european cancer ORGANISATION

Unlocking Potential:
New Treatment Paradigms in European Cancer Care

ECO POLICY ACTION REPORT

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Acknowledgements

This report summarises the key presentations, contributions and recommendations shared at the European Cancer Organisation (ECO) Community 365[1] Roundtable Meeting on New Treatment Paradigms[2].

It was held in June 2024, facilitated by the co-chairing of Nikolina Dodlek, ECO Board Member and Young Cancer Nurse, European Oncology Nursing Society and Dr Eric Briers, ECO Patient Advisory Committee Member and Vice Chairman of Europa Uomo. We thank all speakers who contributed their perspectives and expertise on how to better understand the role of various new treatment developments that can assist Europe in better treating patients with cancer in all countries. We also thank those who provided contributions via the online roundtable's chat function during the meeting and provided supplementary commentary after the meeting. Finally, we also convey gratitude to all those who took time to review and comment upon this report and its recommendations during its wider review, as part of ECO's Policy Approval Pathway process[3].

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1 Community 365 is a group of charity, philanthropy, and industry contributors to the Focused Topic Networks of the European Cancer Organisation. Community 365 provide ideas, guidance, practical support, and resources for our work in convening stakeholders and building consensus in the European cancer community. Community 365 contributors do not have a decision-making role in our policy work. Rather, policies of the European Cancer Organisation, such as those represented in this document, are agreed by our Board after consultation with our Member Societies and Patient Advisory Committee, via our Policy Pathway process. More information here: https://www.europeancancer.org/community-365

2 Find more information concerning the report here : https://www.europeancancer.org/events/288:community-365-roundtable-new-treatment-paradigms.html#overview

3 https://www.europeancancer.org/content/policy-decision-making.html

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Executive summary of recommendations

A wave of new and groundbreaking techniques for cancer detection, diagnosis and treatment is revolutionising the European health landscape. Nevertheless, medical breakthroughs entail numerous challenges which must be addressed by policy-makers at European, national, regional and local levels if those innovations are to reach the patients in need and achieve their full potential for improving outcomes, care and treatment.

The European Cancer Organisation's Community 365 roundtable on New Treatment Paradigms[4] was organised to consider and reflect upon the challenges in integrating cutting-edge therapies, like cell and gene therapy, radioligand therapy, and liquid biopsy, across Europe. Overall, the meeting brought attention to the urgent need to enhance healthcare infrastructure, training, and regulatory frameworks to make advanced therapies more accessible and effective for cancer patients in all parts of Europe.

Headline recommendations from the ECO Community 365 roundtable on New Treatment Paradigms are summarised below.

Cell therapy

Thousands of patients in Europe with haematological malignancies remain in need of cell therapy to more effectively treat their cancers. In too many countries processes such as having in place recognised treatment centres and referral systems are not yet instituted. Several particular themes were identified in the discussion:

Delivery of treatment through qualified centres

The roundtable emphasised the need for a network of qualified treatment centres specialised in cell therapy, such as CAR-T.

The European Commission's regulatory framework for advanced therapies, including updates in the **EU Regulation on Substances of Human Origin (SoHO)**, supports the establishment of standardised centres for delivering advanced therapies safely across the EU. This framework aims to enhance quality standards and improve access to specialised treatments by streamlining approval processes for therapeutic centres.

While increasing the number of centres with expertise to provide cell therapy will remain a policy requirement, there are also clearly identified needs to help improve systems for referral to a specialised centre, and to support patients more effectively with the travel and time burden that will arise from having treatment potentially far from their place of residence.

The improvement of referrals to specialised centres should be taken on board in respect to present and future implementation of EU policy initiatives such as, but not only, the emerging EU Network of Comprehensive Cancer Centres.

The role of the multi-disciplinary team, including nurses

The roundtable recognised the critical role of multidisciplinary teams (MDTs), and with some particular attention to the role of cancer nursing, to ensure holistic patient care before, during, and after cell therapy. The roundtable panel firmly conveyed a need to support improved access to cell therapy by investment in education and awareness of MDTs.

New opportunities should be facilitated to enable healthcare professionals to travel to other countries and observe the implementation of new treatment paradigms in other settings to better support their translation into practice in their own country

An example to learn from and sustain in this respect includes European Innovation Council (EIC)[5] supported initiatives to foster educational exchanges and training programs, enabling healthcare professionals to learn about best practices in cell therapy across different countries, ultimately enhancing implementation quality and patient care.

4 https://europeancancer.org/events/288:community-365-roundtable-new-treatment-paradigms.html

5 Taberna, M., Moncayo, F. G., Jané-Salas, E., et al. (2020). "The Multidisciplinary Team (MDT) Approach and Quality of Care." *Frontiers in Oncology*, 10, Article 85. doi:10.3389/fonc.2020.00085. & El Saghir, N. S., Soto Pérez de Celis, E., Fares, J. E., et al. (2021). "Team-based approach to cancer care: Role of multidisciplinary teams in improving quality and outcomes." *Current Opinion in Oncology, 33(5), 366–373. doi:10.1097/CCO.0000000000000757.*

Improving approaches to data and long-term follow up

The roundtable clearly identified the need to improve approaches that can ensure patients receiving cell therapy treatment can easily report on the outcomes they experience, for example through the collection of **patient-reported outcome measures (PROMs)** and other forms of real world data collection. Promoting this is critical to not only better understand long term efficacy, but also to ensure good management of symptoms and any potential side effects of treatment.

EU supported efforts to standardise approaches to patient reported outcome measures, and to achieve the strongest use of well-formed questionnaires should be sustained and enhanced.

An example to learn from and sustain in this respect includes the EMA's Regulatory Science Strategy to 2025[6] which supports the integration of PROMs in clinical assessments, aiming to unify reporting standards and improve long-term monitoring across the EU. This initiative encourages digital data collection for better management of patient experiences and outcomes, supporting data-driven care improvements.

Radioligand therapy

Addressing the shortage of specialist expertise

It was a repeated refrain across presentations and interventions during the roundtable that a lack of specialist professionals in the field of radioligand therapy will continue to impose limits on its uptake. **In keeping with the role that the EU takes in ensuring adequate supply of medicine in Europe, including radionuclides, the EU should help address health workforce shortage. The proposal from the Belgian Presidency of the European Union that an EU Health Workforce Plan be created and implemented should be pursued with some urgency, and be reflective of where workforce shortage is holding back adoption of innovations in treatment**.

See also ECO's ongoing campaign on addressing workforce shortage for further recommendations and to get involved: https://www.europeancancer.org/workforce

Meeting the needs of patients when providing radioligand therapy

The session indicated the scope to do more in helping patients access radioligand therapy in a manner that is more convenient and reflective of their needs. The roundtable made suggestion that policies on patient hospitalisation during treatment be as flexible as possible towards the patient preference, allowing scope for choice on issues like overnight stay.

Radioligand therapy as a European research success story

The session had an overall positive tone about the promise of radioligand therapy but also identified unique health economic aspects for attention. Drawing in more specialists to the field will inevitably have a salary and remuneration component. Lengthy and bottlenecked approval mechanisms could lead to a scenario of a European led innovation being capitalised elsewhere.

Within the spirit of the new European Commission's pursuance of the Draghi Report agenda on EU competitiveness, radioligand therapy could be helpfully taken as a current case study for application of the Draghi principles.

