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Welcome of the OECI President: the OECI strategy 2024-2026

Giovanni Apolone¹ 1. OECI President



Dear OECI Members,

Dear Readers,

I am delighted to introduce you to the first issue of the OECI Magazine 2024, which aims to shed light on the strategy OECI will be implementing in 2024-2026, during my Presidential mandate.

We are growing on a truly global scale. Today, OECI regroups 139 of the world's leading cancer centres. Several new members will be joining our Organisation at OECI General Assembly on 14 June 2024, thus bringing our membership to over 150 centres and institutes across Europe and beyond its borders.

We are called to adapt and improve the way we are addressing our member's needs, in the attempt of building an open community of physicians, scientists, administrators who work together towards the same goal: closing the cancer gap and offering to our patients the best available treatments.

In order to achieve this goal, OECI endorses the 10 flagship initiatives and multiple supporting actions helping Member States to turn the tide against cancer, as described in the Communication from the Commission to the European Parliament and the Council on a European Cancer Plan.

Our mission to build a strong community of cancer centres/institutes also closely aligns with the EU Cancer Mission. It includes the Comprehensive Cancer Infrastructures for Europe (CCI4EU) CSA. CCI4EU was launched on 1 May 2023 under the coordination of OECI, bringing together a large network of 27 Member States and 5 Associated Countries in a capacity building Programme designed to rethink the cancer culture and reduce inequalities.

As we continue expanding outside Europe, we are also intensifying our international activities. This is the reason why during my Presidency, OECIWORLD will be launched. The initiative is thoroughly outlined in the first article of this issue by Prof. Thierry Philip, OECI Past President and chairperson of this new Programme.

OECIWORLD will comprise institutes in Latin America, in Asia, in Africa, in Turkey, in Moldova and Ukraine, and it will seek to enable our Associate Members Type B to easily participate in OECI activities, define joint programmes and access international research grants. This initiative will also prepare the ground for some of these centres to participate in the OECI A&D Programme and to create twinning with other OECI interested members.

As challenges and needs arise specific to individual countries and healthcare settings, OECI achieved a significant milestone in 2023 when it certified our first extra European cancer centre in Chile – Instituto Oncológico Fundación Arturo López Pérez (FALP), now an OECI Cancer Centre. This laid a foundation stone toward a new OECI sister organisation, to be established in the near future grouping 10 Latin-American cancer centres in a network tailored on the OECI organisational model and standards.

Closely related to this is the challenge we face in securing a sufficient and qualified oncology workforce to match the rising incidence of cancer in years to come. Another tier of the strategy I established for my presidential mandate is about training future generations of research leaders. I refer to the OECI Academy: a new Programme specifically designed for junior scientists, oncologists and research managers. The final goal is to produce wellrounded oncologists who can perform top-level innovative science, secure funding for their research, and lead their teams with confidence and integrity. The OECI Academy is introduced in this issue.

Over the past years, we have been increasingly thinking about innovative practices to engage our most important

stakeholders: our patients. As a host of studies reveals the benefits of proactively involving patients in the decisions related to their cancer journey, OECI is strongly involved in EUonQoL, an innovative action that brings forth the importance of empowering patient-centered healthcare.

This is an important step forward, and the reason why OECI is remodeling its Patient Working Group into the Enhancing Patient Involvement in Cancer Care and Research (EPIC-CARE) WG. The mission of this revitalized WG is to promote meaningful collaboration between cancer patient organisations, Comprehensive Cancer Centers (CCCs) and Cancer Centres (CCCs), and all our Members, to ensure patient perspectives on cancer prevention, diagnosis, care, rehabilitation, and survivorship are integrated in a quality approach where patients are strongly involved in cancer research.

A real network is something more than a list of members. It is a community of people who cooperate in a dynamic multidirectional system. One of the objectives of my Presidency, in addition to ensuring continuity and sustainability, will be to further galvanise our Members' involvement in our Organisation's Programme of activities, which include, among others:

- Enlarging the OECI Board, mindful of a healthy geographic and gender representation
- Creating an Advisory Board of young scientists to the OECI President and the OECI Board
- Redirecting and creating new Working Groups on emerging topics of interest to our community
- Providing training courses on topics related to European projects
- Selecting and co-financing projects proposed by young researchers
- Reducing fees for institutes in countries afflicted by geopolitical or economic difficulties

In essence, transforming the points that now identify the OECI Members on the map into a more interactive network, a living community connected by common objectives and shared activities to prepare the future in comprehensive cancer care.

We are taking steps to digitise our publishing materials to reduce paper use and minimise our environmental impact. In order to become more sustainable, this issue of the OECI Magazine will only be printed in a limited number for the Oncology Days. The bulk dissemination will be carried out in digital format.

In order to maximize dissemination of the OECI Magazine, and help your teams take advantage from our initiatives, I warmly invite the Directors of our Members to sustain the dissemination of information within their centres/ institutes. We also suggest organising focused internal meeting in order to present our Organisation.

I hope that our readers will appreciate and enjoy the resumes and articles appearing in this issue, which closes with an article that we hope will prepare the ground for deep reflection and further debate and action: "Health inequalities in Europe: causes and actions - The case of cancer".

OECI THE LARGEST NETWORK OF CANCER INSTITUTES ACROSS EUROPE AND BEYOND ITS BORDERS

OECIWORLD: A network of OECI Associate Members Type B*

Thierry Philip¹, Claudio Lombardo¹



 Organisation of European Cancer Institutes, Past-President and Chairperson OECIWORLD Programme
 Organisation of European Cancer Institutes, General Manager

The expansion of the OECI membership on other continents (Asia, Africa, Latin-America), and countries such as Ukraine, Moldova and Turkey has spurred OECI to launch an initiative that can enable these countries to easily participate in OECI activities, define joint programmes and access international funding sources involving OECI Members.

This initiative also aims to prepare the ground for the best centres in these countries to participate in the OECI A&D Programme. In addition, it should foster bilateral collaborations, drive participation in research initiatives and international research grants.

The OECI Board discussed and approved the proposal to establish a new OECI Programme and establish the "OECIWORLD Network" included in the Strategic Programme of the OECI Presidency 2023-2026.

The responsibility of this New Programme has been assigned to the former OECI President, which has been charged to connect the cancer centres/institutes in the interested countries creating a network that could stimulate better interactions with other OECI Members.

Preliminary contacts took place with Vietnam, Lebanon, Jordan, Chile, Colombia, Brazil, Ukraine, Moldova, Tanzania, Algeria and Turkey.

In Chile, the Instituto Oncológico Fundación Arturo López Pérez (FALP) in Santiago, has already been certified by the A&D Programme as OECI Cancer Centre; Jordan and Brazil are now about to enter the OECI A&D Programme, whilst Tanzania and Ukraine are evaluating this possibility.

In order to move ahead with practical actions, a first constitutional meeting to set-up the OECIWORLD Network, will take place on 10-12 September 2024 at Villa Verganti – Veronesi in Inveruno (Milan) https://villavergantiveronesi.com/en/

The OECI President, Dr. Giovanni Apolone, will welcome the participants and introduce the whole OECI Strategy for his presidential mandate, followed by the OECIWORL objectives and the OECI Accreditation and Designation Programme.

FALP will present input and insights after its participation to the OECI Quality Programme, alongside a new initiative, which will group 10 Latin-American cancer centres in a network tailored on the OECI organisational model and the OECI A&D Core standards. The discussion will explore the best way to help establish a new OECI Sister Organisation, which would manage a steady connection among the Latin-American partners, whilst maintaining a close relationship with the mother-organisation.

All participants will be asked to introduce their priorities

The World Health Organisation and the International Agency for Research on Cancer accepted to participate in the meeting to better understand the objective of this initiative, offer their suggestions and discuss the feasibility of a link with their funding programmes.

At the end of the meeting a Memorandum of Understanding will be signed between OECI and all the Parties involved.

Objectives of the OECIWORLD Network

- Create new bilateral collaborations between European and extra-European institutes;
- Develop projects on international financing funds;
- Promote the concept of quality in their institutions;
- Access, where possible, the OECI Accreditation and Designation Programme;
- Define new certification models adapted to local contexts;
- Collaborate in the establishment of new oncology networks that bring together specific countries on a continent tailored on the OECI model;
- Support the adoption of national cancer plans;
- Support the concept of patient as a recipient of the best treatment opportunities notwithstanding his/her residency;
- Bring OECI and institutes from other continents closer to the WHO and IARC programmes;
- In particular for countries such as Ukraine or similar, the collaboration will focus on:
- promoting awareness and education programmes to reduce the negative impact of tobacco and alcoholic beverage consumption;
- promoting healthy eating, physical activity and a healthy lifestyle among the population;
- raising public awareness of harmful environmental factors that have carcinogenic effects;
- increasing vaccination of new-borns against hepatitis B;
- increasing the number of hepatitis B and C cases treated;
- increasing the level of vaccination against human papillomavirus;
- raising public awareness of cancer prevention measures.
- setting up cancer screening and early diagnosis programs;
- increasing the effectiveness of primary care;
- increasing the level of early detection of childhood cancer;
- reducing the incidence of cervical cancer;
- reducing the incidence of colorectal cancer;
- increasing the proportion of cancer cases diagnosed at an early stage in children and adults;
- reconstructing healthcare systems damaged by military conflict.

The Inveruno meeting marks the formal establishment of the OECIWORLD Network. OECI will be taking charge of the collaborative activities with the cancer centres and members involved.

* The OECI Associated Members Type B are those cancer centres/institutes that do not fulfil the conditions provided for in Article 4 of EEC Regulation n° 2137/85 of 25 July, 1985 on the creation of a European Economic Interest Grouping. Are therefore excluded Members in the European Economic Area (EEA) + UK and Switzerland.



The OECI Academy - Empowering the next generation of

oncologists and scientists

Giovanni Apolone^{1,2}. Paola Gabaldi³. Chiara Gabbi⁴

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- 2. Istituto Nazionale Tumori di Milano, Italy, Scientific Director
- 3. Fondazione Don Gnocchi, Milan, Italy, Managing Director for Research
- 4. Humanitas medical care, Milan, Italy, Physician



1. European Context

Skills are of utmost importance for researchers. They enable the execution of high-quality research, which in turn contributes to the development of a robust and resilient European Research and Innovation (R&I) system that can withstand challenges and maintain competitiveness. Therefore, it's crucial that researchers are equipped not only with research-specific skills, but also with transversal skills. These skills allow them to be interoperable between academia and other sectors, including industry and business. This interoperability is key to turn innovative ideas into business, leading to social, environmental, and economic profitability.

