european cancer ORGANISATION

GETTING THERE ON TIME: TIME TO TREATMENT IN CANCER IN EUROPE

AN ECO POLICY ACTION REPORT

Contents

Acknowledgements

This report summarises the key presentations, contributions and recommendations shared at the European Cancer Organisation (ECO) Community 365[1] Roundtable Meeting on Time to Treatment online on Tuesday 2 July 2024[2].

It was held in July 2024, facilitated by the co-chairing of Prof Peter Albers, ECO Board Member and Professor of Urology, Düsseldorf University & Division Head, German Cancer Research Center (DKFZ) and Aleksandra Kaczmarek, Public Policy Manager, Digestive Cancers Europe. We thank all speakers who contributed their perspectives and expertise on how to better understand the nature, features and impacts of cancer treatment delay across Europe, and who brought forward suggested means by which these problems could be better addressed. 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. Read more: https://www.europeancancer.org/content/policy-decision-making.html

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Executive Summary of Recommendations

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

Overall Recommendations

- Realistic timeline goals for cancer treatment commencing after diagnosis should be embraced within clinical guidelines, national policy (including cancer plans) and European cancer initiatives, such as the EU Network of Comprehensive Cancer Centres.
- Data on the length of time that patients in countries are needing to wait for cancer treatment to commence should be routinely captured and published to best allow improvement opportunities to be identified and acted upon.

On the Use of Digitisation

- The EU Network of Comprehensive Cancer Centres is being established with a key standard including the presence of fully operational digitised medication management systems, interfaced with electronic health records. This is an important advance for improving quality cancer care in all countries and should be fully supported through to implementation in all health systems.
- The example of the National Cancer Information System (NCIS) in Ireland was commended as a means of integrating all hospitals in a country to one national system covering a significant range of daily processes in cancer care, including digitisation of medication management systems.
- Effective implementation of digitisation in cancer care, especially at a national level, and where it involves daily working processes, will likely mean greater standardisation of processes across hospitals in a country being required. Time and effort will need to be invested into such standardisation efforts.
- Digital systems deployed in cancer centres should be utilised to bring greater visibility to the time being taken between processes in a patient's treatment journey. This enables better visibility for management on areas of time lag and where improvement might be most effectively made.
- When implementing new digitisation programmes in hospitals and cancer centres it is important that the vendor pays the very closest attention to the realities of the healthcare professional's daily workflows. This is critical to avoid unintentionally implementing a very disruptive system that ends up not well supported by the intended user.

On Improving the Patient Pathway Management

- The cost savings for healthcare systems in reducing treatment delay should be better understood to help incentivise necessary investment in improving processes.
- Clinical guidelines should have evidence-based suggestions on reasonable time periods within the patient pathway to help ensure best outcomes from treatment.
- The UK NHS approach of having a set of national standards on waiting times for treatment were commended as delivery political accountability and energy for improvement action.
- However guidelines on time intervals in the patient pathway must be realistic and based in level 1 evidence. Adherence to guidelines also requires a suitable supporting system of incentivisation for their achievement.
- The one-day diagnosis model of Gustave Roussy Cancer Campus was commended for its vision and its record of delivery. The concepts of setting up structures to achieved time-based targets on rapid diagnosis appear to the Report authors as readily achievable in other settings with organisational will.

- The shortage of healthcare professionals (HCPs) across Europe exacerbates waiting times, leads to less time being available for a patient and their healthcare professional, creates environments in which patient safety can be compromised, and hinders the efficient delivery of cancer care. The recommendations of the ECO Workforce Campaign should be taken up to address this particular aspect of the time to treatment challenge.

On Improving the Timelines of Access Decision-Making

- Pan-European evidence suggests that the average time across the EU27 between a new cancer treatment receiving regulatory approval and it being made available in a country for patient access is continuing to grow, currently standing at a 559 day delay. This is becoming a growing concern requiring remedial action.
- Accelerated access schemes can be an effective means to help overcome entrenched delays in a new treatment advancing from approval to patient access. However, evidence of their operation so far points to an ongoing need to align internationally on the evidence package requirements associated to their use. Inconsistent evidence requirements otherwise retards the effective adoption of such schemes.
- Early access not only accelerates treatment but also provides hope, significantly impacting the psychosocial well-being of patients and caregivers. This aspect should not be underestimated when considering the broader benefits of such programmes.
- Healthcare data infrastructures still require enhancement to fully leverage the role of real world data to better support value-based healthcare.

Introduction

Since the launch of Europe's Beating Cancer Plan in 2021, significant advancements in science and technology have accelerated the pace of cancer detection, diagnosis, and treatment across Europe. Innovations such as digitalisation, improved coordination of patient pathways, and enhanced access to novel treatments are reshaping the oncology landscape. However, despite these advancements, substantial delays still occur at various stages from the suspicion of cancer to the initiation of treatment. These delays can have critical consequences, potentially diminishing the effectiveness of treatment and worsening patient outcomes.

For these reasons, the European Cancer Organisation determined to convene a multi-stakeholder online Community 365 roundtable to interrogate the issues of treatment delay further with a particular focus on such matters as:

- The role of digitisation in improving efficiency and reducing waiting times;
- Means and methods to better coordinate the patient pathway;
- Tackling delay in new treatment access.

The full recording of the roundtable is available on the **roundtable webpage.** A summary of the roundtable, and policy recommendations arising from the discussions follows.

In opening the roundtable, Roundtable Co-Chair Professor Peter Albers, Professor of Urology at Düsseldorf University and Division Head at the German Cancer Research Centre (DKFZ), emphasised, 'Time to treatment must be integrated into guidelines as mandatory. Policy should unify around the principle that as soon as cancer is diagnosed, quick and efficient treatment is essential.' Aleksandra Kaczmarek, Public Policy Manager at Digestive Cancers Europe, and fellow Co-chair of the roundtable, concurred, stating that 'evaluating the time between cancer diagnosis and treatment is crucial, as timely intervention improves survival rates, reduces patient anxiety, and enhances treatment efficacy and efficiency.'

Figure 1. Cancer screening participation

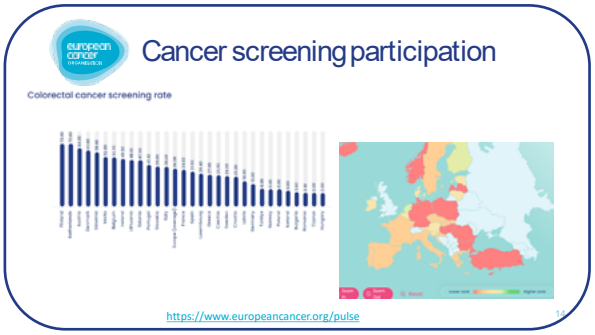
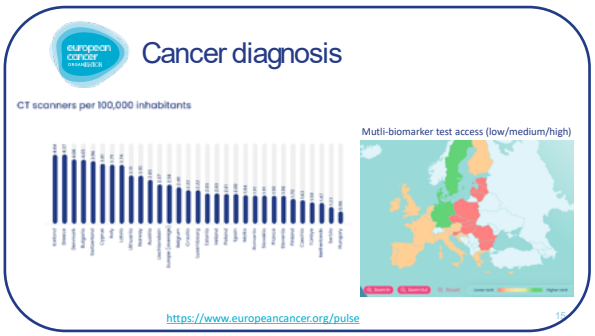