Liquid biopsy

Headline themes for policy attention from the roundtable discussion on liquid biopsy are presented below:

Giving greater attention to the quality and availability of testing

The roundtable gave emphasis to not only the need for liquid biopsy testing to be in place as part of regular practice in oncology treatment across Europe, but also for the testing to be of sufficient high quality. This becomes especially the case at the scientific understanding in the field grows, including in respect to resistance mutations.

6 https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy#:~:text=Regulatory%20Science%20Strategy%20to%202025,-On%2031%20March&text=catalysing%20the%20integration%20of%20science,for%20human%20medicines%20only)%3B

Standardising and harmonising approaches across Europe

There are many precedents in which the EU has been able to assist countries in improving quality in healthcare by advancing harmonised recommendations on practice and approach. Good examples of this would include in respect to health and safety approaches, manufacturing approaches, and recommended approaches to cancer screening. Participants in the roundtable conveyed a view that EU investment in supporting greater harmonisation of approach to liquid biopsy testing across Europe would help to support wider and faster uptake of the technology.

Seeing things as a whole. Understanding the value of testing

The session heard of the difficulties of reimbursement of testing, with national processes too often making an artificial divorce in considering the value of a test and the treatment entirely separately. Both depend upon each other and yet in some countries it may be entirely different units of agencies or governments making decisions on test and treatment reimbursement.

Expanding cancer screening policy to include biomarker testing

Through Europe's Beating Cancer Plan, great improvements in cancer screening policy are being advanced across Europe. Yet the value of early detection of cancer is intimately linked to having a patient rapidly commencing the best treatment for their cancer soon after detection. The roundtable considered that cancer screening policy should also seek to ensure that detection of a cancer is rapidly followed by diagnostics and treatment decision, including use of liquid biopsy.

Meeting the training and education needs of healthcare professionals

The value of supporting innovation adoption with ensuring the training and education needs of healthcare professionals are met was emphasised throughout the roundtable, including in the discussions on improving uptake in the use of liquid biopsy testing.

Introduction

Since the launch of **Europe's Beating Cancer Plan** in 2021, science and technology have not stood still. New and innovative approaches towards cancer detection, diagnosis and treatment are arriving at an ever-rapid pace, and include, but are not limited to, for example, cell therapy, radioligand therapy and the use of liquid biopsy.

In June 2024, the European Cancer Organisation convened a Community 365 roundtable on the topic of 'New Treatment Paradigms'[7], with a focus on the three aforementioned examples. The Roundtable discussed **the exciting potential of these approaches**, and the policy challenges associated to their wider uptake. Experts from the clinician, patient, governmental and political environments provided their experience and perspectives, which are summarised in this report, alongside captured recommendations to help unlock the potential of new treatment paradigms in European cancer care.

The stated aims of the roundtable were:

1. To explore the full benefits of new treatments available in the European Union, i.e cell therapy, radioligand therapy and liquid biopsy

2. To identify key pitfalls and obstacles faced by patients, caregivers, healthcare professionals and innovators to effectively implement genomic tumour testing

3. To generate upbeat policy recommendations on how to overcome such barriers, grounded of the insights and knowledge shared during the Roundtable discussion

The full recording of the roundtable is available on the roundtable website here: https://europeancancer.org/events/288:community-365-roundtable-new-treatment-paradigms.html. A summary of roundtable, and policy recommendations arising from the discussions follows.

7 https://europeancancer.org/events/288:community-365-roundtable-new-treatment-paradigms.html

Cell therapy

"We must address significant physical, financial and logistical challenges faced by patients undertaking cell therapy." (Natacha Bolanos)

Co-chaired by **Dr. Dan Tovar**, Senior Director Medical Affairs, Kite, and **Nikolina Dodlek**, ECO Board Member and Young Cancer Nurse, European Oncology Nursing Society.

Dr. Dan Tovar, Senior Director Medical Affairs at Kite gave the first presentation of the session, introducing cell-therapy and the role it can play on a patient's medical journey. T-cells are defined as the cells of the immune system which can fight infections and destroy cancerous ones, when developed in the right environment. In a nutshell, **CAR-T cell therapy is a type of immunotherapy which generates cells to attack cancer cells in the patient**. The patient's T cells are modified in a laboratory to recognise and react to cancer, after being reinfused by intravenous. In this sense, it **represents a unique and innovative treatment option for patients**.

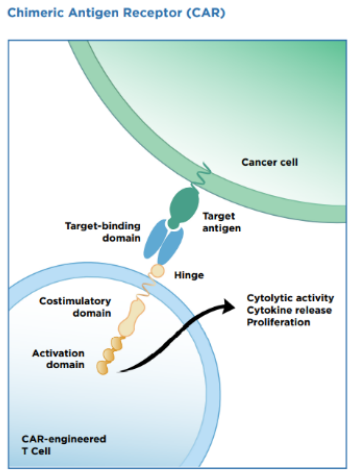
Figure 1: Understand CAR-T Therapy and its effects on the patient's immune system (Kite Pharma, 2023)

Understanding Chimeric Antigen Receptor (CAR) T-cell Technology

CAR T-cell therapy is a type of immunotherapy harnessing the power of a patient's own immune system by engineering T cells to recognize and attack cancer cells.

The T cells help the body detect and attack cancer cells. CAR T-cell therapy activates the T cells so they can better identify cancer cells to attack.

The CARs are engineered proteins that are added to a patient's cell, making that cell able to recognise cancer cells and send signals to the T cell to attack it.



Cell Therapy Uses the Power of the Patient's Own Immune System

COLLECT
patient's white blood cells

ISOLATE
and activate T cells

ENGINEER
T cells with CAR gene

GROW
and expand number of T cells

INFUSE
same patient with engineered T cells

Cell therapy harnesses patient's T cells to selectively target and kill cancer cells. Each treatment is specific to the individual patient.

Given their unique nature, **CAR T-cell manufacturing fundamentally differs from conventional pharmaceutical production**. Indeed, each lot is individualised to match each patient, which requires a chain of traceability throughout the process. Treatment is also coordinated in a specialised treatment centre. These factors can therefore bring forward some particular obstacles to access to overcome.

Natacha Bolaños, Regional Manager for Europe for the Lymphoma Coalition, first underlined the hope that cell therapy is bringing now to so many cancer patients, including in the Lymphoma community. In some cases it offers curative possibility. This is balanced as well by an understanding that, like in other treatment areas, observance for any potential side effects is an important component for systems of care to address as well. Another element for consideration is the support needed to help patients manage other burdens related to the treatment which will include for many a potential lengthy trip to a specialised centre, time off work, childcare impacts and other factors.

Other issues that might be tackled include difficulties in the referral system, sometimes related to lack of awareness of cell therapy options among the health system in some countries. This points to an ongoing need for education and awareness activity about cell therapy and cancer with the multidisciplinary team. Natasca identified nurses as a special part of that team in particular, due to the time the nurse will be spending with a patient before, during and after treatment. Their advice and the information they can impart needs to be recognised.