Indeed, the European Commission has taken significant strides in this regard. It has identified a set of skills and occupations that are pertinent to researchers. This has contributed to the update of the European Skills, Competences, and Occupations (ESCO) classification (1), ensuring a standardized and comprehensive framework for researcher competencies across Europe. Moreover, the Commission has finalized the European Competence Framework for Researchers (ResearchComp) (2). This framework contains the competences that researchers should have for a successful and interoperable career in academia and beyond.

- It is structured around **seven competence areas** (figure 1):
- 1. Cognitive Abilities
- 2. Doing Research
- 3. Managing Research
- 4. Managing Research Tools
- 5. Making an Impact
- 6. Working with Others
- 7. Self-Management

This structured and detailed approach ensures a comprehensive understanding of the skills and competencies required at different stages of a researcher's career, facilitating continuous learning and development. It's a significant step towards enhancing the quality of research and fostering a culture of excellence and innovation in Europe.

2. The OECI Academy

The OECI-Academy is a novel programme specifically designed for junior scientists, oncologists and research managers. It is a strategic component of the OECI Presidential Strategy 2024-2026. Leveraging the ResearchComp (figure 1), the programme aspires to offer an extensive agenda of training initiatives. The final goal is to produce well-rounded oncologists who can perform top-level innovative science, secure

		Figure 1 is a schematic representation that provides
ResearchComp	OECI Academy	a comprehensive overview of the ResearchComp
Competence Area	Training	Competence Areas. These areas are integral to the
Doing Research	 European policy 	European Competence Framework for Researchers and are designed to foster a wide range of skills in
 Managing Research 	Grantsmanship	researchers. The figure also outlines the planned training
 Managing Research Tools 	 Science methodology 	courses of the OECI Academy that are specifically
 Making an Impact 	 Intellectual Property Strategy 	designed to enhance the skills of unior scientists
 Working with Others 	 Scientific writing 	tailored to align with the competencies outlined in the
 Self-Management 	Communication	ResearchComp framework. The aim is to provide
 Cognitive Abilities 	Leadership	junior scientists and oncologists with the necessary
U U U U U U U U U U U U U U U U U U U		knowledge and skills to excel in their respective fields.

funding for their research, effectively communicate their findings to a diverse audience, and lead their teams with confidence and integrity.

2.1. Training

- The Academy will offer a wide range of training events (figure 1) including:
- European Policy: This training is designed to equip researchers and managers with fundamental knowledge pertaining to legislative processes, regulatory frameworks, and the operational mechanisms of the European Commission Horizon Europe Programme. The objective is to empower participants to discern the most suitable opportunities that align with their research domain and competencies.
- Grantsmanship: Workshops on grant writing and funding strategies. These will help participants secure funding for their research projects.
- Science Methodology: Courses on research design, data analysis, and interpretation. These will equip the students with the necessary tools to conduct rigorous scientific research.
- Intellectual Property Strategy in Research: Workshops on how to manage IP in a research setting. This includes understanding when and how to file a patent, how to handle IP rights when collaborating with other researchers or institutions. These will equip students with the necessary knowledge to possibly protect and commercialize their scientific innovations.
- Scientific Writing: Training on how to effectively communicate scientific findings in written form. This includes writing research papers, review articles, and case reports.
- Communication: Courses on effective communication skills, both in a scientific context (e.g., presenting at conferences) and in a clinical context (e.g., communicating with patients). A particular emphasis will be placed on providing guidance on effective interaction with patient cancer organizations.
- Leadership: Training on leadership skills, such as decision-making, strategic planning, and team management. These skills are crucial for leading research teams and projects.

2.2. Structure

The Academy will adopt a **blended learning approach** for its training courses, leveraging the benefits of both online and on-site learning environments. This approach is designed to provide a flexible and comprehensive learning experience for the students.

The online component of the training will be delivered through a **digital learning platform** offering online webinars and workshops with real-time interaction between the students and the faculty. On-site training will be conducted at leading **OECI European Institutions**. Beside lectures, these sessions will also provide hands-on training, group work, and networking.

2.3. Faculty

The faculty at the OECI Academy will be a diverse and experienced group of professionals from various sectors including universities, research institutions, private sector, industries, not-for profit organization, regulatory bodies.

2.4. Partners

Within the framework of OECI, the Academy serves as a pivotal platform for cultivating alliances, establishing contacts, forging partnerships, and facilitating the exchange of information. It plays a significant role in nurturing an environment of integrated and open collaborations, where various stakeholders come together to co-create valuable research and innovations. In particular the OECI Academy will seek partnership with scientific societies in the field of oncology engaging leading experts in the field and with oncological foundations considering also patients, survivors, and their families. This is to ensure a holistic approach towards research and innovation in the field of oncology.

2.5. Conclusions and next steps

In conclusion the OECI Academy ambitiously aims to empower junior professionals in the oncological field with the scientific knowledge, technical expertise and soft skills necessary to advance cancer research and **patient care**. The final goal is to contribute to the global fight against cancer by training the future scientists and leaders in the oncological field.

The inaugural training course is scheduled for Autumn 2024. We invite all interested parties to stay informed about the announcements of future training courses through the OECI website, our social media channels, and regular newsletters.

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Advancing Molecular Pathology through Education: Exploring the European Masters in Molecular Pathology

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In today's rapidly evolving field of medicine, Molecular Pathology stands out as a crucial driver of innovation, prompting professionals to broaden their expertise beyond conventional pathology training. While the traditional practice of scrutinizing tissues under a microscope remains vital, the emergence of molecular technologies necessitates a deeper grasp of the genetic and molecular mechanisms underlying diseases. Diagnostic tissue pathology traditionally involves three levels of examination: macroscopic assessment, histologic analysis, and more recently, molecular evaluation. The first two levels of examination benefit from established shared knowledge and international standardization. However, the molecular level lags behind due to the swift pace of technological advancements and the absence of uniform standards. This discrepancy poses a challenge for ensuring consistency and accuracy in molecular pathology practices. As such, efforts to establish standardized protocols and enhance training in molecular pathology are crucial to meet the demands of modern healthcare and optimize patient outcomes.

In molecular pathology, inconsistency can lead to severe consequences, such as misdiagnosis and ineffective treatment outcomes. This lack of uniformity may result in erroneous treatment strategies, delayed or missed diagnoses, and the administration of therapies that prove ineffective. Moreover, inconsistent practices pose obstacles to research endeavours, impeding collaboration and potentially stalling progress in the field.

To tackle these consequences, it's vital to implement standardized protocols, supported by strong quality control measures and ongoing educational initiatives and partnerships within the field of molecular pathology. To this end, several European experts and entities, such as the Pathology Section of the European Union of Medical Specialists (UEMS) and the European Society of Pathology (ESP) have opened a two-year Master's degree program, coordinated at the University Côte d'Azur, Nice, France, entitled the European Masters in Molecular Pathology (EMMP) **https://univ-cotedazur.eu/msc/european-msc-molecular-pathology**. This initiative is endorsed through collaborations with several esteemed European universities, including those in Seville, Graz, Groningen, Tübingen, Munich, Leuven, Radboud, Porto, Berlin, and Trieste. Notably, the program has also formed strategic partnerships with key institutions such as OECI, Ulysseus University, ESMO, the European Liquid Biopsy Society, IHU RespirERA, BigPicture, and Thermo Fisher Scientific.

The curriculum develops specialized theoretical and practical competencies covering a wide range of methodologies and technologies in molecular diagnosis and research *https://online.fliphtml5.com/oegkb/tzop/#p=41*. It is designed specifically for practicing Pathologists or junior pathologists currently in their Residency, with a solid foundation in morphology. Its core objective is to cultivate a fresh cohort of Molecular Pathologists, empowering them with the expertise and insight required to propel Molecular Pathology forward on both European and global fronts. The curriculum employs a blended-learning approach, combining online asynchronous and synchronous sessions with on-campus classes and hands-on training (Figure 1), and two six-week internships in practical training.



Figure 1. Coordination of Program Modules by European Universities.

The European Masters in Molecular Pathology serves as a cornerstone in shaping the trajectory of molecular pathology through specialized education and training. Embracing technological advancements and promoting interdisciplinary collaboration, the program effectively addresses the dynamic nature of the field. Its significance lies in its capacity to enhance professional skills and promote a standardized approach to molecular diagnostics.

Ensuring equitable and efficient deployment of precision medicine, including Molecular Pathology, is a global challenge that requires patient access to validated molecular tests, a consistent regulatory and reimbursement environment offering incentives for test development, and concerted efforts by practice and health system leaders to develop the multidisciplinary workforce and information infrastructure necessary to create a standardized precision cancer care delivery system. Putting these pieces in place with all stakeholders would not only close the genomic testing gap in cancer care but could transform outcomes for many patients with cancer.

We advocate for a robust partnership between OECI and the European Masters in Molecular Pathology to greatly benefit future molecular pathologists and, ultimately, patients. As such, formal discussions are underway with OECI to establish an agreement aimed at promoting the Master's program.

Building capacity in research and innovation – why CCI4EU matters



Simon Oberst, FCA^{1, 2} 1. Improving Cancer Services 2. Organisation of European Cancer Institutes Director of Quality and Accreditation

When the Horizon Europe call *MISS-2022-CANCER-01-02: Strengthening research capacities of Comprehensive Cancer Infrastructures* was made in 2022, OECI immediately began discussions with key partners in Europe to see what could collaboratively be achieved. OECI seemed to be the natural player to coordinate a bid for this action, on account of our large membership of Cancer Centres (at the time 141) mainly in the EU. However, there remained the knotty question of what was meant in the call by "Comprehensive Cancer Infrastructures" (CCIs).

The Mission Board of the EU Mission on Cancer had defined Comprehensive Cancer Infrastructures as 'national or regional infrastructures that provide resources and services to support, improve and integrate cancer care, research, training of care professionals and education for cancer patients, survivors and families/carers.' This seemed, on due reflection, to be a wide and flexible view on infrastructures, embracing Cancer Centres (some of them Comprehensive), Cancer networks of different kinds, medical and nursing schools, diagnostic services, cancer registries and screening services. The vision was, and is, to integrate these infrastructures so that they work together effectively and compassionately for cancer patients, and, in terms of screening, for the wider population.