Figure 2. Cancer diagnosis



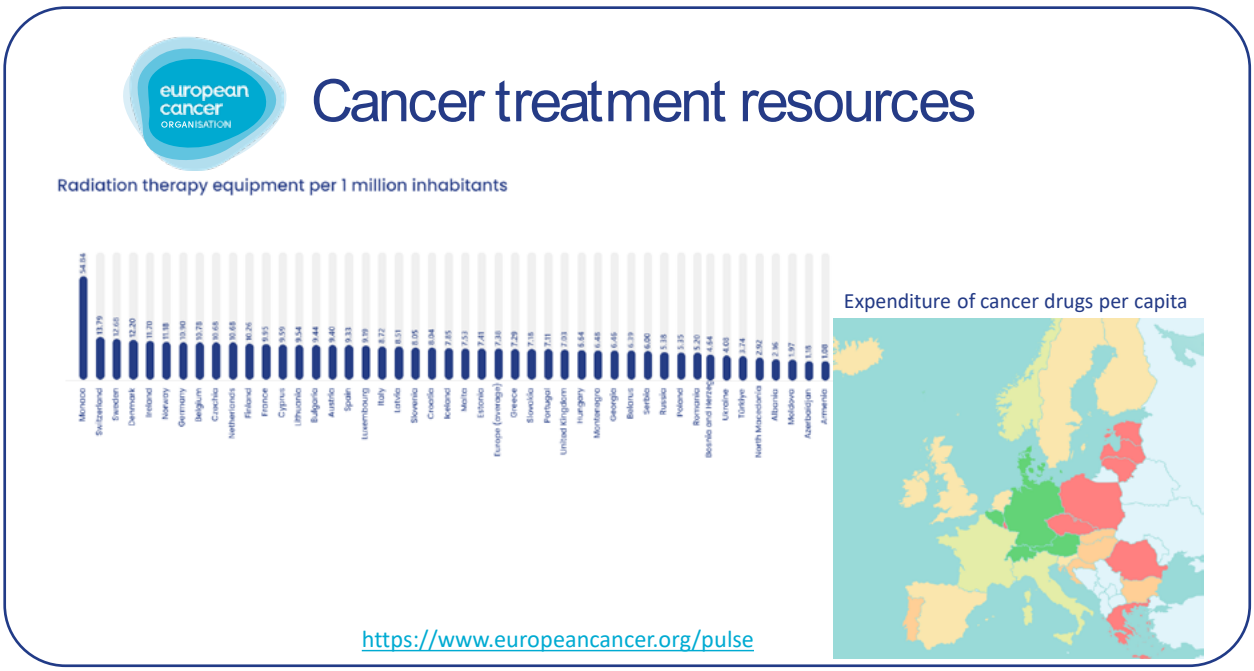
The European Cancer Organisation's (ECO) Community 365 Roundtable on Time to Treatment aimed to address these challenges by examining the current levels of delay across different stages of cancer care in Europe. The roundtable explored the multifactorial nature of these delays, which can arise from individual factors like socioeconomic status and a patient's area of residence, as well as infrastructural and system factors such as the availability of diagnostic tools, specialised care centers, and the complexities of reimbursement processes. Addressing these inequities within national health systems is essential, as even a four-week delay in treatment initiation has been associated with increased mortality. Through focused discussions on minimising these delays, the roundtable sought to identify effective policies and strategies that can help to reduce the times that patients experience in commencing treatment of cancer after diagnosis.

European Cancer Pulse insights

Zoë Parker, Policy Research and EU Projects Assistant at the European Cancer Organisation (ECO), helped to set the context for the roundtable sessions by providing some insights from data promoted within the ECO European Cancer Pulse[4]. Many factors can be identified in creating treatment delay, including the form of national cancer screening policy, imaging approaches, systems for biomarker

testing, radiation therapy equipment availability, workforce shortage and systems for referral to specialist centres. To illustrate this, Zoë shared data visualisations illustrating the substantial variance across European countries in respect to issues. For example, while Finland is recorded as achieving a colorectal cancer screening rate of almost 80%, this is less than 3% in Hungary. A similar disparity can be seen in indicators such as availability of CT scanning equipment per 100,000 people, with a rate of almost 5 in Iceland, to less than 1 in Hungary.

Figure 3. Cancer treatment resources



4. Read more: https://www.europeancancer.org/pulse

Session 1: The role of digitisation in reducing waiting times

Co-Chaired by **Aleksandra Kaczmarek,** Public Policy Manager, Digestive Cancers Europe and **Jose Luis Gomez Ruiz,** Vice President, Public Policy and Advocacy Europe, Middle East and Africa, BD

Speakers and panelists explored the role of digitisation in reducing waiting times within oncology, examining this issue from multiple perspectives. A European-wide shortage of healthcare professionals is leading to professionals needing to undertake increased workloads. This in turn can cause fatigue, burnout, increases in patient safety issues, such as medication errors, and delays in patients being able to commence treatment. The session underscored how digitalization could play a crucial role in mitigating these risks, particularly by reducing medication errors, thus enhancing patient safety and treatment outcomes. In opening the session Jose Luis Gomez Ruiz also identified the opportunities presented by such developments as the EU Network of Comprehensive Cancer Centres which sets the presence of digitised medication management systems as a key European standard of cancer care. In this context, several case study examples were invited to present evidence of their work, findings, reflections and recommendations.

The 'OncoOptimal' project and Optimization of oral chemotherapy in outpatient clinics in Spain

A study presented by Dr. Jesus Garcia-Foncilla, President, Fundación ECO

The **ONCOptimal project** (Optimizing the efficiency of oncology day hospitals) is a scientific initiative of the ECO Foundation, in which several entities related to the field of Oncology have collaborated, with the aim of preparing a **report with recommendations on optimizing efficiency in oncology day hospitals (HDO)** in Spain[5].

Dr. Jesus Garcia-Foncilla opened his presentation by giving an overview of the daily work processes fulfilled in cancer centres across Spain. In doing so, he noted that while many cancer treatments can now be delivered in oral form, it remains the case that most of the time the cancer patient is required to come to a hospital for administration of medication, with a great many spending 4 or more hours in the hospital for this. It was to such issues and more that the ONCOptimal project has been seeking to give attention and recommendation for improvement. Opening goals of the project included:

1. Reducing waiting times for newly diagnosed patients and those returning for ongoing treatment;

2. Humanising care by reducing medication administration time and minimising hospital stays;

3. Preventing adverse effects through stringent medication management practices. The goal is to enhance patient experience and safety while optimising the use of limited resources in a strained healthcare system.

To fulfill these goals, the project brought together healthcare professional societies in Spain and patient organisations in order to conduct survey-based study of current approaches to care delivery, and to study the impact of technology on infusion strategies. The studies have been supported by the Francisco de Vitoria University in Madrid.

Figure 4. ONCOptimal project partners

5. Read more: https://fundacioneco.es/project/oncoptimal/

Taken together, the ONCOptimal studies shine light on particular bottlenecks and inefficiencies that occur within cancer care. One bottleneck identified was the capacity of a pharmacy to service the level of requests received for medication preparation. Opportunities to improve efficiency were identified including: ensuring strong systems of electronic (rather than paper-based) prescribing, and the means by which pharmacies and medication administration units are in contact with other on the status of a particular preparation e.g. providing access to data portals on preparation status rather than requiring many phonecalls for updates.

Another identified inefficiency related to the requirement for nurses to manually document administration of medication. This could be reduced by introduction of electronic systems that enable fast and automatic documentation update e.g. through a scan of a barcode.

Dr. Jesus Garcia-Foncilla

President, Fundación ECO

A critical early insight for the project was the significant lack of national information in respect to measured, monitored and published data on waiting times for cancer patients in Spain from diagnosis to treatment.

The study made a projection that full computation of medication prescribing, processing, preparation and administration processes could reduce average patient waiting times in Spain by 8 days and gather an overall budget saving to the Spanish healthcare system of more than 2 billion USD, including from reduction of medication error.

Figure 5. Bottlenecks and inefficiencies in the preparation of medication

Preparation of medication	**Bottleneck:** The capacity of the pharmacy service to prepare medication is limited. Until the medication is prepared, it cannot be sent to the administration area. **Inefficiencies:** • Lack of electronic prescribing systems linked to the pharmacy service. • Lack of a system that prioritizes the preparation of medication based on the patient's condition. • Lack of an electronic system for the preparation of medication. • Lack of an electronic system that displays the status of the preparation of medication by patient and that enables effective coordination between the pharmacy and the administration service, to avoid constant phone calls that reduce the efficiency of both services. • Delays due to waiting time in the preparation of medication reduce the capacity of the ODH and lengthen patients' stay in the facility. • If the synchronization between the pharmacy department and the medication administration department is not effective, it will result in inefficiencies in both departments, leading to delays and prolonged patient stays. • On top of this, if the Pharmacy and ODH are a significant distance apart there will be an added delay due to transport.

Figure 6. Bottlenecks and inefficiencies in the administration of medication and final checks

Administration of medication	**Bottleneck:** number of chairs as well as human resources as the limiting factor when it comes to increasing the number of patients receiving medication. **Inefficiencies:** • Delays and lack of synchronization in the process up to the point of assigning the medication are a major inefficiency, resulting in vacant, unoccupied chairs waiting for the patient to go through all the above processes and be ready to receive their medication. • Lack of protocols for selection of infusion systems and/or intravenous therapy teams in ODH treatment areas. • Lack of electronic systems that allow the identification of the patient/medication/pump by bar code. • Lack of smart pumps with safety and self-programming systems.
Final check	**Bottleneck:** availability of Nursing to document the administration of medication. **Inefficiencies:** • The time the Nursing service spends on manual documenting the administration is time that is not spent administering medication to other patients. • This manual process could be automated by means of electronic patient/medication/pump identification systems using bar codes and smart pumps.

Figure 7. Analysis of new technologies

Solution	Efficiency generated	Penetration in the ODHs ONCOptimal	Average reduction in the number of waiting days
Electronic prescription systems	10 minutes	95%	Not significant due to high penetration
Gravimetric medication preparation systems (Hospital Pharmacy)	35%	26%	8 days
BCMA: Bar code medication administration	43%	30%	8 days
		TOTAL	8 days
Microbore system	9 minutes and 11 seconds	--	260 more patients per year per HDO of medium-sized*
Point-of-care blood sampling systems	No evidence available	46%	4,795 hours

*Estimated time reduction calculation for a Chemotherapy Unit type: 12 chairs, with a rotation of 1.5 patients per chair/day: 18 patients/day

Digitised medication traceability systems help improve:

1. Coordination between pharmacy department and administration areas;
2. Visibility of the status of the medication preparation by administration area;
3. Prioritisation of medication for pharmacy;
4. Planning of chairs & beds;
5. The preparation and administration of medication.