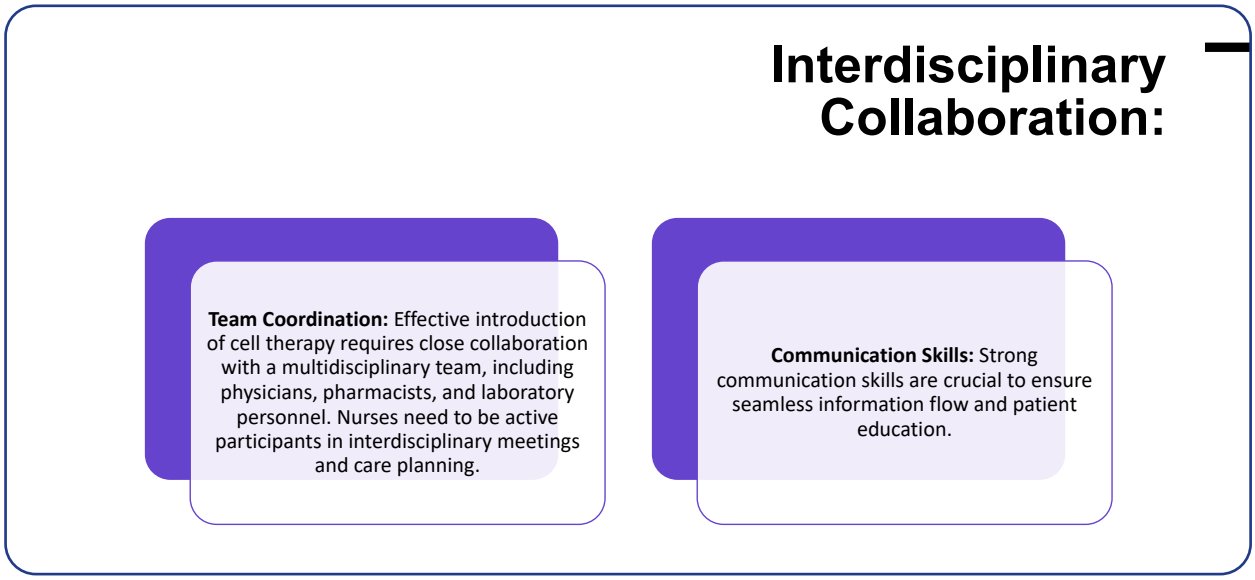
The other significant theme in Natascha's remarks related to the role of data capture in improving the introduction of cell therapy in cancer. In particular, this relates to symptom management and being able to accurately and effectively respond to still emergent data about long term impacts of treatment, alongside survival benefits. Such data can also help to ensure reimbursement criteria are kept continuously up to date with clinical evidence. This points to a broader need across the cancer and health system to invest in and bring forward the power of Patient Reported Outcomes. There is unfulfilled potential for greater standardisation of questions and registries. It is recommended this be a focus of EU energy in health policy.

Nikolina Dodlek
European Oncology Nursing Society

'Nurses need to be active participants in interdisciplinary meetings and care planning.'

Nikolina Dodlek, Board Member and Young Cancer Nurse, European Oncology Nursing Society, explained the **pivotal role played of nurses in helping patients understanding cell therapy and managing expectations**. Nurses remain a key central point of contact for the patient. It is therefore of prime importance that healthcare professionals get access to the adequate knowledge, on the outcomes, benefits, setbacks but also on social aspects such as the financial toxicity such treatments may entail. For instance, **witnessing how such treatments are delivered in other countries**, **or co-training** represent a concrete cross-border solution. Medical oncologists should consequently

Figure 2: Interdisciplinary Collaboration



work with the rest of the healthcare team to share their knowledge. The latter must also continuously be refreshed, for patients to benefit from the most up-to-date information. **Nikolina Dodlek** also underlined the importance of maintaining registries to collect data, conduct research, inform future treatment and contribute to the general knowledge on cell therapy.

Dr. Matti Aapro, Past-President of the European Cancer Organisation and UICC Board member, stressed the need to **bring forward the patient outcome data about cell therapy**, considering both survival benefits but also the long-term effects on quality of life. This can help achieve better monitoring of late effects. In this sense, **high-quality real-world data** is crucial for overcoming many challenges in the healthcare system, particularly in cancer treatment. Such data can significantly enhance decision-making processes by providing insights into the effectiveness and safety of treatments in diverse patient populations. However, there are obstacles to obtaining and utilising this data effectively, including data privacy concerns, standardisation issues, and the need for robust data analytics capabilities.

Matti Aapro also emphasised the importance of **multidisciplinary collaboration and clear communication among healthcare professionals**. Cancer treatment often requires input from various specialists, including oncologists, surgeons, radiologists, and nurses. Seamless collaboration and communication across these disciplines ensure comprehensive care for patients, addressing all aspects of their treatment and recovery.

Matti Aapro also underscored the need for more efficient hospital system planning at the governmental level for specialised cancer treatment across all of Europe, allowing for patient access to be increased.

On a broader scale, Dr Aapro conveyed the ample space for **health systems to get much better at improving their efficiency**. The Organisation for Economic Co-operation and Development (OECD) has published some significant findings and recommendations on this matter[8].This significant wastage underscores the need for streamlined processes and better resource management to ensure that innovations translate into improved patient outcomes. **Disjointed policies can lead to fragmented care**, inefficiencies, and suboptimal patient outcomes. Integrated health policies are essential to ensure cohesive and coordinated care across various levels of the healthcare system. A European agenda on combatting inefficiency in healthcare, and including guidance on health system infrastructure investment, could be assistive in creating a better environment for new treatments to be brought into practice sooner.

8 https://www.oecd.org/content/dam/oecd/en/topics/policy-issue/health-spending-and-financial-sustainability/tackling-wasteful-spending-on-health-highlights-revised.pdf

Recommendations from the cell therapy session

Thousands of patients in Europe with haematological malignancies remain in need of cell therapy to more effectively treat their cancers. In too many countries processes such as recognised treatment centres and referral systems are not instituted. Several particular themes were identified in the discussion:

- **Delivery of treatment through qualified centres**. The roundtable emphasised the need for a network of qualified treatment centres specialised in cell therapy, such as CAR-T. While increasing the number of centres with expertise to provide cell therapy will remain a policy requirement, there are also clearly identified needs to help improve systems for referral to a specialised centre, and to support patients more effectively with the travel and time burden that will arise from having treatment potentially far from their place of residence.
- **The improvement of referrals to specialised centres should be taken on board in respect to present and future implementation of EU policy initiatives such as**, **but not only**, **the emerging EU Network of Comprehensive Cancer Centres**.
- **The role of the multi-disciplinary team**, **including nurses**. The roundtable recognised the critical role of multidisciplinary teams (MDTs), and with some particular attention to the role of cancer nursing, to ensure holistic patient care before, during, and after cell therapy. The roundtable panel firmly conveyed a need to support improved access to cell therapy by investment in education and awareness of MDTs.

New opportunities should be facilitated to enable healthcare professionals to travel to other countries and observe the implementation of new treatment paradigms in other settings to better support their translation into practice in their own country.

The EU supported pan-European Inter-specialty Cancer Training Programme could also be assistive in bringing the full multi-disciplinary team up to date with new treatment paradigms.

- **Improving approaches to data and long-term follow up**. The roundtable clearly identified the need to improve approaches that can ensure patients receiving cell therapy treatment can easily report on the outcomes they experience, for example through the collection of **patient-reported outcome measures (PROMs)** and other forms of real world data collection. Promoting this is critical to not only better understand long term efficacy, but also to ensure good management of symptoms and any potential side effects of treatment.
- **EU supported efforts to standardise approaches to patient reported outcome measures**, **and to achieve the strongest use of well-formed questionnaires should be sustained and enhanced**.

