



Seizing the Moment: Europe as a Global Leader in Cancer Science and Care

Policy recommendations on cancer and competitiveness



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Foreword

Europe is home to many of the world's leading cancer researchers, clinicians, scientific societies and healthcare institutions. European researchers continue to produce groundbreaking discoveries, develop exciting new technologies, and advance scientific knowledge. Yet too often Europe struggles to translate these achievements into rapid adoption, widespread implementation, and improved outcomes for patients. Scientific excellence alone is not enough.

As the EU embarks on an ambitious 'competitiveness agenda', oncology provides a valuable case study of what is needed to translate scientific excellence into tangible societal and economic value. Creating an environment in which scientific discoveries and new technologies can move efficiently from the laboratory into clinical practice will strengthen both the health of Europe's citizens and the resilience of its economy. Understanding and addressing the barriers to implementation, strengthening collaboration between research and healthcare systems, and creating the conditions needed to attract and sustain investment can help Europe translate more of its scientific potential into better outcomes for patients, while reinforcing its position as a global leader in life sciences.

The European Union has already established many of the building blocks needed to achieve this ambition. Flagship initiatives such as Europe's Beating Cancer Plan, the EU Cancer Mission and complementary research and development programmes, including the Cancer Imaging Initiative and, potentially, the European Health Data Space, have created shared objectives, encouraged collaboration across Member States and provided common frameworks for investment and implementation. These initiatives are not isolated health policies, but components of the wider infrastructure needed to strengthen Europe's resilience and competitiveness. Strengthening Europe's global competitiveness will depend on the effective implementation of these initiatives, alongside the financial, technological, and workforce capacity to translate state-of-the-art research into routine healthcare.

Europe possesses an exceptional ecosystem of scientific societies, healthcare professional organisations, patient organisations and research networks. These organisations provide expertise, develop clinical standards, facilitate collaboration, support implementation and help translate research into practice. Their contribution is a strategic asset within Europe's healthcare ecosystem.

The European Commission has begun taking important steps to modernise the regulatory environment through initiatives such as the updated General Pharmaceutical Legislation, the proposed EU Biotech Act under current legislative scrutiny, and broader measures to strengthen Europe's life sciences sector. These represent positive progress. However, further action will be required to reduce fragmentation, streamline administrative and regulatory processes, strengthen clinical research capacity and support faster adoption of new treatments, technologies and approaches across Member States.

'Seizing the Moment: Europe as a Global Leader in Cancer Science and Care' sets out a series of policy recommendations designed to help Europe take full advantage of its present strengths and lead not only in scientific breakthroughs, but also in ensuring follow-through in clinical practice. By strengthening the environment for cancer research, development and adoption, the European Union can improve outcomes for people affected by cancer while advancing its wider ambitions for competitiveness, resilience and sustainable economic growth.

A further recommendations paper from the European Cancer Organisation (ECO) will examine and make proposals on how Europe's Competitiveness Agenda can better reflect the contribution of strong cancer care and control systems to national resilience and prosperity. In the meantime, we trust that *'Seizing the Moment: Europe as a Global Leader in Cancer Science and Care'* can serve as a timely contribution to this discussion.

Cancer & competitiveness: A vision

Patients affected by cancer across Europe should have timely and equitable access to the most effective new treatments, technologies and approaches to care. Europe should become a much more attractive place to discover, develop, test, manufacture and adopt new technologies and approaches in cancer treatment and care.

Every EU Member State should be able to contribute to and benefit from collaborative cancer research that improves patient outcomes and reduces inequalities in cancer care.

Europe should lead not only in scientific discovery but also in translating research into practice that serves patient needs.

Advances in cancer prevention, treatment and care should become a cornerstone of Europe's global competitiveness strategy.



Summary of recommendations to reach this vision

1. Build a much more attractive environment for cancer research and technology development in Europe

- Make Europe's leadership in advancing new technologies for cancer treatment and control, and access to these advances, a flagship priority of the EU Competitiveness Agenda.
- Sustain and expand long-term investment in Europe's Beating Cancer Plan and the EU Cancer Mission beyond the current Multiannual Financial Framework period as an available means to support this goal.
- Develop a dedicated **European Strategy for Cancer Research, Development and Implementation**, bringing together research, industrial, regulatory and health policy to strengthen Europe's capacity to translate scientific discoveries into better cancer prevention, diagnosis and treatment.
- Recognise that creating the conditions for faster development and uptake of, and access to, new approaches in cancer treatment and care is both a health priority and an economic competitiveness priority.

2. Make Europe a preferred location for generating real-world evidence, cancer research and clinical trials

- Establish Europe as a region where high-quality clinical trials in cancer can be initiated promptly, without compromising patient safety.
- Implement the recommendations of the *Reducing Bureaucracy in Clinical Trials* coalition.
- Improve hospital contracting, ethics processes, site activation and patient recruitment, where current delays are greatest.

- Support a European agenda for networks of Comprehensive Cancer Centres and strengthen their capacity for research collaboration.
- Increase support for investigator-led and multinational academic cancer trials.
- Support the development of federated clinical registries and electronic health records (EHRs) to complement evidence that cannot be generated through clinical trials, and to support and accelerate the decision-making process (from regulatory approval to health technology assessment (HTA)).

3. Improve European leadership and coordination

- Bring forward enhanced European governance arrangements capable of providing long-term and highly effective coordination of cancer research, development and health policy, at a level that can help Europe compete globally over the long term.
- Establish a European observatory to monitor emerging scientific, technological and regulatory challenges earlier and respond more rapidly.
- Utilise Europe's active community of scientific societies, healthcare professional organisations, patient associations and academic and research centres ('the cancer community') as permanent strategic partners in shaping competitiveness policy for cancer treatment and care, including workforce development, skills and the implications of AI for healthcare.
- Develop measurable European indicators tracking research performance, clinical trial activity, the uptake of new approaches and technologies, and patient access to care and treatment.

Introduction



Europe is falling short of what we could achieve if we acted as a community. *Mario Draghi, 2024*

Scale matters. *Enrico Letta, 2024*

It is time to restart Europe's innovation engine. We have the political will. Now, what matters is speed and unity. Because the world is not waiting for us. *Ursula von der Leyen, European Commission President at the launch of the EU's 'Competitiveness Compass', January 2025.*

The European Commission's commitment to advancing its policy agenda on competitiveness has so far been a case of words matched by action. At an accelerated pace, new legislative initiatives such as the EU Biotech Act have been published to address concerns about regulatory burden, scale-up and financing challenges, and workforce shortages, among others. Furthermore, the architecture of EU programme funding is set to undergo significant changes in the 2028–34 budget period, to reorient EU projects and initiatives towards the economic competitiveness goal.

Through this paper, *'Seizing the Moment: Europe as a Global Leader in Cancer Science and Care'*, the European cancer community recognises both the challenges and the opportunities in achieving a

better environment in Europe for cancer research and development.

Europe has a long history of cancer research and scientific discovery, supported by excellent research institutions and treatment centres, frameworks for improving standardisation and interoperability between countries, EU-level frameworks for cooperation through Europe's Beating Cancer Plan and the EU Cancer Mission, and a highly skilled workforce in research and cancer care.

Europe therefore has many of the requirements to become a stronger global centre of cancer research and development in cancer care over the coming decades. Achieving this ambition, however, will require a targeted political agenda that removes barriers and creates an environment in which patients have timely access to new and improved treatments and approaches, and cancer research and development thrives in all parts of Europe.

'Seizing the Moment: Europe as a Global Leader in Cancer Science and Care', seeks to support the further development of such a political agenda by:

1. Appraising Europe's position in the global race to advance cancer treatment and care.
2. Highlighting the fields in which Europe has the greatest opportunities to demonstrate leadership in cancer research and care.
3. Providing recommendations to strengthen the policy and regulatory environment needed to translate scientific advances into improved outcomes for cancer patients.

We urge the European Commission and EU Member States to consider these recommendations as they develop and implement a new European Competitiveness Agenda.

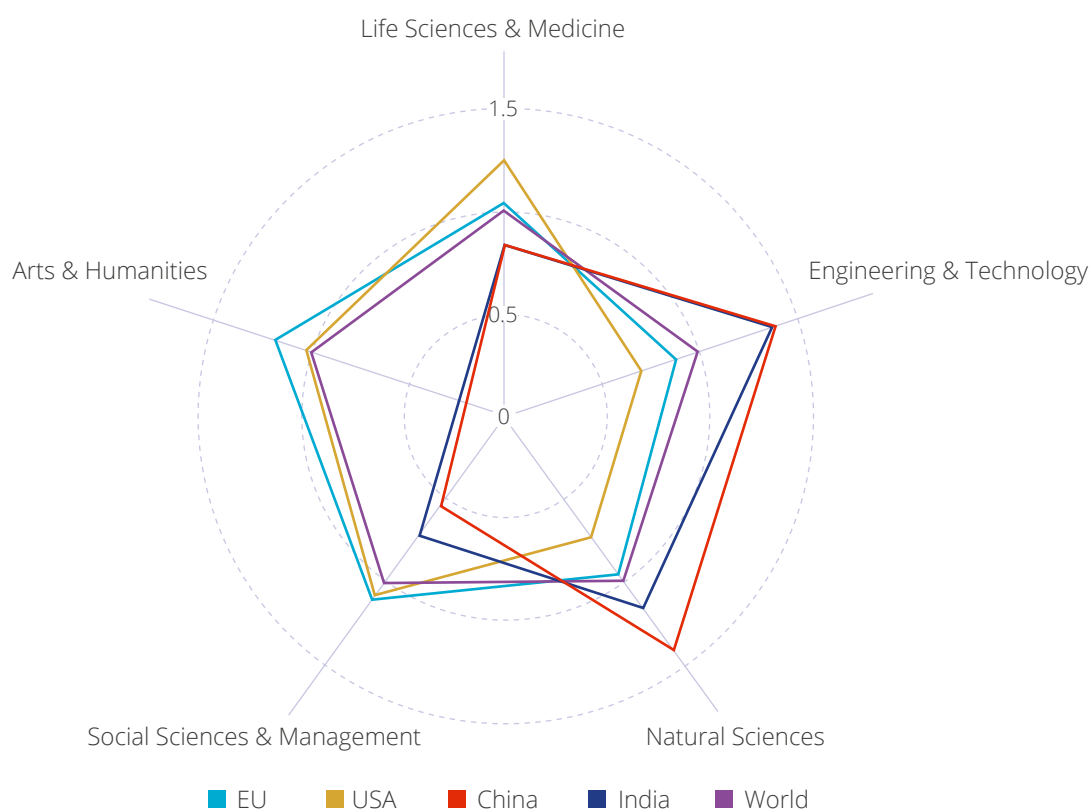
1. Assessing the cancer research and development environment in Europe

1.1. Harnessing opportunities for academia and industry synergy on cancer research and development

Cancer is a useful test case for Europe's research and development ecosystem as a whole. Cancer carries one of the largest disease burdens in every European country and is projected to become the leading cause of death in the EU by 2035 (OECD and European Commission, 2024). The innovation pipeline to meet the growing need is unusually broad, spanning diagnostics, devices, data infrastructure and therapeutics, with long chains between laboratory discovery and routine care.

Europe's capacity for research and development in oncology, as in other fields, rests on a strong overall position in biomedical science. For example, Europe holds a 22% share of all research articles published globally. This productivity is driven by a diverse ecosystem where established nations like Germany, Italy, France, and Spain account for nearly two-thirds of the EU's scholarly output. In specialised biomedical fields like biotechnology, the EU and China each hold a 25% global share of research output, highlighting Europe's critical mass in these strategic sectors (Elsevier, 2025). This now places China on a comparable footing to the EU on research, reflecting how quickly China's research base has grown in recent years.