Nevertheless, given this definition, the imprimatur was to build capacity in research and innovation. The putative partners in the bid considered that this covered discovery and translation science, clinical research, outcomes research and Real World Data, and innovation in its widest form. All this had to be geared towards improving the diagnosis and care of cancer patients, not simply academic production. Much ink had already been spilled on the optimum role and structure of Comprehensive Cancer Centres¹, on the barriers

which exist in the research continuum in cancer², on the present inequalities in cancer research in Europe³, and on the wider role of the Cancer Mission⁴. From these publications it is evident that many of the ideas behind comprehensiveness, Comprehensive Cancer Centres and Networks, taken up by Europe's Beating Cancer Plan and the Cancer Mission, and the need for investment in research and innovation, has come from the OECI and the European Academy of Cancer Sciences.

An attempted summary of these challenges regarding capacity and capability in cancer research and innovation would be to address the facts that:

- Investment in the EU per GDP is approximately 10% of the equivalent in the U.S.³
- Expenditure on cancer research in Central and Eastern European Member States is approximately 10% of that in other Member States of the EU³.
- Comprehensive Cancer Centres are proven engines of integrated research and care, but to what extent do the results reach the wider population of patients^{1,4}?
- Cancer research in the EU is heavily weighted towards research into systemic therapies, and insufficiently focussed on prevention, early detection, and outcomes/implementation research³.

In consultation with our bid partners, we defined capacity building as: "a typical 'complex intervention' from a methodological standpoint, to be implemented in different realities⁵. Capacity building will have the possibility of a

large range of interventions to impact the aspects identified for improvement (which, in a given CCI, might include clinical, translational and epidemiological research, integration between health care and research, improving integration within clinical and research networks, data utilisation, patient empowerment, quality assurance programmes including development and utilisation of indicators of performance, process and outcomes). Capacity building involves a series of actions tailored to the context with the aim of enabling an organisation to act as an infrastructure. It will operate at various levels, as depicted in the Figure".



Finally, we were conscious that this is a Coordination and Support Action, meaning that its intent is to prove concept of which tailored interventions are successful in building capacity in a given CCI. We thought to take risks, which might result in some interventions not being entirely cost effective, or not being optimal in the medium term. For this reason, the aspect of evaluation of the effectiveness of the interventions is absolutely key to long-term planning of future investment.

One year on, and the planning and data collection stage of CCI4EU is almost complete. The criteria and Maturity Model have been finalised.

99 experts for interventions have been recruited. We await the final results of the survey of CCIs and the self assessment of maturity of those CCI within our specially designed "Maturity Model". These should be complete at the date of publication of this article, in time for the Plenary Meeting and General Assembly of CCI4EU on 27-28th June in Milan.

Then the implementation stage begins, with the following main interventions:

- Up to 9 'Deep Dives' in CCIs. A Deep Dive is an intensive series of consultancy visits to the CCI by a team of subject experts in the themes/domains which require capacity building. The methodology of the interventions will consist of: situational analyses; gap and barrier analyses; prioritisation of actions which can achieve swift and effective change; expert consultation; establishing networks and collaborations. 99 such experts have already been recruited for this task, together with 9 Project Managers. These groups will have orientation and coaching in a conference on 3-4 September.
- Free attendance at one of the 3 conferences being organised throughout the CSA. These will include the consideration of use cases brought by CCIs
- Free attendance at 10 brand new online courses around CCIs and research and innovation capacity
- Use of a new Resources Centre with suggested templates of Standard Operating Policies, patient pathways and other material
- · Preceptorships in a more mature CCI
- Site Visits and exchanges between CCIs.

The interventions will have approximately 18 months to be completed, and their impact evaluated in a "Global Efficacy Score". This will take into account the baseline, the nature of the intervention, and the movement in maturity of that CCI afterwards, adjusting for any external factors beyond the intervention. Therefore, our intention is to provide the European Commission with the relevant information to enable future capacity building interventions to be even more targeted, ultimately resulting in increased capacity in cancer research and innovation, better equality between Member States, and faster translation into improved diagnoses, treatment and care for cancer patients.

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Collaborating with cancer patients and informal caregivers in the EUonQoL project: why, how, and what have we learned so far?

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Health research is increasingly conducted with patients and members of the public, rather than for or about them. This is also called Patient and Public Involvement (PPI). PPI has the potential to increase research relevance, quality, and impact, and can be an enriching experience for everyone involved. Important values and principles of PPI include respect, openness, inclusion, diversity, transparency, responsiveness, and accountability. We describe here how PPI is applied within the European project "Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe" (EUonQoL), and what the lessons are that we have learned so far.

The EUonQoL project (*https://www.euonqol.eu/*), already introduced in recent issues of this magazine, started in January 2023 and aims to develop the Oncology Quality of Life Toolkit (EUonQoL-Kit), a new set of quality of life questionnaires aimed at (former) cancer patients in Europe. The project is based on PPI principles; therefore, five cancer patients and informal caregivers are involved as co-researchers in all project phases. The workload of the EUonQoL project is divided over multiple 'work packages' focusing on the various stages of the project, such as EUonQoL-Kit development, validation, and dissemination.



How did we start: preparation of PPI in EUonQoL

Co-researchers were recruited via a call for action that circulated on social media (LinkedIn, X) and through the OECI Newsletter. Especially the Newsletter proved to be a fruitful way of recruitment because of its pan-European reach and wide audience. Potential co-researchers who expressed their interest first received additional information via e-mail and were then invited for a video call to meet, to provide information about the project, and to discuss their potential involvement. In the final selection, attention was paid to diversity in age, gender, country of origin, cancer type, disease stage, and treatment phase.

To ensure good implementation of PPI principles in the EUonQoL project, a group of researchers with expertise in PPI (hereafter referred to as "PPI researchers") were identified to facilitate PPI activities and to support coresearchers. At the start of the project, they wrote a handbook for the EUonQoL consortium on how to collaborate with co-researchers. It contains a theoretical background on PPI, practical aspects that need to be considered when engaging in PPI, and good practices for collaborating with co-researchers. The handbook also includes a checklist of items to be completed at the start of research activities, such as agreement on roles, tasks and responsibilities, language, frequency of contact, reimbursement, and support possibilities.

The PPI researchers also organized training for co-researchers. They asked other EUonQoL researchers to describe in which specific tasks co-researcher would be involved in at various stages of the EUonQoL project and discussed this with the co-researchers. Based on their needs, training sessions were developed. The training program consisted of three sessions: a kick-off meeting in which the co-researchers and PPI researchers got to know each other and the EUonQoL project was introduced, a second session where the project and its work packages were discussed more in detail, and a third session reserved for specific training wishes of the co-researchers. However, it turned out that the co-researchers did not have many specific training wishes. Instead, the PPI researchers organized a training workshop for the other researchers because many of them were doing PPI for the first time and it turned out that they had a need for practical tools to do so.



What are we doing now: PPI in all stages of the EUonQoL project

After training, the co-researchers were each linked to three of the projects' work packages based on their skills and preferences. The researchers leading each work package were asked to schedule a formal introductory meeting with the co-researchers and the work package teams to get to know each other, and jointly discuss roles, tasks, responsibilities, and expectations of co-researchers. A tool that can be used to guide this conversation, and was in fact used in several work packages, is the Involvement Matrix. This tool helped researchers and co-researchers to discuss roles and tasks of co-researchers in distinct phases and activities of a work package.

The introductory meetings were the starting point for further collaboration in the work packages. This is taking place now, mostly through online and in-person meetings and consultation through other means, such as e-mail. Regular meetings between co-researchers and researchers of different work packages are planned during the EUonQoL project to optimize collaboration. The frequency of these meetings varies between once a week to once every few months and depends entirely on the needs of both the researchers and the co-researchers.

To maintain an overall view of the workload and needs and wishes of co-researchers when collaborating with different researchers in various work packages, the PPI researchers organize regular support meetings. These informal meetings focus on building relations to create a safe space where co-researchers feel confident to ask for help and share experiences with each other and with researchers. Co-researchers also have the possibility to reflect on their roles and contributions in the research teams and discuss specific topics of interest in more depth, for example, the development of the EUonQoL-Kit and the consensus process that preceded its finalisation.

Start EUonQoL project January 1	Handbook & checklist delivered March 31	Training of co-researchers completed June 31	Co-researchers introduced to all work packages November 30
u			
January 2023	Recruitment co-research finalised April 30	t of Start of regular ers support meetings with co-researchers September 1	December 2023

Timeline of co-researcher involvement in the EUonQoL project during its first year.

How will we proceed: future outlook

Regarding PPI, the first year of the project was mostly dedicated to starting up and making sure everything goes well. We learned that this can be a messy process, during which it is important to invest time in getting to know each other and the project. Building a good relation is key to create a comfortable and safe space for collaboration. Everyone involved needed to explore new ways of working together and we found that flexibility is important. On multiple occasions, approaches were adapted based on the continuous reflections that were conducted with both researchers and co-researchers.

We are now well underway in the second year of the project and find that there is more room for structured evaluation and reporting of the PPI process and impact. PPI researchers have developed an evaluation form to be used within the EUonQoL project, based on the existing PPI impact log. Also, the standardized GRIPP2 reporting checklist will be used to systematically report on PPI activities. Structured evaluation and reporting will gradually lead to the development of a stronger PPI evidence base, which will facilitate more effective implementation of PPI in future (cancer) research.

TOOLBOX - to start with PPI in your own research

- -Handbook & checklist on participatory research:
- https://www.euonqol.eu/docs/results/D2-1_Handbook_checklist_final.pdf -Involvement Matrix:
- https://www.kcrutrecht.nl/involvement-matrix/
- -PPI impact log:
- https://arc-w.nihr.ac.uk/patient-and-public-involvement/resources/patient-and-public-involvement-impact-log/ -GRIPP2 reporting checklists:
- https://www.bmj.com/content/358/bmj.j3453

BEACON: Disparities and Barriers in accessing psycho-oncological support in Europe

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Psycho-oncological Care Disparities in Europe

Disparities in psycho-oncological care across Europe stem from various factors affecting both access and quality of support for cancer patients¹. These disparities, notably prevalent in Eastern and Southern European countries, are influenced by economic, awareness, and socio-demographic factor². Limited resources, low mental health awareness, and healthcare systems prioritising somatic treatments exacerbate these challenges. Consequently, unequal access to support services impacts the well-being and quality of life of cancer patients throughout Europe.

