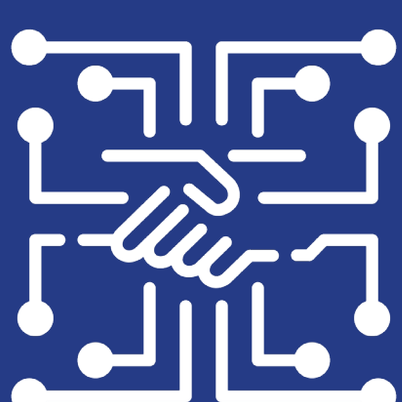
european cancer ORGANISATION

# Harnessing AI for Cancer Care in Europe

## Opportunities, Challenges, and Policy Recommendations



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# Acknowledgements

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### Contributors

Enormous thanks are due to all those members of the Digital Health Network, and other members of the European Cancer Organisation and its Patient Advisory Committee, who took the time to comment on various drafts of this report, provide reference material, advice and other commentary.

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# Executive Summary of Recommendations

Artificial intelligence (AI) offers transformative potential to improve cancer prevention, diagnosis, treatment, survivorship and research across Europe. Realising these opportunities requires coordinated action to ensure ethical use, legal clarity, data quality, professional readiness, and patient trust.

## Key Recommendations for EU Institutions and Member States:

1. Establish clear national standards for AI in cancer care, with specialty-specific validation frameworks and robust post-market monitoring, co-created with oncology professionals and patient representatives.

2. Allocate EU funding to implement EU Ethics Guidelines for Trustworthy AI, promote environmentally sustainable AI, and enhance inclusiveness and representativeness of oncology data.

3. Develop a voluntary EU product certification scheme for AI in health and cancer care, modelled on existing EU level data protection and cybersecurity certification frameworks to ensure transparency and trust.

4. Clarify legal responsibilities for healthcare professionals and institutions using AI, providing plain-language guidance and fostering collaboration among regulators, trade associations, and companies.

5. Guarantee patient and caregiver representation in EU and national decision-making on AI in cancer care, including in bodies such as the EHDS Management Board.

6. Invest in pan-European AI training initiatives and set measurable EU-level literacy goals, aiming for at least 50% of oncology professionals to be confident in AI use by 2035.

7. Provide clear EU guidance and independent reporting on GDPR and AI Act implementation, ensuring continuous improvement through strong clinician and patient involvement.

8. Use the European Health Data Space to harmonise data infrastructures, modernise cancer registries, and support Member State investments to build representative and unbiased datasets.

9. Deploy EU Multiannual Financial Framework (2028-2034) funding to make Europe a global leader in AI for cancer care, considering the creation of a European Cancer Institute to coordinate long-term initiatives in oncology, including AI.

# Foreword

**Annemiek Snoeckx**

**Alexandru Eniu**

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Across the world, societies are entering an era of profound transformation powered by Artificial Intelligence. Cancer care in Europe is an integral part of this change. From prevention and early detection to diagnosis, treatment, survivorship, quality of life, and research, AI is rapidly expanding its role, offering new opportunities to achieve long-held ambitions for precision, quality and equity in cancer control.

AI is reshaping what is possible, and with it comes a call to address emerging challenges. Innovation is advancing fast, and health systems must adapt responsibly, balancing progress with the duty to protect patient safety and trust in evidence-based implementation. Recognising these demands, the European Cancer Organisation's Digital Health Network has convened experts, practitioners and patient representatives to explore how Europe can best employ AI's transformative potential for cancer care.

This paper, Harnessing AI for Cancer Care in Europe: Opportunities, Challenges, and Policy Recommendations, reflects a period of rich dialogue and collaboration. It sets out a roadmap for action, calling for trustworthy standards, ethical oversight, legal clarity, data quality, workforce preparedness and sustained investment. These steps are essential to ensure that AI in oncology remains patient centred, equitable and environmentally responsible.

Europe has long pioneered high standards for science, health and ethics. Now is the moment to extend that leadership to the responsible integration of AI in cancer care. With coordinated effort, forward-looking policy and shared commitment, we can transform innovation into tangible progress, enhancing outcomes for patients, and supporting health professionals in their role.  This way we can reaffirm Europe's role as a front runner in cancer research and care.

We extend our gratitude to all our valued stakeholders who have engaged with this paper and have contributed to the conversation. Together, through vision, collaboration and trust, we can shape a future where AI becomes a true ally in Europe's mission to defeat cancer.

