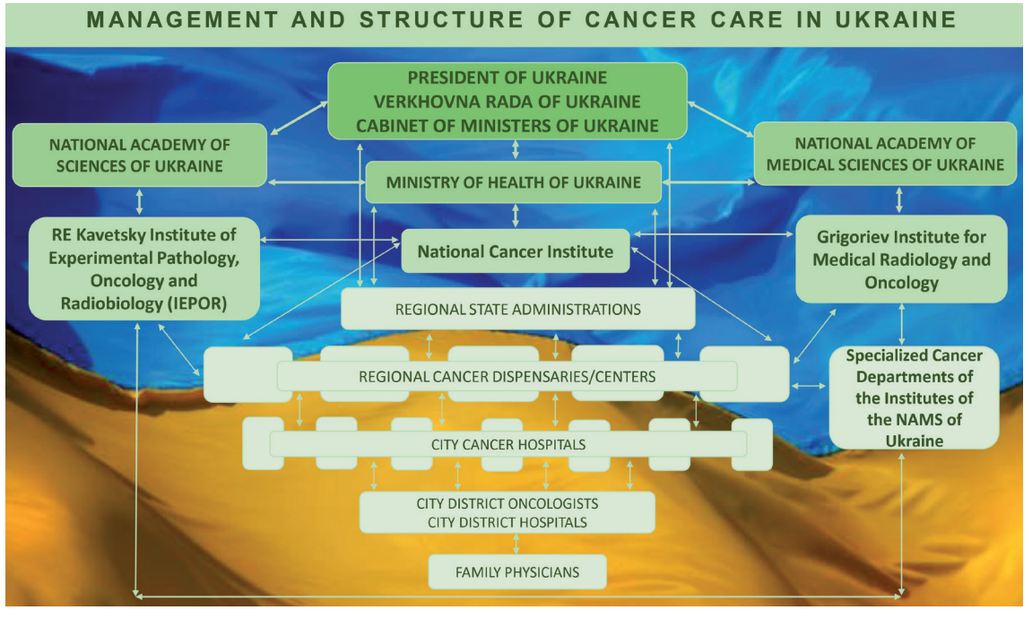
Throughout the world, life expectancy, incidence and mortality rate are and remain the main criteria of population health. In Ukraine, malignant neoplasms cause 13.4% of all cases of death and 25% of disability. Due to cancer mortality, the country's population loses more than 270 thousand people/life-years in working age. The consequences of cancer go far beyond the medical problem and have a negative impact on the social and economic development of the country.

During the Ukraine' independence, three state targeted Programs aimed at combating cancer were implemented. Despite the results of their realization, cancer incidence and mortality continue to increase. Both environmental pollution factors and low levels of organizational activities in cancer prevention have a huge impact on cancer incidence increase in the country.

The deep analysis of European experience concerning the anti-cancer combating, its adaptation to the modern realities and the economy state of Ukraine, will allow to optimally implement the main aim of whole medical reform and, in particular oncology service, targeted in favor of patients' interests along with the possibility of equal access to high quality medical care. We must do it even in these extreme conditions.

The cornerstone in achieving the optimal productivity of the Ukrainian oncology service is the problem of tight coordination and cooperation between specialists in research and clinical spheres. The deepening of interdisciplinary approaches will improve the quality of cancer services.



We are aware that the status of the EU candidate country, given to Ukraine, is not a sprint, but rather a marathon with many checkpoints and various obstacles that need overcoming during our way to the EU. We consider it is advisable to concentrate the efforts on the first steps that will it facilitate:

1. Working over the formation of the Comprehensive Cancer Infrastructure in order to create a system of integration and coordination between health care and research in Ukraine.
2. Development of the Action Plan for foundation of the Comprehensive Cancer Centre according to the OECI standards aimed at implementation of best practices: working out the concept and structure; team training; and digital support.
3. Development and reconciliation of point projects in cooperation with the OECI to strengthen certain areas of the oncology service in Ukraine and adapt it to the EU standards (in particular, screening and early diagnosis, biobanking, development and implementation of artificial intelligence service, database enlargement, etc.).

Unfortunately, today we still cannot say when the war will end, but after the victory of Ukraine, we have to accelerate democratic and social progress in all spheres.

We now have some time to gather the best specialists and the most experienced experts, decision-makers, stakeholders and political leaders, so that they will direct their knowledge and energy for Ukraine's medical restoration. Nowadays, it is just that time when we have precisely determine tasks and step-be-step plans of restoration and modernization of our oncology service, which will become an innovative hub of high quality and efficiency of medical care of cancer patients.

Professor Giorgio Stanta and Claudio Lombardo at the IEPOR for the conference "Tumor and host" jointly organised with OECI.

The EBCP and Mission on Cancer: synergies and cooperation

Marc Van den Bulcke[1], ***Marie Delnord***[1]
1. Cancer Centre, Sciensano, Belgium

About €4 billion euro being earmarked for actions addressing cancer, through the EBCP which is a policy-driven initiative running from 2021-2027 and the Mission on Cancer (MoC) with €1.25 billion from the Horizon Europe Framework Programme for Research and Innovation. EU Missions are a coordinated effort by the Commission to pool the necessary resources in terms of funding programmes, policies and regulations, as well as other activities. They also aim to mobilise and activate public and private actors, and citizens as well to boost societal uptake of new solutions and approaches.

Additional funding opportunities within the Digital Europe programme for cancer are also foreseen, what articulates a need for a coordinated response from the whole European cancer community bringing all stakeholders to work closely together in a streamlined well-coordinated manner.

Across EU-MS, the aim is that the different consortiums and projects supported jointly by the EC and MS will spearhead the establishment of a European Cancer ecosystem that should endorse the realization of the aims set by the EC: lowering inequalities in cancer care and control at EU level, provide high quality cancer care to 90% eligible cancer patients and improving the lives of more than 3 million people by 2030 through prevention, cure and for those affected by cancer including their families, to live longer and better.

The Roadmap of the EBCP has thus entered its first phase and supports initiatives that will endorse the realization of the next steps of the cancer challenges. Over 60 cancer related projects were launched since the start of the EBCP in 2021 covering organisation of cancer control and care, integrating innovative approaches, empowering cancer patients and survivors in optimizing their quality of live and filling well-known gaps in our understanding of cancer.

Sciensano is actively participating to date in several European projects amongst which:

The Joint Actions **CRaNE** and **JANE**, network infrastructures covering the entire EU territory are to be build which should allow to support giving access to cancer control and care to more than 90% of the eligible persons. CRaNE will develop the blueprint to build on the necessary medical and research infrastructure to provide an overarching network of comprehensive cancer centres and infrastructures, while JANE will establish new expert knowledge networks on complex aspects of cancer and challenging technical/clinical domains. Both new networks will have to somehow closely interact with each other and collaborate with the existing cancer ERNs and several EC initiatives that have been established for a long time already (e.g. ELIXIR, BBMRI, EUROGIM, ECRIN, …).

The joint action **eCAN** will provide the framework for further integrating digital health in tele-monitoring and tele-consultation and support MS in guaranteeing safe and secure data-handling by novel high-quality digital tools. In all these efforts, patient and citizen input is essential and is readily incorporated in the different actions from the beginning.

The recent recommendations of the EC on screening programmes is supported by the launch of a distinct Joint action **PERCH** on supporting HPV vaccination campaigns, aiming at raising the HPV vaccination coverage in the EU but also providing the framework to precisely monitor the combined screening/vaccination cervical cancer preventive actions. Such integrated preventive approach should allow the EU to eliminate cervical cancer in the near future. Importantly, together with the IARC cancer screening indicators will be updated in the **CanScreen-ECIS** project.

Sciensano is also coordinating the EU4Health **Can.Heal** project which will address both the application of new diagnostics and treatments as the integration of public health genomics in cancer perevention, diagnosis and treatment. Can.Heal will build on outcomes from previous Joint Actions CanCon and iPAAC and closely collaborate with projects related to the 1+Million Genomes project. Several usecases of Can.Heal could be integrated in the later phases of the EBCP roadmap as good/best practice, e.g. in the upcoming Joint Action on Health determinants for cancer and other NCDs.

The Roadmap for the Mission on Cancer is being established in the Coordination Support Action **unCAN** through which EU Research and innovation on Cancer in support of the EBCP will be set. It is clear that such mission requires a highly performant governance which streamlines and direct the necessary activities and resources towards the final goals. The Mission on Cancer has a strong conviction that we are to date capable of engineering the solution to beat cancer but only when we are putting all efforts together. It is conceived that collaboration with the similar US Moonshot initiative launched recently should be considered.

All EU research infrastructures will need to be mobilized, strengthened and integrated. Data will become the key driver of many breakthroughs in our understanding of cancer. The EC launched herefor the development of several major data-driven infrastructures such as the **European Health data space**, the Genomics Data (**GDI**) and EU Cancer Imaging Infrastructure (**EUCAIM**). Establishing these complex infrastructures demands strong collaboration between experts teams, clinicians, academics, industry, patient and civil organisations and policy makers.