Patient safety in oncology hospitals is always a top priority. Adverse events in cancer patients are more prevalent than in other types of patients and have a high human, social and economic cost. The main adverse events that jeopardise patient safety in the administration of medication to oncology patients in cancer centres are: medication errors, catheter-related infections and those related to infusion therapy.

Reflecting on the results of the OncoOptimal project, Dr Garcia-Foncilla was reassured to learn that recent standards have been developed to support the creation of the EU Network of Comprehensive Cancer Centres and include within them (6.2.10) a clear requirement for 'an electronic drug prescription and administration system to be in place, which controls the entire drug pathway and interfaces with the patient record.'

It is to be hoped that the good practices and opportunities identified and promoted by the OncoOptimal project can be spread and achieved across Europe with support from the new EU Network of Comprehensive Cancer Centres.

Figure 8. Analysis of new technologies

Adverse effects	Magnitude of the problem	Economic impact	Solutions
Medication errors	8.1 errors per 100 clinic visits	Spain: €2 billion	• **CPOE:** Computerized Provider Order Entry • Gravimetric medication preparation systems • **BCMA:** Bar code medication administration • **Smart pumps:** with DERS system (medication error reduction software) and infusion stations with centralization tablets, or pumps with self-programming capability
Infections, phlebitis and extravasations	0.05 and 6.8/1000/day	Spain: €17,221,000/year	**Infusion therapy protocols** with algorithms for infusion system selection based on medication, patient's venous status and duration of treatment.
Bacteraemia			
Extravasations	3.454/año	España: 15.635.000 €	
Phlebitis	1.049/año	España: 1.257.400 €	
TOTAL		Spain: €2,034 million	

Figure 9. Technologies in Oncology Day Hospital

Technologies in the ODH	
Computerized Provider Order Entry (CPOE) and preparation systems	
Have a computerized provider order entry system	95%
Electronic medication preparation system	48%
Do not have a gravimetric preparation system	55%
Communication between Medical Oncology and the Pharmacy Service carried out using paper	18%
Electronic connection systems between departments	
Communication between Medical Oncology and the Pharmacy Service carried out electronically	80%
"Patient/medication/pump" bar code identification systems	30%
Smart pumps	
Average number of infusion pumps for the administration of treatment	34
Do not have dual-channel infusion pumps	57%
Infusion pumps are programmed manually	84%
Do not have sufficient infusion pumps available to care for unscheduled patients requiring unplanned care, ensuring their continuum of care	84%
Does not have a protocol in place to manage requests for new infusion devices for the administration of chemotherapy treatments	41%
Microbore* infusion systems	
Reduction in overall infusion times through the use of intravenous infusion devices with primary and secondary microbore systems such as those available in BD BodyGuard Duo	9'11''
Point-of-care testing.	
Have a Point-of-Care system for blood collection	46%

Computerising the national information system – The Irish case study

Presented by Grant Carroll, Chief Pharmacist, National Cancer Information System (NCIS)

Professor Grant Carroll, Chief Pharmacist, presented the National Cancer Information System (NCIS), a comprehensive computerised system designed to record and manage information related to a patient's cancer case, diagnosis, and treatment in Ireland.

Starting in 2019, the NCIS project was prioritised within Ireland's Cancer IT program under the Government's eHealth Strategy. The NCIS aims to deliver a robust clinical information system to support oncology and haematology patients, including those receiving Systemic Anti-Cancer Therapy (SACT). Some of the key functionalities of the NCIS includes:

- Prescribing systems;
- Electronic medication administration records;
- Support for aseptic compounding, Multi-Disciplinary Meeting (MDM) documentation, and reporting.

Professor Grant gave an overview of the functionalities of the system created to ensure timely and appropriate access to patient treatment records for all relevant healthcare providers, and enhancing coordination and efficiency in cancer care across designated cancer centers, satellite centers, and other treatment locations.

NCIS

In particular, the efficiency of the NCIS relies on the 'one single system' framework. A single system is crucial as patients could, depending on the treatment, move from hospital to hospital. Therefore, a patient-centered, longitudinal and accessible care record, within and across hospitals, has a significant impact to have the right information available at the right time in the right place, ensuring safe and effective chemotherapy prescribing and administration and data sharing.

It is considered that Ireland may be the first EU country to put in place this kind of integrated health IT system, which now include 19 of the 26 hospitals in the country and with aspirations to include all 26 soon.

Figure 10. Longitudinal Patient Record

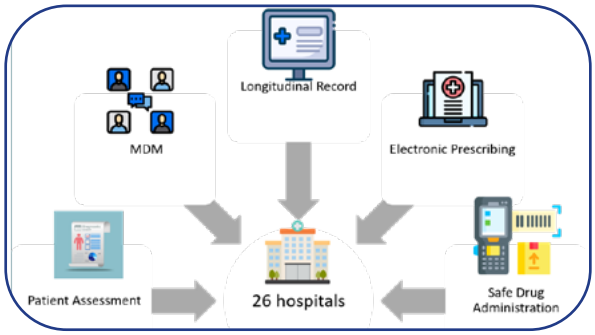


Figure 11. Irish Cancer Services

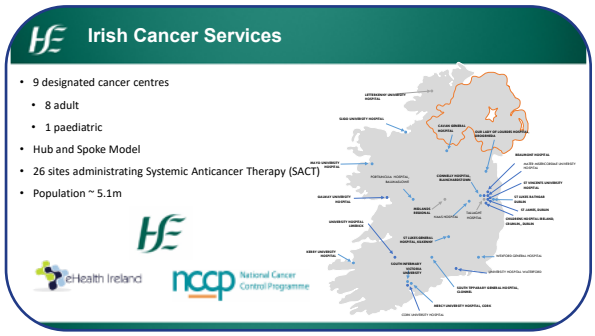


Figure 12. The NCIS Solution

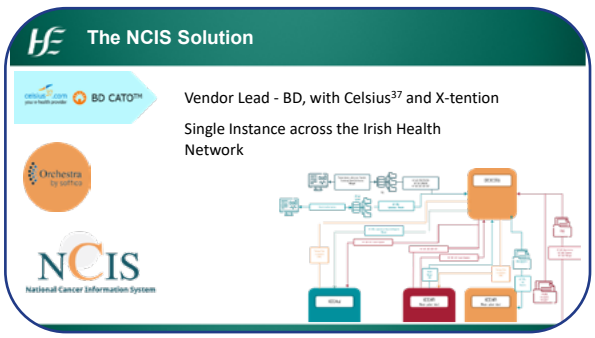
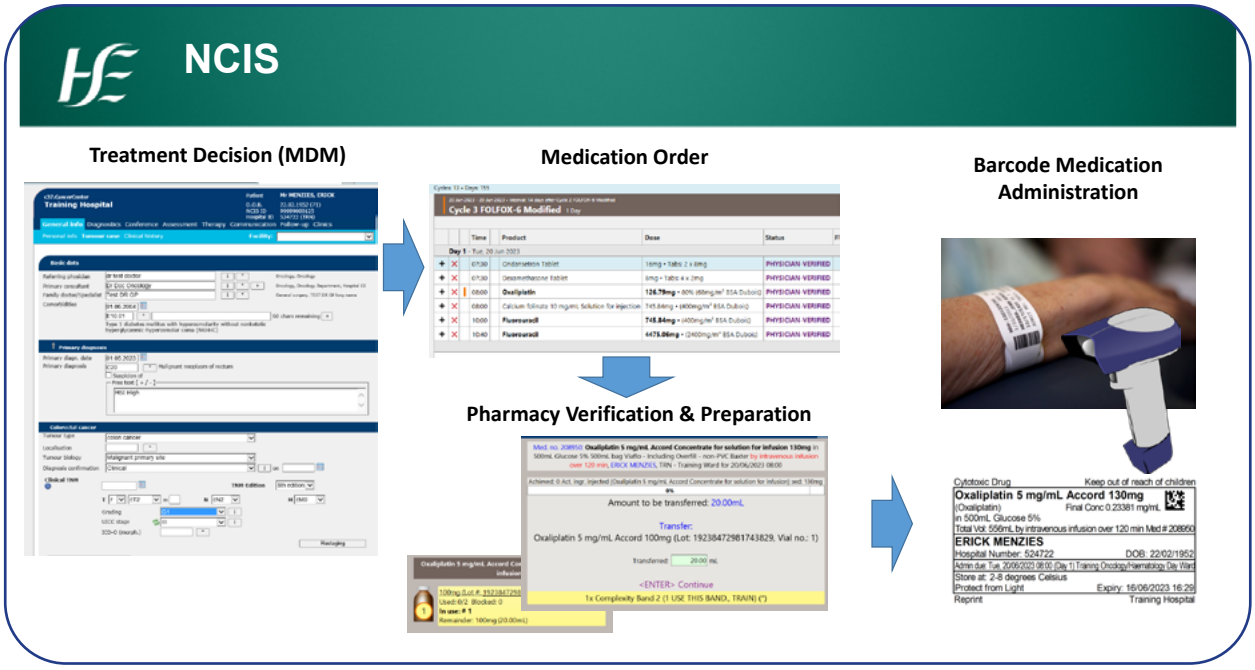