# 1. Scope and Purpose

Industries, service providers, manufacturers, and entire economic sectors across the globe are in the midst of an era of profound transformation as a result of the innovation-stimulating impacts of current AI technology adoption. Cancer care in Europe is no exception to this rule. The use of AI is both widening and deepening, providing support for interventions at all stages of the cancer care continuum: from prevention, early detection and diagnosis, treatment, to post-treatment and research. Whilst this is occurring, AI technology itself continues to rapidly evolve, leading to situations in which both governments and health systems often struggle to keep pace with the development of regulatory and oversight needs.

In this spirit, the European Cancer Organisation's Digital Health Network is determined to convene key stakeholders in relevant areas to:

- **Explore how AI is presently being applied in cancer care;**
- **Examine the future potential of AI to support progress in cancer care and control;** and,
- **Advance timely policy recommendations to overcome obstacles and manage risks in applying AI to cancer care and control.**

The following paper reflects the conversations, contributions and suggestions brought forward during 2025 by a wide range of experts, individuals and associations, duly recognised in the Acknowledgements section.

We welcome further debate and comment upon our conclusions and recommendations and duly furnish them towards relevant policy decision-makers across Europe.

Further rapid advances in the deployment and possibilities of AI in cancer care can be reasonably expected in the years to come. ECO's Digital Health Network therefore anticipates additional positioning and interventions on the AI and cancer policy debate that will build upon Harnessing AI for Cancer Care in Europe: Opportunities, Challenges, and Policy Recommendations. This is especially the case given timely developments in the wider, yet highly connected, political context. This includes the preparation of and agreement upon a new 7-year EU multiannual financial framework, the advent and implementation of a new EU 'Competitiveness' Agenda, and the further implementation of Europe's Beating Cancer Plan and the EU Research Mission on Cancer.

# 2. AI and Cancer: Review and Commentary upon the Opportunities

## AI Application across the Cancer Care Continuum

Use cases for AI in cancer care and control are emerging at a rapid rate. For the purposes of brevity and succinctness, our paper does not set the ambition of providing an exhaustive list of all known new applications of AI in cancer care.

Rather, we aim to provide a flavour. In so doing, the comprehensiveness of the technology's applications towards improvement is conveyed. AI provides new opportunities to achieve long-held ambitions for high-quality cancer care and control.

The following is a brief overview of how AI is already transforming multiple areas of cancer care:

**Areas of cancer care being transformed by artificial intelligence**

| In supporting primary prevention of cancer | In achieving earlier detection of cancer |
|---|---|
| • Potential for greater and faster access for citizens to tailored and reliable health information<br>• AI agents supporting individuals with smoking cessation and other health behaviour improvements<br>• Improved research possibilities for currently unknown/unproven carcinogens. | • AI chatbot support to individuals with concerns about symptoms<br>• Improving health literacy about early warning signs<br>• AI application in risk stratification for cancer screening invitation<br>• At-risk stratification for raising individuals' awareness on their at-risk status for certain cancer types<br>• AI already in use for improving speed and accuracy of screening results |
| **In improving diagnosis efficiency** | **In improving treatment approaches** |
| • Automated triage of imaging studies to prioritise suspected cancer cases for faster reporting<br>• AI-driven quantification of tumour burden (e.g. volume) to support diagnosis and staging<br>• AI-assisted image interpretation to detect lesions<br>• Predictive models to estimate the likelihood of malignancy in indeterminate lesions<br>• Deep-learning-based image reconstruction techniques to improve image quality while reducing radiation dose<br>• AI tools to standardise and automate reporting<br>• Integration of imaging and clinical/genomic data through AI models for differential diagnosis<br>• Radiomics and texture analysis to identify imaging biomarkers predictive of histology, subtype, etc.<br>• AI applications in flow cytometry analysis, blood smear interpretation, and minimal residual disease detection | • Support in the creation of personalised treatment plans<br>• Support in checking and predicting drug interactions<br>• Increasing inter-investigator alignment (potentially lower bias of human error in analysis)<br>• Support in documenting patient visits through ambient listening to allow for more time spent directly with the patient<br>• Prediction of treatment outcome<br>• Improving efficiency in care planning<br>• AI-driven image guidance, auto-segmentation, auto-planning, and motion tracking to enhance precision and to streamline workflow in adaptive radiotherapy<br>• AI-guided surgery<br>• Anticipating potential adverse drug reactions<br>• AI assistance to tumour boards<br>• AI assistance for biomarker testing<br>• AI supported education to help ensure all in the cancer care team are up to date in knowledge, skills and competence<br>• AI-driven donor matching algorithms for stem cell transplantation |