The EBCP and MoC require a granulated real-time activity and knowledge visualization support that allows stakeholders to be informed on who does what where and by when. Putting all efforts together, analyzing and integrating the outcomes of all the initiatives in to reality necessitates that all stakeholders have a clear and precise view on all actions. The need is obvious, and the quality of the "how" should to be guaranteed by the EC project review boards and the Policy and expert groups supporting the EBCP and MoC. Efficient matching of local needs with EBCP opportunities could be realized by establishing so-called mirrorgroups wherein local stakeholders and policymakers together develop the required environment for implementation of the appropriate EBCP outcomes.

Full exploration and vitalization of the outputs from these projects will require new ways of collaborating, new AI-driven tools and might necessitate even require legislative actions beyond the current state of play. The challenge is to integrate these across cancer domains, and align those with relevant societal concerns. We are only at the beginning of this challenging journey but we are convinced that all together the EBCP and the MoC can make a difference for cancer patients, their relatives and society at large. Key will be that we work tightly together in an open, fair and equal way towards a single goal: a better Europe for all.

Joint Action CraNE kicked-off!

Tit Albreth[1]
1. Scientific Coordinator, National Institute of Public Health of Slovenia

Introduction and kick-off

After one year of preparations of its contents and formalities, Joint Action (JA) CraNE finally held its kick-off in Brussels on 3 and 4 November 2022 with the official start of the project set at 1 October 2022.

Background and legal base for JA CraNE contents

The main aim of CraNE JA is to create an EU Network of the already existing and newly established CCCs to support the implementation of quality-assured: early detection, screening, diagnosis & treatment, support to cancer survivors, and training of the cancer workforce. This aim follows Flagship 5 of the Europe's Beating Cancer Plan (EBCP), where the setup of such a Network was laid out. EBCP furthermore defines that by 2030 access to high quality cancer care provided by CCCs should be available to 90% of the respective target populations nationally. JA CraNE will develop a sound model, which will define the professional, scientific, educational, training and administrative framework for a sustainable structure. The target group of JA CraNE are the main actors concerned in the future development of the EUNCCCs: representatives of Member States, Networks of CCCs, European organisations in the field of cancer, experts.

JA CraNE partners

JA CraNE attracted a lot of interest from partners so we have a total of 44 partners on the project, out of which there 25 competent authorities, which are lead partners nominated nationally by the respective Ministries of Health as well as 19 affiliated entities from 25 different countries. It is important to underline that all the relevant stakeholders at the European level are involved, among which OECI, involved in the development of one of the two work packages dealing with the framework of the EUNCCCs. We gather a great potential of a total of 102 experts from 24 different countries participating on the project.

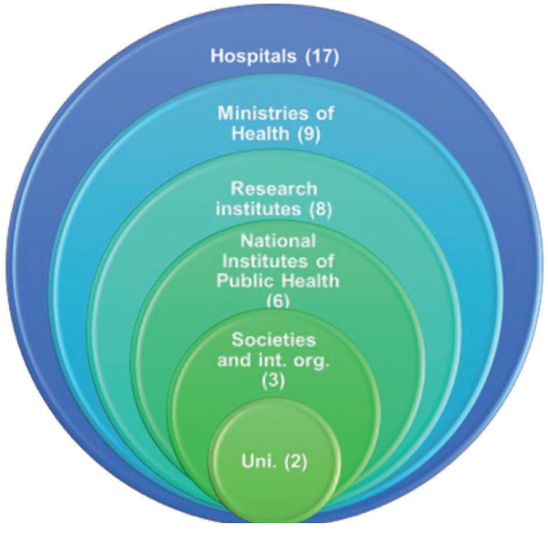


Figure 1. Typology of partners on JA CraNE.

Structure of the project

JA CraNE will have the classical structure of such projects, consisting of four compulsory work packages: WP1 Coordination, led by the National Institute of Public Health of Slovenia, WP2 Dissemination led by the 1st Health Authority of Greece, WP3 Evaluation jointly led by Cancer Centre from Cluj, Romania and the Croatian National Institute of Public Health, WP4 on Sustainability will be led jointly by Sciensano from Belgium and the Polish National Institute of Public Health.

On the core WP side, there are two pairs of work packages, each contributing to one of the key pillars of the future network. WP5 led by Alleanza contro il Cancro (ACC) will provide the governance, administrative and functional elements of the model for the future EUNCCCs. This will be complemented by the work of WP7 where leadership is provided jointly by the CCC of the Oslo University Hospital (OUH) and the French National Institute of cancer (INCa), with essential and key support by the OECI. This institutional trio will work on the standards of care, quality, professional development and research criteria as well as training for the Network. WP7 will also be responsible for the carrying out of the Stakeholder For a, the broadest consultation body, which we had successfully used to involve non-participating stakeholders and other interested parties in the discussions around the outcomes of the project. WP6 and WP8 will continue their work on the further development of the Comprehensive Cancer Control Networks as an organisational modality present in many countries, but which includes, by the definition laid out by JA CanCon (***www.cancercontrol.eu***), the central role of a CCC. WP6 will be led by a German consortium consisting of the Federal Ministry of Health, German Cancer Society, German Cancer Aid and the German Cancer Research Centre from Heidelberg and will further elaborate on standards of care in the context of the CCCNs. On the other hand, WP8 under the leadership of the Catalan Institute of Oncology will elaborate the typologies of CCCNs and their relationships and coordination with CCCs.

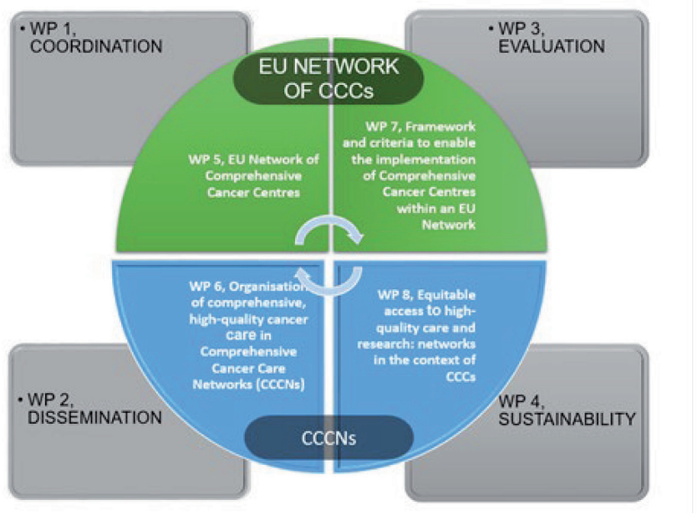


Figure 2. Schematic representation of the organisational structure of JA CraNE. Source: JA CraNE.

Duration, expected outcomes and implementation

Duration of the project will be of 24 months. The expected outcome is the full model, which would be implementable in the period after the completion of JA CraNE. The European Commission has already envisaged an implementation project in order to secure equal and balanced implementation of the results and elements of the EUNCCCs across the EU. This project will be a part of the Working Programme of the EU Commission for 2023, which means that it will start in 2024, in time to pick up on the results of JA CraNE.

For further information, do not hesitate to contact us as: ***crane@nijz.si***

JANE: Joint Action on European Networks of Expertise

Paolo Casali[1,2]
1. Fondazione Istituto Nazionale dei Tumori Milan
2. Coordinator JANE Joint Action

JANE is one of a series of complementary Joint Actions rooted in the European Commission's Beating Cancer Plan. It is coordinated by a team at Fondazione IRCCS Istituto Nazionale dei Tumori based in Milan, led by Prof. Paolo G. Casali. JA JANE will prepare the groundwork for the establishment of seven new EU Networks of Expertise (NoE), to support specific, challenging cancer conditions, benefiting from cross-border cooperation and European Union know-how. These conditions include Personalised primary prevention; Survivorship; Palliative care; Hi-tech medical resources; Omic technologies; one or more Complex and poor-prognosis cancer(s); and Adolescents and young adults (15-39 years at cancer diagnosis) with cancer. It complements in particular the JA CraNE, tasked with establishing National Comprehensive Cancer Centres (CCCs), besides collaborating with eCAN in relation to aspects of telemedicine and teleconsultation. Sixteen countries (Belgium, Czechia, Croatia, France, Germany, Greece, Hungary, Italy, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovenia, Spain) are involved, with a total of 36 partners. The JA started on 1st October, 2022 and will run for 24 months.

Five Transversal Task Forces are also envisaged, covering issues particularly affecting healthcare networking in the cancer domain in the EU today. They will cover Integration between EU networking and MSs; Integration among information-technology infrastructures and electronic health records, including the use of artificial-intelligence tools; Integration between health care and research; the ERN model in rare cancers; and Patient involvement in the NoEs. One additional work package on Sustainability will operate transversally to all work packages.

The envisaged NoEs will be new kinds of networks. Unlike European Reference Networks (ERNs) and National CCCs, which are both linked directly to patients, their mandate is to provide healthcare services and tools to healthcare cancer institutions and networks in Europe on the indicated conditions.

The Joint Action has two primary goals:

a) to set the foundations for the launch of the new NoEs.

b) to critically evaluate existing models of current and future EU networking with a view to optimising the functioning of the new NoEs.