Figure 13. The Irish National Cancer Information System (NCIS)



Dr Carrol considered that there are a wide range of wider good practices evident within the NCIS that could serve as inspiration for other European countries. The treatment decision (MDM) functionality of the NCIS demonstrates significant advantages, particularly in:

- Recording standardised disease-specific cancer case details;
- Planning and scheduling MDMs;
- Adding the patient to the MDM conference;
- Conducting MDM conferences/tumour boards, including recording the attendance of decision-makers at a patient level;
- Concluding the MDM with structured therapy recommendations;
- Documentation and communication.

Implementation remains a complex phase for such systems. The main challenges that the Irish healthcare system, and others, may face include governance, specifically how to handle standardised documentation on the conduct and outcomes of multidisciplinary team meetings, including relevant data about the patient's cancer case. Moreover, the system alone is not sufficient. It must be incorporated into a broader effort involving the allocation of resources, personnel, and infrastructure capable of supporting this model and creating the standardisations necessary to ensure its effectiveness.

The 'Dénia Hospital' paperless experience

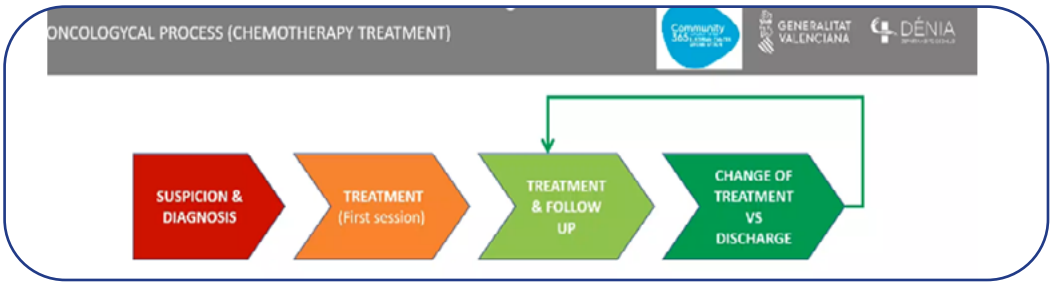
Presentation by Juan Manual Lacalle, Head of Quality and Patient Management at Dénia Hospital

The Dénia Hospital, located in the southeast of Spain has been awarded the QH quality badge from the Institute for the Development and Integration of Healthcare (IDIS Foundation). The QH (Quality Healthcare) recognition acknowledges healthcare organisations that continuously implement progressive quality systems and obtain necessary certifications to ensure maximum process guarantees.

The hospital's digitization programme has been intended to:

- Complete digitalisation of cancer treatment: The entire cancer treatment process, from prescription to administration, is fully digitalised.
- Achieve a unified information system: This system provides a single repository for medical records, facilitates collaboration and communication at all levels, and brings standardization and security to processes. It also integrates results from various computer applications, creating an interoperable environment that allows control over process times.

Figure 14. Oncological process



The ultimate goal of this design is to implement effective and efficient processes characterised by reliability and security and the key feature of reducing time in diagnosis and treament and enhance interoperability.

Nurse case managers can access detailed information through listings, enabling them to track the status and timing of each patient's situation accurately. Throughout the follow-up and treatment evolution, healthcare professionals can monitor the general state of the treatment and track all tasks performed or not performed, with reasons for any omissions. Decisions regarding patient discharge, the initiation of new treatment schemes, or modifications are systematically recorded.

One of the key roles of the digitised system at Dénia hospital is enabling open monitoring of time between processes. This enables better visibility for management on areas of time lag and where improvement might be most effectively made.

Juan Manual Lacalle

Head of Quality and Patient Management at Dénia Hospital

The goal is to ensure that every patient begins their first chemotherapy session within 24-48 hours of consultation confirmation.

Juan Manual Lacalle summarised some of the digitisation benefits achieved at Dénia hospital:

1. Timely Treatment Initiation: The goal is to provide the first chemotherapy session within 24-48 hours of consultation confirmation. This requires the complete prescription of the treatment scheme, including all sessions, complementary medications, follow-ups, and nursing tasks, integrated into a treatment protocol designed by multidisciplinary teams.
2. Task Activation: During the treatment, patient check-in triggers all related tasks, including tests (even from external labs), medication preparation, and task assignments. Prescriptions and pharmaceutical validations are managed within the system.
3. Comprehensive Monitoring: Throughout treatment and follow-up, the doctor can monitor treatment progress, task completion, and patient status via a clinical station designed for a holistic view of collected data and parameters, including all appointments and visits.
4. Decision Recording: Decisions regarding patient discharge, or initiation of new treatment schemes, or modifications are recorded

In the discussion component of the session Grant Carrol emphasized how important it is when implementing new digitisation programmes in hospitals and cancer centres that the vendor pays the very closest attention to the realities of the healthcare professional's daily workflows. This is critical to avoid unintentionally implementing a very disruptive system that ends up not well supported by the intended user.

RECOMMENDATIONS ON THE USE OF DIGITISATION

- The EU Network of Comprehensive Cancer Centres is being established with a key standard including the presence of fully operational digitised medication management systems, interfaced with electronic health records. This is an important advance for improving quality cancer care in all countries and should be fully supported through to implementation in all health systems.
- The example of the National Cancer Information System (NCIS) in Ireland was commended as a means of integrating all hospitals in a country to one national system covering a significant range of daily processes in cancer care, including digitisation of medication management systems.
- Effective implementation of digitisation in cancer care, especially at a national level, and where it involves daily working processes, will likely mean greater standardisation of processes across hospitals in a country being required. Time and effort will need to be invested into such standardisation efforts.
- Digital systems deployed in cancer centres should be utilised to bring greater visibility to the time being taken between processes in a patient's treatment journey. This enables better visibility for management on areas of time lag and where improvement might be most effectively made.
- When implementing new digitisation programmes in hospitals and cancer centres it is important that the vendor pays the very closest attention to the realities of the healthcare professional's daily workflows. This is critical to avoid unintentionally implementing a very disruptive system that ends up not well supported by the intended user.

Session 2: Means and methods to better coordinate the patient pathway

Co-chaired by **Prof Peter Albers,** Professor of Urology, Düsseldorf University & Division Head, German Cancer Research Center (DKFZ) and **Dr Ilya Gipp,** Chief Medical Officer, GE HealthCare

In opening remarks to the session, Dr Gipp highlighted some of the key literature on the importance of time to treatment with some articles suggesting that **every month of delayed cancer treatment can increase the risk of death by around 10%.**

Research shows that mean annual and cumulative healthcare costs up to four years post-diagnosis are notably higher for patients diagnosed at later stages compared to earlier stages. This is particularly evident in stage IV diagnoses, where the steep increase in cumulative costs underscores the importance of early detection. Early diagnosis enables more efficient treatment, improves patient outcomes, and reduces healthcare costs.

Dr Ilya Gipp

Chief Medical Officer, GE HealthCare

As well as improving outcomes, it should be noted that the evidence strongly shows that shortening the time to treatment also secures significant cost savings for health systems.