| | |
|---|---|
| | • AI for optimising conditioning regimens pre-transplant<br>• Toxicity prediction in intensive chemotherapy protocols |
| In enhancing policies for cancer patient survivorship and quality of life needs | In improving the efficiency and productivity of cancer research |
| • AI therapy companions<br>• Support social prescribing<br>• use of AI to interpret patient-reported outcomes (e.g., pain, fatigue, nausea) and flag when interventions are needed<br>• Better anticipate severe toxicities from chemo/ radiotherapy (e.g., neutropenia, neuropathy) and recommend supportive care adjustments<br>• Improving access to patient support tools online, with the possibility to reach vulnerable populations easier | • AI to speed up and optimise the drug discovery process<br>• Summarisation of complex longitudinal medical notes to support continuity of care with different providers<br>• Supporting researchers in quickly synthesising already available knowledge<br>• Opening new possibilities for drug repurposing<br>• Employing deep learning to identify hidden mutational signatures and tumour subtypes<br>• Improved stratification of patients for clinical research<br>• Improved clinical trial recruitment by linking patients with relevant clinical trials<br>• Time-efficiency in meeting administrative requirements of clinical trials<br>• Delivering benefits of real-world data application<br>• Opening new possibilities for research into cancer causation |

In the compilation of this paper, the author team conducted outreach with stakeholders to bring forward their commentary upon the identified opportunities. What follows is a summary of some of the views brought forward.

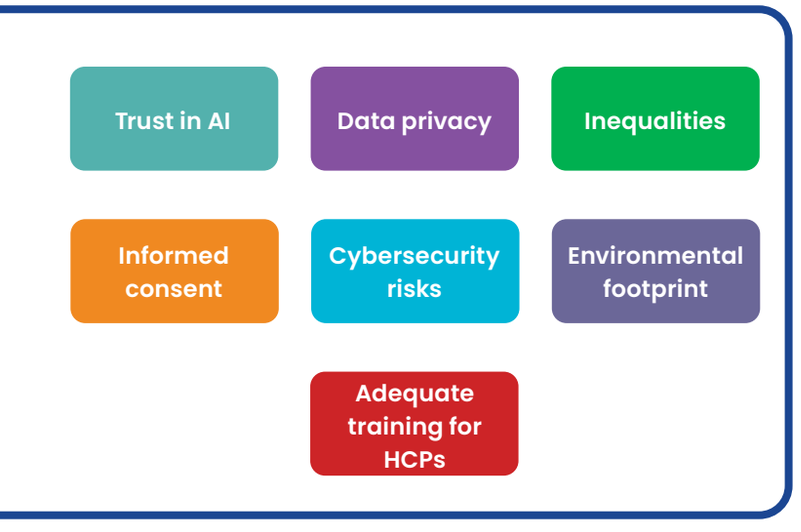
Overall, the European Cancer Organisation and its member community broadly welcome the opportunities that artificial intelligence heralds for improvement across all areas of cancer care. However, care and attention are required in order to meet implementation challenges, including in respect to trust, privacy, inequalities, training for healthcare professionals and other healthcare staff, and environmental impact among others. The following section examines those challenges and makes connected recommendations.

# 3. AI and Cancer: Responding to Identified Concerns

ECO's Digital Health Network, while ultimately optimistic and enthusiastic about the overall benefits that can be achieved from effective deployment of AI in cancer care, nevertheless recognises some of the concerns and risks linked to its use. It is appropriate that political, regulatory and health system decision-makers be alert to these and be ready and informed to respond in time.

Medical use of AI is considered high-risk under the EU Artificial Intelligence Act[1] due to inherent risks that may impact patient wellbeing. Certain Generative AI applications, such as chatbots, may fall under the low-risk category, depending on the specific usage. However, there is a need to be aware of data input sources, as well as data protection. When implementing new digital technologies there are several safety implications that need to be taken into account.

Several ethical concerns have been identified:




Ensuring trustworthy AI application in cancer care is a central priority. The risk of deteriorating the quality of the overarching interaction between patients and healthcare systems should not be underestimated. When introducing AI applications at different steps of the cancer pathway, the relationship between patients and cancer care professionals should be safeguarded.

Ultimately, innovation acceptance relies on public trust. Securing trust in AI as a tool capable of assisting healthcare professionals in their decisions and actions is essential. This requires particular attention on informed consent, transparency (algorithms, codes, datasets, etc.) and health data protection, as well as strong scientific evidence confirming the tools' accuracy, safety and clinical effectiveness, both in medical research and at every step of the care pathway.

Health data is protected under GDPR article 9[2], recognised as a "special category" implying specific and robust safeguards aimed at ensuring data privacy (e.g. obligation to obtain explicit patient's consent). AI's application to healthcare must develop within this existing regulatory framework, for the purpose of protecting personal and sensitive data and ensuring continued trust of patients in the healthcare system.