The ambition of JANE is to bring about new NoEs that can function effectively, building on previous and ongoing EU networking experiences, and finding solutions rooted in the European oncology community. Accordingly, the outputs of the discussions and the consensus reached within the Transversal Task Forces in relation to current problems of EU health networks will be shared with the European oncology community and MSs, through a green paper and a European conference. Healthcare networking could become a privileged hallmark of the EU, having the potential to provide for the health of its citizens in a highly coordinated fashion.

4.UNCAN.eu prepares a European platform to UNderstand CANcer

Erik Solary[1,2]
1. ISERM
2. Coordinator UNCAN CSA

Starting in September 2022, a 15-month Coordination and Support Action (CSA, 4.UNCAN.eu) prepares a blueprint for creating UNCAN.eu platform. This initiative is promoted convergently by the Directorate-General (DG) for Health and Food Safety (DG Sante) and the DG for Research and Innovation (DG RTD) of the European Commission, being one of the ten flagships of the Europe's Beating Cancer Plan and one of the 13 recommendations of Cancer Mission, respectively.

Coordinated by INSERM in France, the CSA involves 10 other core partners (Germany, Hungary, Italia, Netherlands, Spain, together with European Cancer Patient Coalition, Chilhood Cancer International-Europe, International Agency for Research on Cancer, Organisation of European Cancer Institutes, and the European Society for Paediatric Oncology), working with representatives of 14 Member States and diverse consultation partners.

UNCAN.eu platform was introduced as a new level of investment in innovative research, "including high-potential/high-risk projects […] to interrogate interactions between poorly understood cancers and their host". This is in contrast with the Cancer Mission implementation plan (HORIZON-MISS-2021-UNCAN-01-01) that reduces the proposal to "a fully-fledged, sustainable platform" […] "fully contributing to the European Data Strategy".

While the creation of a Federated Cancer Research data hub will be central in the final blueprint, CSA members plan to include research programs as use cases with two objectives. One is to feed the data hub with research data generated prospectively in a standardized and inter-operable way. The other one is to involve from the beginning researchers and patients across Member States in UNCAN.eu creation. A bottom-up approach will define the most important challenges to tackle collectively at the supranational level and generate the data to be stored. Selected use cases will be ambitious, innovative, transdisciplinary and highly competitive at the international level.

The CSA place importance on the role of patients and citizens in defining use cases, in close interaction with researchers. Another objective is to reduce inequities in cancer research between member states. UNCAN.eu will interact with several ongoing initiatives of the European Commission, including the Comprehensive Cancer Center / Infrastructure networks.

Most importantly, the blueprint for UNCAN.eu platform will propose a model of governance of the Cancer Research Data Hub. Together with the infrastructure that will host the database, the CSA will develop legal, ethical, and technological frameworks for protecting personal data and regulating data sharing and use.

The global ambition of UNCAN.eu is to achieve significant new knowledge as a basis for saving millions of lives and improving the quality of life of cancer survivors.

European Cancer Mission Hubs expectations

Hugo R. Soares[1], ***Anabela Isidro***[2]
1. Science Manager: Research and Innovation Networks at AICIB
2. Member of the Board of AICIB

The fight against cancer can no longer be an isolated endeavour. Virtually, no single adult in Europe is strange to cancer, either because him/herself, a family member, a friend, a colleague, or a neighbour suffered from it. This reality calls for a wider and coordinated action. As clearly stated at the launch of the Intergroup of the Parliament on cancer by Stella Kyriakides *"Together, we will strive for more"*[1], a clear reference to multidisciplinary and cross-sectoral collaboration between EU, Member States authorities, policymakers, medical professionals, researchers, patient groups, civil society and industry. Aligned with this statement, researchers, medical doctors, caregivers, and social workers have, for a long time, reported the need to cooperate outside their community to provide better support to patient needs. Nowadays, words such as *cooperation, collaboration, participatory, synergies, co-design*, and co-creation, are widely common in EU initiatives against cancer.

However, countries are not all in the same starting position. While for some countries this call to act was the trigger to create a national strategy to fight against cancer, for others this was a moment to align country's situation and needs with EU initiatives. In a recent appeal the European Commission (EC) challenged Member States and Associated Countries (MS/AC) to coordinate and mobilize national, regional and local structures towards cancer mission to join efforts in research, innovation, policy development, and beyond[2]. Aiming an orchestrated movement across Europe, the EC launched a call for the creation of *National Cancer Mission Hubs* (NCMH) in MS/AC. Vested with the responsibility to create awareness on cancer mission and to coordinate EU and National initiatives, NCMHs must promote synergies between multiple stakeholders surpassing the impact of isolated actions across regional and sectorial boarders.

Aligned with a "Cancer in all policies" collaborative approach, NCMHs are expected to promote multiple policy dialogues on cancer with the society at large, including citizens, policymakers, patients and their relatives, formal and informal caregivers, and representatives of for-profit and non-for-profit organizations (Fig.1). In the coming years, policy dialogues should evolve to an integrated, multi-stakeholders', movement against cancer able to answer the needs of patients and their families, the needs of healthcare systems, the needs of the research and innovation community and of the needs of society in general resulting in informed citizen-centred policies. In addition, NCMH should be able to facilitate synergies between multiple European initiatives promoting a process of co-creation, co-development and co-assessment towards the development of responsible citizen-centred innovation (Fig.1). Both processes, stakeholders' participation and synergies, should be coordinated in a positive feedback loop towards continuous improvement.

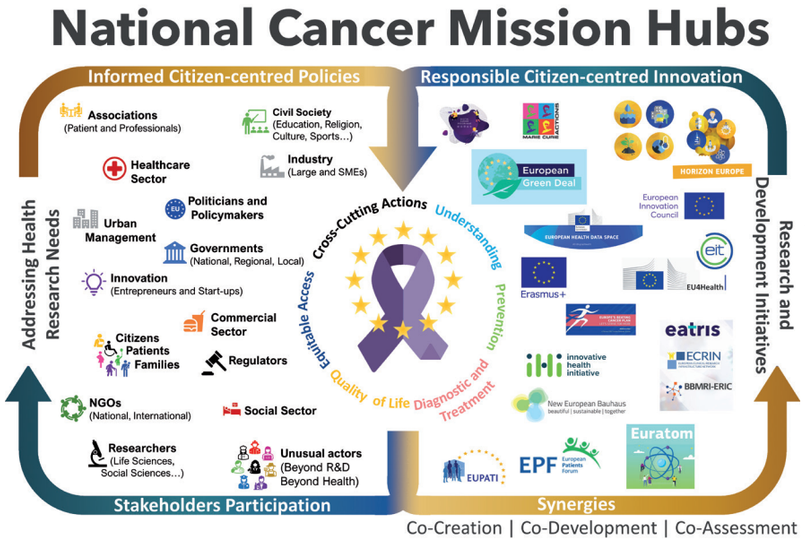


Fig. 1
Graphical illustration of the role of NCMH in facilitating policy-making processes and synergies in cancer. A non-exhaustive and generalist list of stakeholders and initiatives is represented.

Despite the long journey and the challenges ahead, this is a thrilling moment in cancer research. This is also the opportunity to set the pace for the implementation of more inclusive approaches in policymaking throughout Europe, impacting not just cancer and health but also the remaining 4 EU Missions. Will there be courage to support and empower NCMHs and we may be witnessing a change of paradigm – from reflective top-down policymaking processes to participatory bottom-up – with consequent break of longstanding silos in health, research, and beyond.

While the most distracted may consider this to be as simple as organizing events and drafting a handful of documents, others are aware of the herculean task lying ahead. The implementation of NCMH and their empowerment to mobilize and lead key national and international initiatives on cancer will, in many cases, challenge the status quo of more conservative organizations. Exactly how NCMHs are implemented is a crucial element to guarantee its political and technical influence over European and national policymakers. It is determinant to assure high level engagement of Member States authorities, including financial engagement, and a strong leadership. Equally important is the creation of a formal network of NCMH enabling the development of joint transnational initiatives and the alignment of policies between member states. This network should start to be built at a similar pace as the NCMH to stand as a facilitator of the development of individual hubs and a reinforcement of NCMHs political influence.

Portugal has initiated this process in the beginning of 2022 with the creation of the National Cancer Hub (NCH-PT). The NCH-PT is co-coordinated by the Agency for Clinical Research and Biomedical Innovation and by the Directorate General for Health through the Director for the Nacional Oncology Programme. Its structure is inspired by the penta-helix model for community-based participation[3] and is composed of two groups: the Policy Group, hosting representatives of 11 public organizations – named by an interministerial order in November 2021[4] – and the Stakeholders' group, composed by more than 400 participants from diverse sectors of the society from Health and Research to Economy, Education and Social Area, including patient advocates and caregivers. In less than 1-year, the NCH-PT has engaged in transdisciplinary discussions both in the Policy Group and in the Stakeholders Group. We are now looking towards increase the participation of unconventional sectors in the NCH-PT, such as individual citizens, artists, educators and other professionals from Social Sciences and Humanities. For 2023, we will create a third group, the "Citizens and Patients Forum" dedicated to developing initiatives to engage individual citizens not enrolled in associations or other organizations (Fig.2) to enable the development of inclusive projects with greater impact in the society at large.