Relative Activity Index (RAI)

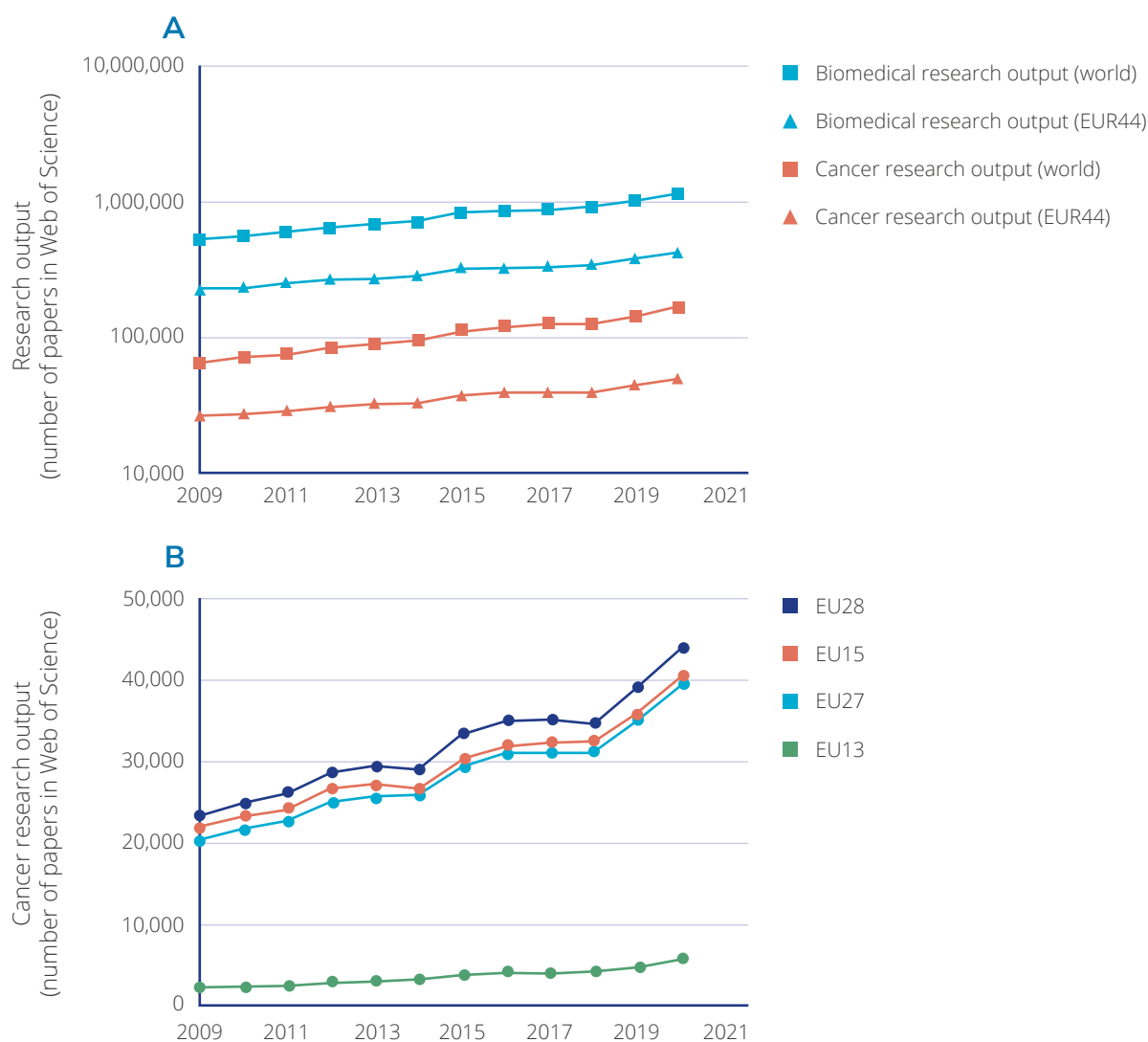


Source: Elsevier (2025)

The chart shows the relative activity index of each discipline for selected countries, meaning the relative share of output in each discipline compared with the global average.

Zooming in on oncology, across the wider European region of 44 countries, Europe produced 39.4% of the world's biomedical research papers between 2009 and 2020 and 33.8% of its cancer research

papers. European cancer research output grew more slowly over that period (5.1% per year) than output in the rest of the world (8.1% per year), pointing to a gradual contraction in Europe's share of global cancer research. This relative decline is also uneven within Europe: cancer research activity in the EU15¹ roughly doubled over the period, while the EU13 Member States of central and eastern Europe² saw little change (Lawler et al., 2023).

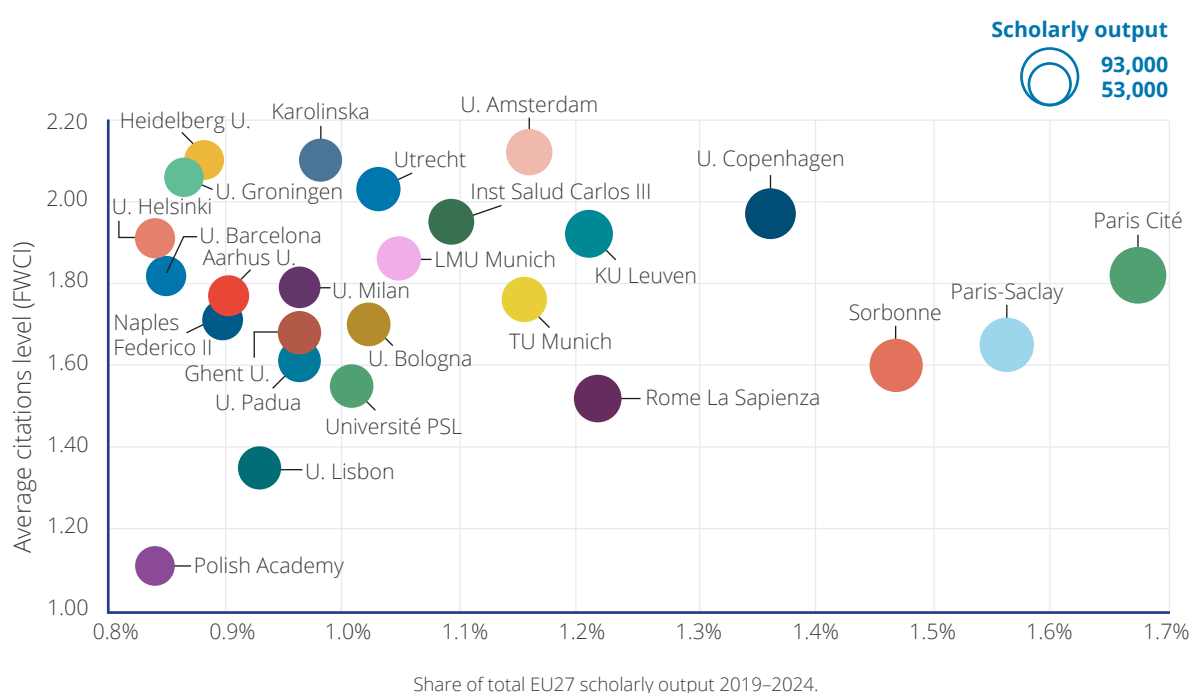


Source: Lawler et al. (2023)

¹ EU15 refers to the Member States that were in the EU before the 2004 enlargement: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden and the UK.

² EU13 refers to the 2004 accession group (Cyprus, Czechia, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia), as well as Bulgaria, Romania (2007), and Croatia (2013).

25 most prolific universities in the EU27, showing volume, EU share of output and field-weighted citation impact FWCI (2019–2024)



Volume is only part of the picture. Academic excellence is concentrated in high-density research engines, notably the Paris region with Paris Cit , Paris-Saclay, and Sorbonne University, which are the three most prolific universities in the EU. Specialised health centres also play a vital role. For instance, Spain’s Instituto de Salud Carlos III is the top-ranked institution for biotechnology research volume in the EU. While volume is high in Southern and Central Europe, the highest citation impact in clinical and health research is consistently achieved by Northern European countries such as Denmark and Sweden (including the Karolinska Institute), as well as the Netherlands and Belgium (Elsevier, 2025). Translating excellence into impact across EU will require reinforced cross-border cooperation and stronger networks that connect leading institutions with emerging research centres.

Europe’s innovation capacities are increasingly channelled through targeted innovation hubs and clusters that rank among the most intense globally. These are groups of independent undertakings

(start-ups, small, medium and large enterprises, and research organisations) that operate in a sector and region and stimulate innovation through collaboration, facility-sharing and the exchange of knowledge and expertise (European Commission, 2006). Within the EU, Helsinki and Eindhoven lead in innovation intensity, followed closely by clusters in Stockholm, Copenhagen, and Munich (WIPO, 2025). The synergy between academia and industry remains an important strength of the European innovation model.

However, Europe is less successful than the United States and China at converting those collaborations into globally competitive companies, rapid commercialisation, industrial scale-up, and, ultimately, timely therapeutic progress for patients.

As Mario Draghi, former Prime Minister of Italy and President of the European Central Bank, has advised the EU, Europe’s weakness is **not scientific excellence**, but the failure to translate research into commercial success (Draghi, 2024).

With regard to breakthroughs and major developments in cancer care in recent decades, cancer centres and research institutions in Europe have long been active in investigating new treatment methods. Some examples are provided in the table below.

CAR-T cell therapy	Leading cancer centres in Europe such as Vall d'Hebron Institute of Oncology, Charité – Universitätsmedizin Berlin, and Leiden University Medical Center have all been highly active in areas such as early solid tumour CAR-T research, first-in-human studies and manufacturing innovation.
PD-1/PD-L1 cancer immunotherapy	Gustave Roussy, the Netherlands Cancer Institute, and European Organisation for Research and Treatment of Cancer (EORTC) have been central to early trial testing and the coordination of multicentre trials.
mRNA technology for therapeutic cancer vaccines	The modern field of mRNA cancer vaccines has particularly deep European roots, especially in Germany, with fundamental research and translational development being led out of centres in Heidelberg, Mainz, Tübingen and Erlangen.
Radioligand therapy	European researchers and nuclear medicine specialists have been pioneers in developing targeted radiopharmaceuticals over several decades. Many of the landmark clinical studies were led by European investigators, particularly in Germany, Austria, Italy, France, the Netherlands and Belgium.

Seizing the moment for improved academia-industry collaboration in cancer research: Recommendations

The foundations for strong academia-industry collaboration in cancer research and development are firmly established in Europe. The continent is home to world-leading universities, cancer centres and research institutes that combine scientific excellence, clinical expertise and a long tradition of pioneering discovery. Some cities and centres of scientific research have shown great progress and leadership in this regard, such as Paris, Leuven, Eindhoven, Stockholm, Munich and Copenhagen. These approaches could be further scaled and practices spread to other countries, with cancer care innovation more strongly embraced as part of the networked approach.

Spotlight: Paris is strengthening public-private collaboration in cancer research

The Paris Region is one of Europe's most concentrated cancer research ecosystems, accounting for around 40% of France's cancer research activity and bringing together leading universities, research institutes, Comprehensive Cancer Centres, hospitals and industry. It also hosts three of the five French bioclusters accredited in 2023, including the **Paris-Saclay Cancer Cluster (PSCC), the first accredited biocluster dedicated specifically to oncology.**

The PSCC is built around partnerships between academic, clinical and industrial actors. It connects promising researchers and developers with expertise, funding, data, samples, technologies, infrastructure and laboratory capacity, while also linking innovators with investors and other sources of finance.