These concerns associated with AI application in cancer, and healthcare in general, call for thorough regulation and strong implementation frameworks at both national and EU levels. Governments and the EU regulatory framework have a critical role to play in protecting citizens against the threats outlined herein and should be considered as means of achieving stability and clarity.

The following sections consider different frameworks to protect citizens' rights and serve public interest when applying AI solutions within cancer care.

# 4. Trustworthy AI in Cancer Care and Cancer Research

The use of artificial intelligence in cancer care and research is not only a matter of performance: it is also about trust, accountability and patient safety.

Treating AI as traditional software is insufficient, particularly when algorithms perform differently across patient groups. Establishing clear standards for accountability, transparency, and clinical validation, alongside mechanisms to trace and explain AI-driven decisions, will be essential to protect patients and provide legal certainty for healthcare providers and developers. ASCO's six guiding principles for AI in oncology[3] can serve as a basis:

- **Transparency** – AI tools and applications should be transparent throughout their lifecycle.
- **Informed Stakeholders** – Patients and clinicians should be aware when AI is used in clinical decision-making and patient care.
- **Equity and Fairness** – Developers and users of AI should protect against bias in AI model design and use and ensure access to AI tools in application.
- **Accountability** – AI systems must comply with legal, regulatory, and ethical requirements that govern the use of data. AI developers should assume responsibility for their AI systems, its decisions, and their adherence to legal, regulatory, and ethical standards.
- **Oversight and Privacy** – Decision-makers should establish institutional compliance policies that govern the use of AI, including protections that guard clinician and patient autonomy in clinical decision-making and privacy of personal health information.
- **Human-Centred Application** – Human interaction is a fundamental element of health care delivery; AI does not eliminate the need for human interaction and should not be used as a substitute for sensitive interactions that require it.

In cancer care, where the stakes are often life and death, uncertainty when it comes to AI tool deployment is especially concerning, as a missed tumour, an overlooked genetic risk, or an inappropriate treatment recommendation can clearly have the most serious of consequences. Building trustworthy AI in this field requires accountability, transparency, and rigorous clinical validation, alongside strong, well-coordinated oversight and efforts to ensure that patients and healthcare professionals feel confident using these tools.

Ultimately, trust will not come from technical accuracy alone. AI implementation frameworks should be grounded in clear rules, fairness and accountability to make the system as safe as it is smart. Maintaining a human-in-the-loop approach, where clinicians are actively involved in the development and deployment of AI-based tools is also required. At the same time, their successful adoption depends on practical integration into clinical workflows, including the management of findings and diseases.

## To meet the challenge of AI trust, Harnessing AI for Cancer Care in Europe recommends:

- All national health systems work to achieve clear standards for accountability, transparency, and clinical validation of AI tools within cancer care systems. ASCO's six guiding principles for AI in oncology can serve as a basis. This should include:
    - The development of specialty-specific validation frameworks for AI algorithms and their implementation in different oncology fields.
    - The development of robust post-market surveillance systems, as a framework for ongoing monitoring and reporting is essential for maintaining trust and patient safety.
- Such national standards for AI adoption in cancer care systems, should be public and well communicated, as well as co-created and validated with oncology professionals and patient advocates.

### 4.1. Promoting a Digital Health Ethics Approach

The adoption of AI in cancer care must be more broadly guided by ethical principles that protect patients, support healthcare professionals, and promote societal trust. Such concepts have been helpfully advanced by a range of government level initiatives including:

- The EU Ethics Guidelines for Trustworthy AI (2019)[4] – which later formed the basis of the EU AI Act
- The OECD AI Principles (2019)[5] – later adopted by the G20

More recently, this has been supplemented by a further expression of European ethical principles for digital health adoption, that were formulated and promoted under the French Presidency of the European Union Council in 2022, providing a useful conceptual framework for responsible AI and digital innovation.[6]

Subsequent to 2019, recognition has continued to grow about the environmental considerations to be made about AI and digital health use. Training large AI models, for example, consumes significant electricity. One study estimated that training a single large model could emit as much $CO_2$ as five cars over their lifetimes[7]. Recent expert opinions have suggested that new large data-centre facilities being constructed to support generative AI are likely to consume the same amount of electrical power as tens of thousands of residential homes[8]. Understanding has also developed in connection to AI and inclusivity needs. Prospective response to this latter ethical challenge is provided later in this paper.