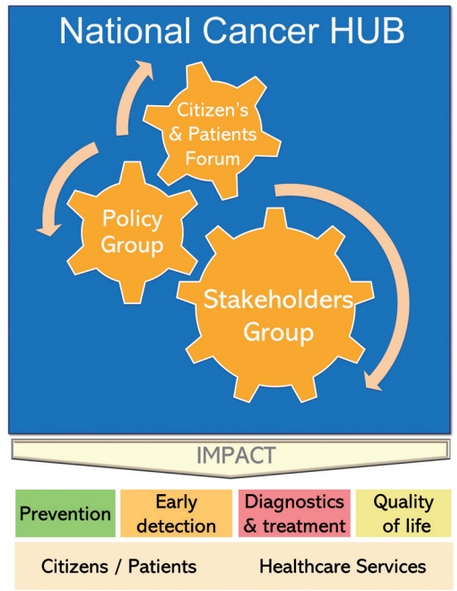


Fig. 2
Graphical representation of the Portuguese National Cancer Hub (NCH-PT) Structure, including references to Policy Group, Stakeholders Group and to the Citizen's and Patients Forum (to be created in 2023).

1. *https://ec.europa.eu/commission/commissioners/2019-2024/kyriakides/announcements/speech-commissioner-kyriakides-launch-intergroup-parliament-cancer-europes-beating-cancer-plan_en*
2. *https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-miss-2022-cancer-01-05*
3. *https://archpublichealth.biomedcentral.com/articles/10.1186/s13690-021-00544-0*
4. *https://files.dre.pt/2s/2021/11/225000000/0011800119.pdf*

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

Cinzia Brunelli[1,2]
1. Fondazione Istituto Nazionale dei Tumori Milan
2. OECI Cancer Outcome Research Working Group

The improvement or preservation of quality of life (QoL) is one of the three pillars of the EC Mission on Cancer, which underpins the needs of patients from cancer diagnosis across treatment, survivorship, and advanced terminal stages of non-curable cases. The burden of cancer on quality of life is well recognized, while clinical trials and real-world data show the positive effects of routine quality of life assessment on patient wellbeing and use of health care resources. Nonetheless, full implementation of QoL assessment in routine oncology practice is not yet part of standard of care. In the same way, health care systems and cancer control programs do not take into consideration quality of life measures when devising clinical, societal, and healthcare policymaking systems. **The overall goal of this project is therefore to be instrumental to the progress of the Mission on Cancer plan, through the development, validation and exploitation of the European Oncology Quality of Life toolkit (EUonQoL-Kit) among European cancer patients and survivors**.

Plenty of generic and either disease or treatment-specific questionnaires have been developed and validated to measure QoL of patients with cancer, mainly being used in cancer research context. However, most QoL instruments have been developed a few decades ago, by researchers to meet their own information needs and designed to be filled in by paper and pencil format. **This project aims to review existing scales and to develop new metrics overcoming the limitations of previous tools. The EUonQoL it will be a new digital system for quality of life self-assessment, available in several European languages and developed from the patient perspective**. In fact, the overall project in based on participatory co-design research principles, through the involvement of a representative panel of stakeholders, including patients and their caregivers throughout all project phases (Fig 1).

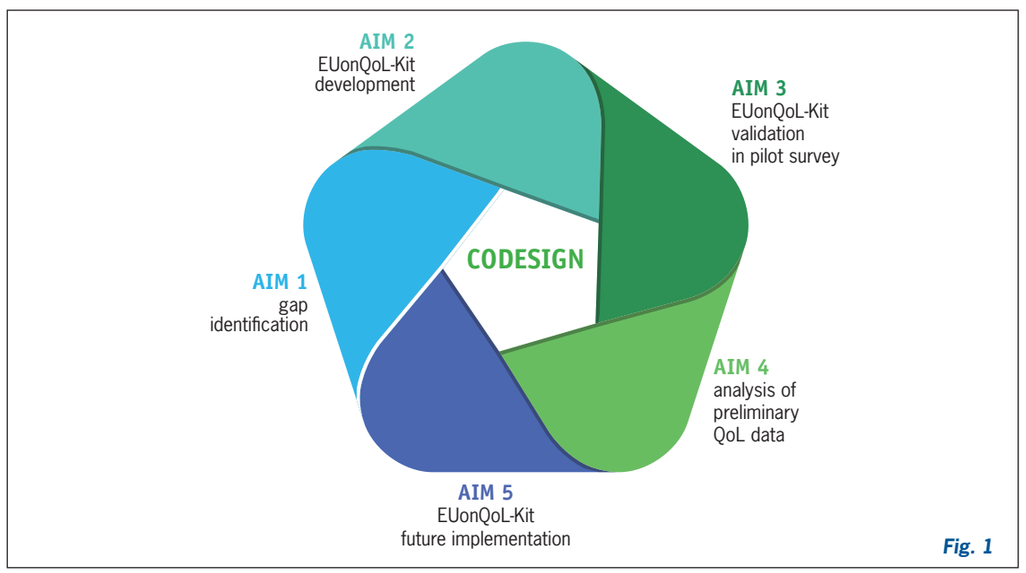


Fig. 1

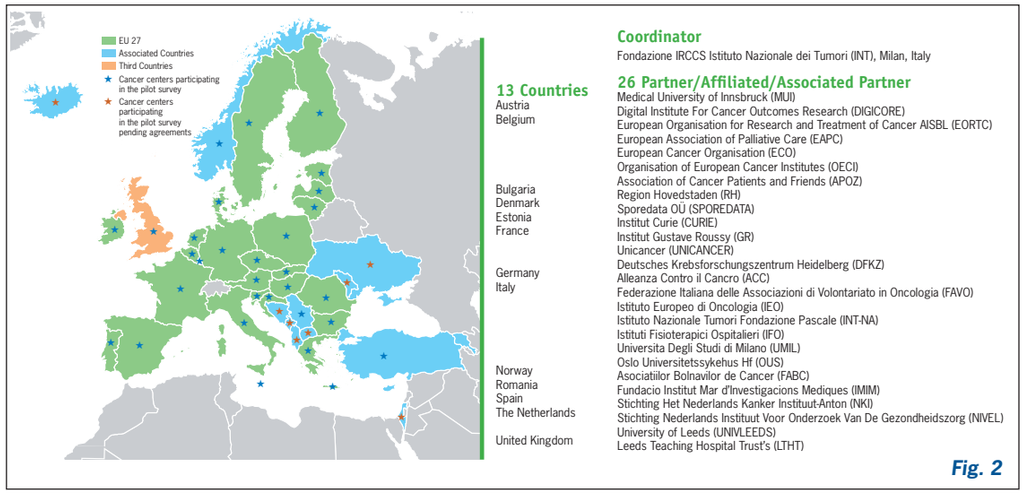


Fig. 2

More specifically EUonQoL aims at:

– identifying gaps in the body of evidence and in currently available QoL assessment tools.
– developing the EUonQoL-Kit, an innovative, unified system for QoL assessment for cancer patients in different disease stages of their disease trajectory: those receiving treatment, survivors and in need of palliative care.
– validating the EUonQoL-Kit in a pilot survey of 4,000 cancer patients and survivors enrolled in a cooperative network of cancer centres covering the EU27 Member states.
– identifying individual and country specific factors associated to QoL in Europe.
– developing procedures and actions aimed at establishing the basis for future monitoring of QoL in European cancer patients and survivors using the EUonQoL-Kit.

The EUonQoL brings together the most knowledgeable expertise in the field of quality-of-life research, cancer patients' organizations, administrators, policy makers, and comprehensive cancer centers in Europe (Figure 2). This wide collaboration will promote the use of the EUonQoL-Kit as a unified standard European QoL assessment system.

OECI
FOR PATIENTS AND WITH PATIENTS

Strengthening the research capacities of European cancer infrastructures building

Giovanni Apolone[1,2]
1. Scientific Director Fondazione IRCCS Istituto Nazionale dei Tumori - Milano
2. President Elect Organisation of European Cancer Institutes

Cancer is the second leading cause of death in Europe with an expected increase of about 25% by 2035. A wide and unacceptable variability in terms of access to innovation quality care exists between and within countries, to the detriment of vulnerable citizens. European citizens and societies still hold on to traditional views on cancer, reflected in stigmatisation and discrimination of patients and survivors, and resulting in substantial preventable disease burden. The time has come for the society in the MSs to rethink cancer and the cancer culture at all levels, in line with the objectives of the Recommendation #13 *"Transform cancer culture, communication and capacity building"* and the Specific objective 3 *"Optimise diagnostics and treatment"* of the Mission on Cancer.

On May 24th 2022, the EC open the Horizon Mission Cancer 01-02 CSA call on: strengthening the research capacities of European cancer infrastructures building

OECI with 54 Partners, including some European Cancer Organisations and Representatives of all the EU Countries and several Associated Countries, answered to the call with the application: Comprehensive Cancer Infrastructure for the European Union "CCI4EU".