This ecosystem has continued to develop in 2026 with the opening of **THE HIVE at Campus Grand Parc in Villejuif**, providing a dedicated setting for oncology research, entrepreneurship and collaboration. Together, these initiatives offer an example of how Europe can build on existing scientific excellence by creating environments that bring research, clinical expertise, industry and investment closer together. (Cancéropôle Île-de-France, n.d.; Pharmaceutical Technology, 2026)

If Europe's competitiveness agenda is to succeed, including in the field of cancer research and development, centres of cancer research excellence must continue to be recognised, nurtured and increased in number, by both the European Union and its Member States.

There is enormous further value to be gained from pre-existing EU infrastructures that support excellence and collaboration in cancer research. Realising it requires sustained and predictable research funding, investment in shared infrastructure, simpler frameworks for public-private partnership, and continued links with leading hubs in associated countries, such as the United Kingdom and Switzerland. National and international cancer societies and networks should also be drawn on more systematically. That release of value can improve cancer research productivity in Europe and, in turn, support Europe's competitiveness agenda, with patient care always the ultimate beneficiary.

More specifically, these infrastructures for research include the EU Network of Comprehensive Cancer Centres, the European Reference Networks, Cancer Mission initiatives such as UNCAN.eu, the network of National Cancer Mission Hubs, the European Federation for Cancer Images (EUCAIM), and the future European Health Data Space.

At the same time, European initiatives that strengthen collaboration between cancer centres, promote common standards, facilitate knowledge exchange and support capacity-building across all Member States provide an important opportunity to broaden the geographical reach of research and innovation excellence. That excellence should be smart as well as strong. Innovation that improves outcomes while also raising efficiency and reducing costs deserves particular priority, which makes health economics and health services research an integral part of Europe's competitiveness.

It is therefore recommended that the European Union and its Member States sustain long-term support for initiatives under Europe's Beating Cancer Plan, the EU Cancer Mission and the other cooperation initiatives mentioned, with a view to increasing Europe's productivity in cancer research and development, in every EU country.

An important example that could be considered at EU level is the 'Cancer Grand Challenges' initiative, founded by Cancer Research UK and the UK National Cancer Institute. It awards competitive grants of up to \$25 million for multidisciplinary research initiatives tackling major unsolved challenges in cancer. A similar European approach could support ambitious, high-risk high-reward research, with potential to address significant unmet needs and deliver transformative advances in cancer care.

A clear political ambition should be expressed: to ensure that every Member State benefits from high-quality, high-impact cancer research and development.

The tools and frameworks to achieve this goal are already being created via Europe's Beating Cancer and the EU Research Mission on Cancer. The missing ingredient is political promise that they will be sustained.

Failure to build on these platforms, by contrast, would be to neglect a major strategic asset in Europe's potential claim for global leadership in cancer research and development.

1.2. The urgency of addressing Europe's attractiveness as a clinical trial destination

1.2.1. Europe's declining position in clinical trials

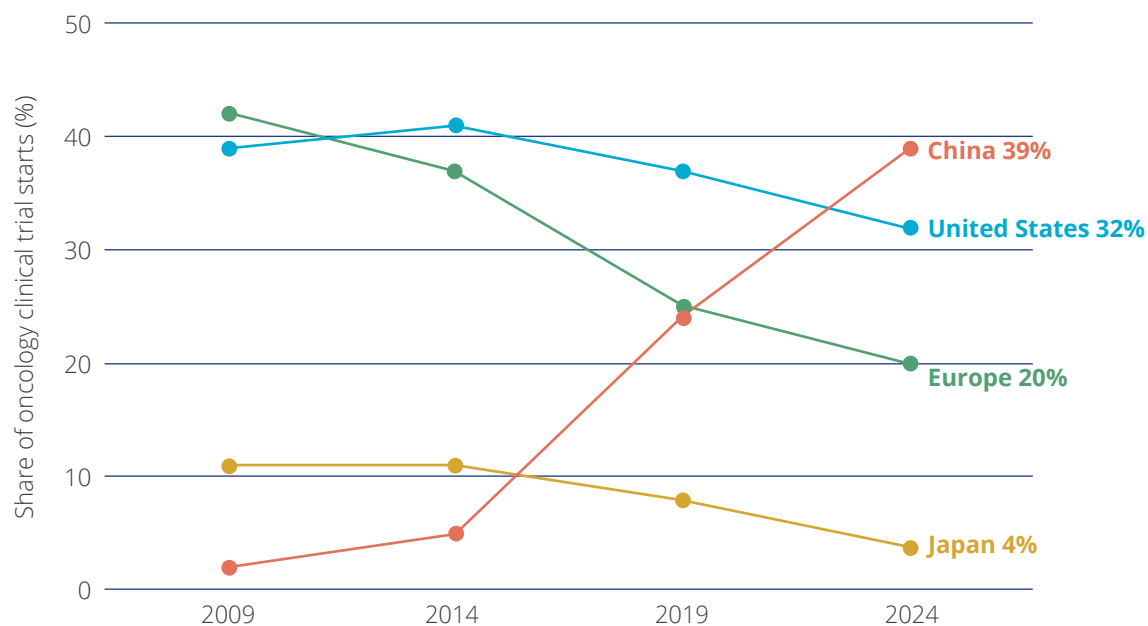
Europe's position as a global leader in cancer research is being questioned. On several measures that determine whether a clinical trial takes place here, Europe's position has been gradually weakening for over a decade. This matters beyond competitiveness, affecting patients' access to treatment.

Europe's share of global oncology clinical trials fell from 41% in 2008 to 21% in 2023 (Manzano et al., 2025), and the absolute number of oncology trial starts by European companies fell by 8% between 2008 and 2023. China's share rose from under a quarter to nearly two fifths over the same period, up from barely 2% in 2009, meaning China has now overtaken both the United States (down five percentage points since 2019, to under a third) and Europe (IQVIA Institute, 2025).

Trials run only in the four largest European Union countries plus the United Kingdom fell to just 5% of all cancer trials worldwide in 2024, down from 7% in 2015. Trials run only in China rose from 7% to 40% over the same period.

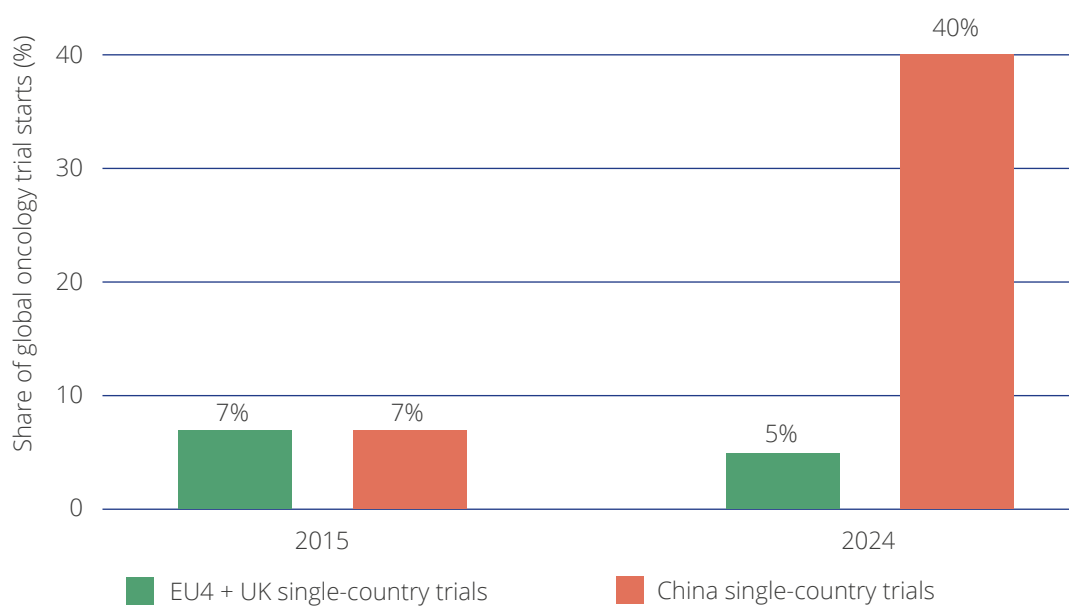
When examining the reasons for Europe's slipping position in trial research, regulatory burden is often cited.

Share of oncology clinical trials by sponsor headquarters region: China overtakes Europe and the United States, 2009–2024



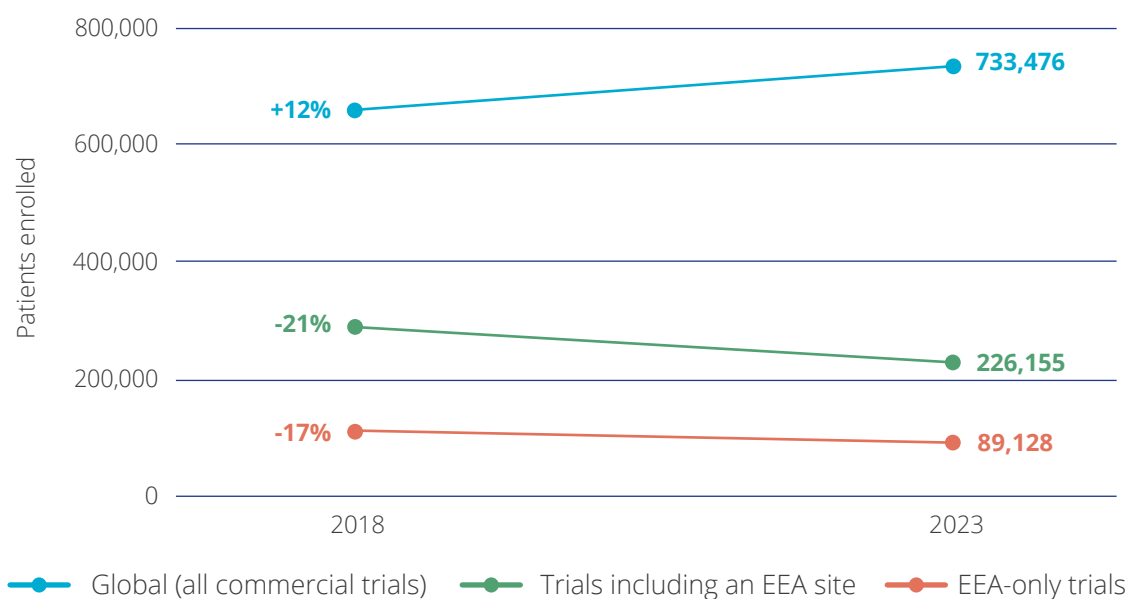
Source: IQVIA Institute (2025), Global Oncology Trends 2025, Exhibit 3.
Note: data points reflect the years reported in the source (2009, 2014, 2019, 2024), not a continuous annual series.

Where cancer trials are actually run: China's single-country share overtakes the four largest EU countries plus the UK, 2015–2024



Source: IQVIA Institute (2025), Global Oncology Trends 2025, Exhibit 22.

Patients enrolled in commercial clinical trials, 2018 vs 2023: global growth, European decline



Source: IQVIA / EFPIA / Vaccines Europe (2024), Assessing the Clinical Trial Ecosystem in Europe. Only 2018 and 2023 figures are shown; intermediate years follow a similar pattern with a COVID-era peak around 2021.