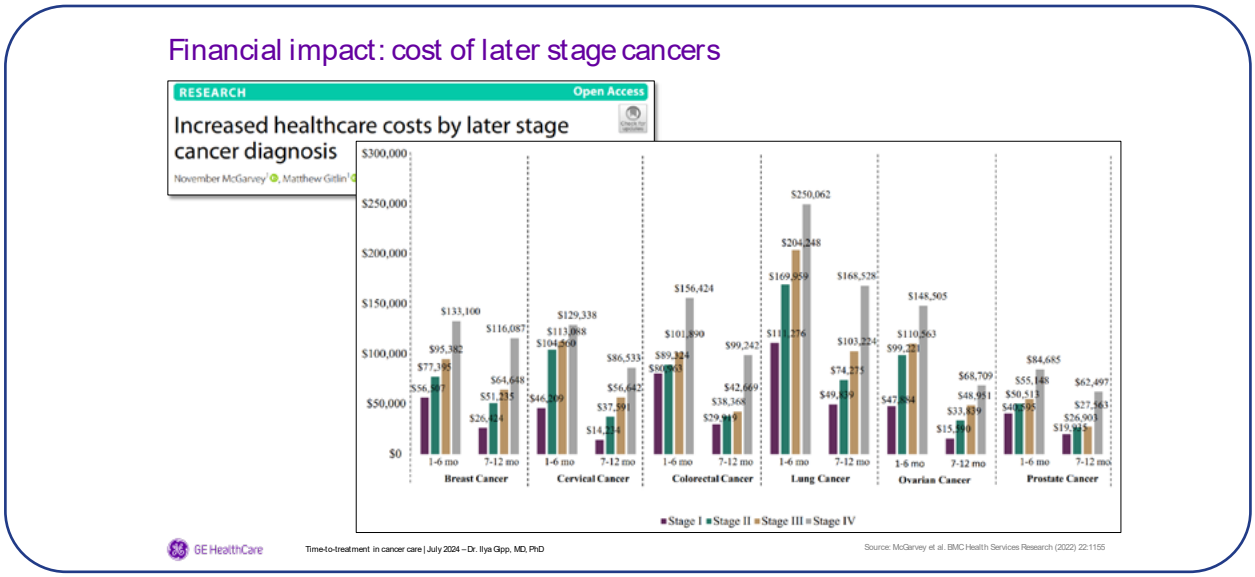
However, within this goal of reducing time to treatment, it remains imperative that patients receive optimal pre-treatment assessments rather than rushing the treatment. Future research should focus on examining clinical characteristics to determine an optimal time-to-treatment to achieve the best possible survival for patients with particular cancers, such as non-small-cell lung cancer (NSCLC).

The psychological/psychosocial dimensions of cancer and treatment delay should not be underestimated. It can be both a cause and a consequence of treatment delays.

Dr Gipp then referenced the UK NHS's 'National Cancer Waiting Times Monitoring Guidance' (August 2023) as a good example of country setting national targets. These include:

- **The 28-Day Faster Diagnosis Standard** states that people should have cancer ruled out or receive a diagnosis within 28 days of an urgent cancer referral.
- **The 31-day standard** states that people with

Figure 15. The cost of late stage cancers

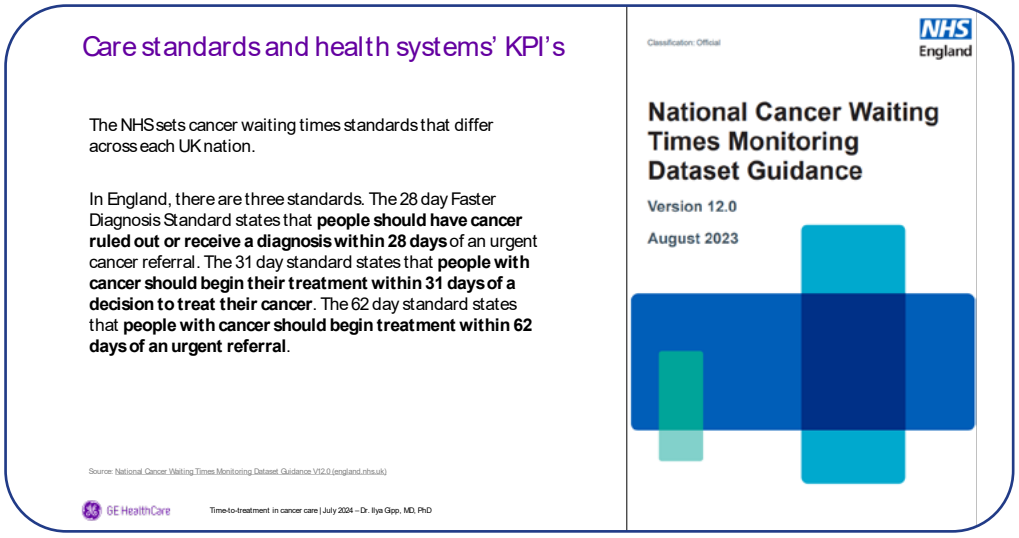


cancer should begin their treatment within 31 days of the decision to treat their cancer.

- **The 62-day standard** states that people with cancer should begin treatment within 62 days of an urgent referral.

This guidance provides a set of rules to ensure that cancer waiting times data are recorded consistently and in a way that allows transparent and accurate reporting.

Figure 16. Care standards and health systems' KPIs



Dr Gipp summarised his recommendations for improving time to treatment:

- Early Detection and Screening: Enhance personalised risk assessment through deeper patient knowledge, predictive detection, public awareness campaigns, and liquid biopsy testing.
- Simplify Referral Processes: Integration of primary care, use of electronic referrals, etc.
- Improve the Efficiency of Diagnostic Pathways: Rapid diagnostic centres, standardised protocols, etc.
- Enhance Access to Specialists: Implement telemedicine and ensure effective multidisciplinary decision-making.
- Optimise Treatment Planning: Coordinate care efficiently, for example, through the effective management of tumour boards.
- Educate Patients: Provide clear and accessible information, support services including psychological and logistical assistance, and financial counselling.
- Policies and System-Level Interventions: healthcare policies; resource allocation; guidelines.

All of these improvements require healthcare policies aimed at ensuring necessary resource allocation and establishing guidelines that incorporate innovations and the use of new technologies.

The one-stop breast clinic model

Presented by Dr Corinne Balleyguier, Radiologist, Head of Imaging Department, Gustave Roussy Cancer Campus

Dr. Corinne Balleyguier, Radiologist and Head of the Imaging Department at Gustave Roussy Cancer Campus, provided an in-depth overview of the one-stop breast clinic model, which serves as an exemplary approach to rapid and integrated cancer diagnosis. This clinic, inaugurated on 5th April 2004, is dedicated to individuals identified with suspicious but not yet diagnosed breast lesions. It operates on the principle of delivering highly accurate diagnoses within a single visit, aiming to reduce the time to treatment, improve patient outcomes, and serve as a model for similar initiatives in other healthcare settings.

Key Features of the One-Stop Clinic

1. Comprehensive Diagnostic Process:
   - Target Population: The clinic is designed for patients presenting with abnormal or

suspicious breast findings.

- Diagnostic Tests: The clinic provides a full suite of diagnostic services, including imaging, cytological sampling, and tissue biopsies, all performed on-site. Essential imaging and tests are available at every stage of the patient's care journey.

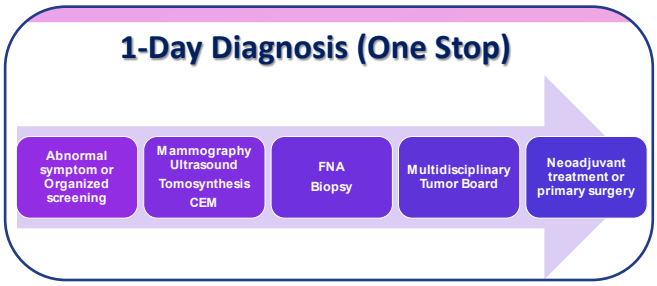
- Multimodal Imaging and Biopsy Techniques: Utilises advanced techniques like ultrasonography-guided fine needle aspiration and stereotactic biopsies for accurate diagnosis.

- Rapid and Accurate Diagnoses: The clinic aims to provide a diagnosis within one day, with 75% of cases receiving an exact diagnosis on the same day. The sensitivity of the one-stop clinic's diagnosis ranges from 90.3% to 98.5%, and specificity from 94.3% to 99.8%.

2. Multidisciplinary Collaboration:

- The clinic relies on the close collaboration of a multidisciplinary team, including surgeons, radiologists, medical oncologists, pathologists, nurses, and dedicated technicians. This team-based approach ensures comprehensive care and immediate decision-making.