*The **CCI4EU** main goal is to support MSs and ACs in improving or developing their existing or future Comprehensive Cancer Infrastructures (CCIs), focusing on expanding their research innovation and digital-related capacities and their integration with cancer care. A tailored Capacity Building (CB) programme is proposed to achieve that 90% of cancer patients are treated in CCIs by 2030.*

This has been identified as a means of decreasing mortality, improving survival and quality of life for patients with cancer and for survivors.

A "capacity building program (CB)" is a typical *"complex intervention"* from a methodological point of view which must be implemented in different realities and which requires some relevant steps which will be implemented by **CCI4EU**:

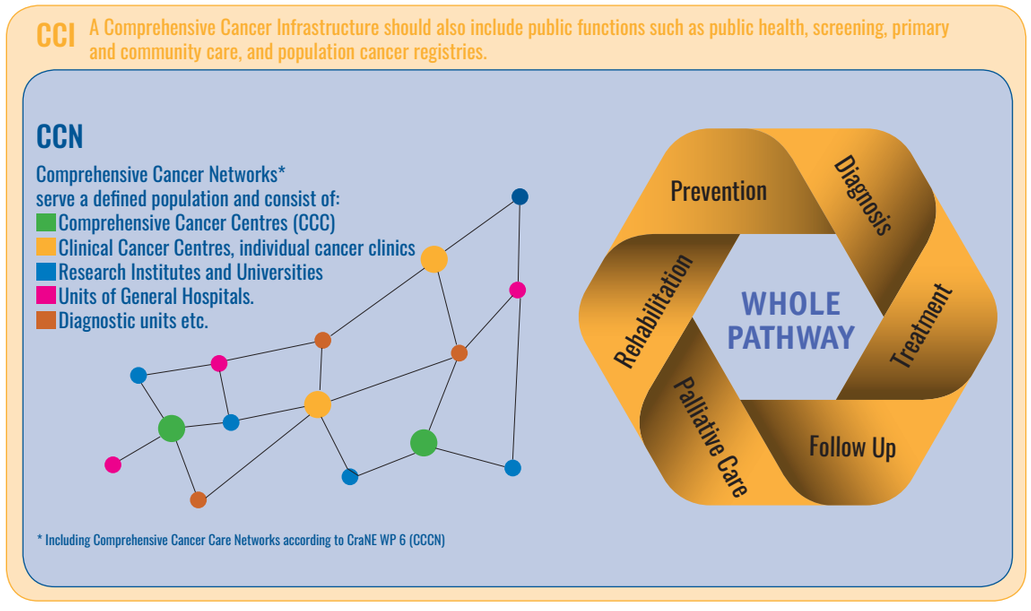
- Finalize a standardised matrix of cancer research/care performance indicators, and a CCI Maturity Model (CCI MM), to be used to analyse the maturity of CCIs across the EU.
- Map the maturity of CCIs across all EU MSs according to the agreed matrix of cancer research/care performance indicators; thereby clustering CCIs according to maturity.
- Plan a Capacity Building (CB) programme tailored to each identified CCI, and further customising tailored interventions (in agreement with the relevant public authorities), giving precedence to those MSs and a few ACs with absence of, or a low maturity of, CCIs.
- Identify and coach CB subject experts to deliver the onsite tailored interventions ('Deep Dives') and for online lectures and 3 F2F regional conferences.
- Execute the CB programme, covering all EU MSs and ACs at various levels of tailored intervention (all having access to online interventions, and some having onsite interventions according to a co-creation model1, reporting on the impact and recommended sustainable follow-up actions for each CCI site.

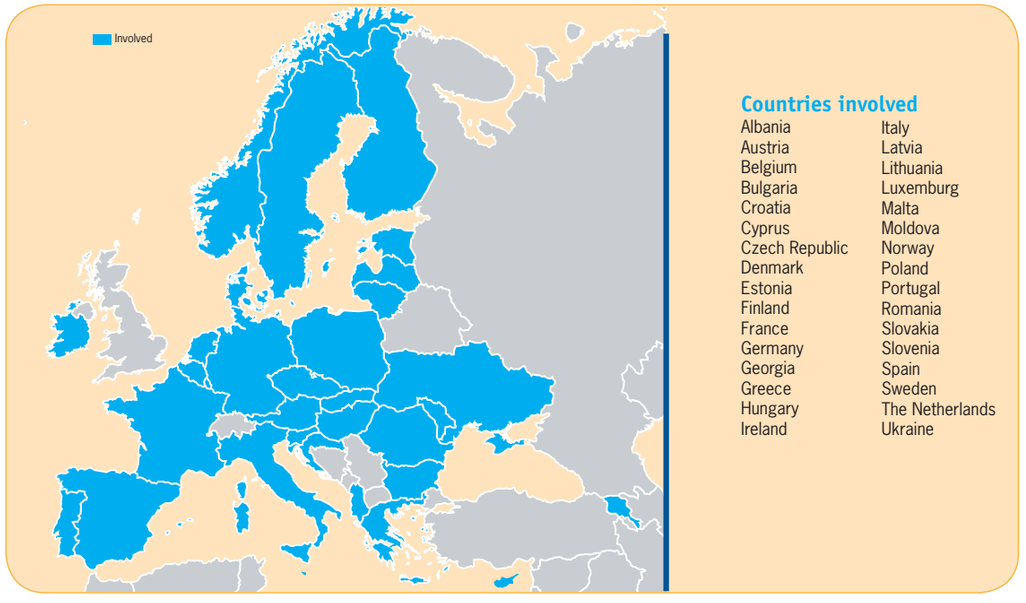
Dissemination and communication to the relevant stakeholders (i.e., research and healthcare professional, policymakers, citizens including patients, patients' associations, and informal caregivers) of the CB lessons learned and best practices, to further exploit the CB beyond the project will be implemented.

CCI4EU brings together all the largest Comprehensive Cancer Centres (CCCs) in the EU which have the combined multidisciplinary experience necessary to build capacity in less well developed CCIs. There is no area of cancer expertise which is outside the capability of these major cancer centres, including expertise on rare cancers, AI, novel therapies, innovative clinical trials, and excellence in nursing and patient engagement. The **CCI4EU** Consortium includes also health authorities who are well versed in the challenges of research capacity and capability. Other important actors involved are major cancer network organisations in the EU, European organisations providing oncology training courses, European largest umbrella cancer patients' association and major actors in previous and present EU Cancer Actions.

On December 9th, the CCI4EU application has passed the evaluation phase and the grant preparation has started.

The European Cancer Community is called to a new challenge to offer to all cancer patients the best available treatments.





EACR-OECI Joint Conference

MOLECULAR PATHOLOGY APPROACH TO CANCER

Bergamo, Italy
28-30 March 2023

www.eacr.org/conference/molecularpathology2023/index

This meeting will provide participants with a broad view of the scope, methodologies, future directions and challenges in addition to practical approaches for molecular pathology, focusing on comprehensive genomic profiling in cancer, in research and in clinical settings. We will discuss innovative approaches for empowering the next generation of molecular pathologists from practical and educational viewpoints. Upcoming applications of multiparametric immunoanalysis, liquid biopsy and artificial intelligence in pathology will be addressed. The meeting will help participants to establish a network of interactions and to build bridges to foster cross disciplinary studies. We are preparing for the future and for the unknown discoveries still to come.

Topics to be covered:

- Next generation molecular pathology
- Comprehensive cancer profiling in clinical diagnostics
- Perspectives of artificial intelligence (AI) in pathology
- Novel approaches for developing and implementing biomarkers in oncology and pathology
- Tumor heterogeneity - Spatial and longitudinal markers

Target audience

This conference will be of interest to a diverse audience including pathologists, molecular pathologists and pathology residents, researchers in the field of molecular diagnostics and precision oncologists. The conference population will thus simulate the multidisciplinary teams that act in the real world to facilitate interdisciplinary research and the multidisciplinary teams caring for patients with cancer.

Scientific Programme Committee

- ***Ragnhild Lothe**, Oslo University Hospital, Norway*
- ***Eli Pikarsky**, The Hebrew University of Jerusalem, Israel*
- ***Giorgio Stanta**, OECI, Italy*
- ***Luigi M Terracciano**, University Hospital Basel, Switzerland*
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OECI Awards

5 awards will be offered to selected applicants working in OECI member institutes.
Click here ***www.oeci.eu/Membership.aspx*** to check if your institute is an OECI member.
The awards provide a full registration free of charge and funds of up to €500.
Applicants for the award are asked to include a recent CV with a list of their most important publications from the last 5 years.
Applications must be sent to ***oeci@oeci.eu*** no later than: January 31st 2023.

The winners will be announced by February 15th.

EACR Conference Series
European Association for Cancer Research
www.eacr.org

Jointly organised by
European Association for Cancer Research
and
Organisation of European Cancer Institutes

OECI Organisation of European Cancer Institutes

IDEA4RC - Intelligent Ecosystem to improve the governance, the sharing and the re-use of health Data for Rare Cancers

Annalisa Trama[1,2]
1. Fondazione Istituto Nazionale dei Tumori Milan
2. Coordinator IDEA4RC RIA

IDEA4RC

Every year in Europe 650'000 people receive a rare cancer diagnosis[1]. Taken together they represent nearly 25% of all cancer diagnoses in the continent. Due to their rarity, the biggest challenge in the research on rare cancers is the need to aggregate and exploit data across different clinical centers and countries.