Under the current EU Clinical Trials Regulation, for example, it still takes a median of 118 days from submitting an application to getting a decision, and only around 40% of trials manage to start recruiting their first patient within the Regulation's own 200-day target (European Medicines Agency, 2026). Beyond regulation, coordination buffers between the bodies involved (institutions, ethics committees, research networks) add further delay to meeting this target.

This has a direct cost to patients, not just to Europe's competitive standing. Current regulatory reform has not yet reached the goal of making participation in clinical research the norm for cancer patients. Between 2018 and 2023, the number of patients enrolled in trials run only in the European Economic Area (EEA) fell by 20%, and in trials that include at least one EEA site by 22%. Global enrolment over the same period rose by

12%. Fewer trials in Europe means fewer patients getting access to life-saving treatment.

Supporting real-world registries that can flexibly complement trials is also becoming essential. As new treatments emerge during the course of ongoing trials, and as endpoints, clinical care, and treatment paradigms continue to evolve, clinical trials alone often struggle to keep pace. Registries that generate longitudinal, adaptable data can help bridge this gap. An effective evidence landscape anticipates the evidence decision-makers will need and proactively works to fill those gaps ahead of time.

As part of its call for a smoother, less burdensome framework for conducting clinical trials in Europe, the EU and its Member States are strongly urged to give the fullest consideration to the laudable work and recommendations of the Coalition for Reducing Bureaucracy in Clinical Trials:

Reducing bureaucracy in clinical trials

The **Coalition for Reducing Bureaucracy in Clinical Trials** is a broad European alliance of medical societies, patient organisations and research stakeholders, established in 2020 under the leadership of the European Hematology Association (EHA). It was created in response to growing concerns that increasing administrative and regulatory requirements were making clinical trials slower, more expensive and less attractive to investigators, without necessarily improving patient safety or research quality.

The Coalition's recommendations focus on making Europe's regulatory environment more efficient while maintaining high standards of patient protection and scientific integrity. Its principal regulatory recommendations include:

- **Greater harmonisation** in the implementation of the EU Clinical Trials Regulation across Member States, reducing inconsistent national interpretations.
- **A proportionate, risk-based approach** to regulation, ensuring that low-risk and pragmatic trials are not subject to unnecessary administrative requirements.
- **Simplified and centralised safety reporting**, reducing duplication and allowing investigators and regulators to focus on clinically meaningful safety signals.
- **More streamlined informed consent procedures**, with shorter, clearer and more patient-friendly information that improves participant understanding.
- **Reduced administrative burden** through common EU templates, coordinated assessments and wider use of digital processes.

Collectively, these recommendations seek to eliminate bureaucracy that does not demonstrably improve patient safety or data quality, while preserving robust ethical and regulatory oversight. The Coalition argues that a more streamlined and harmonised framework would strengthen Europe's competitiveness as a destination for clinical research, reduce costs and delays, support both commercial and academic studies, and ultimately accelerate patient access to important new treatment options.

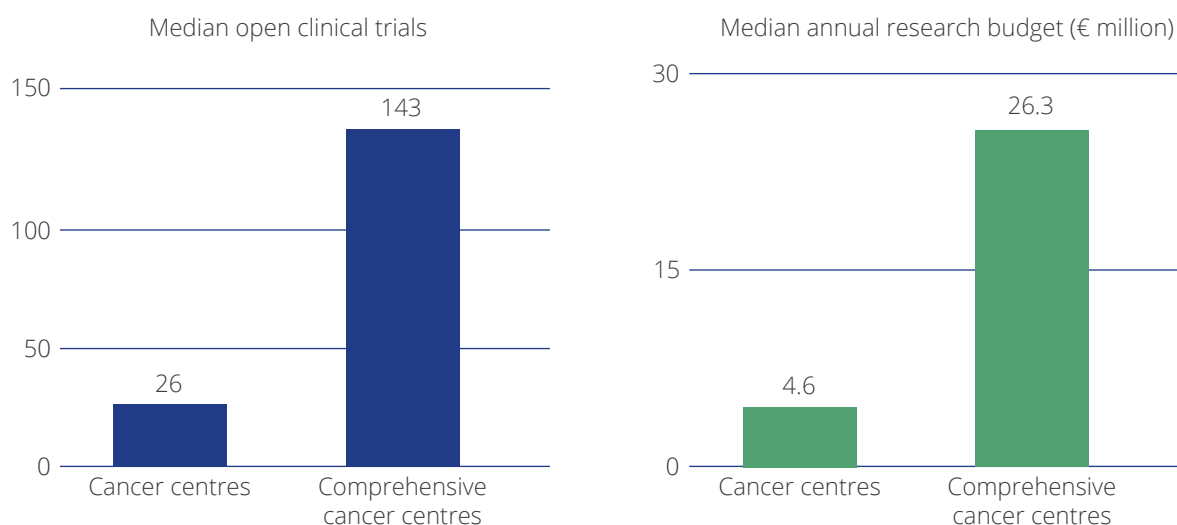
More information about the Coalition and its recommendations is available here: <https://bureaucracyincts.eu/>

1.2.2. *The necessity of scale, the value of Europe's Comprehensive Cancer Centres.*

Beyond welcome reforms and improvements to Europe's clinical trial regulations promoted through the EU Biotech Act, other solutions to Europe's trial competitiveness challenge reside in better fostering the research assets that are Europe's Comprehensive Cancer Centres.

Comprehensive Cancer Centres in Europe accredited by the Organisation of European Cancer Institutes (OECI) run a median of 143 open trials against 26 at

Clinical trial capacity and research funding: cancer centres vs comprehensive cancer centres across OECD-accredited institutions (2015–2020)



Source: Lawler et al. (2023), pp. e30-e31.

non-Comprehensive Cancer Centres, with median annual research budgets of 26.3 million euros compared with 4.6 million euros (Lawler et al., 2023).

According to Lawler et al. (2023), independent trials show a similar pattern of concentration. Comprehensive Cancer Centres enrol around 10% of new patients into prospective interventional trials, compared with 3.4% at non-Comprehensive Cancer Centres, and run a median of 23 early-phase studies against just 2. The largest centres run close to 100 open Phase 1 or 1/2a studies at any given time. An additional challenge is that the majority of cancer patients (70–80%) are treated outside the catchment area of a Comprehensive Cancer Centre (Heitor et al., 2026).

Since 2021, Europe's Beating Cancer Plan and the EU Cancer Mission have recognised Comprehensive Cancer Centres as essential to delivering high-quality, research-driven cancer care. Beyond their clinical role, these centres are among Europe's most valuable strategic assets for cancer research, development and talent growth. Continued investment in initiatives that strengthen high-quality, research-intensive Comprehensive Cancer Centres across all Member States should

therefore be viewed not only as a cornerstone of European health and research policy, but also as a strategic investment in Europe's global competitiveness. By integrating cutting-edge research with clinical care, Comprehensive Cancer Centres can help establish Europe as a world-leading hub for cancer research, innovation and translation into patient benefit.

1.2.3. Appreciating the value of European trial activity in treatment approval processes

'Seizing the Moment' brings attention as well to another important dynamic in how Europe values trial research.

As clinical trial research is increasingly conducted outside Europe, treatments are more frequently being submitted for European regulatory approval on the basis of studies that include few or no European participants.

The first concern raised by this trend is the clinical question of whether treatment effects observed almost entirely in one population necessarily translate to Europe. Potential differences can include genetics, tumour biology, environmental

factors, and microbiome characteristics. Cancer biomarkers may differ markedly between populations. For some tumour types such as lung cancer and gastric cancer, such differences can be especially pertinent.

Declining trial activity in Europe also carries consequences beyond the evidence base. Without clear incentives or expectations for developers to include European sites, the shift of clinical research to other regions is likely to accelerate. This would weaken Europe's research capacity and its attractiveness for investment. It would also deepen inequalities in access to trials, both between Europe and other regions and between Member States.

Seizing the Moment for improving Europe's clinical trial environment: Recommendations

On improving the regulatory environment for clinical trials in Europe

Seizing the Moment recommends:

The regulatory framework for clinical trials should be proportionate to the level of risk involved. Regulatory requirements should reflect the specific risks posed by different types of trials. Lower-risk studies, including trials using medicines already authorised and used within the terms of their marketing authorisation, should face a simplified administrative regime. This recommendation is in line with the Biotech Act's proposed category of 'minimal-intervention clinical trials'.

The overarching objective should be to **make participation in clinically relevant research a routine part of cancer care, so that the majority of cancer patients across Europe have the opportunity to take part.** This is consistent with the European Code of Cancer Practice, which recognises patients' right to be informed about relevant research and their eligibility to participate. Regulatory reforms should therefore also enable more patients and clinical centres to participate in research.

Ethics review requirements should be interpreted more consistently across Member

States. The same protocol should not face materially different scrutiny depending on where it is submitted. *Seizing the Moment* further recommends that the potential of a process for a centralised, European-wide ethical approval be formally examined.

Fragmentation across the approval chain should be reduced. Parts of trial approval remain at national level or sit under separate frameworks. For example, where a trial also involves a medical device or in vitro diagnostic under investigation, the medicine and the device are currently assessed under separate regimes. The Biotech Act proposes a single assessment process for combined studies involving a medicine together with an in vitro diagnostic or device. This proposal should be supported.

Real-world evidence offers unique opportunities to fill evidence gaps and bring safe medicines and medical devices to market faster. Once operational, the **European Health Data Space** should be considered as a tool to support faster identification and enrolment of eligible patients, a step that remains one of the least visible but most persistent delays in the system. Its role in supporting the identification and re-use of federated datasets will enable evidence gaps to be filled more quickly, support clinical trials by increasing population diversity, allow research into rare diseases to broaden its study populations and enable patient-centred understanding of how comorbidities impact disease trajectories and quality of life.

On fostering Comprehensive Cancer Centres as engines of research and innovation

Seizing the Moment recommends:

The European Union should make a long-term political commitment to establishing and strengthening the European Network of Comprehensive Cancer Centres. Throughout the next Multiannual Financial Framework, sustained support should be provided to initiatives such as, or similar to, JANE, CrANE, CCI4EU and EUnetCCC, enabling them to realise their shared vision of high-quality, research-intensive Comprehensive Cancer Centres operating across all parts of Europe.

Comprehensive Cancer Centres are not only providers of the highest standards of multidisciplinary cancer care; they are also essential engines of biomedical research, clinical innovation, education and international collaboration. By embedding research within routine care, they accelerate the translation of scientific discoveries into new diagnostics, medicines and treatment approaches, while providing patients with access to cutting-edge clinical trials.

Strengthening Comprehensive Cancer Centres and the networks around them will expand Europe's research capacity, widen access to high-quality clinical trials, reduce geographical disparities in access to new treatment options as well as improving Europe's global competitiveness. These centres should be recognised as strategic research infrastructure, central to Europe's ambition to lead in cancer innovation. Most patients, however, are treated outside them. Their value therefore depends on strong links with regional and community hospitals, so that research and innovation reach patients where they receive care. The EU and Member States should commit to building cancer networks around Comprehensive Cancer Centres that serve entire populations through shared patient pathways, drawing on the OECI Cancer Network Standards.

On protecting the incentives and reasoning for trial conduct in Europe

Seizing the Moment recommends:

Sponsors should be expected to include meaningful participation from European clinical centres in pivotal, multiregional clinical trials intended to support European Medicines Agency (EMA) approval wherever scientifically and operationally feasible.

Marketing authorisation applications relying on pivotal data from clinical trials with limited or no European participation should include a scientific justification demonstrating the relevance and generalisability of the evidence to European populations. Where this cannot be adequately demonstrated, additional evidence

should be expected. The criteria for acceptable justifications, and who assesses them, should be transparent. The criteria should also account for rare cancers, where recruitment within Europe alone may not be feasible.