Figure 17. 1-Day Diagnosis



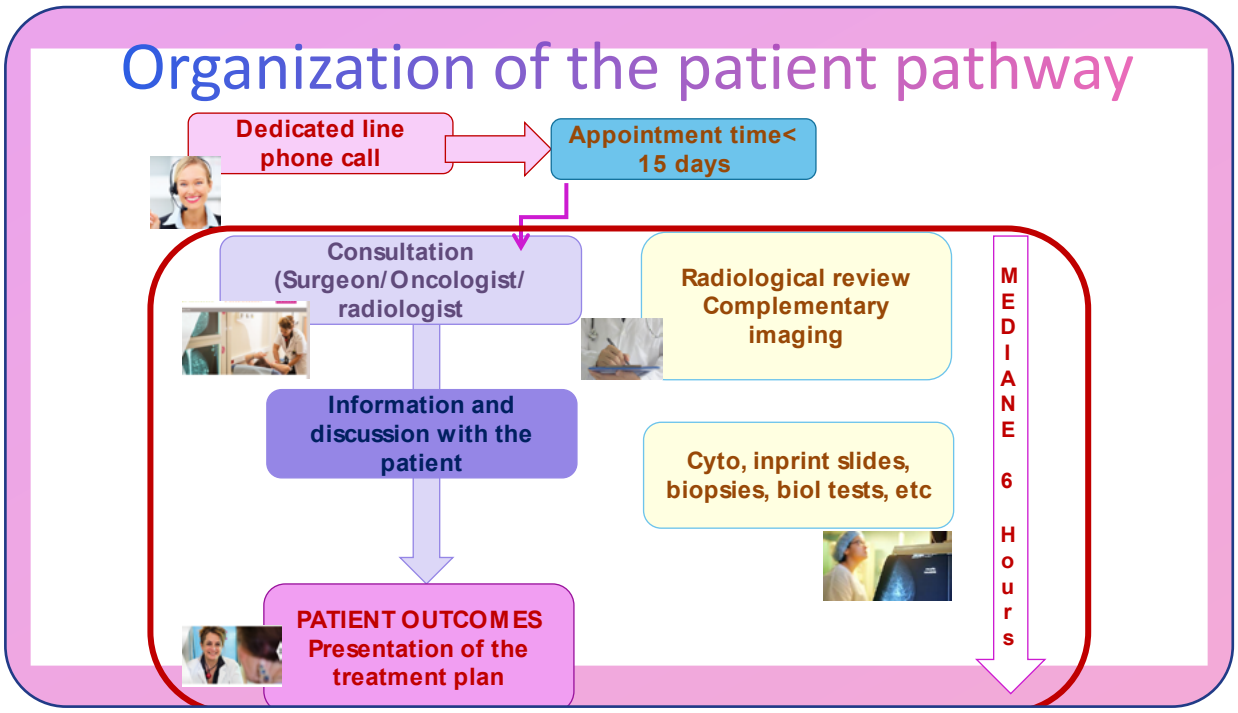
- Nurse Coordinators and Dedicated Technicians: These roles are vital for ensuring smooth operations and patient flow, as well as for supporting the complex logistics of same-day diagnosis.

3. Patient-Centric Care:

- Patient Information and Treatment Planning: The clinic places a strong emphasis on providing patients with clear and timely information. After diagnosis, patients receive a personalised treatment plan, which is developed and communicated by the multidisciplinary team.

- Reduction of Treatment Delays: By centralising all necessary diagnostic tools and expertise in one location, the clinic significantly shortens the time between diagnosis and treatment initiation, which is crucial for improving patient outcomes.

Figure 18. Organisation of the patient pathway



Outcomes and Impact

Between 2004 and 2012, the clinic treated 10,602 individuals with suspicious breast lesions. Of these, 69% had masses, while 31% presented with micro-calcifications or other non-mass lesions.

In terms of cost-effectiveness, the average medical cost per patient for the one-stop diagnostic procedure was €420, with these costs largely covered by public insurance, making the service accessible to patients with national insurance coverage.

The clinic's model has proven to be not only efficient but also highly accurate, with a positive predictive value of 99.7% and a negative predictive value of 99.0% in the base-case analysis.

Future Developments

Technological Advancements: The clinic is exploring new technologies, such as confocal microscopy, to further reduce diagnostic times. The goal is to achieve a histological diagnosis within 10 minutes through immediate tissue analysis using fresh sample staining, slide scanning, and rapid interpretation. These advancements aim to further enhance the clinic's ability to provide rapid and accurate diagnoses, thereby improving the overall benefit/risk ratio of breast cancer screening and treatment.

Ongoing Challenges

Despite its success, the clinic continues to face challenges, particularly in maintaining and improving the sensitivity and specificity of its diagnostic processes. Ongoing efforts are focused on refining these aspects to ensure the highest possible standards of care.

Additionally, the clinic underscores the need for ongoing investment in multidisciplinary collaboration, integrated care, and the adoption of new technologies to keep pace with the growing demand for rapid and accurate cancer diagnosis.

In summary, the one-stop clinic at Gustave Roussy represents a significant advancement in the rapid diagnosis and treatment planning for breast cancer patients. By centralising care, leveraging multidisciplinary expertise, and incorporating advanced diagnostic technologies, the clinic not only improves patient outcomes but also sets a benchmark for similar initiatives in other healthcare system.

The stark inequities in cancer care across Europe

Martina Fontana, Policy & Research Officer, Europa Donna

Martina Fontana, Policy & Research Officer at Europa Donna, highlighted the stark inequities in cancer care across Europe, emphasizing the significant disparities in patient pathways from detection to treatment. These inequities manifest in various ways:

Variability in Quality and Accessibility

In many regions, there is a lack of coordination among services, **absence of multidisciplinary teams, and insufficient comprehensive cancer units,** all contributing to inconsistencies in care delivery.

Challenges in Harmonisation

The difficulty in comparing patient pathways across different countries stems from these disparities in care quality and accessibility. Inequities also exist within countries, influenced by income, education, and social factors, making cancer care a broader societal issue.

There is a pressing need for a harmonised approach to cancer care across Europe. **Guidelines and national cancer plans are essential,** but they must be realistic and achievable to be effective. The inclusion of patients' perspectives in the development of these guidelines is crucial to ensuring that they are patient-centred and practical.

Resource and Policy Gaps

The shortage of healthcare professionals (HCPs) across Europe exacerbates waiting times and hinders the efficient delivery of cancer care. National cancer plans, with active patient advocacy, are essential to address these systemic issues and ensure that human resources are adequately allocated.

The shortage of healthcare professionals (HCPs) across Europe exacerbates waiting times and hinders the efficient delivery of cancer care, and a certified cancer system ensures better outcomes through centralisation of care. However, this centralisation requires patients to travel for treatment, which can impose a significant financial burden, particularly on those from lower socio-

economic backgrounds.

Best Practices and Future Directions

Dr. Corinne Balleyguier's one-stop clinic model at Gustave Roussy serves as a best practice that could be deployed in other cancer centres across Europe. While resource-intensive, this model offers a blueprint for improving diagnosis and treatment efficiency with minimal modifications.

Training of specialists, especially pathologists, is identified as a critical need. Establishing training systems and schools to teach new techniques could elevate the quality of care in laboratories and cancer centres across the continent.

Addressing the disparities in cancer care across Europe requires a coordinated effort involving realistic guidelines, enhanced resources, and patient-centred policies, alongside the adoption of proven models like the one-stop clinic for rapid and accurate cancer diagnosis.

In the discussion component of the session Prof Albers commented on the difficult balancing act that may be required in some cancer cases between not delaying time to treatment but also ensuring the quality of diagnosis is of sufficient quality to justify the chosen treatment. He also emphasised that achieving fast and quality diagnosis often points to the need to have cancer patients cared for within highly specialized centres that can better guarantee such quality and reduced time delays. Martina Fortuna was sympathetic to the point but urged a consequent attention to supporting the transport, cost and other logistic needs of cancer patients to travel to such centres.

In final remarks, Prof Albers also pointed to laudable examples such as the Gleason grading system for evaluating the prognosis of men with prostate cancer using samples from a prostate biopsy. Such common approaches can then be implemented across countries and are a ready tool for heightening quality across a global region.

RECOMMENDATIONS ON IMPROVING THE PATIENT PATHWAY MANAGEMENT

- The cost savings for healthcare systems in reducing treatment delay should be better understood to help incentivise necessary investment in improving processes.
- Clinical guidelines should have evidence-based suggestions on reasonable time periods within the patient pathway to help ensure best outcomes from treatment.
- The UK NHS approach of having a set of national standards on waiting times for treatment were commended as delivery political accountability and energy for improvement action.
- However guidelines on time intervals in the patient pathway must be realistic and based in level 1 evidence. Adherence to guidelines also requires a suitable supporting system of incentivisation for their achievement.
- The one-day diagnosis model of Gustave Roussy Cancer Campus was commended for its vision and its record of delivery. The concepts of setting up structures to achieved time-based targets on rapid diagnosis appear to the Report authors as readily achievable in other settings with organisational will.
- The shortage of healthcare professionals (HCPs) across Europe exacerbates waiting times and hinders the efficient delivery of cancer care. The recommendations of the ECO Workforce Campaign should be taken up to address this particular aspect of the time to treatment challenge.

Session 3: Tackling delay in new treatment access

Co-chaired by **Aleksandra Kaczmarek,** Public Policy Manager, Digestive Cancers Europe and **James Laubner,** Director International Government Affairs - Europe, Canada, Mid-East, Africa and Latin America, Amgen

Speakers and panelists presented and commented on the role of early access schemes in providing patients with access to new treatments in accelerated time pathways. Mihai Rotaru, Director Market Access at EFPIA, presented the main results of the Patients W.A.I.T. Indicator Survey series. Marie Phillips, from Tufts University School of Medicine, presented recent research on multi-stakeholder perspectives on managing accelerated patient access to potentially beneficial medicines[6].