These disparities underscore the need for a closer examination of the barriers hindering comprehensive psychooncological care, including challenges in assessing psychological distress, and in accessing, providing, and using psycho-oncological services. In our recent publication³ we synthesised the existing literature on barriers to psychooncological support. Firstly, the identification and the assessment of psychological distress face obstacles due to the absence of standardised assessment tools and limited awareness among patients and healthcare providers. Moreover, the stigma surrounding mental health, personal barriers to disclosure, and healthcare providers' lack of confidence or training in addressing psychological distress are considered further impediments to assessment efforts. Additionally, institutions may lack clear guidelines for routine assessment due to resource constraints and competing healthcare priorities. Along with difficulties in assessment, additional barriers can limit access to psycho-oncological support for patients who need it or request it in many European countries. Access to psychooncological support is hindered by both personal factors related to the patient such as geographical location, physical impairment, and socioeconomic status, but also by structural aspects, such as the lack of referral from healthcare providers, who may not actively direct patients to support services due to lack of awareness on patients' needs. Insufficient information about available services and inadequate physical spaces for confidential discussions pose further challenges. Moreover, some healthcare providers may face constraints in providing psycho-oncological support due to time limitations, heavy workload, personal beliefs or attitudes, and competing clinical priorities. These barriers collectively contribute to a gap in the provision of psychological support for cancer patients, despite its recognised importance for their well-being and quality of life. Therefore, there is an impellent need for medical training on psychosocial issues and support from clinic leaders to enhance providers' commitment to psycho-oncology.

Lastly, even when access to psychological support is possible, it is not always implemented. Patients' willingness to engage with support services is influenced by societal stigma, perceptions of normalcy regarding distress, and personal coping mechanisms. Healthcare providers' discomfort or lack of motivation to discuss emotional issues with patients, as well as institutional challenges such as limited support duration, also impact utilisation. These barriers collectively contribute to disparities in accessing, providing, using, and benefiting from psychooncological support services, necessitating comprehensive strategies to address them and enhance psychosocial care for cancer patients.

Our project

The above-mentioned findings align with results from a qualitative study conducted within the BEACON project⁴. BEACON is a European project funded by EU4Health and it aims to identify and reduce disparities in cancer care across Europe, by mapping the main capacities and capabilities of cancer centres in Europe with respect to the prevention, diagnosis and treatment of cancer disease. By collecting qualitative data directly from our stakeholders through dedicated focus groups, we explored possible reasons for inequalities in access to and utilisation of care from the perspective of cancer patients (n=48), who are recipients of these treatments, and healthcare providers and researchers (n=16), who are responsible for their administration in Italy, Croatia and Slovakia. Our stakeholders experienced disparities in accessing adequate care, lack of resources and long waiting lists. Additionally, both patients and providers emphasised the need for clear and reliable information about cancer

care, treatment options and adequate nutrition and lifestyle. Most importantly, patients reported a critical need for psycho-oncological support, emphasising the psychological burden of heavy treatment, exhaustion and physical changes, such as the loss of hair or impairment of body parts. Patients often reported the feeling of being treated like numbers by healthcare providers who did not always consider the emotional impact of their condition. Nonetheless, psycho-oncological support did not always prove as accessible, due to multiple barriers related to healthcare systems and individual characteristics. Patients expressed frustration with long waiting lists and a lack of awareness about the availability of psychological services, which hindered access to such support. In general, patients require comprehensive knowledge of the availability of services and providers, to meet their needs during the cancer journey. Similarly, healthcare providers emphasised the value of having a psycho-oncologist as an integral part of a multidisciplinary team, recognising the importance of their constant presence for a better and more comprehensive clinical practice. However, they noted that resource and time constraints can make referral to and collaboration with the psycho-oncologist difficult.

What we aim for

BEACON is aimed at three key objectives. Firstly, it poses the goal of mapping and improving the capacity and capability of cancer centres across the European Union. Additionally, BEACON aims to develop a decision support tool that will assist our four stakeholders: patients in finding the best cancer centres, providers in sharing resources and expertise, researchers in sharing data, and policymakers in tailoring and aligning funding allocation with patients' priorities. Lastly, BEACON attempts to establish training and education mechanisms to uphold the quality standards of care, ensuring that patients receive a high level and comprehensive cancer care.

Our stakeholders

The BEACON project is dedicated to providing high-quality, reliable, and accessible metadata on various sources of cancer information, tailored specifically to meet the needs of four key stakeholders: patients, providers, researchers, and policymakers. Patients will be provided with comprehensive information about cancer related associations, available medical services, and ongoing clinical trials within OECI-accredited centres, ensuring they have access to vital resources and support networks. Providers will benefit from access to information regarding clinical practice guidelines, learning resources, and the expertise of specialists available at the mapped centres, facilitating the delivery of high-quality care. Researchers will be supported with aggregated metadata from various sources, including administrative databases, cancer registries, clinical trials, surveys, and biobanks enabling them to access valuable data for their studies and analyses. Policymakers will be equipped with essential information on policy making initiatives, reports, and comparative analyses of cancer care disparities across EU regions. This data aids in informed decision-making processes and policy development aimed at improving cancer healthcare systems.

Conclusion

In conclusion, cancer remains a significant challenge to global health, impacting various facets of patients' lives, including psychological well-being. While efforts at national and international levels have improved outcomes, disparities persist across Europe in oncological care. These disparities highlight the urgent need for targeted interventions aimed at better allocating resources and funding, as well as enhancing guidelines on education and training initiatives to ensure the implementation of accessible, and high quality, psycho-oncological support services throughout Europe. The BEACON project aims to address these disparities through mapping cancer care capacities, creating a decision support tool, and fostering collaboration among stakeholders. By encouraging such collaboration among diverse stakeholders. BEACON aims to catalyse transformative change within the European healthcare landscape. This collaborative approach not only facilitates the identification of existing barriers to psycho-oncological support but also paves the way for the implementation of targeted strategies to overcome these challenges. Moreover, by engaging patients as active participants in the design and delivery of care, BEACON ensures that interventions are tailored to meet the unique needs and preferences of those affected by cancer. At the heart of BEACON's mission lies a commitment to equity, compassion, and excellence in cancer care. Through strategic resource allocation, enhanced education and training initiatives, and robust collaboration among stakeholders, BEACON endeavours to diminish inequalities and enhance the quality of care for individuals affected by cancer across Europe. By working together towards this common goal, we can create a future where all individuals receive the support and compassion they need to navigate their cancer journey with dignity and resilience. It is also imperative to consider the sustainability of these interventions. Ensuring the long-term effectiveness and accessibility of initiatives like BEACON requires careful planning and consideration of various factors. Delving into the critical considerations regarding sustainability it is crucial to address not only the immediate challenges but also the long-term sustainability of interventions aimed at reducing psycho-oncological care disparities. This entails evaluating the scalability and durability of initiatives like BEACON beyond the project's lifespan. Factors such as securing continued funding, fostering institutional commitment, and integrating these initiatives into existing healthcare systems are paramount. Additionally, assessing the potential impact of socioeconomic and demographic changes on the effectiveness of interventions over time is essential. By prioritising

sustainability, we ensure that efforts to bridge psycho-oncological care gaps remain effective and accessible to cancer patients across Europe well into the future.

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Contact details

For more information please visit our website: https://www.ieo.it/beaconproject/ Twitter account: https://twitter.com/beaconcancer22?s=11&t=O6NX5vjv1KiSiaBkcmc6TA LinkedIn account: https://www.linkedin.com/showcase/101300437/admin/feed/posts/

If you have any questions, please contact us at: beaconcancer@gmail.com



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INSTAND NGS4P close to the finishing line



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NGS and Cancer

Next-generation sequencing (NGS) has reached a level of maturity such that not only targeted sequencing (gene panels) but also sequencing of large parts (e.g. the expressed part of a genome, the exome by Whole Exome Sequencing, WES) or of the entire human genome (Whole Genome Sequencing, WGS) is feasible and affordable both in research and clinical diagnostics. In many countries in Europe and across the globe, health systems are striving to integrate NGS tests into routine clinical practice. Major applications for NGS in medical diagnostics are cancer and rare diseases. In cancer, which is regarded as a disease of the genome, comparing the patients' genomes of the tumour and the baseline germline allows the identification of cancer-causing mutations, so it can serve as a diagnostic tool and to support patient stratification for therapy. Furthermore, the genome impacts on the efficacy and side effects of several drugs used in patient care.

The Instand-NGS4P Project

Instand-NGS4P is an EU-funded Pre-Commercial Procurement (PCP) project for improving cancer patients' benefit from NGS by developing integrated and standardized NGS workflows for common and rare cancers in adults and children. To enable companies to join and develop products separately in different parts of the workflow, it was divided into four parts, i.e., Lots 1 to 4 (schematic representation Figure 1).



Figure 1: Instand-NGS4P workflow divided into 4 different Lots

Challenges

The whole project is based on patients' and clinicians' needs, and addresses certain specific challenges including that the final solution should cover a complete workflow from collection of samples from patients to the support of decision making at the bedside and producing reports for patients.

- Since the workflow should be used for medical diagnosis it has to comply with requirements of the European in vitro diagnostic medical device regulation (IVDR) as well as applicable standards.
- The workflow includes the analysis of cancer-related genetic alterations as well as the analysis of pharmacogenomics variants in order to increase the patient's benefit from NGS.

- An additional challenge is that the solutions to be developed should also be suitable for rare cancers, for some
 of which no CE-marked IVD will be developed because of economic reasons. Therefore, solutions should on
 the one hand be compliant with IVDR for IVDs manufactured by industrial manufacturers, and on the other hand
 for IVDs manufactured by the health institutions for internal use so called. This requires that solutions are open
 enough that they can also be used by heath institutions for lab-developed tests in case no CE-marked IVD is
 available.
- Another challenge that emerged from the Open Market Consultation is that, particularly for rare cancers, there is increased medical need for using whole exome or whole genome NGS platforms. Although these platforms are technically well advanced there is neither experience on how the massive data generated can comply with IVDR nor FDA requirements in case of diagnostic application.

Instand-NGS4P Consortium

- 7 leading European medical centres from 5 countries (two are coordinating European Reference Networks) as the Buyers' group Medical University of Graz (MUG the lead procurer AT), University of Florence (UNIFI IT), ERASMUS University Medical Centre (EMC NL), University of Milano-Bicocca (UNIMIB IT), University Clinics of Schleswig-Holstein (UKSH DE), St. Anna Children's Cancer Research Institute (CCRI GmbH AT) and the Centre Leon Bérard (CLB FR).
- European patient advocacy group, represented by the Italian Patient Association (FAVO IT),
- a standardization organization (German Institute of Standardisation (DIN)),
- University of Munich (TUM DE), University of Ljubljana, University of Manchester (Uniman UK), University of Liverpool (UoL – UK), Organisation of European Cancer Institutes (OECI – BE), University of Helsinki (UH – FI) and one SMF. BioXPedia.