Further improvements should be examined regarding the publication of geographical recruitment, ethnic diversity and European patient numbers within clinical trials.

On creating new opportunities for value-adding trial research

Seizing the Moment recommends:

The EMA is encouraged to make greater use of post-authorisation evidence generation, including through linkage with European registries, real-world evidence, and independent post-licensing clinical trials, to help confirm effectiveness and safety within European healthcare settings.

Regulators already monitor and act on emerging safety data for licensed medicines, whatever its source. However, no equivalent process exists for efficacy. Evidence that an existing medicine is effective in a new indication, often generated through academic and non-commercial research, may not be systematically captured within the regulatory framework or reflected in the product label. A 'drug evidence watch', as proposed by Pantziarka et al. (2023), could provide a mechanism for regulators to identify and assess such evidence systematically. Just as pharmacovigilance can lead to changes in a medicine's safety profile and label, a similar approach to monitoring emerging evidence on efficacy could support label extensions and, ultimately, broader access to repurposed cancer medicines where supported by robust evidence.

Such an approach could also strengthen Europe's competitiveness by ensuring that high-quality research is translated more efficiently into clinical application, maximising the value of Europe's biomedical research base and making better use of medicines and health-system resources already available.

1.3. From breakthrough to follow-through: addressing barriers to the uptake of cancer research and development

The value chain that goes from research to innovative products that improve citizens' lives in the EU is less effective compared to the US and China.'

Mario Draghi, 2024

Europe needs a stronger ecosystem for the adoption of new technologies and modalities in cancer treatment and care. Above all, this is essential to ensure that patients can benefit from the most effective new diagnostics, treatments and models of care as quickly and equitably as possible, improving outcomes and quality of life. At the same time, a more predictable and efficient pathway from innovation to patient access would strengthen Europe's attractiveness as a place to develop, launch and scale new cancer treatments and diagnostics, giving researchers, healthcare providers and innovators greater confidence that investment in European cancer research will translate into meaningful patient impact.

Cancer care and control technologies are advancing across a wide range of areas, including, for example: new screening technologies, advanced diagnostics, the deployment of genomic technologies to better guide treatment, robot-assisted surgery, radioligand therapy and the integration of artificial intelligence (AI) to improve processes and procedures.

Europe's challenge is therefore to turn this range of scientific breakthroughs into medical follow-through, with new technologies taken up into routine clinical practice.

Cases that demonstrate the problem include:

- **Major delays in patient access to new medicines.** The average time from EMA marketing authorisation to patient availability for oncology medicines is now 655 days across the EU27 – almost 22 months. Only around half of newly authorised cancer medicines are available to patients across Europe, with access varying dramatically between Member States (EFPIA, 2026).
- **Slow implementation of evidence-based cancer screening.** Although the Council of the European Union updated its Recommendation on Cancer Screening in 2022 to include the phased introduction of lung cancer screening for high-risk populations and to encourage risk-based approaches for prostate and gastric cancers, implementation remains limited across much of Europe. Years after the recommendations were agreed, most eligible citizens still do not have access to organised programmes despite strong evidence that earlier diagnosis improves survival.
- **Persistent inequalities in access to modern radiotherapy, advanced surgical technologies and precision oncology.** New technological treatment possibilities such as stereotactic body radiotherapy (SBRT), MR-guided radiotherapy, proton beam therapy and robot-assisted cancer surgery remain concentrated in relatively small numbers of centres and countries. The same situation arises with respect to next-generation sequencing, molecular tumour profiling, comprehensive genomic testing and the use of molecular tumour boards, which are central to the management of many cancers. European professional societies have repeatedly documented substantial geographical variation in access to modern equipment, specialist expertise and multidisciplinary care, meaning that access to new treatment options often depends more on where a patient lives than on clinical need.
- **Uneven adoption of (AI) and digital innovation.** AI has demonstrated considerable potential to improve cancer imaging, pathology, radiotherapy planning and clinical workflow. However, implementation into routine care remains fragmented owing to regulatory uncertainty, interoperability

challenges, workforce readiness and limited digital infrastructure, leaving many validated innovations confined to pilot projects rather than routine clinical practice.

- **Health system capacity as a barrier to advanced therapies.** Cell therapies such as CAR-T have curative potential and require only a single-course treatment, but their delivery requires accredited centres, trained staff, intensive care capacity and functioning referral pathways. Where these are missing, patients are not treated, regardless of whether the therapy is authorised and reimbursed.

Taken together, these examples suggest that Europe's principal challenge is increasingly not the generation of new cancer science or technological possibilities for treatment and cancer control, but its systematic diffusion into routine clinical practice. Improving this 'last mile' of the journey from research discovery to patient care should therefore become a central intersection between Europe's future cancer policy and the EU competitiveness agenda.

1.3.1. Towards a greater 'single market' in translating cancer science into practice?

Europe has enormous collective scale: 450 million citizens, world-leading cancer centres, shared regulatory processes, and many mechanisms to support EU Member States in responding together to challenges in the uptake of new forms of cancer treatment and care.

But there is unexploited opportunity to make use of this scale. Examples include:

a) Turbocharging Europe's position as an oncology data leader.

High-quality oncology data are rapidly becoming one of the most strategic assets underpinning cancer research and development. They enable more efficient clinical research, accelerate the development and validation of AI applications,

improve precision medicine, strengthen health system planning and facilitate continuous improvements in the quality of care. As cancer care becomes increasingly data-driven, Europe's ability to compete globally will depend not only on scientific excellence but also on its capacity to generate, connect and responsibly use high-quality health data at scale.

Europe possesses unique strengths on which to build. Universal healthcare systems, comprehensive cancer registries, organised screening programmes, longitudinal patient records, growing genomic initiatives and strong public trust in health institutions provide foundations that few regions of the world can match. Combined across Member States, these assets represent one of the largest and most diverse oncology datasets anywhere. The challenge is that these data remain fragmented between institutions, regions and countries, limiting their value for patients, researchers and innovators.

Important initiatives are already laying the foundations for a European oncology data ecosystem:

- The European Health Data Space will establish new mechanisms for the secure secondary use of health data for research and development.
- EUCAIM is developing a federated European infrastructure for cancer imaging to support AI development
- The Cancer Data Node Digital Platform developed through the EU Cancer Mission's UNCAN.eu initiative, together with initiatives such as CANDLE and the European Cancer Patient Digital Centre (EU-CIP), demonstrates how interoperable infrastructures can support research, personalised medicine and cross-border collaboration.

The challenge now is to move beyond excellent individual projects towards a coherent, sustainable European oncology data ecosystem.

The European Health Data Space, hopes and concerns

The European Health Data Space (EHDS) Regulation (EU) 2025/327 entered into force in March 2025. It creates a common framework for the secondary use of health data for research, development, and policymaking. Each Member State will set up a Health Data Access Body to grant access to health data for approved purposes. The rules on secondary use will apply in stages, from 2029 for most data categories and from 2031 for others, such as genomic data.

The hopes

For cancer, the EHDS could be transformative:

- Faster identification and enrolment of eligible patients in clinical trials.
- Larger and more diverse datasets for developing and validating AI.
- Better evidence on how treatments perform in routine care.
- Stronger support for rare cancers, where no single country has enough patients to study.

Stakeholders see particular potential for clinical trials and digital pathology, and in connecting the data generated by Europe's registries, screening programmes and cancer centres.

The uncertainties

- Stakeholders raise concerns about privacy and the handling of personally sensitive data, such as genomic information, or data with high commercial sensitivity.
- It is not yet clear what levels and quality of data access will likely be achieved in practice.
- It will place new demands on healthcare providers and on Member States with less developed digital infrastructure.
- Trust will have dependence on how patients and citizens are informed and involved.

What is needed

The European Health Data Space will deliver for cancer patients and Europe's research and development agenda if:

- All Member States are in a position to contribute high-quality data.
- The various sensitivities connected with health data are respected.
- Implementation (and preparation for implementation) is adequately resourced.
- Governance involves all stakeholders, including patients, clinicians, researchers and other impacted, and seeking to bring value, from the European Health Data Space.

***Seizing the Moment* recommends that oncology data infrastructure be recognised as a major strategic asset of the EU: for better care, and for strengthened research and development capacity.**

Europe has invested billions in research laboratories and scientific facilities. The same long-term strategic investment should now be applied to interoperable oncology data infrastructure, recognising that high-quality data are becoming essential research infrastructure in their own right. The existing projects mentioned above are all components of this asset development and should be supported into the future.

But the major digital divides that exist between EU countries cannot be ignored. **Dedicated European investment should support those Member States with the least developed oncology data infrastructures, ensuring that every country can contribute to—and benefit from—the future European oncology data ecosystem.**

National health systems must also align their practices further to embed data collection into routine clinical practice, including structured clinical data, genomic data, and quality-of-life data.

Europe's greatest strategic advantage may not lie in producing more cancer data than any other region, but in producing the world's most trusted, interoperable and clinically meaningful oncology data ecosystem. By connecting high-quality data generated through routine care across diverse populations and

healthcare systems, Europe could create a series of unparalleled platforms for oncology discovery, evaluation and implementation. Such an ecosystem would accelerate research, strengthen AI development, improve patient outcomes and make Europe the preferred location for developing, validating and deploying the next generation of cancer research and development.

b) Strengthening the coordinating mechanisms for EU cancer policy

Over the past four decades, the European Union has progressively established one of the world's most ambitious supranational agendas for cancer policy. From the Europe Against Cancer programme in the 1980s, through to Europe's Beating Cancer Plan, the EU Cancer Mission and allied initiatives such as the European Reference Networks, and numerous research and infrastructure initiatives, EU action has demonstrated clear added value in areas where collaboration between Member States delivers greater impact than national action alone. It has helped establish common priorities, mobilise investment, reduce inequalities and stimulate research and development across the cancer continuum.

Additional recommendations for the improvement of cancer policy coordination that are being promoted by stakeholders within the cancer community at this time include using the European Semester process more systematically to monitor and address cancer policy. Cancer-specific, standardised and comparable indicators could be embedded into the Semester, allowing progress to be assessed country by country and potentially reflected in Country-Specific Recommendations (CSRs).

The EU mission on cancer

The EU Mission on Cancer was launched in 2021 under Horizon Europe. Its goal is to improve the lives of more than 3 million people by 2030 by focusing on prevention, cure and, for those affected, longer and better lives. It works alongside Europe's Beating Cancer Plan and is organised around four objectives:

- Understanding cancer.
- Prevention and early detection.
- Diagnosis and treatment.
- Quality of life.

What it has built

The Mission has created infrastructure of lasting value for cancer research and development. Flagship initiatives include, but are not limited to:

- **UNCAN.eu**, which is developing a European platform for sharing cancer research data.
- **The network of National Cancer Mission Hubs**, linking EU action with national stakeholders.
- **The European Cancer Patient Digital Centre**, supporting patients to access and share their own data.

The challenges

- It is too early to judge how the Mission has improved Europe's competitiveness in cancer research and development.
- Time-limited projects raise challenges in sustainability and scale-up.
- Participation is uneven across Member States, highlighting the East–West divide in funding uptake.

What is needed

- A long-term political and financial commitment to cancer research beyond 2027.
- A plan to sustain the infrastructures it has created.
- Clear indicators to measure the Mission's contribution to patient outcomes and to Europe's competitiveness.