Radioligand therapy

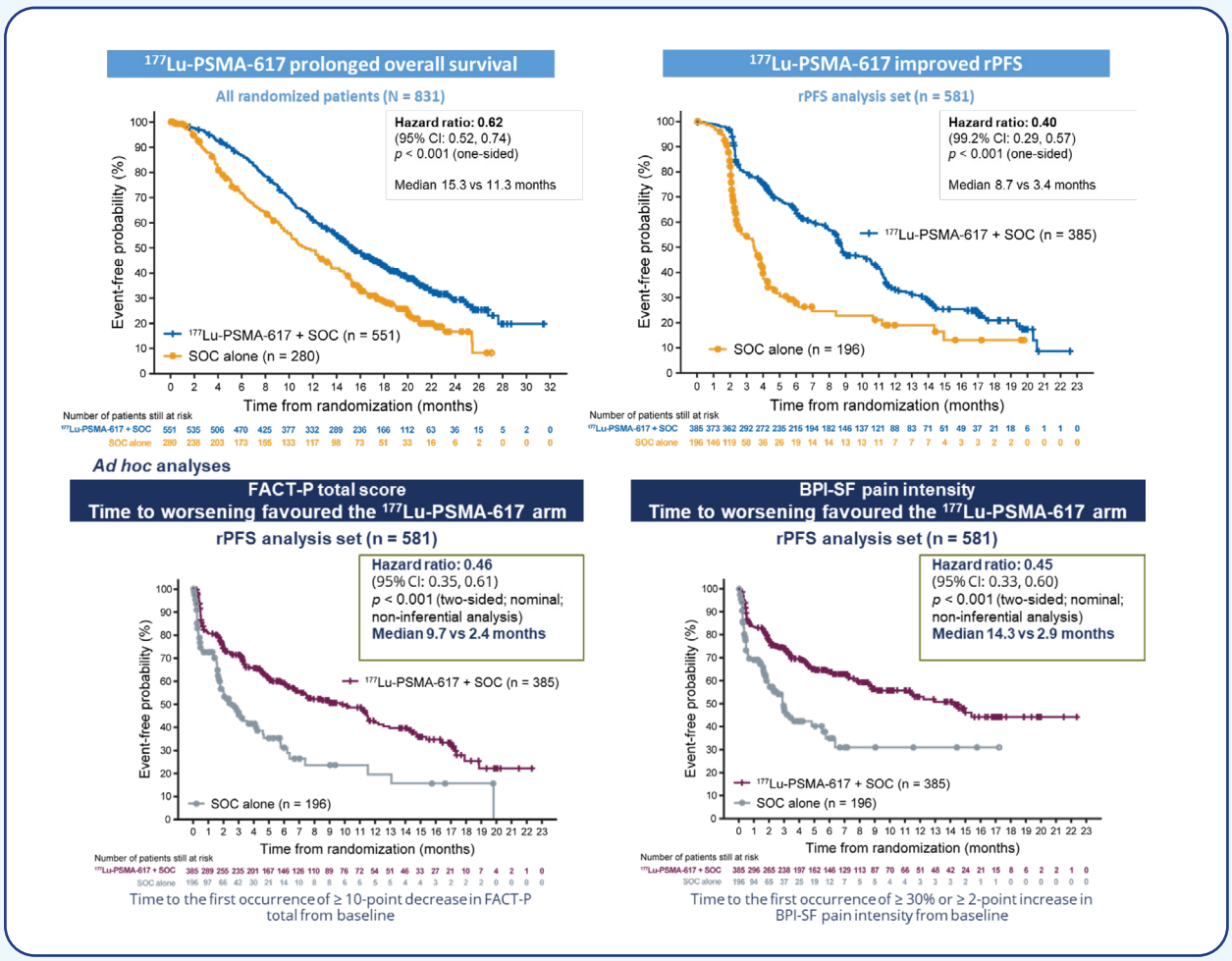
'Capacity, accessibility and availability of the therapies should be the same for all European patients.' (Mark McDonnell)

Co-chaired by: **Prof. Ken Herrman**, Chair of the Theranostics Piloting Group, European Association of Nuclear Medicine (EANM); and Dr. Erik Briers, Vice Chairman of Europa Uomo.

Dr. Erik Briers introduced the discovery of radiotherapy, which marked a **pivotal milestone in cancer treatment**, leveraging the properties of radiation to target and eliminate cancerous cells. Radiotherapy can be defined as a form of targeted nuclear medicine, that doctors use to treat multiple types of cancer. Radioligand therapy **delivers radiation to certain cancer cells and are made up of two key parts joined together by a chemical**[9]. On the one side, the radioisotope releases radiation to target and destroy cells, whereas the ligand directs the radioisotope to cells. This technology has advanced to a point where precision to the millimetre is achievable, significantly improving treatment outcomes. Although radiation can inadvertently affect healthy tissues, innovative techniques have emerged, particularly benefiting prostate and thyroid cancer treatments. Among the particularities brought forward by advances in radioligand therapy is the involvement of a unique set of regulator actors comprising, as examples, both the European Medicines Agency, and national and international nuclear regulatory authorities.

Professor Ken Herrmann, **Chair of the Theranostics Piloting Group**, **European Association of Nuclear Medicine (EANM)**, introduced participants to the benefits of radiotheranostics, emphasising not only survival benefit, but also the positive effects on patients' quality of life.

Figure 3: Benefits of radiotheranostics

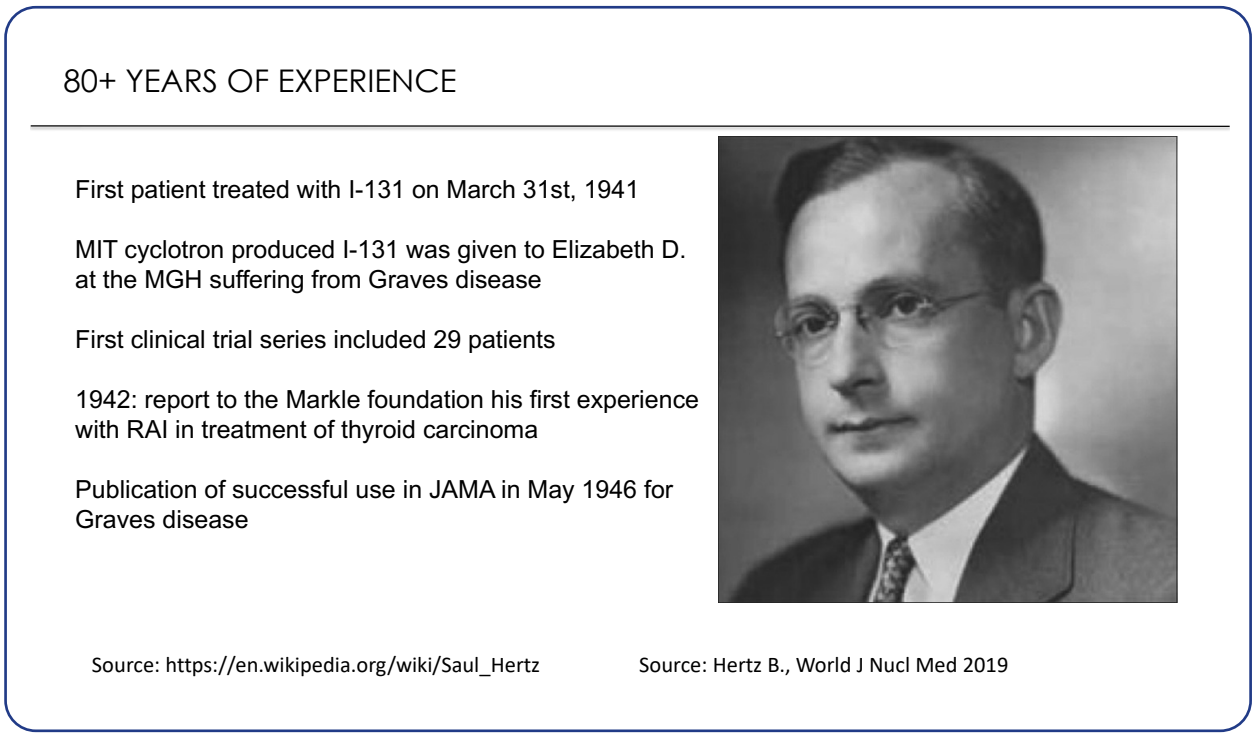


9 https://www.novartis.com/us-en/sites/novartis_us/files/rlt-manufacturing-factsheet.pdf

He introduced participants to the **prostate-specific membrane antigen (PSMA) radioligands**, which delivers precise radiation in the case of prostate cancer and can be used for either imaging or therapeutic purposes[10].