4 Project Phases



- In the **Preparation Phase**, an Open Market Consultation was carried out to provide insight into clinical and patient needs, as well as technical innovation potential. Also, an analysis of the current standardization landscape found that all NGS-related standards focused on the research environment rather than on the diagnostic application. It also revealed gaps with regard to covering complete NGS workflows.
- Based on the outcome of these activities, a call for tender was published, attracting 24 tenders in total from which 15 tenderers were selected for **Phase 1**.
- Ten of these Solution Designs were subsequently developed into prototypes in Phase 2 and, of these, eight were selected for the third and final Phase, which commenced on the 15th of April 2024.

Phase 3 Testing of fully integrated NGS workflows (April 2024 to May 2025)



Phase 3 will focus on the testing by the Buyers' group of usability and performance in a realworld diagnostic environment of the solutions developed by the Contractors. To achieve this, the Buyers will install the newly developed NGS workflow components at their sites. The protocols will be performed on real cases alongside the established and routinely performed diagnostic procedures at the hospital. The Buyers, with regular support and training from the Contractors, will assess usability, performance and innovative advantages, as well as the quality of integration

of the solutions into complete workflows.

The expected innovation arising from the project will be disseminated throughout Phase 3 to potential buyers, which include smaller clinical centers as well as larger hospitals.

Phase 3 Contractors

Contractor Details	Key Features (for full abstract, please visit the website)		
QIAGEN GmbH	 The TRInity project aims to improve NGS testing by developing new preanalytical solutions, optimise available ones and integrate all into complete standardised preanalytical workflows as part of entire Sample-to-Insight NGS workflows. Solutions are built on major market trends, customer and stakeholder needs: Multi-specimens capabilities (processing different specimen types from the same patient), multi-analytes capabilities (e.g. gDNA, ccfDNA and RNA from a single specimen) and compliance with ISO and CEN standard documents. For allowing flexibility, TRInity's solutions provide multi-specimen and multi-analyte capabilities but can also be used for single specimen & single analyte testing. 		
Twist Bioscience Corporation TWIST Platomics GmbH	 "Standardized flexibility" - our innovative solution empowers oncologists an diagnostic labs to establish personalized Laboratory Developed Tests (LDT derived from the In Vitro Diagnostic Regulation (IVDR)-compliant Master Panel. Physical sub-panels, along with IVDR-compliant documentation, streamline th setup, documentation, validation processes, providing unparalleled flexibilit through a standardized procedure, ensuring the highest diagnostic quality. Presently, laboratories face a dilemma of either using limited solutions wit restricted analysable targets or resorting to extensive, costly panels. The TPI consortium's solution revolutionizes this scenario, enabling the design an production of a customized genetic diagnostics solution that aligns with th specific requirements of individual labs. 		

 Platomics GmbH
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 Oncoursities
 Charité Universitätsmedizin Berlin (Charité)
 Charité Cancer Center Universitätstumorzentrum

- Introducing OncOmicsX, a unified NGS data analysis solution designed for IVDRcompliant NGS diagnostics.
- This platform combines the strengths of an ISO13485-compliant infrastructure called PlatoX Somatic and a versatile tool known as the "One Touch Pipeline" (OTP). The former ensures regulatory compliance for routine clinical NGS diagnostics, while the latter offers a flexible approach to delve into new and experimental biomarkers, addressing diagnostic needs beyond the confines of strict regulations.
- OncOmicsX integrates a core set of equivalent workflows for alignment, germline, and somatic variant calling in both PlatoX and OTP. PlatoX caters to IVDR-compliant diagnostics, while OTP extends the analysis to explore translational questions and generate streamlined NGS data for research projects.
- Automated generation of regulatory documents for Laboratory Developed Tests (LDTs) in accordance with IVDR standards. This integration empowers users to expedite and simplify the setup, validation, and documentation processes for their NGS tests, reducing the time needed to transition innovations from research to clinical adoption.

CENTRO NACIONAL DE ANÁLISIS GENÓMICO (CNAG)

LOT 3:

- Cancer Analysis GPAP enables streamlined and user-friendly management and analysis of NGS data in adult and paediatric cancers, common and rare. The development of the platform has leveraged the RD-Connect Genome-Phenome Analysis Platform, built upon a big data architecture and a friendly graphical user interface (GUI), accessible through web browsers.
- Modular design built upon Singularity containers, enabling installation in High Performance Computing (HPC) clusters and typical Cloud Computing Services such as Amazon AWS. This provides flexibility while facilitating updates and backups.
- Security was incorporated in all the stages of the Software Development Life Cycle to follow the EU GDPR and relevant ISO and IVDR requirements.
- LOT 4:
- Cancer Reporting GPAP is a user-friendly solution integrating NGS results, emedication data and clinical evidence for therapy decision making in adult and paediatric cancers, common and rare.
- Enables user-friendly interpretation and pathogenicity ranking of the NGS variants, according to standard guidelines, using functional and medical annotations through external resources and OncoClassify, which has been developed in Lot 4 to highlight potential oncogenic mutations, known mutations and actionable biomarkers.
- Customisable report for clinicians supporting medical decision-making. Patients may access a simplified version of the report via a secure mobile app.

Congenica Ltd



- Congenica has developed a cost-effective software platform that automatically and accurately profiles genetic changes in a tumour, and based on these changes either recommends targeted treatment options, or if no such treatment options exist, identifies clinical trials that this patient may be eligible for.
- It also analyses each patient's general genetic makeup to understand how a
 patient might process specific cancer medicines as well as companion medication
 to provide holistic treatment recommendations, reduce side-effects that may be
 caused by these medicines, increase survival chances and in general improve a
 patient's quality of life.
- LOT 3: Once a tumour sample has been sequenced, the data will be sent to Congenica to be automatically analysed and interpreted in under six hours.
- LOT 4: All relevant information about the results and the associated therapy guidance is initially provided to the clinical director/clinical scientist for sign-out and then sent to the physician for consultation in a format that is clear and easy to understand so that relevant treatments or requests for clinical trial access can be initiated without any delays. Once reviewed, patients are provided with a personalised report.
- The platform will be integrated with patients' Health Records and reports will be available on or off-line to allow Physicians rapid access to all patient-relevant information and history, whether at a Physician's office, or at the bedside.



 The EU ONCO-PLATFORM consortium has seamlessly integrated the workflows of our three companies into a sophisticated working prototype using standard data formats and descriptions to create a professional and easy-to-use solution in the field of precision oncology.
 The new platform represents a leap forward in automating and expediting the

annotation, filtering, classification, and interpretation of genomic data while keeping a tight control on input data quality.

It not only ensures clinical performance and standardisation but also prioritises patient perspective in terms of personalisation, cybersecurity, and regulatory compliance.

Advances in Standardisation

Standardisation of the NGS diagnostic workflows is of major importance for a trusted diagnostic result. Experts in CEN Technical Committee 140 "In vitro diagnostic medical devices" and ISO Technical Committee 276 "Biotechnology" together with experts from the Instand-NGS4P project consortium and some of the Instand-NGS4P product developers published two European diagnostic NGS Technical Specifications in November 2023:

In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 1: Human DNA examination CEN/TS 17981-1:2023

In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 2: Human RNA examination CEN/TS 17981-2:2023

European companies and diagnostic laboratories developing NGS products or lab-developed tests can now purchase these Technical Specifications from their national standard institutes for future implementation. The next step is the further development into global ISO Standards via the Vienna agreement.

Outlook

The aim of Instand-NGS4P is to develop innovative NGS workflow solutions for testing in a real-world medical environment. This then provides a basis for bringing the products to market. As a next step it is planned to apply for a follow up EU-funded project – Public Procurement of Innovative Solutions (PPI) – in order to bring the developed solutions to the market. We would therefore now appreciate engaging with a larger user community of cancer centres to form a consortium for the follow up PPI project. Interested centres should please contact us at the email below.

For further information on the Instand-NGS4P project, please visit **https://www.instandngs4p.eu/** Contact: Prof. Kurt Zatloukal; kurt.zatloukal@medunigraz.at



Integrated and Standardized NGS Workflows for Personalised Therapy

New leadership for the Biobanks and Molecular Pathology WG



Olli Carpén^{1,2}

1. Department of Pathology, University of Helsinki, Helsinki, Finland, Professor 2. Organisation of European Cancer Institutes, Biobanks and Molecular Pathobiology WG Chairperson

It is with great enthusiasm and respect that I write this column as the new chairperson of the OECI Biobanks and Molecular Pathobiology working group (BMP-WG). I want to start by thanking Professor Giorgio Stanta, the previous chairperson, for his outstanding work in leading this WG in the previous 8 years. Professor Stanta's vision to include molecular pathology and biobanking into the core of OECI programme was insightful, indeed, as over the last decade these objectives have proven to be the cornerstone of precision oncology. Due to his personal activity, OECI established important connections with the European Society of Pathology, BBMRI-ERIC (the European biobanking infrastructure) and several other relevant organisations. In addition, OECI has been actively involved in several projects under the EC Research Framework Programmes, such as INSTAND-NGS4P (https://www.instandngs4p.eu/), with a goal towards standardised next generation sequencing workflows in routine cancer diagnostics. In line with the INSTAND-NGS4P goal, a recurring important theme in the OECI Oncology Days BMP-WG sessions has been quality, an essential element both in molecular pathology and in biobanking. This theme will remain among our focus.

A few words of my background. I am Professor and Chairperson of pathology at the University of Helsinki. Apart from teaching and clinical work, I lead a research group studying ovarian cancer and identifying tissue-based biomarkers for predictive diagnostics. I have been actively involved in biobanking for almost two decades, both in Finland, where I have established two hospital-integrated biobanks, and in the European context. In BBMRI-ERIC, as a delegate of the Assembly of Members, I have witnessed the important role of biobanking, not just as a research infrastructure but also as a bridge between research findings and their implementation in healthcare. As scientific director of the Helsinki biobank, I am also witnessing the opportunities that professional implementation of biobanking into hospital routine can bring to variable aspects of precision medicine, from cancer prevention to improved diagnostics and targeted treatments. In my personal view, (hospital integrated) biobanks are an essential and vital element in the transition towards personalized medicine, and their role in OECI activities needs to remain strong.

This year's BMP-WG session during the Helsinki OECI Oncology Days includes talks on following burning themes:

- . how biobanks can advance cancer diagnostics and bring targeted treatments to cancer patients
- digital image repository to advance AI in pathology
- how can we collect and use large medical datasets in the rapidly changing regulatory landscape
- · European master's programme on molecular pathology.