However, the success of EU cancer policy has also generated a new challenge: governance. As a recent report of the European Court of Auditors outlined, although much EU cancer policy is well conceived, highly relevant and delivering significant added value, it needs stronger governance, clearer milestones and indicators, less overlap between initiatives and better monitoring (European Court of Auditors, 2026).

In an era of increasingly complex cancer research and care, coordination has become a critical instrument of success and competitiveness. Better coordination can allow Europe to translate scientific advances into practice more quickly, avoid duplication, scale up

successful pilots, coordinate research priorities, share infrastructure, benchmark performance and accelerate implementation.

Recognising these challenges, several organisations have proposed strengthening Europe's permanent governance arrangements for cancer. Among these, the European Academy of Cancer Sciences (EACS) have argued that, while Europe possesses considerable scientific expertise, it often lacks sufficient coordination to translate discoveries into improved patient outcomes (Adami et al., 2018).

Furthermore, in 2022, the European Parliament's Special Committee on Beating Cancer (BECA) concluded that Europe required stronger coordination of cancer policy and research and called on the European Commission to examine the creation of a European Cancer Institute (European Parliament, 2022). The Committee envisaged such a body as a coordinating hub capable of supporting research, promoting excellence across Comprehensive Cancer Centres, improving implementation of novel technologies, and helping reduce inequalities in cancer care between Member States.

More recently, the European Cancer Organisation has sought to broaden the debate beyond the research community. Its 2025 Green Paper, *Optimising EU Investment in Cancer Research: A Strategic Framework for Better Impact*, reviewed international models, outlined several possible functions for a European Cancer Institute, and launched an open consultation among researchers, clinicians, patients, policymakers and industry. Findings and White Paper recommendations from this exercise will be published later in 2026.

While differing proposals on **an enhanced coordination mechanism for EU cancer policy** can be envisaged, finding a solution to the coordination challenge is an integral part to solving Europe's 'breakthrough to follow-through' problem when it comes to research and development in cancer treatment and care.

c) Enhancing the use of the EU Health Technology Assessment (HTA) regulation.

The HTA Regulation was born out of a desire to avoid duplication across the 27 different EU member state HTA procedures, each with its individual timelines and requirements. To do so, the Regulation has aimed to create a coordinated, EU-level HTA procedure, with a hoped-for purpose of reducing delays, costs, uncertainties, and shortening timelines for new treatments to reach patients. However, while the Regulation brings forward new Joint Clinical Assessments for new therapies, countries may still choose to operate a supplementary assessment on top of the joint one. This continues to provide concern that, contrary to its original intention, the Regulation might in fact lead to additional delays to patient access. **As the operation of the Regulation develops, it may be necessary to provide additional guidance and advice to EU Member States to help limit unnecessary duplication of processes and ensure that assessments consistently reflect the outcomes patients value most, including pain and quality of life.**

Further integration of EMA and HTA requirements and processes should be sought, to ensure commonality in evidence requirements where possible and optimal data sharing between EMA and HTA bodies. Stakeholders contributing to this reported have emphasised that this can be of particular importance to rare and paediatric cancers due to the limited number of patients that can participate in the trials.

Additionally, scientific dialogue and coordinated assessment has scope to better align evidence requirements for new therapies with the diagnostic procedures that are essential for their deployment.

d) Predicting and responding to emergent challenges nimbly and as a community

Europe's approach to cancer research and development must be capable not only of addressing today's barriers, but also of responding rapidly to the emerging challenges that will shape tomorrow's competitiveness. The pace of

change in the global life sciences environment has accelerated considerably in recent years: geopolitical developments, technological disruption, changing investment patterns and supply chain vulnerabilities can alter the conditions for cancer research and the development of new treatments and technologies within a matter of months rather than years. A policy framework designed primarily to address historic challenges risks leaving Europe reactive rather than resilient.

Recent developments illustrate the nature of this challenge. As an example much in conversation at the time of this report's drafting, proposals by the United States administration to pursue a 'Most Favoured Nation' approach to medicines pricing have generated uncertainty regarding the future investment and development environment for new medicines worldwide. While the ultimate consequences remain unclear, such developments underline that policy decisions taken outside Europe may have significant implications for the oncology research and development environment within Europe. Combined with existing concerns over the timeframes by which patients can access improved treatment options, collectively these developments reinforce a need for Europe to promote a policy agenda that supports it remaining a thriving place to discover, develop, and bring to patients, new technological approaches to cancer treatment and care.

Other strategic pressures are also emerging. Competition for world-leading scientific talent is intensifying, while advances in AI, genomics, digital pathology and data-driven research are placing increasing importance on Europe's technological capabilities and digital infrastructure. At the same time, recent experience has demonstrated the importance of resilient supply chains for medicines, diagnostics, medical technologies, radiopharmaceuticals and critical research

materials. Increasingly, these issues extend beyond the remit of health policy alone and intersect with industrial strategy, research policy, trade, digital policy, education and economic competitiveness.

These developments suggest that Europe's competitiveness and success in cancer research and development will depend upon its ability to anticipate emerging risks, assess their potential impact and coordinate timely policy responses. In a rapidly evolving global environment, institutional responsiveness may prove as important as institutional strength.

Responding effectively will require greater coordination both within Member States and across the European Union. Emerging challenges to cancer research and development rarely fall neatly within the responsibilities of a single ministry or Directorate-General. Health ministers, research ministers, finance ministers, industry and trade ministers, together with relevant European institutions and agencies, should be encouraged to engage in more systematic dialogue on issues affecting Europe's cancer research and development ecosystem. Such collaboration would help ensure that policy responses are coherent, timely and aligned with Europe's wider ambitions for competitiveness, economic resilience and health security.

***Seizing the Moment* recommends establishing** a more agile mechanism for strategic foresight and cross-government coordination on cancer research, development and competitiveness. Through regular horizon scanning and structured collaboration between relevant ministries, European institutions, agencies and stakeholders, the European Union should be better equipped to anticipate emerging threats and opportunities, coordinate policy responses and safeguard Europe's attractiveness as a global leader in cancer science, research and development.

2. Identifying today's opportunities for tomorrow's leadership in European cancer research and development

Europe's future leadership in cancer research and development will be determined by its ability to recognise and invest in the technologies and approaches that are now emerging. Global leadership in healthcare research and development is built through sustained support for promising scientific advances, coordinated investment in research and infrastructure, regulatory frameworks that encourage responsible technological advances, and healthcare systems able to support patient access to new treatment options and technologies for disease control.

As previously presented, Europe possesses many of the scientific, clinical and industrial capabilities needed to lead the next generation of cancer research and development. Yet too often these emerging opportunities are viewed in isolation rather than as strategic assets capable of strengthening both cancer outcomes and Europe's wider competitiveness.

Identifying these areas early is therefore not simply a research priority but a strategic policy imperative. Timely recognition can help direct investment, foster collaboration between academia, healthcare providers and industry, build the necessary skills and infrastructure, and create an environment in which innovation can be translated into improved patient care while also supporting Europe's competitiveness agenda.

2.1. Leading the world in cancer innovation: areas of opportunity (a short selection)

The following case studies do not in any way constitute either an exhaustive or comprehensive list of areas of cancer innovation where Europe has a chance to lead the world. Rather they serve as illustrative examples of a much broader whole, the rapidly developing and exciting world of progress in oncology treatment and care.

2.1.1. Radioligand therapy

Radioligand therapy (RLT) is a type of targeted cancer treatment that uses a radioactive drug to find and destroy cancer cells while minimising damage to healthy tissue.

Europe is exceptionally well positioned to become the global leader in radioligand therapy. Over the past decade, European researchers, universities and companies have helped establish one of the world's strongest theranostics ecosystems, with Europe leading many of the pivotal clinical trials that have brought radioligand therapies into routine cancer care. This success has been driven by close collaboration between academia, healthcare providers and industry. Indeed, many European companies are at the forefront of innovation in this field.

The challenge is ensuring that health systems can keep pace with new advances. Radioligand therapy requires specialised multidisciplinary teams, production facilities that meet good manufacturing practice (GMP), dedicated imaging capacity, radiation-safe treatment environments and, in many cases, purpose-built isolation facilities. While major Comprehensive Cancer Centres are increasingly able to provide these services, many hospitals lack the infrastructure and trained workforce needed to deliver treatment at scale. Without coordinated public investment in workforce development and treatment capacity, Europe's scientific advantage risks becoming a bottleneck rather than a competitive strength.

Policy and regulatory frameworks must also evolve to reflect the distinctive nature of radiopharmaceuticals. Existing regulatory pathways have largely been designed for conventional medicines and do not always accommodate the combined diagnostic and therapeutic characteristics of radioligand therapies. Greater alignment between medicines

legislation, radiation protection requirements and rules governing in-house production would provide greater certainty for innovators and healthcare providers alike. **Continued work by the European Medicines Agency to develop clear, proportionate guidance for radiopharmaceuticals should be supported.**

Europe should also pursue a strategic industrial policy for radioligand therapy.

As new indications continue to emerge, demand for medical isotopes, manufacturing capacity and specialist expertise is expected to grow substantially over the coming decade. Strengthening secure European supply chains, supporting domestic production and encouraging continued collaboration between industry, universities and clinical centres would help ensure that Europe remains at the forefront of scientific and clinical progress, while improving resilience against global supply disruptions.

Finally, **professional societies have an essential role in translating new scientific and treatment developments into routine care.** By developing clinical guidelines, supporting professional education, promoting high-quality evidence generation and facilitating collaboration across disciplines, they can accelerate the safe and equitable adoption of radioligand therapies throughout Europe. Policymakers should therefore view these organisations as strategic partners in building a world-leading radioligand therapy ecosystem.

Together, these actions would allow Europe not only to retain its current scientific leadership but to become the world's leading environment for developing, evaluating and delivering radioligand therapies—transforming both cancer outcomes and Europe's global competitiveness in precision oncology.

2.1.2. Digital pathology

Digital pathology is the shift from analysing tissue samples under a microscope to viewing and analysing digitised slide images on screen, enabling AI-assisted diagnosis, remote review and large-scale quantitative analysis.

Europe retains a strong manufacturing base in this field, with several firms among the leading scanner producers. Europe's comparative advantage lies in the clinical application, quality control and training infrastructure required to embed digitisation reliably into routine practice. The European Society of Pathology's expert opinion paper on the digital transformation of pathology (Eloy et al., 2025) sets out recommendations in this area, noting that **a successful transformation requires a multidisciplinary approach and significant investment in human, structural and informatic resources, alongside clear policies on hardware renewal, data storage and interoperability.** It also identifies workforce shortage in pathology as a constraint on adoption, and points to digital transformation as a means of attracting and retaining new entrants to the profession.

There are working examples of coordinated implementation at scale. The DigiPatICS initiative, which is transforming the Catalan Health Institute's network of eight hospitals, offers a documented case of multi-site adoption of digital pathology (Temprana-Salvador et al., 2022). The EU-funded BIGPICTURE project provides a further example (Moulin et al., 2021), bringing together a consortium of major European pathology departments to build a platform for quality-controlled whole slide imaging to support AI development in the field. Both show that success depends on sustained investment in data storage, interoperability, training and change management.

2.1.3. New screening techniques and technologies

Thanks in great part to EU-level frameworks such as the Council Recommendations on Cancer Screening and accompanying EU-supported initiatives, Europe has made great progress in cancer screening methods and programmes. Boosted by Europe's Beating Cancer Plan and the EU Cancer Screening scheme, the evidence generation, implementation science and population-based organisation methods deployed in cancer screening in Europe are of global standing. Such a framework for encouraging uptake of new cancer screening procedures could

have strong application to other areas of cancer care advance, such as precision diagnostics.