Theranostics refers to the combination of diagnostic imaging with therapeutic radionuclides (RLTs). Such methods were developed over 80 years ago under the leadership of Dr. Saul Hertz, emerging as a true success story in cancer treatment.

Figure 4: 80+ years of experience



Professor Ken Herrmann stressed that the future of radiotheranostics appeared bright. What is driving energy into the RLT agenda includes:

- New targets
- New radionuclides
- New indications
- New combination treatments
- New dosing concepts

A currently unfulfilled role of the EU would be to give further assistance to ensuring that uptake of RLT is supported through a growth of the necessary specialists in the health professions. The concurrent need for new specialist theranostics centres across the continent was also emphasised.

Currently, 38 companies are making significant strides in RLT development, with eight out of 45 clinical stage programs having reached the 3rd pre-approval stage . However, Dr Hermann expressed some concern that lengthy and bottlenecked approval procedures could dissuade investment and prevent RLT becoming a case study of European research to access success stories.

Dr. Uwe Holzwarth, Scientific Officer at the Joint Research Centre of the European Commission highlighted how inequalities in access to new treatments, such as radioligand therapy, contribute directly to further inequalities in cancer survival across Europe. He presented the EU's role in supporting increased access to radioligand therapy, as part of Europe's Beating Cancer Plan and EU Research Mission on Cancer, yet also to raise awareness.

The European Commission supports **the continuous, uninterrupted radionuclide supply in Europe**. This is highly strategic as the continent experienced severe shortages in 2010, preventing access to treatment. Some critical materials are currently only produced outside the EU, a hurdle which must be addressed. To tackle this issue, the EU created the **Strategic Agenda for Medical**

10 von Eyben FE, Virgolini I, Baum R. Review on the Increasing Role for PSMA-Based Radioligand Therapy in Prostate Cancer. Cancers- (Basel). 2024 Jul 12;16(14):2520. doi: 10.3390/cancers16142520. PMID: 39061160; PMCID: PMC11274522.

Ionising Radiation Applications (SAMIRA) action plan in 2021, the EU's first comprehensive plan to support the safe, high quality and reliable use of radiological and nuclear technology in healthcare. The SAMIRA Action Plan aims at securing the supply of medical radioisotopes and improving radiation quality and safety. It is a good example of how different parts of the EU's structures can collaborate well in order to assist countries overcome particular obstacles for new treatment access.

Dr. Uwe Holzwarth

Joint Research Centre of the European Commission

'Inequalities in access to new treatments, such as radioligand therapy, contribute directly to further inequalities in cancer survival across Europe.'

Dr. Uwe Holzwarth mentioned the prospective role that could be played by other EU-supported projects such as INTERACT EUROPE, which is providing a common EU inter-specialty cancer training programme to multi-disciplinary teams in hospitals all over Europe. However, he regretted to observe that the current curriculum does not include written reference to radioligand therapy. He recommended this be addressed. Overall, **Dr Holzwarth also well recognised that lack of specialists within the health workforce will be a continuing limiting factor in improving the uptake of radioligand therapy**.

Leonhard Schaetz, Head of Radioligand Therapy Healthcare System Readiness and Partnerships in Novartis, presented the remaining policy challenges in the field of radioligand therapy. Central to these challenges is **the issue of equity** and ensuring fair access to treatment for all patients. **Leonhard Schaetz** also emphasised the critical role of the healthcare workforce, attracting and retaining talent being of prime importance. Indeed, the question of how to reward and incentivise professionals is paramount, to enable innovation. This is a particular component of the health economic challenge of RLT.

''The vast majority of those in health systems are not aware of the benefits of radioligand therapy simply because they do not yet know it exists. That is a significant awareness challenge to address." (Leonhard Schaetz)

Mark McDonnell, Chairperson of the NET Patient Network and President of the International Neuroendocrine Cancer Alliance (INCA), gave his perception of the landscape based on many years working with patients in the neuroendocrine sector and reflecting on the past 15 years of RLT's application towards neuroendocrine cancer patients. Among his chief reflections was on how to better support patients with the logistical issues presented by the nature of the treatment, including travelling long distances to specialist centres. This can include needs for: overnight stays, multiple visits, and adherence to specific guidelines, such as avoiding sleeping with partners. These extensive travels, requirements and hospital stays can represent a financial and emotional burden, impacting one's quality of life. For instance, the need to take time off work may be detrimental to one's career journey. On another note, undergoing such therapies may create fears and anxiety, due to misconceptions about nuclear medicine. An assessment is pursued to ensure this is the correct treatment, and patients must be educated to understand their safety.

During the discussion period, different ideas were raised on how to reduce potential burden of RLT treatment for the individual patient. Different case studies were mentioned in this context, such as Italy where treatment has moved to an in-patient model, and Germany where two night hospitalisation remains the normal practice. **Leonhard Schaetz recommended that approaches such be patient and person-centric, matching their own preferences, rather than through blunt application of mandatory policies**.

Recommendations from the radioligand therapy session

- **Addressing the shortage of specialist expertise**. It was a repeated refrain across presentations and interventions that a lack of specialist professionals in the field of radioligand therapy will continue to impose limits on its uptake. In keeping with the role that the EU takes in ensuring adequate supply of medicine in Europe, including radionuclides, the **EU should help address health workforce shortage**.
- **The proposal from the Belgian Presidency of the European Union that an EU Health Workforce Plan be created and implemented should be pursued with some urgency, and be reflective of where workforce shortage is holding back adoption of innovations in treatment**.

See also ECO's ongoing campaign on addressing workforce shortage for further recommendations and to get involved: https://www.europeancancer.org/workforce

- **Meeting the needs of patients when providing radioligand therapy**. The session indicated the scope to do more in helping patients access radioligand therapy in a manner that is more convenient and reflective of their needs. **The roundtable made suggestion that policies on patient hospitalisation during treatment be as flexible as possible towards the patient preference, allowing scope for choice on issues like overnight stay**.
- **Radioligand therapy as a European research success story**. The session had an overall positive tone about the promise of radioligand therapy but also identified unique health economic aspects for attention. Drawing in more specialists to the field will inevitably have a salary and remuneration component. Lengthy and bottlenecked approval mechanisms could lead to a scenario of a European led innovation being capitalised elsewhere.
- **Within the spirit of the new European Commission's pursuance of the Draghi Report agenda on EU competitiveness, radioligand therapy could be helpfully taken as a current case study for application of the Draghi principles**.