The first presentation by prof. Kimmo Porkka (Helsinki University Hospital, Finland) describes how prospective biobank cohorts can improve cancer care. Prof. Porkka's work in profiling haematological malignancies from samples collected in a biobank context and utilising this information for targeted therapies could serve as model for other cancers as well. The second presentation by head of pathology Anna Boden (Region Östergötland, Sweden) describes the ongoing IMI-funded international BIGPICTURE-project (*https://bigpicture.eu/*), which collects the world's largest repository of digitalized pathology images. This project is an example of how artificial intelligence will shape pathology diagnostics and it highlights the role of biobanks and hospital pathology archives in the transition of pathology towards digitalisation and improved analytics by computational methods. The third presentation by Tommi Nyrönen (CSC, Finland), head of ELIXIR node Finland, deals with the changing landscape of health data regulation in Europe and the opportunities and challenges in sharing large health data sets across countries for research purposes. Finally, the fourth presentation by prof. Marius Ilié (University Côte d'Azur, France) will describe the European molecular pathology master's programme that was introduced last year. This programme, that received the OECI auspices, will train next generation pathologists, not just in morphological analyses, but also molecular methods, quality issues, biobanking and emerging techniques. You can find more information of the master's programme in a separate article in this issue of the Magazine.

Assessing the Impact of Collaboration between Comprehensive Cancer Centers and Cancer Patients NGOs

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Introduction

Cancer is not merely a medical condition; it is a multifaceted challenge that requires a holistic approach encompassing medical treatment, emotional support, advocacy, and community engagement. In this regard, the collaboration between Comprehensive Cancer Centers (CCCs) and Cancer Patients Non-Governmental Organizations (NGOs) emerges as a beacon of hope, bridging the gaps in cancer care and empowering patients with comprehensive support systems.

<< Cancer remains one of the most formidable challenges in modern healthcare, impacting millions of lives worldwide. In the battle against this complex disease, collaboration emerges as a crucial weapon, particularly between Comprehensive Cancer Centers (CCCs) and Cancer Patients (NGOs). >>

Complementary Resources

One of the primary advantages of collaboration between CCCs and Cancer Patients NGOs is the pooling of complementary resources¹. While CCCs provide specialized medical services and treatments, NGOs offer a diverse range of support services such as psychological counseling, emotional support groups, alternative treatment information, and financial assistance programs. This synergy ensures that patients receive not only medical care but also holistic support tailored to their individual needs, thereby enhancing their overall well-being throughout the cancer journey.



Figure 1. Collaborative practice in oncology²

Empowering Patients Through Support

Cancer diagnosis often plunges patients into a whirlwind of fear, confusion, and uncertainty. In such challenging times, the support provided by Cancer Patients NGOs plays a pivotal role in empowering patients and their families³. Through support groups, educational programs, and community events, NGOs create a nurturing environment where patients can share their experiences, glean valuable insights, and derive strength from collective resilience. This emotional support complements the medical treatment offered by CCCs, fostering a sense of hope and solidarity among patients facing similar struggles.

Advocacy and Awareness

Beyond individual patient support, collaboration between CCCs and Cancer Patients NGOs amplifies the voice of cancer patients on a broader scale⁴. NGOs are instrumental in advocating for patients' rights, lobbying for improved access to innovative treatments, and driving policy changes to enhance the healthcare system's responsiveness to cancer care needs. By partnering with CCCs, NGOs gain valuable insights into the challenges faced by patients within the healthcare system, enabling them to advocate more effectively for systemic reforms and equitable access to quality care.

Education and Information Dissemination

In the fight against cancer, knowledge is a powerful weapon. Cancer Patients NGOs serve as invaluable sources of information, providing patients and their families with comprehensive resources on cancer types, treatment options, side effects, and palliative care⁵. By collaborating with CCCs,

these NGOs can ensure the timely and accurate dissemination of vital information to patients, empowering them to make informed

decisions about their care and treatment journey.



Conclusion

The collaboration between Comprehensive Cancer Centers and Cancer Patients NGOs represents a beacon of hope in the fight against cancer. By leveraging their respective strengths and resources, these entities create a powerful synergy that enhances the quality of cancer care and support systems. From complementary resources to advocacy efforts and educational initiatives, the impact of this collaboration reverberates across the entire spectrum of cancer care, empowering patients, and fostering resilience in the face of adversity. As we navigate the complexities of cancer care, let us remember that together, we are stronger, and through collaboration, we can pave the way towards a brighter, cancer-free future.

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ČÍ EU

Access to Effective, Innovative Treatments and SocioEconomic Impact Prominent topics on Agenda of Working Group on Cancer Economics

On behalf of the board of the Working Group Cancer Economics W. H. van Harten^{1,2}, Valesca P. Retèl^{2,3}

- 1. Department of Health Technology and Services Research, University of Twente, Enschede
- 2. Netherlands Cancer Institute, Amsterdam, Senior Research Group Leader
- 3. Netherlands Cancer Institute, Amsterdam, Netherlands and Erasmus University Rotterdam (ESHPM), Rotterdam, Head Health Technology Assessment (HTA) unit



The objective of this working group is to raise awareness on health economic- and technology assessment related issues and methods in cancer research and services. An important driver is the growing awareness within the cancer research community on the increasing importance of Health Technology Assessment (HTA) and health economics in translational cancer research. HTA in early phases of R&D can assist in creating optimal conditions for coverage of innovative treatments and adequate implementation in practice.

The board consists of Lionel Perrier (Lyon), Michael Schlander (Heidelberg), Edit Pornecy (Budapest), Davide Gallegati (Meldola), Wim van Harten (Chair, Amsterdam) and Valesca Retèl (Coordinator, Amsterdam).

The working group on Cancer Economics unites representatives from over 30 Cancer centers and works through knowledge exchange, common projects and participation in European Initiatives. In the past year three digital- and one face to face meeting were organised in which projects were presented and discussed. Furthermore, members of the WG have active participation in EU projects (in the majority as work package leaders) that are relevant for OECI (COST-Intercept, CanHeal, CCI4EU, OncoValue). The WG on Health Economics will organise a special session during the OECI Annual Oncology Days in Helsinki to cover a number of the recent activities.

In 2024-25 the WG will continue its activities in especially three domains.

SocioEconomic Impact (SEI) of Cancer

Recently three papers have been finalized on SocioEconomic Impact (SEI) of cancer. Through participation and support OECI and OECI member institutions are showing commitment in bringing the topic on the research- and policy agenda's. Especially the consensus and taxonomy paper on SEI from the taskforce chaired by Michael Schlander that was recently published in The Lancet Oncology is a landmark in setting the agenda for increased interest and further research on this topic. We have shown that SEI is not only a prominent and pressing issue in most, and also economically more developed EU countries, but especially Young and Young Adult patients are prone to SEI related issues and distress. The WG will follow up on these findings and prioritize instrument development and interventions to diagnose and prevent SEI in an early stage.

Access to innovative treatments

The availability and access to innovative medicines is another important issue. Health Technology Assessment (HTA) is essential to justify coverage. First we see an increasing number of drugs entering the market with suboptimal evidence on effectiveness (such as survival) or with mainly reporting secondary outcomes. The use of biomarkers is possibly helpful to identify candidates or subgroups of patients for targeted treatment, but research that justifies coverage is lagging behind. Involving centers in this development through education and research projects is an important step to contribute to effectiveness insights and selecting optimal treatments. Further pricing and real world costs of medication are aspects that will be further explored in close cooperation with the European Fair Pricing Network.

Involvement in European projects

Lastly the WG is be involved in a number of European projects.

The COST-Intercept program focuses on early detection and screening in oral Cancer, where we lead the work package on HTA focusing on the development of an HTA framework to anticipate on reimbursement of early cancer detection programs.

In the large CCI4EU project building of Comprehensive cancer Infrastructures is stimulated and supported through a number of capacity building activities. Education and dissemination activities on development of HTA capacities within- or connected to those Comprehensive Cancer Infrastructures requires involvement of the Cancer Economics Working Group.

There is growing awareness that the data that Cancer Centers have been assembling in their data warehouses or data lakes, can be used to generate real world evidence on actual effectiveness in practice. This will be conducted in close cooperation with the OncoValue project consortium, an EU sponsored Horizon project on using Hospital based Real World Data for HTA.

In the Canheal project a multidimensional impact framework for genomics for treatment and prevention/early detection will be initiated.

BRINGING RESEARCH INSIGHTS INTO CLINICAL IMPLEMENTATION



CCI4EU First Capacity Building Conference

Save the

Date!

The OECI A&D programme: a driving force for the development of European cancer centres

Patricia Doherty¹, Jean-Yves Blay^{2,3}, Outi Nikunen⁴, Jean-Benoît Burrion^{5,6}

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- 2. Centre Léon Bérard, Lyon, France, General Director
- 3. UNICANCER, France, President
- 4. Finnish Cancer Center FICAN, Finland, Senior Planning Officer, Coordinator
- 5. HUB/Jules Bordet Institute, Brussels, Belgium, Head of Prevention & Screening Clinic
- 6. Organisation of European Cancer Institutes, Chair of the Accreditation & Designation Board





Since its launch in 2008, the OECI accreditation programme has continued to evolve and develop, attracting exponential interest. More than 80 Cancer Centres (CC's) are now accredited or in the process of being accredited, across Europe and even beyond. The programme is currently running at 20 audits per year (2024). One of the strengths of the programme is certainly its dynamism, driven by the teams (Auditors, Accreditation Committee, Coordinators, Board) and the CC's themselves. We are currently in the fourth revision of the standards, a highly structured procedure that combines efficiency and broad consultation. The review will be completed by the end of 2024. We are about to embark on the second edition of the selection and presentation of best practices by accredited centres. The programme is attracting attention outside Europe, particularly in Latin America.

The success of the OECI accreditation programme lies not only in helping the CC's improve their governance, organisation, quality of care and research, but also in its ability to harmonise practices between CC's and to enable their networking. To illustrate this point, this article proposes three examples from 3 different contexts:

- the development of the national Cancer Centres network FICAN, using the OECI A&D programme as a common framework (Finland);
- the added value of the OECI A&D programme in the UNICANCER dynamic (France);
- the 2024 meeting of the 7 Irish CCs in Dublin around OECI standards: a unique and unprecedented initiative (Ireland).

The development of FICAN - using the OECI A&D programme as a common framework

The establishment of the Finnish Cancer Center FICAN represents a significant milestone towards a unified approach to cancer care and research in Finland. Consisting of five regional cancer centres, each covering a designated collaborative area for healthcare and social welfare, alongside a national coordinating unit, FICAN represents a joint effort among key parties; wellbeing services counties (including university hospitals & central hospitals), HUS Group, the joint authority for Helsinki and Uusimaa and universities responsible for medical education.