The European Council Recommendations on Cancer Screening (first adopted in 2003 and substantially updated in 2022) remain one of the world's most comprehensive policy frameworks for population screening. It promotes organised invitation systems, quality assurance mechanisms, national screening registries, equity of access, continuous evaluation and evidence-based introduction of new technologies, among other principles. As screening evolves, this framework will need to incorporate advances in risk stratification and personalised prevention, so that screening can be tailored to individual risk while preserving equity and population-level impact.

Lung cancer screening: Europe in the lead

Lung cancer screening is a case study of how such EU-level frameworks can promote novel screening technologies and their adoption. Much of the evidence behind the move from low-dose CT screening to routine policy has come from European trials. Major European studies that have greatly advanced understanding and the readiness for adoption of lung cancer screening include: the NELSON trial in Netherlands and Belgium (de Koning et al., 2020); the MILD trial (Pastorino et al., 2019), and the LUSI trial in Germany (Becker et al., 2020). The NELSON trial in particular demonstrated around a 24% reduction in lung cancer mortality among screened men (and potentially greater benefit among women), providing some of the strongest evidence worldwide for CT screening.

The EU has successfully supported follow-on momentum from this research by not only expanding the EU Council Recommendations on cancer screening but also supporting on-the-ground implementation projects such as SOLACE (Strengthening the Screening of Lung Cancer in Europe). This shows how the EU can help move from 'breakthrough' (the proof that lung cancer screening works) to 'follow through' (implementation): more than 30 organisations, including scientific societies, hospitals, national screening programmes, patient organisations and health authorities from 15 European countries, were brought together to develop practical implementation guidance and quality assurance

standards. The SOLACE European implementation toolbox now equips any country in Europe to adopt lung cancer screening with EU support.

Prostate cancer

In Northern and Western Europe, prostate cancer is either the leading or second-leading cause of cancer death in men, and it is the most frequently occurring male cancer in Europe. PRAISE-U is a three-year project funded by EU4Health that aims to promote the early detection and diagnosis of prostate cancer (PCa) in EU countries. PRAISE-U established a multi-disciplinary consortium of 25 institutions from 12 Member States centred around Europe's leading clinicians and researchers. The consortium includes a balance of universities, regional and national public health agencies and healthcare providers, international organisations, civil society, and professional and patient organisations. The project works to encourage smart methods for early detection and helps countries pilot early detection programmes and to reduce morbidity and mortality caused by prostate cancer in EU Member States.

As it comes to the end of the first three years of the programme, the PRAISE-U project represents an important step towards implementation of a modern, risk-based screening pathway for prostate cancer. The pilot projects that were implemented have demonstrated that the screening pathway is both feasible and acceptable in a number of countries and settings. It substantially reduced MRI and biopsy referrals when compared with current unorganised practices. PRAISE U results have revealed the need for more work on ensuring standardisation and quality assurance across different settings, which will be the key aims of the European Commission Initiative on Prostate Cancer in the coming years. With this in mind, the EU has the potential to be a world-leading example of modern, organised, risk-based prostate cancer screening.

2.1.4. New advanced diagnostics

Genomic and molecular diagnostics identify which patients are most likely to respond to a given cancer treatment, and are foundational to the continued expansion of precision cancer medicine.

This category increasingly includes liquid biopsy, the detection of tumour-derived material such as circulating tumour DNA (ctDNA) in blood. It offers a non-invasive alternative to tissue biopsy and can support diagnosis and treatment selection, with its clearest clinical value where tissue sampling is difficult (Manzano et al., 2025). Newly approved ctDNA companion diagnostics also show its potential to guide the timing and sequencing of treatment by tracking resistance mutations as they emerge. (Bartolomucci et al., 2025)

On genomic testing, adoption across Europe remains slow, is too fragmented and quality of testing is mixed. Access is affected by broader inequalities also present elsewhere in cancer care, including recruitment to clinical trials. Availability across Europe is markedly uneven: single-gene techniques are routinely available in most countries in the WHO European Region, but availability drops sharply for more advanced technologies. Large next-generation sequencing (NGS) panels, whole-exome and whole-genome sequencing, and tumour mutational burden testing still largely confined to research settings and notably less available in Eastern Europe than in Western Europe (Bayle et al., 2023). In most EU countries, fewer than a quarter of tumours were analysed using NGS as of 2020 (Normanno et al., 2022). Regulatory and procedural friction continues to constrain the translation of genomic diagnostics from research into routine clinical practice.

Reimbursement presents a significant barrier to adoption. Innovations in genomic testing can face difficulty securing reimbursement even where clinical benefit is established (European Cancer Organisation, 2024). Reimbursement of genomic testing was identified as a barrier to multigene testing in 59% of countries surveyed, compared with 24% for single-gene techniques (Bayle et al., 2023). This fragmentation is also visible at the regulatory qualification stage: of 86 biomarker submissions reviewed by the European Medicines Agency between 2008 and 2020, only 13 received full qualification, with most rejections turning on unresolved questions about biomarker properties, study design and assay validity rather than fragmented adoption per se (Bakker et al., 2022). The consequences are visible at patient level: one survey found that a third of cancer patients

were never tested for biomarkers before starting treatment, meaning a proportion of patients begin therapy without knowing whether a targeted option exists (Cancer Patients Europe, 2025).

Cancer screening offers a useful comparator: EU-level recommendations and national screening schemes have established a clearer framework for accountability and uptake, an approach not yet replicated for genomic and other diagnostic technologies.

Europe's position in new diagnostics reflects a gap between scientific capability and the adoption structures needed to translate that innovation into practice at scale. Closing this gap requires action on several fronts:

- Reimbursement and HTA frameworks should move away from separate budgets for diagnostics and medicines towards whole-value assessment, recognising that a test's value lies in the treatment decisions it enables.
- Reimbursement timelines for tests and their associated therapies should be aligned, as access too often breaks down after EMA approval.
- A simplified regulatory pathway for modifications to approved tests would allow diagnostics to keep pace with scientific progress.

2.1.5. Interventional oncology

Interventional oncology uses imaging to guide minimally invasive treatments directly to a tumour, through ablation, which destroys tumours with heat or cold, or through therapies delivered via the blood vessels feeding a tumour. It is already established care in liver cancer, where guidelines from the European Association for the Study of the Liver (EASL) recommend liver resection or thermal ablation without preference for patients with cirrhosis and a single tumour of 2 cm or less who are not candidates for transplantation (European Association for the Study of the Liver, 2025).

Its reach is now widening. The European COLLISION trial found that ablation matched surgery for survival in patients with small colorectal liver metastases, while causing significantly fewer complications (van der Lei et al., 2025). In breast cancer, five-year

results from the ICE3 trial showed that freezing small, low-risk tumours without removing them left an estimated 95.7% of older women free of recurrence in the treated breast at five years, with no serious device-related complications (Fine et al., 2024). These procedures usually avoid general anaesthesia and long hospital stays, so they also tend to cost less and allow faster recovery.

Yet interventional oncology remains among the least recognised fields in European cancer policy. Interventional radiology has formal subspecialty status in only 11 of 29 European countries surveyed, with structured training in 17, compared with the United States, where it has been a primary specialty since 2012 (CIRSE European Trainee Forum Subcommittee, 2024).

Access and reimbursement vary widely, and these treatments are often absent from guidelines and multidisciplinary decision-making. European initiatives are working to close the gap, including the quality standards of the curriculum of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) and the IASIOS accreditation system launched in 2021. Assessment frameworks, however, often struggle to value innovation whose benefits are avoided surgery, shorter procedures and faster recovery.

2.2. An EU Strategy for Cancer Research, Development and Implementation

As highlighted throughout *Seizing the Moment*, a coordinated approach should be central to the development of any EU agenda that places cancer research and development within an overall competitiveness strategy for the bloc.

***Seizing the Moment* recommends that cancer research and development be given a recognised and strategic place within the EU's Competitiveness Agenda,**

including through the creation of an EU Strategy for Cancer Research, Development and Implementation. Such a strategy can address critical themes outlined in this paper, including the need for a coordinated strategic approach to research, regulation, industrial policy, manufacturing requirements and workforce considerations, among others. The full opportunity for European global leadership in cancer research and development cannot be achieved unless each area of policy need is addressed effectively and together.

In further activities of ECO's Reach Higher for Cancer Care campaign, additional recommendations on the themes and contents for such a strategy will be brought forward following multi-stakeholder dialogue and consultation. A pillared approach could support development of advances in cancer care across prevention, detection, diagnosis, treatment and survivorship.

3. The regulatory agenda for improving European cancer research, science and implementation

An important component of the EU's new agenda for competitiveness policy has been a greater focus on addressing regulatory burdens across sectors, reflected in part by the new EU Biotech Act. This legislative proposal seeks to address issues of regulatory fragmentation, lengthy clinical trial approval timelines, regulatory duplication and burdensome regulatory support requirements for small and medium-sized enterprises (SMEs).

Seizing the Moment welcomes the chance this agenda provides to re-examine the opportunities for better regulation. Furthermore, it must be recognised that the opportunities for improvement are broad, and go beyond only those regulations covered in the Biotech Act. The table below gives a summary of EU regulations and their intersection with cancer innovation. Two regulations are singled out for particular attention as having not yet featured significantly in discussions about the EU Competitiveness Agenda.

A Professional Qualifications Directive that can keep pace with scientific discovery and progress

The operation of the EU Professional Qualifications Directive must be considered as a component of the competitiveness agenda. The EU Professional Qualifications framework is important for cancer research because it enables the recognition of qualifications across Member States, making it easier for oncologists, pathologists, radiologists, specialist nurses, medical physicists, and other highly skilled professionals to work and collaborate across borders. Yet the mechanisms of the EU Professional Qualifications Directive have not kept pace with the increasing specialisation and multidisciplinary nature of modern cancer care and research. For example, the national implementation of cancer workforce recommendations is uneven, including the development and recognition of subspecialised roles encouraged under Europe's Beating Cancer Plan (i.e. subspecialisation in surgical oncology). A more agile mechanism for recognising new specialties and subspecialties is required and the Directive should be reopened for this purpose.

Tying up the loose ends of GDPR implementation

The goals of the EU's General Data Protection Regulation (GDPR) are laudable, as it set out to replace a complicated patchwork of national data protection laws with a common legal framework across the EU. For research, the Regulation to a large (but not full) extent helps to provide increased legal certainty when conducting research across countries. The Regulation also serves to increase trust, transparency, accountability and oversight in data use in all EU countries.

However, there is further potential to improve the implementation of the GDPR and address legitimate concerns from stakeholders. There has been unwelcome divergence in GDPR's interpretation and implementation at national levels. Researchers conducting multinational clinical trials often complain that they are required to satisfy different interpretations of:

- Legal bases for processing data.
- Ethics committee requirements.
- National data protection rules.
- Biobank legislation.
- Genomic data rules.

For pan-European oncology trials involving 10–20 countries, this substantially increases complexity and delays. Other complaints refer to: uncertainties under the legislation concerning the secondary use of data: confusion between research consent and GDPR consent; difficulties in international data transfer; and, general accumulation of compliance burden.