This is the challenge that the IDEA4RC project funded by the European Union intends to take up. The final objective of IDEA4RC, coordinated by the Istituto Nazionale Tumori in Milan, is the development of a European data ecosystem for rare cancers, where scientific and clinical questions can be addressed by training suitable machine learning models on an ensemble of data sets contributed by several clinical centers across Europe. This ecosystem will be tested by 11 clinical centers of the European Reference Network on rare adult solid cancers, EURACAN, established in 8 European countries. The test will focus on two among the 12 rare cancers domains: head and neck cancers and sarcomas.

To accomplish this task an intense dialogue among different professionals in healthcare and scientific research will take place and new technological solutions have to be devised. For this reason, IDEA4RC will be a truly interdisciplinary project involving 25 partners spanning a wide range of expertise.

First, legal, ethical and privacy related issues have to be worked out in a way that is compliant not only with community and national regulations but also with the willingness to share of the different subjects involved and with their vision about what values this sharing should generate. This is the reason why the IDEA4RC ecosystem will use a privacy preserving federated infrastructure based on data capsules, that will allow to train algorithms on several data sets without moving them from their original location.

Secondly, in order to extract value and knowledge, data need to be harmonized. Researchers and clinicians could benefit both from the aggregation of structured data, such as Electronic Health Records or Cancer Registries, and from non-structured ones, such as electronic medical records, image and pathology reports, into HL7 FHIR standard[2].

IDEA4RC will tackle this challenge thanks to the contribution of renowned scholars in the area of computer science and Natural Language Processing (NLP). With the clinicians' help, they will develop and train NLP models in several languages in order to transform notes and reports in structured data which can finally feed machine learning algorithms.

Those algorithms will be designed to predict for example clinical outcomes based on the type of tumor, the individual characteristics of the patient and the treatments received. These predictions should provide assistance to the decision-making process and thus their objectives need to incorporate not only the clinicians point of view but also that of patients and of their care givers.

Therefore, in building the whole infrastructure a reflection on values will be carried out thanks to the involvement of a group of social scientists with a robust experience in responsible research and innovation.

References

1 G. Gatta et al., The Lancet Oncology 18(8), 1022-1039 (2017).
https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(17)30445-X/fulltext
*2 HL7 FHIR, **https://hl7.org/fhir**, last access October 2022.*

Instand-NGS4P - Integrated and Standardized NGS workflows for Personalised therapy

Peter M. Abuja[1], ***Penelope Kungl***[1] *and* ***Kurt Zatloukal***[1]
1. Diagnostic and Research Center for Molecular Biomedicine, Medical University of Graz

INSTAND-NGS4P is an EU-funded Pre-Commercial Procurement (PCP) project for improving cancer patients' benefit from Next Generation Sequencing (NGS) by developing an integrated and standardized NGS workflow. For this, it will compile information from cancer gene testing, pharmacogenomics testing and e-medication in proper presentation to medical doctors for supporting therapy decision making at bedside widely applicable in health systems.

The EU-cofunded PCP project provides funding for a public consortium to define unmet medical and technical needs as a basis for a request for tenders addressing solution providers (contractors) to develop their products to better meet user needs.

Major challenges to be addressed are:

- Improving the analytical performance by standardizing pre-analytical processes
- Integrating pre-analytical, analytical processes and data analytics into a standardized workflow
- Defining genetic variants with established medical implications for common and rare cancer of adult and paediatric cancers including pharmacogenomic variants relevant for drugs used in cancer care
- Developing reference material for quality control
- Meeting requirements of the European in vitro-diagnostics regulation
- Improving benefits from NGS for patients and health systems

Through the integration of all elements of such a workflow (primary diagnosis, sample collection, library preparation, sequencing, bioinformatics – including pharmacogenomics analysis, and reporting to both physicians and patients) we expect to obtain a versatile and precise decision support tool that conforms to all pertinent regulations, such as the IVDR.

After the Open Market Consultation which gave insight into clinical and patients' needs, as well as technical innovation potential, the subsequent Request for Tender attracted 24 tenders in total from which 15 tenderers were selected for Phase 1. This phase resulted in several ambitious and highly innovative solution designs, from which 11 contracts (Table 1) were awarded for Phase 2 based on the fulfilment of the award criteria including the potential for integration into a complete workflow.

At the end of this prototype development phase (Phase 2, November 2022 to March 2024) analytical performance and integrability will decide to a great extent which of the prototypes will enter the final phase of the project. Phase 3 will focus on the integration of the developed solutions into a complete diagnostic workflow and on the testing of usability and performance by the academic partners in a real world clinical hospital environment.

For further details on the Contractors and their project abstracts, please visit
www.instandngs4p.eu/pcp/phase-2-prototype-development

Lot	Lead Contractor
Lot 1: Pre-Sequencing	Integrated DNA Technologies, BV QIAGEN GmbH Twist Bioscience Corporation
Lot 3: Bioinformatics Analysis	BC Platforms AG Congenica Ltd FUNDACIO CENTRE DE REGULACIO GENOMICA Platomics GmbH
Lot 4: Integrated Reporting	BC Platforms AG Congenica Ltd fragmentiX Storage Solutions GmbH FUNDACIO CENTRE DE REGULACIO GENOMICA

Table 1: Contractors awarded funding for prototype development (Phase 2) in Instand-NGS4P.

INTERACT-EUROPE: Building an Inter-Specialty Cancer Training Programme across Europe

Andreas Charalambous[1], ***Matti Aapro***[2]
1. President of the European Cancer Organisation (ECO)
2. Past-President of the European Cancer Organisation (ECO)

Background

"In 2020, 2.7 million people in the European Union were diagnosed with cancer, and another 1.3 million people lost their lives."[1] To address this growing challenge and improve cancer control and outcomes across Europe, the European Commission made cancer one of its main priorities. This political commitment was reinforced through the development of Europe's Beating Cancer Plan with cancer being one of the EU's five Missions.

Co-funded by the European Commission under the EU4Health programme 2021-2027 and as part of Europe's Beating Cancer Plan, INTERACT-EUROPE[2] started in June 2022. The project is coordinated by the European Cancer Organisation, with OECI being one of the project partners, supporting the development and implementation of an inter-specialty cancer training needs assessment and curriculum and preparing cancer centres and trainees for its delivery.

Funding

The research leading to these results has received funding from EU4Health Programme 2021-2027 as part of Europe's Beating Cancer Plan under Grant Agreement n. 101056995.

The Challenge that the INTERACT-EUROPE project addresses

Cancer management can be complex, which means that cancer care may involve a very wide range of modalities, disciplines and professions across the cancer continuum. High-quality cancer care requires great teamwork where everybody's expertise is used in each patient's diagnosis and treatment.

Multi-disciplinary teams (MDT) and multi-professionalism in oncology are crucial for close cooperation between all professions involved in cancer care to improve person-centered care along the whole cancer pathway, enhance treatment efficiency and overall patient care and experience. The evidence clearly indicates that care provided by multi-disciplinary teams results in better outcomes for patients[3].

INTERACT-EUROPE aims to leverage teamwork to apply knowledge and develop a best-in-class curriculum by consulting leading health organisations and cancer centres. The latest technology will provide better access to training across borders and in different languages.

Impact

The INTERACT-EUROPE project encompasses several aspects of innovative, patient-centred care and aims to produce an impact lasting well beyond the project duration. Building upon the outcomes and contributions of all project partners, the project's Blueprint will ensure the long-standing impact of the initiative by outlining key recommendations and requirements for the successful delivery of a technology Inter-Speciality Cancer Training Programme (ISCTP) in Europe.

Next steps

Further development of INTERACT-EUROPE is aimed at:

- A new European-level consensus and clarity about Inter-Speciality Cancer Training (ISCT) needs
- Multi-partner collaboration in the delivery of the Inter-Speciality Cancer Training Programme (ISCTP)
- Improved patient outcomes and patient care because of higher-functioning multidisciplinary cancer care teams, operating with an enhanced understanding of each other's roles and needs following the adoption of the project's curriculum
- Validation of tools and methods that will become standard of care

For more information on this project, visit our website ***interact-europe.org***

1. European Commission (n.d.) A cancer plan for Europe. Directorate-General for Communication. Retrieved 31 October 2022, from ***https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/cancer-plan-europe_en***
2. European Cancer Organisation (2022) INTERACT-EUROPE. European Cancer Organisation. Retrieved 31 October 2022, from ***http://www.interact-europe.org***
3. Selby P., Popescu R., Lawler M. et al., The Value and Future Developments of Multidisciplinary Team Cancer Care. Am Soc Clin Oncol Educ Book. 2019; 39: pp. 332-340.