In helping to introduce the session, James Laubner gave an overview of the scale of new treatment research and innovation currently undertaken in Europe and globally by companies such as Amgen. However, many evident challenges remain in bringing these new treatments to patient access in reasonable time frames. He looked forward to hearing some of the good practices that could emerge from the session discussion and referred to Project Orbis, a US programme undertaken by the FDA to review and approve promising cancer drugs in an accelerated pathway to help patients access treatments faster. His own review of this, and other accelerated access schemes in operation in Europe and elsewhere, often point to a need to better align between regulators, HTA agencies, researchers and others on the evidence package associated to their use.

Main results of the EFPIA Patient WAIT Indicator

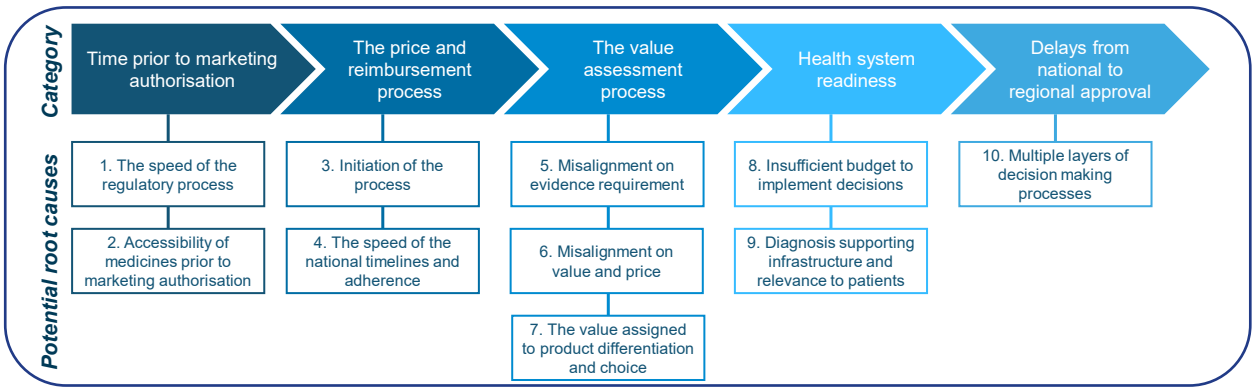
Presented by Mihai Rotaru, Director Market Access, EFPIA

Mihai Rotaru, Director of Market Access at EFPIA, presented the main findings of the EFPIA Patient WAIT Indicator, shedding light on the growing disparities in the time it takes for patients across different EU Member States to access new treatments.

The EFPIA WAIT Indicator Survey, the most comprehensive to date, reveals that the average time to reimbursement for innovative treatments across EU and European Economic Area (EEA) countries remains lengthy, at an average of 511 days. For oncology treatments specifically, the WAIT indicator suggests that the EU27 average is higher than this for oncology treatments, standing at an average of 559 days. This a figure that has risen since the previous WAIT Indicator study.

Moreover, the indicators shows that there are stark contrasts between countries, with patients in Germany waiting approximately 133 days to access new medicines, while those in Romania face a wait of over 899 days.

Figure 19. 10 interrelated factors that explain unavailability and delays



6. Read more: https://academic.oup.com/healthaffairsscholar/article/2/6/qxae069/7679827

Figure 20. Oncology Medicine: availability by approval year (2019-2022)

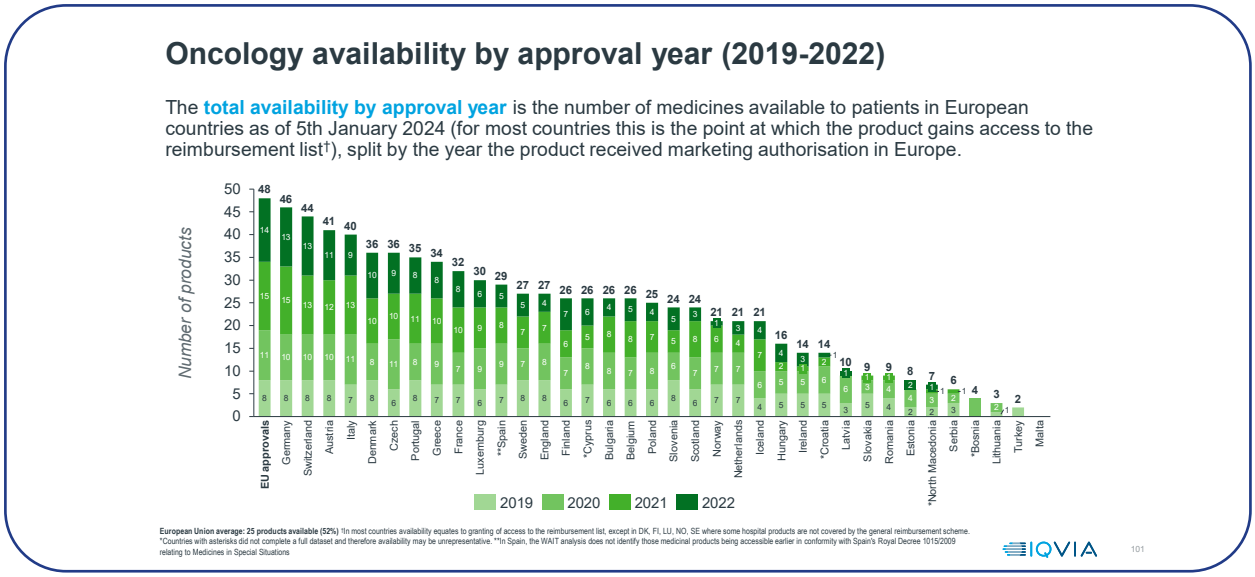


Figure 21. Oncology Medicine: breakdown of availability (%, 2019-2022)

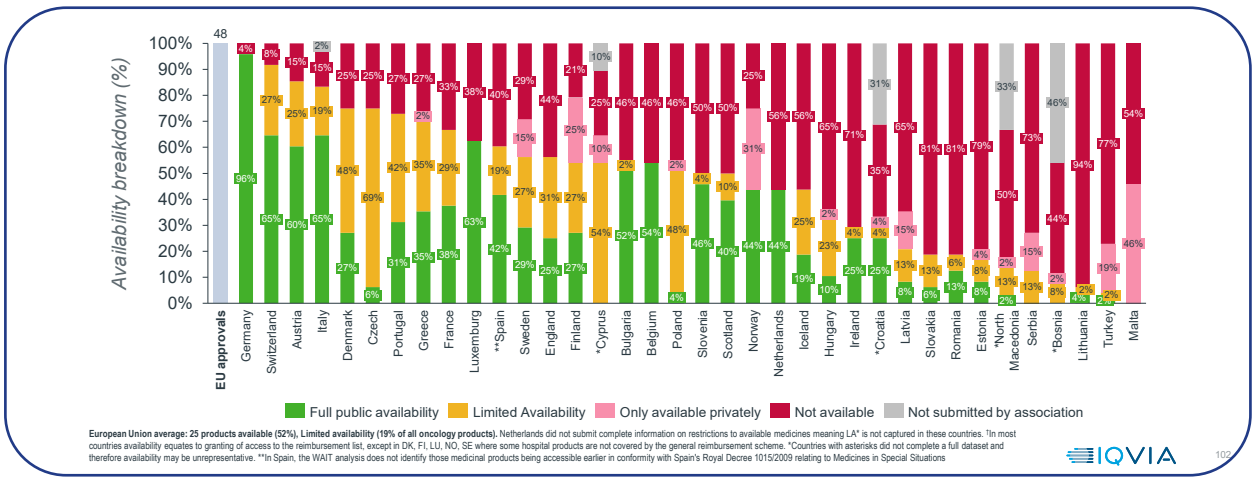


Figure 22. Oncology Medicine: time to availability (2019-2022)