Based on a Finnish Government Decree on the Allocation of Specialized Medical Care and the Centralization of Certain Tasks and binding agreement between the parties FICAN is responsible for harmonizing the entire cancer care continuum and taking measures to enhance the equality of citizens. Nationally, FICAN serves as a comprehensive platform for the development, planning and coordination of cancer care and research, aiming to standardize practices, enhance quality monitoring and support research integration into clinical care across the country.

Helsinki University Hospital (HUS) cancer centre was the first Nordic cancer centre to receive OECI Comprehensive Cancer Center accreditation in 2014. This achievement set a national example, encouraging other centres to pursue accreditation through the OECI A&D Programme. The founding of regional cancer centres under FICAN further reinforced this progress. Currently, 4/5 university hospital cancer centres have obtained accreditation, including HUS CCC, Tampere University Hospital Cancer Center (CC), Turku University Hospital Cancer Center

(CC), and Kuopio University Hospital Cancer Center (CC). Additionally, Oulu University Hospital Cancer Center is currently in the process of accreditation. These accredited centres play an important role within FICAN by enabling the application of these high-quality standards nationally.

Seeking accreditation through the OECI A&D Programme has provided an effective framework and national tool for the harmonized development of cancer care and research in Finland, moving towards shared quality standards. The programme has emerged as a robust approach to advance FICAN's central goal of enhancing national equity in cancer care and research and its integration into clinical practice. By aligning with OECI standards, FICAN works to improve the quality and consistency of cancer care and research nationwide.

Utilization of the OECI A&D Programme as a common framework for the development highlights Finland's dedication to fostering excellence in cancer care and research. Through collaborative efforts guided by shared standards and best practices, FICAN works to realize its vision of being a pioneer in effective and equitable cancer care by improving equitable, high-quality care and translational and clinical research for the benefit of patients throughout the country.

Unicancer and OECI AD programme: shared ambitions at the service of European patients

By virtue of their unique model within the French healthcare system, the cancer centres (Centres de Lutte Contre le Cancer, CLCC) in the Unicancer network are de facto Comprehensive Cancer Centres (CCCs) that have been naturally involved in the accreditation process proposed by the European Organisation of Cancer Institutes (OECI) since the early 2010s. 100% dedicated to cancer care, the French Centres combine three essential missions on their sites: care, research and education in this field.

With their own specific governance structure, headed by a physician-researcher, Unicancer's centres provide comprehensive, multidisciplinary care for their 550,000 patients every year, ensuring a strong link between cancer research and care. Lastly, their regional anchoring means that they can carry out their expert centre missions in partnership with all health establishments and professionals in a specific area, in line with the commitment made by the OECI.

Gustave Roussy (Greater Paris) was the first French centre to be accredited by the OECI in 2012, followed by the Léon Bérard Centre (Lyon) in 2016 and the Institut Curie (Paris) in 2018. Today, eight of our cancer centres are CCC-certified by the OECI or are in the process of renewal, and the other ten are committed to obtaining CCC certification by 2025. For Unicancer, the accreditation programme proposed by the OECI is an essential approach for guaranteeing a quality approach throughout France, centred on innovation, expertise and multidisciplinarity.

The OECI and the CLCC share common ambitions: to offer cancer patients equal access, no matter where they live, to quality care through multidisciplinary teams, to ensure that innovation and research are fully integrated into patient care pathways, and to place patients at the heart of our concerns.

TSJCI: National OECI Networking Forum 'Building Comprehensive Cancer Infrastructures in Ireland'

In January 2024, Trinity St James's Cancer Institute (TSJCI), Irelands first OECI accredited Cancer Center, hosted a 1-day national OECI forum 'Building Comprehensive Cancer Infrastructures in Ireland'. Currently, Ireland does not have a designated comprehensive cancer centre (CCC) and identifying gaps in our research capacity is key to achieving this and aligning with EU Cancer Mission targets of patients treated in research intensive institutes. The most effective cancer centres internationally integrate high-quality clinical cancer care and teaching with outstanding basic, translational and clinical research focused on cancer. These internationally-recognised comprehensive cancer centres provide a structured environment to develop and nurture leaders in cancer medicine and research, nurses and allied health professionals across all disciplines to work together with the common goal of improving outcomes for patients.

Our aim in hosting this event was to strengthen collaborations and relationships between cancer centres nationally. There is a large variation in research capacity between centres and we sought to facilitate improvements by identifying common challenges and gaps.

Nationally, of the 8 NCCP (National Cancer Control Programme) designated cancer centres, 6 are in varying stages of engagement with the OECI process. Teams from each of these centres (plus 2 additional) came together to share knowledge and discuss common issues around quality systems patient involvement, patient pathways, data, nursing, translational research strengths and gaps, infrastructure and training strengths and gaps and areas for collaboration and partnership.

Our objective was to establish a nationwide collaborative network dedicated to the dissemination of knowledge, with the overarching objective of enhancing patient care. We adopted the OECI standards as a foundational framework to guide this. Participants demonstrated high levels of engagement and collaboration and it is hoped that this will become an annual event.

This work was supported by the Irish Cancer Society Translational Cancer Research Networking Award CNRA23DOH secured by Dr Patricia Doherty.





Meeting Irish Cancer Centres, Dublin, 25 January 2024



Education and Training courses on

- designing and managing EU research projects
- quality culture in oncology

SUSTAINABILITY

data protection

INCLUSION

CONTINUIT

• patients' involvement in research (co-researchers)

OECI Young Board

OECI Research grant fund

OECI links with EURACAN

to promote RWD studies on rare solid cancers of the adults

Meetings and Events on relevant topics for OECI

OECIWORLD Network

for OECI members in extra EU countries

Promoting OECI Members' partecipation in EC applications

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Unlock the potential of real-world data of rare solid cancers of adults: the EURACAN data ecosystem to reduce disparities in cancer

Annalisa Trama¹, Gijs Geleijnse², Jean-Yves Blay³

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- 2. Netherlands Comprehensive Cancer Organisation -The Netherlands, Senior Clinical Data Scientist
- 3. Department of Medical Oncology, Centre Léon Bérard & Centre de Recherche en Cancérologie de Lyon (CRCL) General Director & Université Claude Bernard Lyon 1, Lyon, France, Professor

Introduction

Jacqueline M.L. Stouthard¹ 1. Organisation of European Cancer Institutes, Board Member and Gender Equality Committee Chairperson

Gender equality is a fundamental human right and the focus of Goal 5 of EU's 2030 Agenda for Sustainable Development. Much progress has been made in the campaign for gender equality, yet women still face significant barriers to advancement in the workplace.

The 2023 OECD Skills Study reveals that more women have indeed entered the workforce in recent years, but they often experience difficulty in finding a first job, earn less, and are more likely to work part-time. This is particularly true for researchers. Given the paucity of female scientists, OECI considers it essential to ensure that our efforts are geared towards tackling gender inequalities in science and finding ways of engaging women in all aspects of our organisation.

As an organisation, we are convinced that our success crucially hinges on all the contributions from our female scientists who enrich our community and inspire future generations.

In order to showcase the female excellence in our institutes, and in conformity with our Gender Equality Plan, this Edition of the OECI Magazine includes an article from Dr Annalisa Trama - Director of the Evaluative Epidemiology Unit at the Fondazione IRCCS Istituto Nazionale Tumori (INT) and expert on population-based research - introducing a strategic collaboration between OECI and EURACAN.

Coordinated by the French Comprehensive Cancer Centre Léon Bérard in Lyon, France, EURACAN is a virtual network connecting patients and healthcare providers, which comprises 106 highly specialised cancer centres, most of which are OECI members.

In the European Reference Network on rare adult solid cancers (EURACAN), a federated clinical registry for rare cancers has been initiated by Istituto Nazionale dei Tumori (INT) in Milan. The registry is based on federated learning which, in simple words, is a machine learning technique that trains an algorithm across multiple decentralized hospitals/data providers holding data locally, without exchanging them. This federation technology allows to

preserve privacy by interrogating data without centralizing them. Furthermore, the registry re-use data available in electronic health records or rare cancers specific databases available in the hospitals or networks contributing to it. Data from the participating centres/networks are harmonized using the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) and extract-transform-load mechanisms are developed to reduce the burden of transferring clinical data to research data.

EURACAN is dedicated to the 10 families of rare adults' solid cancers, namely rare head and neck cancers (i.e. cancers of nasal and sinus, nasopharynx and of major and minor salivary glands), sarcomas, neuroendocrine neoplasms, tumours of the central nervous system, rare cancers of the digestive system, endocrine, female genital, male genital and urinary tract, chest and skin. The registry was initiated for 2 families (head and neck cancers and sarcomas) and in the next few years it will be scaled up to additional rare cancer families for which a registry is not yet available.

The registry will generate real-world evidence that can be used for population level decisions as well as individualized decision at the patient level.

Increasing the understanding of rare cancers for medical decision making

Medical decision-making is difficult for rare cancers and there is increasing pressure to use real-world data to inform best clinical practice. To this extends, the registry objectives are:

- $1. \ \mbox{to help}$ describe the natural history of rare adult solid cancers;
- 2. to evaluate factors that influence prognosis and treatment response;
- 3. to assess treatment effectiveness;

4. to measure indicators of quality of care (diagnostic and staging procedures, treatment strategies, follow-up etc.).

The data collected for the registry will not entail further examinations or admissions to the hospital and/or additional appointments to those normally provided. Medications, procedures, visits and check-ups are prescribed according to standard clinical practice. The only intervention will be to collect health status data, already present in the clinical file.

In other words, it will be an observational, real-world registry. The registry aims to collect information, where available, on the storage of biological samples and imaging at the premises of the participating healthcare providers to facilitate future translational studies on rare solid cancers.

This will increase the ability to diagnose and treat rare cancers, with the ultimate goal of improving the survival and quality of life of patients with these tumours.

Supporting regulatory decision

The registry was developed to meet the necessary requirements to be a data source of the Data Analysis and Real-World Interrogation Network (DARWIN EU). This is an initiative launched by the European Medicines Agency (EMA) to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, from real world healthcare databases across the European Union (EU).

Furthermore, the EURACAN registry will support registry-based studies to:

- 1. provide comparator groups of patients for a single arm trial where RCT is not feasible or unethical
- 2. support registry-based RCT for patient recruitment
- 3. supplement the evidence generated in the pre-authorisation phase (information on standards of care for the disease, determinants of disease outcomes in clinical practice, validity of a surrogate endpoint)
- 4. contextualise the results of uncontrolled trials
- 5. provide data sources or infrastructure for post-authorisation evidence generation

For these objectives, synergies with organizations like EORTC are being explored.