ECIBC European Commission Initiative on Breast Cancer to improve quality of care and to reduce inequality in Europe

***Luciana Neamtiu*[1], *Gian Paolo Morgano*[1], *Elena Parmelli*[1], *Annett Janusch Roi*[1]**
1. European Commission, Joint Research Centre, Ispra (Italy)

Breast cancer is the most commonly diagnosed cancer in Europe, representing 13.3% of all new cancer cases in 2020 and accounting for 28.7% of all new cancers in women. The last available estimates predict large variations in incidence and mortality rates across the Member States. Estimated breast cancer incidence and mortality rates in 2020 vary two-fold across EU-27 (e.g. incidence ranging from 100 to 194 per 100 000 women in the EU-27).[1] The five-year survival of breast cancer patients diagnosed in 2000-2007 is highest in Northern and Western Europe and lowest in Eastern Europe. On the positive side, mortality trends in the EU-27 are decreasing and this is mainly due to effective treatment and early detection.

Addressing breast Cancer in the EU

Starting with the launch of Europe Against Cancer in 1985, the European Union (EU) has supported various actions targeting cancer, such as several Joint Actions: European Partnership Action Against Cancer (EPAAC), Cancer Control Joint Action (CanCon), Innovative Partnership for Action Against Cancer (iPAAC) and most recently, the Network of Comprehensive Cancer Centres Joint Action (Crane). In December 2003, the Council adopted the "Council Recommendation on cancer screening" and recommended population-based screening for breast, cervical and colorectal cancers in accordance with European guidelines. The adoption of these guidelines are key for ensuring the development of high quality cancer-screening programmes and the recommendation calls on the Commission to ' coordinate the production of such guidelines'.[2] Moreover, in 2008 both the European Parliament Resolution which acknowledged the differences in 'the quality of cancer treatment facilities, screening programmes and evidence-based best-practice guidelines…' and the Council Conclusions on reducing the burden of cancer, called on the Commission to support Member States among others to:

- continue with the implementation of population-based quality-assured screening programmes for breast, cervical and colorectal cancer in line with the Council Recommendation of 2 December 2003 on cancer screening';
- facilitate the development and updating of, and publish, web-based quality assurance and evidence-based guidelines on cancer (breast, cervical and colorectal) …'.
- support the development of European accreditation/certification programmes in cancer screening, diagnosis and treatment based on European quality-assurance guidelines' and
- explore the potential for the development of voluntary European accreditation schemes for cancer screening and appropriate follow-up of lesions detected by screening'.[3]

The development and update of the European guidelines and associated quality assurance schemes across Europe is now at the heart of the European Commission Knowledge Centre on Cancer[4] (managed by the Joint Research Centre), a flagship initiative of the Europe's Beating Cancer Plan, launched by the Commission's President van der Leyen in February 2021. In September 2022[1], the Commission presented a proposal for a Council Recommendation (CR) on Strengthening prevention through early detection. The objective of this proposed recommendation is to increase the number of screenings, covering more target groups and more cancers. The Council has indeed taken forward this proposal and the recommendation has just been published[2].

1. ***https://health.ec.europa.eu/publications/proposal-council-recommendation-cr-strengthening-preventionthrough-early-detection-new-approach_en***
2. ***https://data.consilium.europa.eu/doc/document/ST-14770-2022-INIT/en/pdf***

ECIBC

The European Commission Initiative on Breast Cancer (ECIBC)[5] is the European Commission's response to these calls for action. It is a patient-centred, evidence-based initiative that aims at improving and harmonising breast cancer care in Europe. The initiative is a collaborative effort that brings together the European Commission in the role of scientific, technical and administrative coordinator, with essential guidance and support from expert working groups, including professionals from several relevant disciplines and citizens/patients, as well as input from countries and stakeholders. To reduce inequalities in access to the best quality care, ECIBC proposes a European, evidence-based model.

ECIBC key objectives include the development of:

1. The European guidelines on breast cancer screening and diagnosis. For other care processes, including treatment, rehabilitation and survivorship, and palliative care, trustworthy, evidence-based guidelines developed by other entities reside online as part of a collection of guidelines on breast cancer.
2. A voluntary European quality assurance scheme for breast cancer services.

The development phase of the initiative relied on the collaboration of two working groups the Guidelines Development Group (GDG) and the Quality Assurance Scheme Development Group (QASDG). Working group members were nominated via open calls and the experts were selected based on initial expressions of interest to participate in the initiative. The members of these groups work on a voluntary basis. Possible conflicts of interest are evaluated annually and prior to each meeting. A transparent consultation process takes place during all phases of the project and involves input and participation from different stakeholders. The ECIBC has the collaboration of patients and patient representatives involved in any step of the decision making progress and ensures that the patient's view is properly considered to ensure the development of a person centred initiative. To date, the European Breast Cancer Guidelines include 76 recommendations on screening and diagnosis, 4 good practice statements, and 18 plain language summaries tailored for women and patients. Developed following the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach[6]; [7]), the European Breast Cancer Guidelines are available online

https://healthcare-quality.jrc.ec.europa.eu/ecibc/european-breast-cancer-guidelines

and regularly updated. The updating process allows the evaluation of the impact of new evidence on existing recommendations and the addition of new recommendations on emerging topics deemed relevant by the GDG, such as using artificial intelligence to support the reading of mammograms in screening.

The European quality assurance scheme for breast cancer services includes a set of requirements that breast cancer services have to comply with to be certified under the scheme. The scheme covers all care processes from screening to end-of-life care (fig. 1) as well as four quality domains:

- clinical effectiveness
- facilities, resources, and workforce
- personal empowerment and experience
- safety

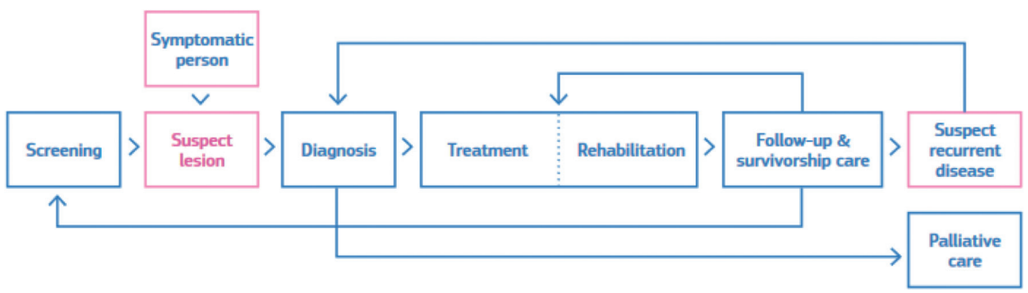


Fig. 1. Breast cancer care pathway.

The QASDG defined requirements according to an adjusted RAND/UCLA Appropriateness Method[10] and, in turn, requirements are selected via Delphi-like rounds. Requirements under consideration were presented to the QASDG along with the underpinning evidence. The QASDG rated each requirement based on relevance, understandability, and technical feasibility. Each requirement is described in a standardised way. Eighty-six requirements covering screening, diagnosis, treatment (surgery, systemic treatment, and radiotherapy), rehabilitation, follow-up and palliative care have been included in the scheme.

The scheme is modular so that different services can participate in all or selected phases of breast cancer care. However, when modules, or processes and sub-processes within modules, are offered by different services, all entities involved in the process should be responsible for meeting the requirements and to ensure continuity of care. Services meeting the European requirements can be certified.

The scheme is described in the form of manuals that are freely accessible at the European Commission's Joint Research Centre's website at:

https://healthcare-quality.jrc.ec.europa.eu/breast-quality-assurance-scheme/manuals

The Scheme Owner Manual describes how the European quality assurance scheme is organised, managed and maintained, while the Manual for Breast Cancer Services includes the requirements and criteria for every process within the entire breast cancer care process. Two additional tools, a self-assessment software and a quality indicators calculator, along with associated user manuals, have also been developed to assist breast cancer services in implementing the scheme.

The scheme is being tested for applicability in different settings (feasibility and pilot run). During the feasibility phase, the requirements developed are tested voluntarily by eight breast cancer services from six member states. The main objectives of the exercise are to check the feasibility of implementing the requirements, including continuity of care aspects and to provide feedback regarding the comprehensibility and interpretation of the requirements, criteria and indicators and the tools provided. To demonstrate compliance, breast cancer services are audited. The audit approach is tested in a pilot run by 17 entities (breast cancer services, certification bodies, national accreditation bodies) from eight EU countries. The results will be available early 2023 and will lead to improvements of the scheme and final delivery of the tools and manuals for implementation.