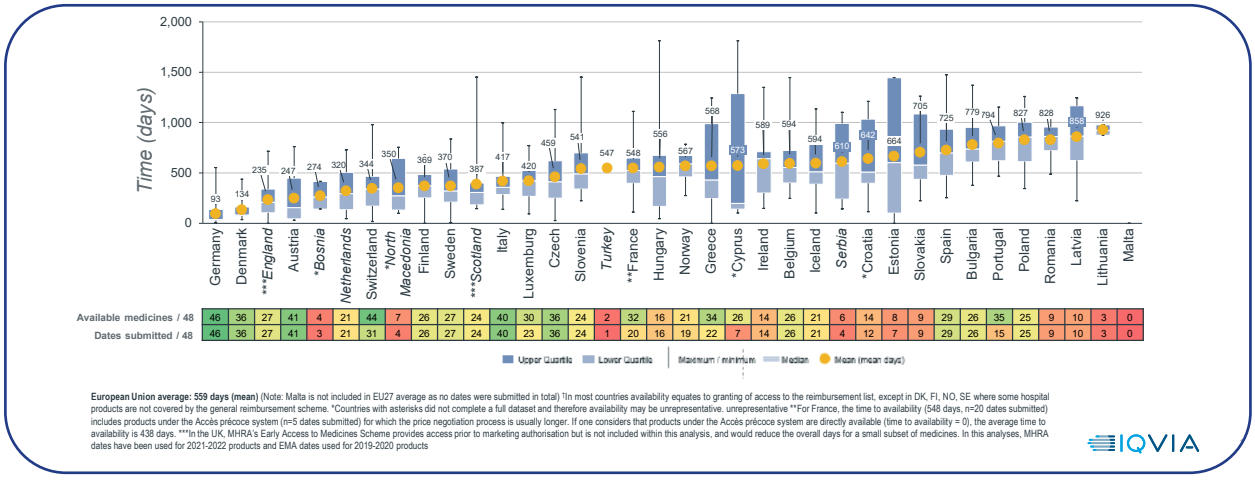


Figure 23. Key observations

Key observations

(EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	43% (45% in 2022)	52% (50% in 2022)	35% (39% in 2022)	32% (39% in 2022)	54% (50% in 2022)
Average time to availability	531 Days (517 days in 2022)	559 Days (526 days in 2022)	542 Days (625 days in 2022)	530 Days (626 days in 2022)	433 Days (426 days in 2022)

The causes for these delays are rooted in medicines access systems and processes currently in operation in EU Member States.

Enhancing stakeholder engagement

Marie Phillips, Research Assistant, Center for the Evaluation of Value and Risk in Health, Tufts University School of Medicine

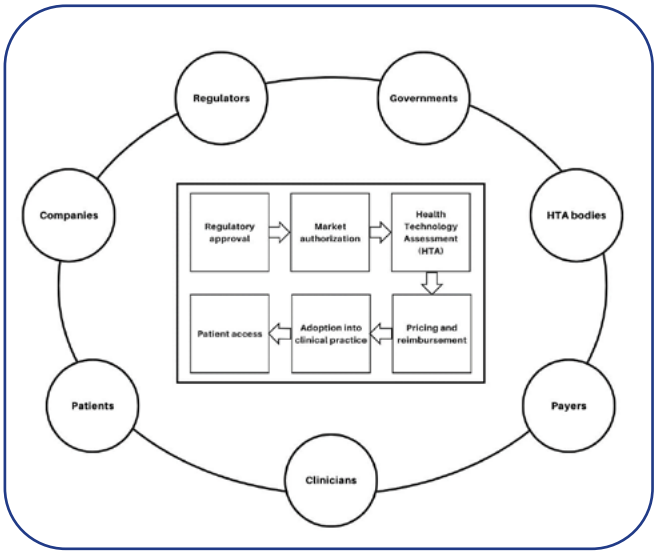
Marie Phillips, brought attention to the importance of enhancing stakeholder engagement within systems of accelerated access. These pathways are designed to provide earlier access to life-saving treatments or those addressing significant unmet needs. They also include programmes like accelerated approval, conditional approval, and exceptional approval, initiated by regulatory bodies such as the FDA and the European Medicines Agency (EMA). However, their effectiveness, appropriate application, and integration with other healthcare processes are often questioned.

The development of accelerated regulatory pathways was a response to the lengthy review timelines at the FDA, which had increased from 14 to 35 months by the early 1980s, brought to some heightened political prominence by the AIDS epidemic when life-saving treatments were urgently needed.

Although regulatory approval is just the first step towards patient access, several critical steps remain, including market authorization, health technology assessment (HTA), pricing and reimbursement, and clinical adoption. These processes involve a wide range of stakeholders, including regulators, HTA bodies, payers, governments, clinicians, patients, and pharmaceutical companies, all of whom must work together within an accelerated access (AA) framework.

While in practice there was general agreement that while early regulatory approval is crucial, it does not automatically lead to earlier patient access. The integration and coordination of subsequent steps are vital to ensure that new treatments reach patients more quickly.

Figure 24. Accelerated Access Framework



In June 2023, a multi-stakeholder international workshop held in Adelaide, Australia, brought together 58 representatives from patient organisations, regulators, HTA/payer bodies, universities, and pharmaceutical companies from across the globe. The workshop focused on the benefits, challenges, goals, and principles of accelerated access, with the aim of identifying opportunities for improvement.

Challenges for Stakeholders

HTA agencies and payers face challenges due to the limited and often uncertain evidence available at the time of accelerated approvals;

There is a need for better coordination between regulators, HTA bodies, and payers to streamline the

process and avoid unnecessary delays;

Patient Perspectives

Patients, particularly those with severe or life-threatening conditions, emphasised the life-saving potential of earlier access to novel therapies. They expressed a willingness to accept greater uncertainty about safety and effectiveness in the face of significant unmet medical needs.

However, patient representatives strongly opposed the lowering of evidence standards for regulatory and reimbursement decisions, as well as the creation of pre- and postmarket evidence requirements that could delay access to essential treatments.

They called for greater flexibility in regulatory and payment systems to facilitate quicker adoption of innovative therapies, citing the example of checkpoint inhibitors, which have shown sustained clinical responses despite initial uncertainties about their risk-benefit profile.

Improving accelerated access pathways

Participants at the Adelaide event agreed that a more coordinated approach to accelerated access is needed, taking into account the perspectives of all stakeholders involved.

Patient advocates also highlighted the importance of communication from decision-makers regarding the benefits, risks, and key uncertainties associated with drugs approved through accelerated access pathways.

There was a strong call to ensure that accelerated access programs are not restricted to first-in-class medicines, as later-generation drugs within the same class may also offer significant improvements in safety and efficacy.

A significant challenge in achieving a more coordinated approach lies in the variability of health system dynamics across different jurisdictions. Standards of care differ internationally, leading to divergent evidence demands from regulators, HTA bodies, and payers in various countries. Additionally, the preferences and priorities of societies, their willingness to pay for health improvements, and differing reimbursement policies further complicate the process of bringing new therapies to patients swiftly.

Marie Phillips gave her view that one means to help address a challenge in accelerated access pathways (issues of evidence requirement) could be the adoption of innovative and flexible pricing models that adjust pricing according to confirmatory data.

The critical importance of early access schemes in improving outcomes for lung cancer patients

Alfonso Aguarón, Policy Officer, Lung Cancer Europe & Rebecca Steele, Secretariat, European Alliance for Value in Health

Early access scheme are crucial in enabling healthcare systems to better utilise and reflect on real-world data about new treatments. They are particularly valuable in ensuring timely access to innovative therapies, which is essential for patients with advanced stages of lung cancer.

Alfonso Aguarón

Policy Officer, Lung Cancer Europe & Rebecca Steele, Secretariat, European Alliance for Value in Health

Early access to new treatments can mean the difference between life and death.

Early access not only accelerates treatment but also provides hope, significantly impacting the psychosocial well-being of patients and caregivers. This aspect should not be underestimated when considering the broader benefits of such programmes.

There is a need for improved healthcare infrastructure across countries and enhanced regulatory monitoring to address early access discrepancies and inequalities.

Figure 25. International Multi-Stakeholder Symposium

Rebecca Steele, Secretariat of the European Alliance for Value in Health, emphasised the importance of early access programmes and the utility of real-world data within them. She recommended:

- Increasing the utility of real-world data for supporting treatment decisions and demonstrating the effectiveness of new therapies in clinical practice. Capturing this data is crucial, yet it has often been underutilised.
- A collaborative approach is needed to ensure that data is captured comprehensively and used to inform treatment decisions. This collaboration should extend across the healthcare ecosystem, including patients, healthcare providers, and pharmaceutical companies.
- A value-based payment model was discussed as a potential solution to address delays in accessing new treatments. By focusing on value-based healthcare, the system can better align incentives to prioritise patient outcomes and expedite the availability of new therapies.

RECOMMENDATIONS ON IMPROVING THE TIMELINES OF ACCESS DECISION-MAKING

- Pan-European evidence suggests that the average time across the EU27 between a new cancer treatment receiving regulatory approval and it being made available in a country for patient access is continuing to grow, currently standing at a 559 day delay. This is becoming a growing concern requiring remedial action.
- Accelerated access schemes can be an effective means to help overcome entrenched delays in a new treatment advancing from approval to patient access. However, evidence of their operation so far points to an ongoing need to align internationally on the evidence package requirements associated to their use. Inconsistent evidence requirements otherwise retards the effective adoption of such schemes.
- Early access not only accelerates treatment but also provides hope, significantly impacting the psychosocial well-being of patients and caregivers. This aspect should not be underestimated when considering the broader benefits of such programmes.
- Healthcare data infrastructures still require enhancement to fully leverage the role of real world data to better support value-based healthcare.

In closing the roundtable, the co-chairs noted the many examples of good practice that had arisen during the sessions and discussions and commended their wider uptake to help reduce the time taken between a cancer patient's diagnosis and the start of effective and optimal treatment.

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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