Supporting data access towards the implementation of the EU health data space

The registry governance is meant to support under strict conditions (https://euracan.eu/registries/starter/ european-registry-governance), that researchers, innovators, public institutions or industry will have access to registry data. Rare cancers are rare, so data potentially crucial to developing life-saving treatments and ensuring better access to healthcare should be widely used by all parties interested in improving the treatment and outcomes of rare cancers. Thus, we welcome the European Health Data Space (EHDS) which creates a strong legal framework for the use of health data for research, innovation, public health, policy-making and regulatory purposes and insights from the EURACAN registry are being used to shape the EHDS.

Promoting international collaborations beyond Europe

The registry uses the OMOP CDM which was developed and promoted by the Observational Health Data Sciences and Informatics (OHDSI) as a tool to support data standardisation. To achieve quality, efficiency, and transparency of observational research, it is necessary to standardize structure, content, and analytics so that they can optimally



The wealth of health data, estimated to make up approximately 30% of data generated worldwide, is often siloed and yet unexploited. This is a well-known missed opportunity especially for rare cancers, those with a yearly incidence of < 6 cases per 100,000 inhabitants. Outcomes for rare cancers are lagging compared to common cancers. A better understanding of the biology, natural history, and effectiveness of treatments could improve the care and prognosis of these patients. However, this is hindered by the low number of patients and thus the difficulty to generate evidence from powered clinical studies. Better utilization of real-world data is therefore key. Where single health care organization may not have sufficient patients to generate meaningful data-driven insights, coordinated multi-center data collaborations have the potential to reach the critical mass of patients and expertise to drive improvements in care and outcomes for rare cancer patients.

support different use cases. OHDSI has established an international network of researchers and observational health databases (2,000 collaborators across 74 countries) with the aim of empowering a community to collaboratively generate the evidence that promotes better health decisions and better care. OHDSI's data network is based on its OMOP common data model, enabling federated analytics amongst collaborators. The OHDSI oncology community in Europe is gaining traction, with initiatives such as PIONEER (prostate cancer), OPTIMA (breast and lung cancer) as well as the Digicore collaboration and its DigiOne project. As OHDSI collaborator the registry could serve as a driving force to expand studies on rare cancers within and outside Europe by leveraging the OHDSI network.

Challenges and perspectives

To include centers into the federated data network, it is necessary to support different technology and data standards, data management systems and infrastructures, legal frameworks, data privacy and data governance policies across EURACAN countries as well as different views on governance on data sharing for research. Furthermore, both at the coordinating organizations as well as at the participating centers, human and financial resources are needed to ensure sustainability of a European rare cancer clinical registry.

The project Intelligent Ecosystem to improve the governance, the sharing, and the re-use of health Data for Rare Cancers (IDEA4RC) leverages on EURACAN's wealth of data, on one side, and on emerging interoperability technologies and Artificial Intelligence approaches for distributed data integration, federated analysis, and knowledge extraction from existing structured (e.g., electronic health records (EHRs), Registries etc.) and unstructured (e.g., clinician notes, image reports, pathology reports). The project ambition is to establish the framework for a first-in-the-field European Data Ecosystem for Rare Cancers, spanning multiple sources in multiple EU countries and supported by (i) a federation of interoperability secure data processing environment; (ii) Al tools for multi-language data processing and analysis; (iii) a Multimodal Data Navigator to assist clinicians and researchers in finding and accessing available data of stipulated quality; and (iii) modern trust-building technologies (e.g. blockchain) to orchestrate data governance and incentivize data sharing and altruism. The developed tools, easy to integrate into routine care may represent the basis for a sustainable and scalable data network for rare cancers in general.

INT and partner IKNL are currently investigating measures to manage, sustain and grow the data network initiated with the registry. It is envisioned that the operations of such a European registry may be better secured at pan-European organization with dedicated staff. With OECI's vision to invest in a clinical data strategy to measure and improve care, it may be an attractive party to host and manage a clinical registry combining the data of its members with those of EURACAN with the ultimate goal of reducing disparities in rare cancers care and outcomes.





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Health inequalities in Europe: causes and actions. The case of cancer

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Health inequalities persist as a significant challenge across Europe. With cancer being one of the leading causes of morbidity and mortality, it is crucial to note that compared to 2020, the numbers of new cancer cases and cancer deaths are estimated to increase by about 20% and 30%, respectively, by 2040. On the other hand, according to the World Health Organization, between 30% and 50% of cancer cases in the EU are preventable¹. Globally, in 2019, 50.6% of cancer deaths among men and 36.3% among women were attributable to modifiable risk factors².

In the 27 European Union Member States (EU27) plus Iceland and Norway (EU+2 countries), the largest risk factor for cancer deaths is tobacco, with more than 25% of cancer deaths in 2019, Alcohol is the second leading cancer risk factor (6.3% of cancer deaths), followed by dietary risks – such as diets high in red or processed meat and low in fruits and vegetables (6.2%), occupational risks (5.9%), high body mass index (5.7%), high blood sugar (5.6%), air pollution (2.0%), physical inactivity (1.2%) and human papillomavirus (HPV) infection (1.2%)³. Thus, the risk of cancer can be reduced by following healthy lifestyles, maintaining a healthy diet, being physically active and refraining from alcohol and tobacco consumption.

However, cancer burden is unequally distributed within and among countries, with differences in risk, uptake of screening, and access to treatment. Despite advancements in medical technology and healthcare accessibility, disparities in cancer outcomes continue to exist. Understanding the causes and implementing effective actions are essential steps towards mitigating these inequalities³. The European Cancer Inequalities Registry monitors and reports inequalities in cancer prevention and care for each EU Member State, Norway, and Iceland from the perspective of different inequalities, ranging from disparities between countries and regions, to inequalities due to age, sex, income, education or even the level of urbanization⁴.

Mortality rates of breast, cervical and colorectal cancer are 2–3 fold higher in Eastern European countries than in Western European countries⁵. Within countries, cancer mortality rates are 75% higher among men than women across EU countries. On the contrary, women with a high socio-economic position have a higher risk of developing breast cancer, thought to reflect nutrition in childhood, reproductive history, and exposure to hormonal therapies⁶. Additionally, less educated individuals have higher mortality rates for nearly all types of cancer than their more highly educated counterparts, especially for tobacco/infection related cancers. However, the magnitude of inequalities varies greatly by country and over time, predominantly due to differences in cancer mortality among lower-educated groups, as for many cancer-types higher-educated have more similar (and lower) rates, irrespective of the country⁷.

The main cause of health inequalities in cancer is economic status which often determines access to healthcare services, including cancer screening, diagnosis, and treatment. Individuals from lower socioeconomic backgrounds are more likely to face barriers such as financial constraints, lack of insurance coverage, and limited access to healthcare facilities. These disparities result in delayed diagnosis and inferior treatment outcomes. Additionally, discrepancies in healthcare infrastructure, both within and between countries, contribute to health inequalities. Rural areas often lack specialized cancer treatment centers and experienced healthcare professionals, leading to disparities in cancer care between urban and rural populations. Important factor leading to cancer inequality is also limited health literacy and awareness about cancer prevention and early detection. Individuals with lower levels of education may not recognize cancer symptoms or understand the importance of screening programs, resulting in late-stage diagnoses and poorer prognosis.

Although high-quality national screening programs are in place in several EU countries to detect cancer at an early stage and reducing preventable deaths, evidence suggests large inequalities in the uptake of cancer screening across EU countries⁸. In 2019, screening coverage still varied cross-nationally: self-reported rates of cancer screening participation among women aged 50-69 years varied 10 times across EU countries, with the highest rates in Nordic countries (Denmark, Sweden, and Finland) and the lowest rates in Eastern European countries (Romania and Bulgaria). Inequalities in the use of cancer screening tests in Europe are associated with household income, educational level, employment status, and country of birth⁹. Individuals who have a lower socio-economic position, or a lower education level tend to be diagnosed at a more advanced stage of cancer and experience worse survival rates, partly as result of lower screening participation.

Significant contributors to health inequalities are also cultural beliefs and language barriers because they can impede access to cancer information and healthcare services, particularly among immigrant populations. Mistrust in the healthcare system, coupled with language barriers, may prevent individuals from seeking timely medical assistance or adhering to treatment regimens. Last, but not least, environmental factors such as pollution, occupational hazards, and lifestyle choices such as smoking and poor nutrition contribute to cancer incidence rates. Disadvantaged communities are often disproportionately exposed to environmental carcinogens. exacerbating health inequalities¹⁰.

Inequalities are observed also in childhood cancer burden, and availability of treatment options between and within countries, indicate that things can be improved¹¹. Suffering and lifetime consequences caused by childhood cancer need to be minimized.

Actions to Address Health Inequalities in Cancer are as follows:

1. Improving Access to Healthcare: Governments and healthcare providers must prioritize initiatives to enhance access to cancer screening, diagnosis, and treatment for underserved populations. This includes expanding healthcare coverage, subsidizing costs for low-income individuals, and establishing mobile screening units to reach rural communities.

2. Investing in Healthcare Infrastructure: Governments should invest in building and upgrading healthcare infrastructure, particularly in underserved regions. This includes establishing comprehensive cancer centers equipped with state-of-the-art technology and ensuring a sufficient number of trained healthcare professionals, including oncologists, radiologists, and oncology nurses.

3. Community Outreach and Education: Targeted educational campaigns aimed at increasing cancer awareness and promoting healthy behaviors are essential. These initiatives should be culturally sensitive and available in multiple languages to effectively reach diverse populations. Community health workers can play a crucial role in bridging communication gaps and providing support to vulnerable groups.

4. Addressing Social Determinants of Health: Efforts to reduce health inequalities must address underlying social determinants such as poverty, education, and housing. Implementing policies to alleviate socioeconomic disparities, such as increasing minimum wage, expanding educational opportunities, and providing affordable housing, can positively impact health outcomes, including cancer incidence and survival rates.

5. Promoting Research and Innovation: Continued investment in cancer research and innovation is crucial for developing more effective prevention strategies, diagnostics, and treatments. Collaborative research efforts involving academia, industry, and healthcare providers can lead to breakthroughs in cancer care and help reduce disparities in access to cutting-edge therapies.

In conclusion, there is an urgent need to address inequalities as stated in the Beating Cancer Inequalities in the EU report in January 2024. Tackling health inequalities in cancer requires a multifaceted approach that addresses socioeconomic, cultural, and environmental determinants of health. By implementing targeted interventions aimed at improving access to healthcare, raising awareness, and addressing underlying social disparities, policymakers and healthcare stakeholders can work towards achieving equitable cancer outcomes for all populations across Europe.

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