References

[1] Source: ECIS - European Cancer Information System. ***https://ecis.jrc.ec.europa.eu***

[2] Council Conclusions on reducing the burden of cancer, 9636 / 08. ***https://data.consilium.europa.eu/doc/document/ST%209636%202008%20INIT/EN/pdf***

[3] Council of the European Union. Employment, social policy, health and consumer affairs - Council meeting on 9 and 10 June 2008. Reducing the burden of cancer - Adoption of Council conclusions. Brussels 9636/08, p.9. 2008. ***https://ec.europa.eu/commission/presscorner/api/files/document/print/en/pres_08_166/PRES_08_166_EN.pdf***

[4] Knowledge Centre on Cancer ***https://knowledge4policy.ec.europa.eu/cancer_en***

[5] European Commission Initiative on Breast Cancer. ***https://healthcare-quality.jrc.ec.europa.eu/***

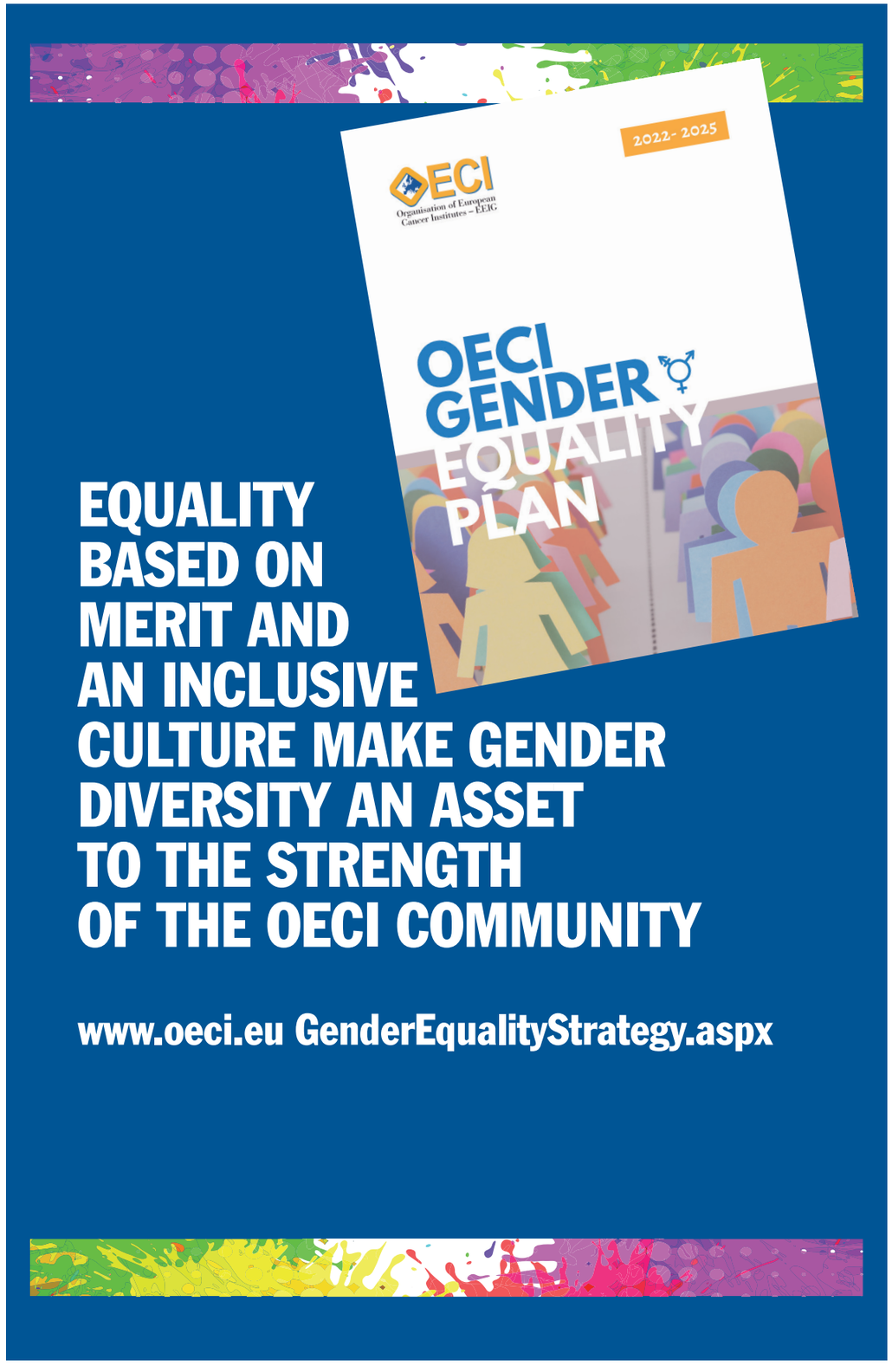
[6] Alonso-Coello P, Schünemann HJ, Moberg J, Brignardello-Petersen R, Akl EA, Davoli M, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. BMJ. 2016.

[7] Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. J Clin Epidemiol. 2011.

[8] Alonso-Coello P, Oxman AD, Moberg J, Brignardello-Petersen R, Akl EA, Davoli M, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines. BMJ. 2016.

[9] GRADEpro GDT. gradepro.org. McMaster University and Evidence Prime Inc. 2015. ***https://gradepro.org/***

[10] Fitch, K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR, Lazaro P. et al. The RAND/UCLA Appropriateness Method User's Manual. Santa Monica, CA: RAND Corporation, 2001.



ONCOVALUE: Generating real world effectiveness data and technology assessment input for cancer treatments in a consortium initiated by OECI member institutions

Wim H. van Harten[1], ***Valesca.P Retèl***[2], ***Marina Borges***[3], ***Ilaria Massa***[4], ***Ulrik Lassen***[5], ***Johanna Mattson*** [6]
1. MD PhD (NKI-AVL)
2. PhD (NKI-AVL)
3. IPOPorto
4. IRST
5. MD PhD (Rigshospitalet)
6. MD PhD (HUS)

The aim of ONCOVALUE is to unlock the full potential of real-world data (RWD) of cancer hospitals and research institutes throughout the EU to enable value-based care and maintain sustainability of the European healthcare system for the treatment of cancer. To achieve this, the ONCOVALUE consortium -initiated by Helsinki University Hospital Comprehensive Cancer Center and The Netherlands Cancer Institute- will (A) enable and guide cancer hospitals to collect, harmonize and analyse high-quality RWD, and (B) empower and train health regulatory and health technology assessment (HTA) bodies to adopt RWD-driven methodologies in their decision-making processes according to the new EU directive for HTA. ONCOVALUE will develop tools for the collection, processing, and evaluation of real-world data to support decision-making of regulators on cost-effectiveness of novel cancer therapies.

Along with the continuous increase of the global cancer prevalence, a rising amount of novel cancer therapies is entering the market. Thus far, the efficacy of new therapies determined by clinical trials and regulatory clearance for market introduction is often based on small studies with relatively little evidence for true value (outcomes, quality of life, cost-effectiveness). Increasingly cancer centers and large hospitals are building “integrated data lakes” linking the stored electronic medical records (EMR) data, imaging and diagnostic data, but also structured PROMS measurements. Although only a minority is working with completely structured EMR entry systems, technologies to process unstructured data are also becoming available. Exploring the value of RWD generated from structured and unstructured data storage systems linked to institutions, is becoming a promising venue.

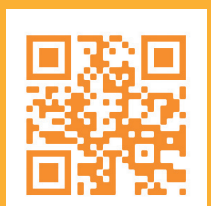
To achieve value-based assessment of novel cancer therapies, ONCOVALUE aims to enable the inclusion of high-quality RWD in regulatory and reimbursement decision-making. This will support the selection of effective medicines, reduce excess spending on drugs that yield little benefit and enable oncologists to promote effective care by improving and promoting evidence-based clinical guidelines that avoid low value treatments. The objective is to build standardized data collection and processing capabilities for European cancer hospitals to enable real-time RWD delivery and evidence creation on value of cancer therapies for HTA and regulatory purposes. Further to develop and test next generation artificial intelligence (AI)-based tools supporting the effective use of structured and unstructured data for HTA of oncology therapies. Lastly to develop capability, governance models, and quality frameworks for HTA/ regulatory bodies across Europe to utilize different types of RWD.

The ONCOVALUE consortium consists of specialized European cancer centres (OECI), AI methods developers, data access experts, RWD specialists, HTA experts, educational experts, and experts in innovation management and sustainability. During this project, we will also provide easy-to-use tools allowing health care professionals to mine the RWD from harmonised data sources while respecting national and international data privacy and safety regulations (e.g., GDPR). In a number of pilot cases the feasibility of the generated approach will be tested.

ONCOVALUE will bring a framework consisting of novel tools and RWD quality standards for cancer hospitals to collect and process RWD, as well as a methodological manual with guidelines and standard Operating Procedures (SOPs) for health authorities and HTA bodies to analyse this data in regulatory and reimbursement decision making. In contrary to previous attempts focussing on point solutions, we will address the issues faced by regulators systematically in the lifecycle of a medicinal product, by integrating standardised and interoperable data collection and reproducible analytics practices in existing HTA workflows. Cases on the use of RWD will focus on treatments of different cancer types such as colorectal cancer, breast cancer and lung cancer, though the technology should allow for generalisation for all cancer types and -stages including metastatic disease.

In the diffusion workpackage a consensus paper with recommendations on the SOPs for RWD collection in cancer hospitals; sharing the analysis of RWD of three different cancer types (i.e., colorectal cancer, breast cancer and lung cancer) across 5 cancer centers is foreseen. Further the project will produce guidelines on next generation AI-based tools supporting the effective use of unstructured data for effectiveness assessment of oncology therapies and HTA. Developing guidelines and conducting education sessions for cancer centers throughout Europe wishing to unlock their data lakes to produce real world evidence, will be the final stage of ONCOVALUE.

Figure representing the ONCOVALUE consortium and partners.



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