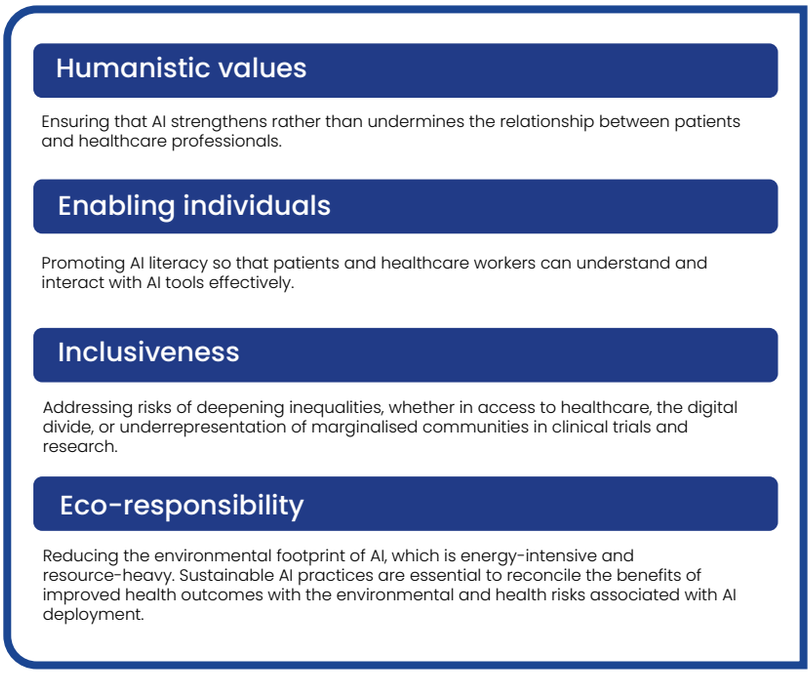



**Figure developed in accordance with guidelines formulated by the French Presidency of the EU Council*

## To improve ethical approaches to AI adoption in cancer care, Harnessing AI for Cancer Care in Europe recommends:

- Funding under the future EU budget 2028-34 should be allocated to support application of the EU Ethics Guidelines for Trustworthy AI.
- This could include research to achieve more environmentally friendly approaches to AI use, and active support to countries in improving the representativeness and inclusiveness of their national health and oncology data systems.

### 4.2. Building Trust with Transparency

How important is public trust when employing AI in cancer care? Paramount.

In cancer care and research, artificial intelligence holds enormous promise, but its value depends on whether patients, clinicians and society can trust the systems and frameworks being used. A central issue is the explainability of AI models. Some models, such as decision trees[9], can show clearly how they reach a conclusion, while others, often described as "black box" systems, offer little insight into their inner workings[10]. In some cases, black-box models could become more transparent by adding solutions to the toolbox of explainable artificial intelligence[11,12].

| Dimension | Explainable Models | Non-explainable Models (Black Box) |
|---|---|---|
| **Examples** | Decision trees, logistic regression, rule-based system | Deep neural networks |
| **Transparency** | Clear reasoning path, easy to audit | Opaque reasoning, difficult to interpret |
| **Clinical Usability** | Facilitates clinician understanding and validation | Requires trust in outputs without clear justification |
| **Regulatory Approval** | Easier to align with ethical and legal frameworks | Challenging to validate for safety and compliance |
| **Performance** | May have lower predictive accuracy in very complex datasets | Often highly accurate and scalable, yet might be susceptible to bias |
| **Risk for Patients** | Lower risk of hidden bias or unexplained errors in the model's output | Higher risk if errors occur without clear explanation |
| **Public Trust** | Builds confidence through transparency and accountability | May undermine trust if perceived as opaque and unaccountable |

When clinical decisions depend on these tools, a lack of transparency creates serious risks for patient safety, clinical practice and public confidence. High-performing but opaque models may deliver accurate predictions, yet if their reasoning cannot be understood, validated or challenged, they are difficult to use responsibly in healthcare. For example, an unexplainable AI medical system would impact a patient's decision-making process, since it limits autonomy[10].

Building trust requires more than technical innovation. It demands a commitment to explainability, openness and accountability, ensuring that AI systems are reliable and that the organisations deploying them are willing to be transparent at every step.

## To meet these challenges of trust in the deployment of AI in cancer care, Harnessing AI for Cancer Care in Europe recommends:

- That, in the context of the AI Act and other relevant initiatives, the European Commission develop (or support others to develop) a voluntary EU level product certification scheme tailored to AI tools intended for deployment in health and cancer care systems.
- Such an approach can follow similar initiatives to address need in other industrial areas. Examples include data protection certification mechanisms (European Data Protection Board) and Cybersecurity Certification schemes (European Union Agency for Cybersecurity).
- A clear understood purpose to be achieved by such an exercise should be to increase the transparency and explainability of AI models and tools used in European cancer care.