Liquid biopsy

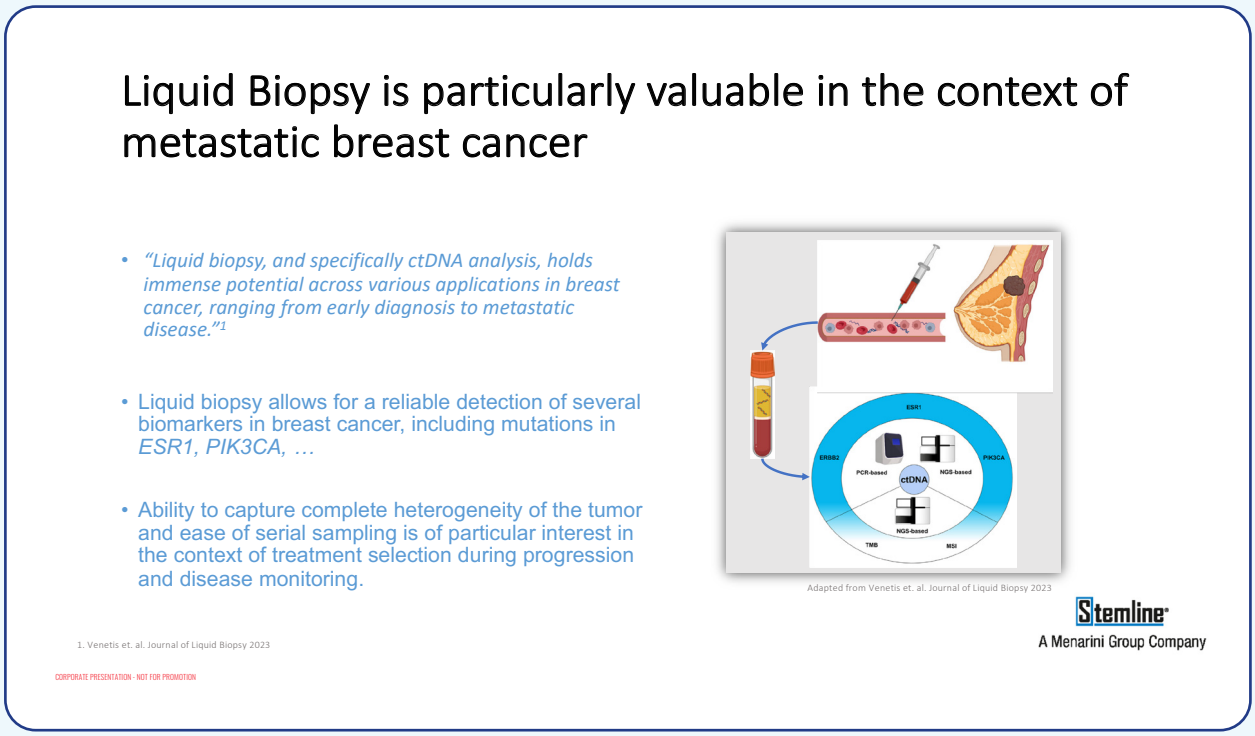
"Liquid biopsy holds immense potential across various applications in breast cancer, ranging from early diagnosis to metastatic disease." (Dr. Umberto Malapelle)

Co-chaired by: **Mounia Mounawar**, Vice President and Global Head of Biomarkers & Companion Diagnostics at Menarini Stemline, and **Nikolina Dodlek**, Board Member and Young Cancer Nurse, European Oncology Nursing Society.

Mounia Mounawar, Vice President and Global Head of Biomarkers & Companion Diagnostics at Menarini Stemline introduced the session by stressing that **precision medicine was a greatly evolving field**. For instance, whereas there were limited options in the past decades, metastatic breast cancer can now be better treated thanks to the evolution of treatments available, such as mutations in the ESR1 gene being tested in liquid biopsy. Liquid biopsy refers to the collection and testing of a body fluid such as blood, urine, semen or saliva, which make the detection of cellular or molecular biomarkers possible to obtain diagnostic, prognostic or predictive information of the disease[11]. This innovative testing approach is particularly valuable in oncology[12], with well-established use in such areas as lung cancer, colorectal cancer and is being established in routine clinical practice for metastatic breast cancer with the ongoing implementation ESR1 mutations testing across Europe.

Dr. Umberto Malapelle, researcher in anatomic pathology, at the Department of Public Health of the University of Naples "Federico II", presented some emerging biomarkers in breast cancer, which are detectable by liquid biopsy testing. Such testing allows for a reliable detection of several biomarkers in breast cancer, including mutations in ESR1, PIK3CA. This ability to capture complete heterogeneity of the tumour and ease of serial sampling is of particular interest in the context of treatment selection and disease monitoring. However, Dr Malapelle underlined that for best results such biomarker testing should be conducted with technologies

Figure 5: Liquid Biopsy is particularly valuable in the context of metastatic breast cancer



11 https://www.sciencedirect.com/topics/medicine-and-dentistry/liquid-biopsy

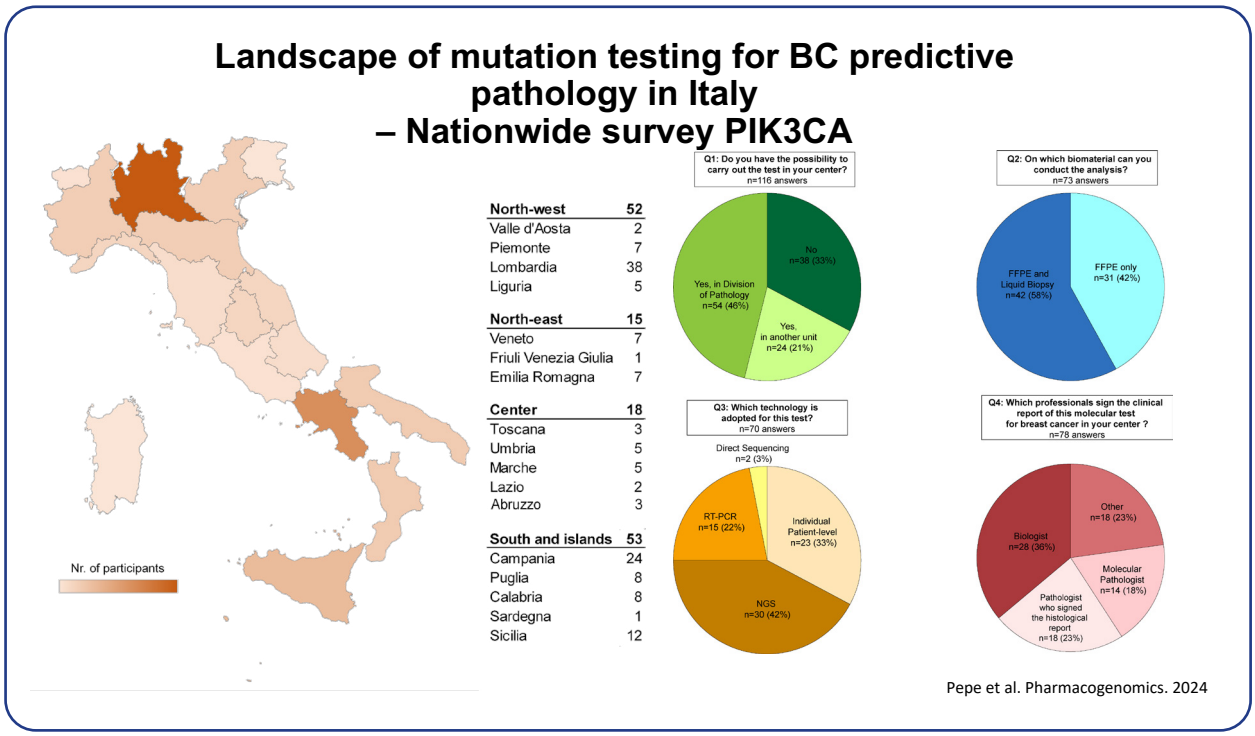
12 Shegekar T, Vodithala S, Juganavar A. The Emerging Role of Liquid Biopsies in Revolutionising Cancer Diagnosis and Therapy. Cureus. 2023 Aug 17;15(8):e43650. doi: 10.7759/cureus.43650. PMID: 37719630; PMCID: PMC10505053.

that deliver reliable high detection sensitivity. This was becoming even more the case as the scientific understanding of resistance mutations grows.