These complaints may be remedied by heightening EU-level guidance on GDPR interpretation. The European Data Protection Board could be mandated to greater levels of proactivity on these matters for example. **Improving the consistency and proportionality of GDPR implementation, especially within critical areas of research, such as cancer, should be a high priority for the next stages of the EU's Competitiveness Agenda.**

3.1. EU Regulations and their intersection with the development of new technologies and approaches for cancer treatment and care: a review

EU Regulation: The EU Clinical Trials Regulation (CTR)		
Why it matters for the development of new technologies and approaches for cancer treatment and care in Europe	The concerns from stakeholders	The way forward
In theory, the EU Clinical Trials Regulation is designed to make Europe a more attractive place to conduct clinical research by harmonising and simplifying the approval and oversight of clinical trials across Member States.	Implementation of the EU Clinical Trials Regulation has been uneven, with continuing delays, and inconsistent interpretation of requirements between Member States. Furthermore, stakeholders have identified a series of ways in which bureaucracy associated the interpretation of Clinical Trials Regulation requirements could be reduced. A review of the Regulation is scheduled for 2027. Nevertheless, it remains to be seen how this will be conducted, or whether its review within the Biotech Act will be considered to have been sufficient.	● Strengthen harmonisation of Member State interpretation of ethics review processes. ● Reduce administrative burden by streamlining documentation and reporting requirements. ● Improve the EU Clinical Trials Information System to make workflows for multinational trials less cumbersome.

EU Regulation: The EU Medical Devices Regulation (MDR)

Why it matters for the development of new technologies and approaches for cancer treatment and care in Europe	The concerns from stakeholders	The way forward
The MDR determines how quickly and efficiently new diagnostic technologies, imaging equipment, radiotherapy devices, digital pathology tools and other medical devices reach patients and clinical practice.	Implementation of the MDR has been plagued by shortages of notified body capacity, contributing to lengthy and unpredictable conformity assessment timelines.	● Increase the transparency of the certification process by openly publishing performance metrics for notified bodies. ● Develop common service standards between notified bodies, including indicative timelines for each stage of conformity assessment. ● Increase the publication of guidance from Medical Device Coordination Group, including detailed guidance on the evidence expected for different classes of devices.



EU Regulation: The EU's In Vitro Diagnostic Medical Devices Regulation (IVDR)

Why it matters for the development of new technologies and approaches for cancer treatment and care in Europe	The concerns from stakeholders	The way forward
The IVDR is critical to cancer innovation because it governs the approval and availability of diagnostic tests—including biomarker and companion diagnostics—that identify which patients are most likely to benefit from targeted therapies, immunotherapies and precision medicine.	Preparing technical documentation, generating additional clinical and performance evidence, implementing quality management systems, and undergoing notified body assessment have increased compliance complexity. A 2026 study from the Vall d'Hebron Institute of Oncology (VHIO) analysed 502 oncology clinical trials between 2023 and 2025. Among trials requiring IVDR approval for non-CE-marked biomarker tests: ● Median time to regulatory approval increased from 112 days to 194 days (an additional 82 days). ● Median time until trials could open at participating hospitals increased from 221 days to 270 days (around 7 weeks longer). Furthermore, once a product is approved, subsequent updates and iterative improvements are hindered by the lack of a simplified regulatory pathway for test modifications.	● Apply greater regulatory flexibility for lower-risk and well-established technologies. ● Simplify requirements for modifications to existing tests where the underlying technology is already well validated. ● Harmonise documentation requirements across notified bodies. ● Better harmonise how notified bodies interpret evidence requirements. ● Improve consistency between notified bodies through enhanced coordination, common training and clearer guidance. ● Expand use of digital regulatory processes including tracking of application status to reduce administrative delays.

EU Regulation: The EU General Data Protection Regulation (GDPR)		
Why it matters for the development of new technologies and approaches for cancer treatment and care in Europe	The concerns from stakeholders	The way forward
The GDPR plays a pivotal role in cancer research because it governs how personal health data can be collected, shared and reused for clinical trials, biomarker discovery, AI, and real-world evidence generation—all of which are essential for developing new cancer treatments	Implementation has often made health research more difficult than intended. A major concern is the inconsistent interpretation and application of the Regulation by Member States and national data protection authorities, creating legal uncertainty for multinational cancer studies, registries, and clinical trials.	● Create clearer, binding EU-level guidance on the application of GDPR to health research. This would reduce the current patchwork of national interpretations that complicates multinational cancer studies. ● Clarify the legal basis for scientific research, particularly the use of the “scientific research” provisions and public interest grounds, so that researchers and institutions have greater legal certainty when processing health data. ● Reduce unnecessary administrative burdens by streamlining ethics and data protection approval processes, adopting standardised documentation, and promoting mutual recognition of assessments where appropriate.

EU Regulation: The EU Health Technology Assessment (HTA) Regulation		
Why it matters for the development of new technologies and approaches for cancer treatment and care in Europe	The concerns from stakeholders	The way forward
The EU HTA Regulation aims to streamline the clinical assessment of new medicines, including cancer therapies, through joint EU-level evaluations, reducing duplication across Member States and potentially accelerating patient access to newly approved treatment options.	Because of compromises in the finalisation of the regulation, the HTA Regulation's Joint Clinical Assessments has the possibility of creating additional duplication and delay if many countries choose to operate their own parallel HTA systems on top of the Regulation's requirements. There are also concerns about whether the new coordination structures have sufficient resources, expertise and capacity to deliver high-quality assessments within ambitious timelines, particularly for complex cancer medicines and precision oncology.	● Strengthen early scientific dialogue. Expand opportunities for joint scientific consultations between HTA bodies, regulators, developers, clinicians and patients so that clinical trials generate evidence that satisfies both regulatory approval and HTA requirements from the outset, reducing uncertainty later. ● Develop more detailed guidance on issues such as indirect treatment comparisons, surrogate endpoints, real-world evidence, biomarker-defined populations and evidence generation for rare cancers, in order to improve consistency across assessments.

EU Regulation: The EU Professional Qualifications Directive		
Why it matters for the development of new technologies and approaches for cancer treatment and care in Europe	The concerns from stakeholders	The way forward
The EU Professional Qualifications framework is important for cancer research because it enables the recognition of qualifications across Member States, making it easier for oncologists, pathologists, radiologists, specialist nurses, medical physicists, and other highly skilled professionals to work and collaborate across borders. By supporting workforce mobility and the rapid sharing of expertise, the framework helps strengthen multinational clinical trials, research networks, and centres of excellence, making Europe a more attractive and globally competitive location for developing and evaluating new forms of cancer treatment and care.	The mechanisms of the EU Professional Qualifications Directive have not kept pace with the increasing specialisation and multidisciplinary nature of modern cancer care and research. While the Directive has improved mobility for many regulated professions, recognition procedures can still be slow, administratively burdensome, and applied inconsistently by national competent authorities, creating barriers to recruiting specialist staff for research projects and Comprehensive Cancer Centres	● Create a more agile mechanism for recognising new specialties and subspecialties. A more flexible system should allow emerging disciplines—such as molecular pathology, cancer genomics, theranostics, interventional oncology and advanced oncology nursing—to be recognised more quickly once they have established European training standards. ● Reform the Directive to give greater recognition of Europe-wide curricula and competency frameworks developed by specialist societies. ● Expand the Common Training Framework mechanism to oncology-related disciplines, allowing specialist qualifications to be recognised more consistently without requiring a full legislative amendment.

EU Regulation: The EU AI Act		
Why it matters for the development of new technologies and approaches for cancer treatment and care in Europe	The concerns from stakeholders	The way forward
The EU AI Act sets the rules for AI systems used across the cancer pathway, from image analysis in screening and digital pathology to risk prediction, radiotherapy planning, robotic surgery and clinical trial recruitment. AI-enabled medical devices and in vitro diagnostics that require notified body assessment are classed as high-risk. The Act therefore directly shapes how quickly these tools reach patients, and whether Europe can turn its research and data strengths into AI leadership in oncology.	The AI Act overlaps with the MDR, IVDR, GDPR and the European Health Data Space, creating parallel assessments and duplicated documentation for the same product, from conformity assessment through to the disclosure of confidential technical data. Clinicians report that even prognostic tools can face certification requirements under both the MDR and the AI Act. Risk classification does not always reflect how a technology is used. Robotic surgery systems, for example, can face higher-risk procedures even though the surgeon remains in full control. Harmonised standards, guidance and notified body capacity are still being developed, creating uncertainty for developers and hospitals. The Digital Omnibus on AI (Regulation (EU) 2026/1744) postponed high-risk obligations for AI in regulated products, including medical devices, to 2 August 2028. However, it did not resolve the duplication with sectoral legislation, which has been left to the separate MDR and IVDR simplification process. Finally, complex consent requirements and restrictive data-sharing rules can limit access to the large, high-quality datasets needed to train AI tools.	● Deliver a single, integrated conformity assessment for AI-enabled devices and diagnostics through the MDR and IVDR revision, removing duplicate requirements. ● Align risk classification with real-world use, taking account of the level of human control over a technology. ● Publish harmonised standards and joint guidance from the AI Office and the Medical Device Coordination Group well ahead of 2028. ● Clarify research exemptions and expand regulatory sandboxes and real-world testing for clinical AI. ● Ensure the European Health Data Space and GDPR guidance enable responsible access to high-quality data for training and validating AI. ● Invest in notified body capacity and in AI literacy across the cancer workforce. ● Monitor the Act's impact on cancer research and development and adjust requirements that add burden without improving safety.

4. Into the future: Our call for action

On embarking on a journey to heighten its global position in the research and developments of new technologies for cancer treatment and control, Europe does not start from a position of weakness. It possesses many of the assets that other regions seek to build: world-leading scientists and clinicians, internationally recognised cancer centres, an extensive network of research collaborations, sophisticated regulatory institutions, and a long tradition of scientific excellence.

Through Europe's Beating Cancer Plan, the EU Cancer Mission, the European Health Data Space and many other collaborative initiatives, Europe has also created a policy architecture that is unmatched in many parts of the world.

Europe already has a high global standing in scientific excellence in researching new cancer treatments and technologies. The case for an EU Strategy for Cancer Research, Development and Implementation rests on being able to convert that excellence into faster patient benefit, and, with that, greater global competitiveness.

The recommendations presented in this paper are therefore not intended simply as proposals for improving cancer policy. They are recommendations for strengthening Europe's wider cancer research and development ecosystem through one of the most scientifically dynamic and economically significant sectors of modern healthcare. Success in cancer research and development brings multiple dividends simultaneously: longer and healthier lives for citizens, greater resilience of healthcare systems, stronger research capacity, more attractive conditions for investment, highly skilled employment, industrial growth and increased strategic autonomy in one of the world's fastest-moving technological fields.

Europe's emerging Competitiveness Agenda provides a rare opportunity to bring these objectives together. If competitiveness policy, industrial strategy, research policy and health policy can be aligned around a common ambition, Europe can establish itself not merely as a centre of scientific discovery, but as the world's preferred environment in which new technologies and approaches for cancer treatment and control are developed, evaluated, manufactured, adopted and made rapidly available to patients. In doing so, Europe would demonstrate that improving health and strengthening competitiveness are not competing priorities, but mutually reinforcing objectives.

Around the world, competitors are investing heavily in life sciences, AI, biotechnology and precision medicine. The pace of change is accelerating. Countries that create the most supportive environments for cancer research and development today will define the standards of cancer care, attract investment, develop the industries and create the skilled employment of tomorrow.

Europe has every opportunity to lead this new era. The scientific foundations exist. The clinical expertise exists. The collaborative culture exists. Increasingly, the political momentum exists. What is now required is the determination to match these strengths with policies that enable cancer research and development to move more rapidly from laboratory discovery to routine patient care. If Europe succeeds, it will not only improve outcomes for millions of people affected by cancer, but reinforce its position as one of the world's leading centres of scientific excellence, technological innovation and sustainable economic prosperity.

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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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