### 4.3. Bringing Clarity on Liability Concerns

Human oversight is central at every stage of cancer care, from early detection and diagnosis to treatment planning, follow-up, and survivorship. Within this continuum, artificial intelligence (AI) can play different roles: supporting the identification of patterns in complex data, assisting in clinical decision-making, or acting as a verification layer to confirm recommendations. These varied applications open possibilities for improving accuracy, consistency, and efficiency, while maintaining the healthcare professional's responsibility for final judgement.

However, while professional responsibility for patient care must not be diminished by the introduction of AI tools, it cannot be ignored that AI deployment also raises new challenges and questions in respect to liabilities for errors and adverse events that could occur, as can be the case for any technology's introduction into the sensitive area of cancer care. This is an area of concern expressed by many stakeholders consulted during the authoring of Harnessing AI for Cancer Care in Europe.

Recent discussions in healthcare have shown that there is still more work to do in properly defining and implementing rules and responsibilities for AI tools used in clinical settings. Many AI applications reach hospitals with limited ecological validity (the extent to which findings from research studies can be generalised to the real-world settings and the everyday practice of medicine and cancer care). If something goes wrong, it is often difficult to know who is responsible, whether it is the developer, the hospital or the individual clinician[13]. To explore liability concerns, a team at Stanford University identified three notable trends in their review of legal cases: first, plaintiffs often face difficulties in pursuing claims when they cannot pinpoint precise design flaws in software, as demonstrating that an error occurred is insufficient without explaining the underlying cause; second, artificial intelligence algorithms may behave inconsistently across different patient populations, complicating efforts to show that a physician should have recognised the limitations of a given output for a specific individual; and third, courts tend to treat AI-based tools in the same manner as conventional software, which risks applying precedents inappropriately across technologies that operate in fundamentally different ways[14].

A clearer definition of the line of accountability, from the design of the AI system to its use in medical decision-making, could help to ensure an improved ethical and trustworthy application of AI in cancer care.

Some stakeholders have also suggested that the regulatory landscape can contribute to difficulties on legal liability understanding as a result of the intersection of different legislative instruments e.g. the EU AI Act, the General Data Protection Regulation, and Medical Device regulations, as some examples.

## To improve clarity on legal liabilities in the deployment of AI in cancer care, Harnessing AI for Cancer Care in Europe recommends:

- All national health systems take measures to clarify and improve the understanding of healthcare professionals and cancer centre/hospital directors in respect to legal liabilities in the deployment of AI in cancer care.
- This could include plain language summaries of liability rules, explanations of relevant legal terminology and communicated learnings from case law.
- Relevant regulatory agencies, trade associations and companies should collaborate to ensure effective understanding of corporate legal liability for the deployment of AI tools in cancer care.

### 4.4. Empowering Cancer Patients and the Cancer Workforce

The increasing use of AI throughout the cancer care continuum requires improved public awareness and giving proper information to patients[15]. Adopting AI in cancer care must not be conducted at any cost to patient autonomy and agency in shared decision-making about their care and treatment. It is critical as well, during a current period of significant political decision-making about AI's deployment in cancer care, that the voice and perspective of the patient is actively sought and fully represented at the decision-making table.

## Harnessing AI for Cancer Care in Europe recommends:

- At both national and European levels, decision-making bodies and advisory panels relevant to AI adoption into cancer care should secure representation and participation from patients and their representatives.
- This should include, by way of example, the Management Board of the European Health Data Space, and decision-making structures related to EU digital health funding. The inclusion of patient representatives in the Board of the EU Research Mission on Cancer and the Board of the European Medicines Agency, serve as important templates.

For healthcare professionals and other healthcare staff, it is crucial to provide them with the support required to adapt their clinical practices to the changes resulting from the introduction of AI. As calls get made for an EU health workforce strategy, attention needs to be given to initial training for new generations and continuing training for experienced professionals, in order to enable this shift towards more digital healthcare.