In reviewing the present landscape of liquid biopsy testing in Europe, Dr Malapelle reflected that inequalities in access exist not only between countries but also within. He used a visual schematic to convey the variance across regions in Italy as an example. His main takeaway is the need to ensure a qualitative and equitable access to testing all over Europe. Italy is a leading example, as pathologists and oncologists have developed efforts in Italy to promote the use of such tests.

'Only 12% of survey respondents were tested for biomarkers, with great gaps between member states: 23% in Germany versus 10% in Italy' (Juan Ventura).

Figure 6: Landscape of mutation testing for BC predictive pathology in Italy – Nationwide survey PIK3CA



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Juan Ventura, Research and Patient Engagement Director at Cancer Patients Europe presented the results of CPE Patient Survey on Metastatic Breast Cancer Biomarkers, conducted amongst 1300 respondents. He underlined that breast cancer was the world's most diagnosed cancer, with liquid biopsy playing an ever growing and valuable role in detecting treatment relevant gene mutations. This being the case, he presented the striking survey result that 75% of patients had not discussed biomarkers testing with their oncologist, and 33% did not know why biomarkers are important in cancer. The survey results also showed the long waiting time for results in many countries. In conclusion, Juan Ventura considered that better harmonisation and standardisation of application of liquid biopsy testing across Europe would be helpful in widening and accelerating their uptake. The survey results also pointed to the further work required to ensure patients have access to relevant information about liquid biopsy testing to assist their discussions with healthcare professionals.

Figure 7: Results of CPE Patient Survey on ESR1 & Liquid Biopsy (i)

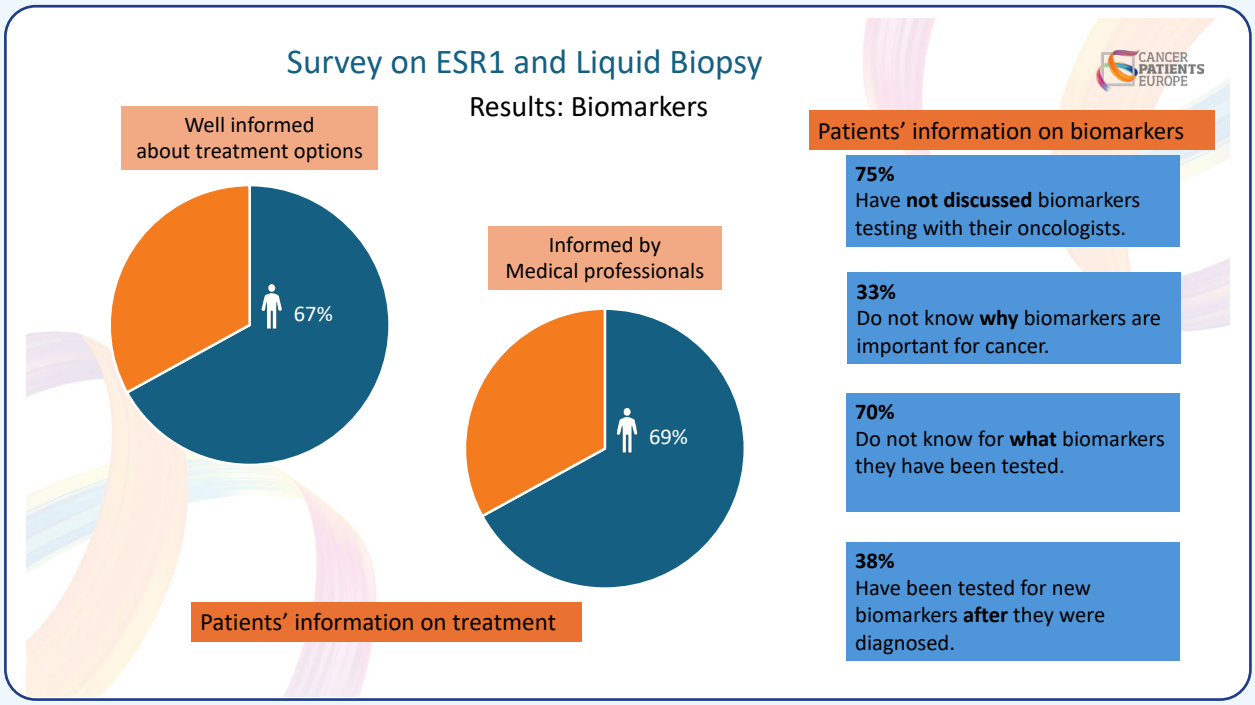


Figure 8: Results of CPE Patient Survey on ESR1 & Liquid Biopsy (ii)