**Dr Christos Poulios**

European Society of Pathology

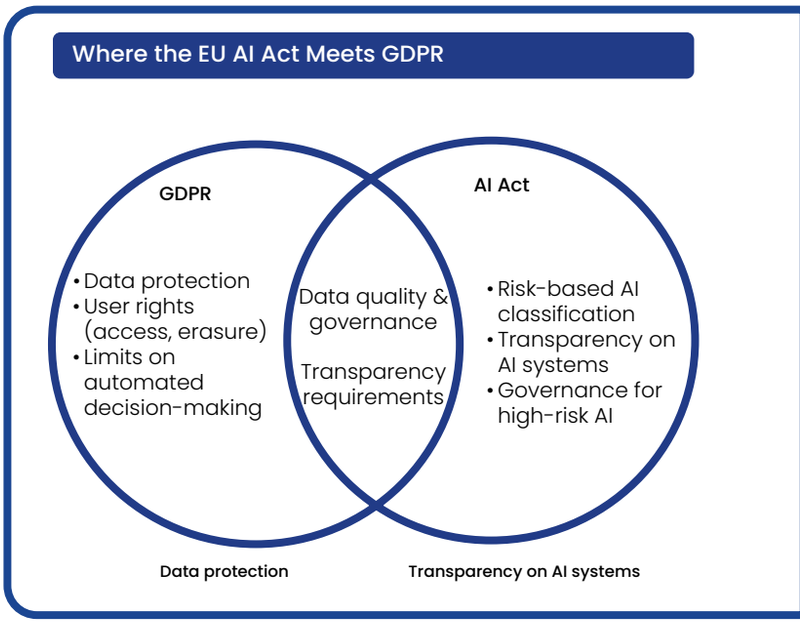
***Effective use of AI in cancer care depends on well-designed digital training, quality control, and the readiness of infrastructure. By offering innovative training methods, actively incorporating feedback from healthcare professionals, and incorporating strategic planning for infrastructure development, we can ensure that staff skills grow alongside technological capacity, enabling AI to be used effectively and safely to improve patient care.***

## Harnessing AI for Cancer Care in Europe recommends:

- To support healthcare professionals in raising skills in AI literacy, EU level investments should continue to be made in the creation and deployment of pan-European training schemes.
- Successful examples of this approach include such projects as INTERACT-EUROPE 100, DigiCanTrain and TRANSiTION.
- This activity could be supported by the adoption of an EU-level goal on AI literacy withing national oncology and healthcare systems which could be measured by EUROSTAT-led sample surveys.
- Such a goal might be: by 2035 achieve a goal of at least 50% of health and oncology care professionals feeling informed, confident, and trained in the appropriate use of AI in their work.

# 5. Data

Health data governance is crucial in enabling the effective application of AI in cancer care. Two main areas require particular attention: data privacy, to ensure that sensitive patient information is protected and handled in compliance with ethical and legal standards; and data quality, to guarantee that the information used to train and apply AI systems is accurate, comprehensive, and representative. Without strong governance frameworks addressing both aspects, the reliability, safety, and acceptance of AI tools in clinical practice are significantly undermined. The EU AI Act[16] and the General Data Protection Regulation (GDPR)[17] serve as the initial primary foundations for governance on the use of data in AI tools. The schematic gives an impression of their inter-relationship.




**Inspired by an original AI-generated image created using ChatGPT by Simona B Symaeys (LinkedIn, October 2025)[18]. The present image was recreated independently using Adobe Illustrator.*

## 5.1. Data Privacy

The rapid advancement of artificial intelligence in healthcare continually challenges data privacy because these systems depend on large volumes of sensitive patient information and often evolve faster than regulations can keep pace with. For example, even when data are stripped of identifiers, new algorithms have demonstrated the ability to re-identify individuals with high accuracy, making traditional anonymisation methods increasingly unreliable[19].

Under Article 9 of the General Data Protection Regulation, strict protections for health-related data are required. Principles such as privacy by design[20], meaning that systems are built with privacy considerations from the very beginning, and data minimisation, meaning that only the minimum necessary information is collected and used, remain essential to safeguarding patients.

There are, however, increasing concerns about the risks of over-regulation. Excessively complex or fragmented requirements between jurisdictions can slow the adoption of innovative tools, impose additional administrative burdens on healthcare providers, and discourage collaborative research. This includes inconsistent national interpretations of the GDPR, which have been made responsible for creating uncertainty and impeding appropriate data reuse. In cancer care, where timely access to high-quality data can directly influence patient outcomes, too rigid an approach could delay the integration of new technologies into practice. A balanced regulatory framework is therefore needed, one that ensures robust protection for individuals, particularly against the risks of re-identification, while also enabling secure and responsible data use to support research, innovation and better patient care.

### Harnessing AI for Cancer Care in Europe recommends:

- Clear EU guidance and regular independent reporting on the application of, conformity with, and implementation difficulties arising, from GDPR and the AI Act.
- That strong stakeholder input to these regulatory monitoring processes be achieved, including from the health and cancer sector (inclusive of clinicians and patient representatives).
- That such reporting inform and activate a more regular cycle of regulatory improvement - ensuring that Europe consistently achieves the right balance of privacy protection without creating a hostile environment for AI in supporting innovation and improvement in cancer care.