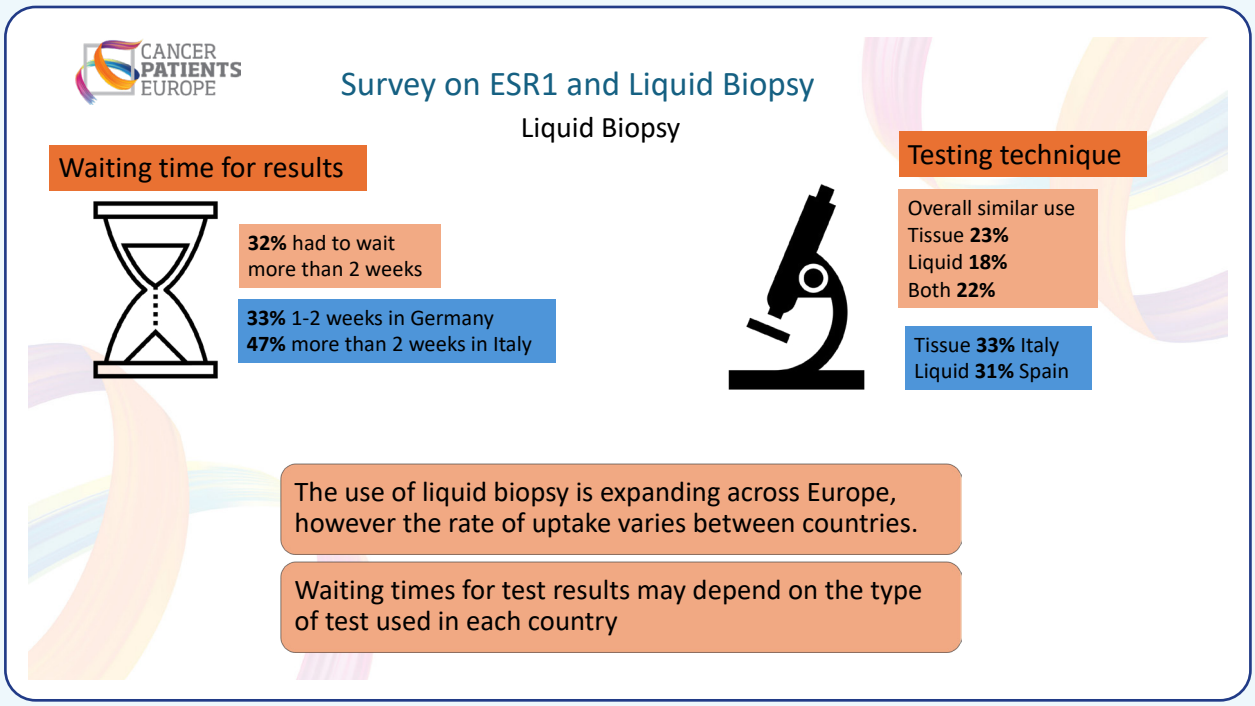
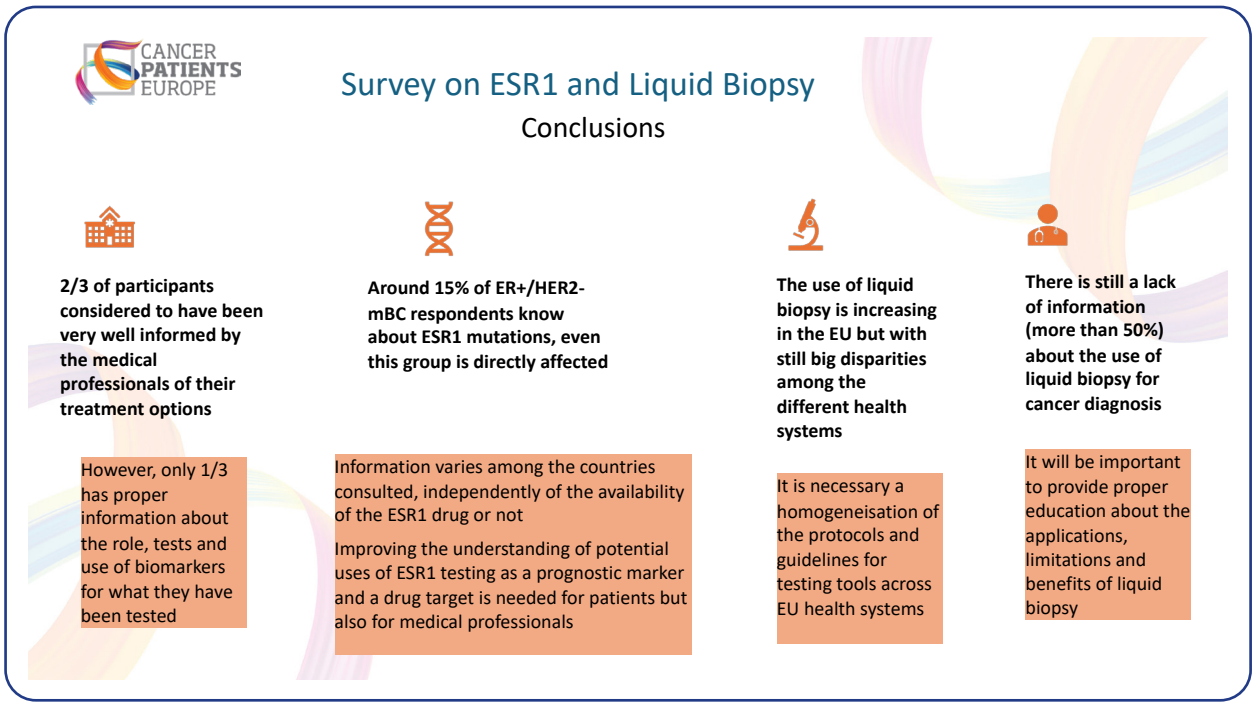


Figure 9: Results of CPE Patient Survey on ESR1 & Liquid Biopsy (iii)



Dr. Christos Poulios, pathologist and Education Manager at the European Society of Pathology (ESP) explained how online training and courses, as well as Master programmes offer a great solution to help healthcare professionals improve their knowledge and understanding about new treatment paradigms such as liquid biopsy. This is something the European Society of Pathology provides, by organising courses on various cancer types and molecular pathology, that are available to all interested healthcare professionals. He also stressed the relevance of programs such as Interact Europe[13] and Interact-100[14], for healthcare professionals to have a better understanding of the latest practice roles of their counterparts in other specialties, such as pathology.

Matias Olsen, Senior Manager for Public Affairs & Policy at the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) underlined the need for patients to have a comprehensive access to all new forms of testing, including genetic and genomic profiling. These innovations enable earlier diagnosis and improved prognosis, targeted therapeutic interventions. He conveyed his view that Europe is now lagging behind other parts of the globe in providing liquid biopsy testing to cancer patients. He considered that part of the issue is that the value of the liquid biopsy test itself is often not well recognised within overall reimbursement systems. He suggested that the recommendations of the European Parliament in the 2022 Special Committee on Beating Cancer (BECA) report[15] should be taken on board in this respect. He closed his remarks with recommendations that the EU's cancer screening policy agenda be expanded to pick up on the need for proper systems of biomarker testing to follow a cancer detection.

13 https://www.europeancancer.org/eu-projects/impact/interact-europe?autmkt=4214
14 https://www.europeancancer.org/eu-projects/impact/interact-europe-100
15 https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2020/2267(INI)&l=en

Recommendations from the liquid biopsy session

Headline themes for policy attention from the roundtable discussion on liquid biopsy are presented below:

- **Giving greater attention to the quality and availability of testing**. The roundtable gave emphasis to not only the need for liquid biopsy testing to be in place as part of regular practice in oncology treatment across Europe, but also for the testing to be of sufficient high quality. **This becomes especially the case at the scientific understanding in the field grows**, **including in respect to resistance mutations**.
- **Standardising and harmonising approaches across Europe**. There are many precedents in which the EU has been able to assist countries in improving quality in healthcare by advancing harmonised recommendations on practice and approach. Good examples of this would include in respect to health and safety approaches, manufacturing approaches, and recommended approaches to cancer screening. **Participants in the roundtable conveyed a view that EU investment in supporting greater harmonisation of approach to liquid biopsy testing across Europe would help to support wider and faster uptake of the technology**.
- **Seeing things as a whole**. **Understanding the value of testing**. The session heard of the difficulties of reimbursement of testing, with national processes too often making an artificial divorce in considering the value of a test and the treatment entirely separately. Both depend upon each other and yet in some countries it may be entirely different units of agencies or governments making decisions on test and treatment reimbursement.
- **Expanding cancer screening policy to include biomarker testing**. Through Europe's Beating Cancer Plan, great improvements in cancer screening policy are being advanced across Europe. Yet the value of early detection of cancer is intimately linked to having a patient rapidly commencing the best treatment for their particular cancer soon after cancer detection. The roundtable considered that cancer screening policy should also seek to ensure that detection of a cancer is rapidly followed by diagnostics and treatment decision, including use of liquid biopsy.
- **Meeting the training and education needs of healthcare professionals**. The value of supporting innovation adoption with ensuring the training and education needs of healthcare professionals are met was emphasised throughout the roundtable, including in the discussions on improving uptake in the use of liquid biopsy testing.

As the not-for-profit federation of member organisations working in cancer at a European level, the European Cancer Organisation convenes oncology professionals and patients to agree policy, advocate for positive change and speak up for the European cancer community.

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