## 5.2. Data Quality

Scientific progress depends on the quality of its foundations: unreliable inputs inevitably lead to flawed outcomes.  As such, we can infer that an AI model is only as performant and as good as the data set it's been given[21,22,23,24].

**Harnessing high-quality, interoperable data is essential for advancing AI in oncology.**

Inter-European collaboration and the secondary use of health data are key to unlocking the full potential of AI. The European Health Data Space (EHDS) provides a framework for secure, standardised access to health data across Member States, enabling both research and clinical innovation while safeguarding privacy and individual rights. The European Health Data Space is a health-specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework. It aims at empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide. It also seeks to promote a single market for electronic health record systems, relevant medical devices and high-risk AI systems. Furthermore, and if consistently implemented across EU Member States, it bears the potential to provide a trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities, referred to as secondary use of data. The European Health Data Space is a key pillar of the European Health Union. It builds further on the General Data Protection Regulation (GDPR) and the NIS 2 Directive (addressing cybersecurity in the EU).

Other initiatives such as the EUropean Federation for CAncer IMages (EUCAIM) highlight the critical importance of high-quality, representative datasets. EUCAIM is the cornerstone of the European Commission-initiated European Cancer Imaging Initiative[25], a flagship of Europe's Beating Cancer Plan (EBCP), which aims to foster innovation and deployment of digital technologies in cancer treatment and care to achieve more precise and faster clinical decision making, diagnostics, treatment and predictive medicine for cancer patients. By building a federated infrastructure for cancer imaging data across Europe, EUCAIM adheres to FAIR principles[26], supporting robust AI development in oncology while allowing data providers to maintain control over their resources.

Unstructured data presents additional opportunities. Integrating pathology reports, radiology notes, and patient records can significantly enhance AI models, as long as interoperability, data quality, and privacy standards are rigorously maintained.

By combining robust datasets with secure, standardised access, Europe can unlock AI's full potential in cancer care. The quality of data is central to whether artificial intelligence can truly support equitable healthcare. **But can artificial intelligence deliver fair and reliable outcomes regardless of race, socio-economic status, disability, sexual orientation, age, or gender[27]?**

Data quality is central to this challenge, yet many existing health datasets underrepresent marginalised groups such as ethnic minorities, older adults, low-income populations, and those living in rural areas. When AI systems are trained on such skewed data, they risk producing outputs that are less accurate or even harmful for these groups, while functioning well for majority populations[28]. This dynamic can unintentionally deepen existing inequalities in access, diagnosis, and treatment, reinforcing systemic gaps in healthcare.

## CASE STUDY: Racial Bias in medical AI

**Examples of potential bias within AI systems: skin cancer detection**
Skin cancer detection systems are often trained on datasets that underrepresent darker skin types, resulting in lower diagnostic accuracy for patients with diverse skin tones[29,30].

**Collection of data: A race and ethnicity data paradox**
The advance of AI in cancer and healthcare is raising new difficulties. One such paradox relates to the identified need to ensure oncology and health data systems make due account for the collection of data related to race and ethnicity. However, meeting this need can in turn raise its own concerns in respect to such matters as privacy concerns and risks of biological reductionism, particularly in societies marked by histories of exclusion, violence, and colonialism[31].

It is vital to strengthen the representativeness and quality of datasets, regularly audit algorithms for bias[32], and design safeguards that embed fairness and inclusivity into every stage of AI development and deployment.

## To meet these challenges, Harnessing AI for Cancer Care in Europe recommends:

- Mitigating the risk of AI applications based upon biased datasets, by utilising mechanisms like the European Health Data Space. This could be a means to help secure more harmonised European health and cancer data infrastructures and to achieve new standards for fully representative health datasets.
- Necessary upgrades required to the operation of cancer registry systems in Europe to achieve this be identified and acted upon.
- Countries could be supported in making such investments through the different mechanism being proposed within the new EU multiannual financial framework.

# 6. An EU Multiannual Financial Framework that Delivers on the Promise of AI's Application to Cancer

The European Union, and its member state governments, are clearly taking seriously the rise of Artificial Intelligence and its application to sectors such as the health and cancer sectors. This is evidenced both by the proposal and passage of new regulatory frameworks such as the Artificial Intelligence Act, as well as important investments in promising pan-European tools such as EUCAIM – the European Federation for Cancer Images and the European Health Data Space (EHDS), among many others.

### Matteo Caridi

European Hematological Association Focus Group on Health Data and AI

***In a fragmented global landscape, where AI holds unprecedented potential to transform healthcare, Europe must ensure its autonomy and self-sufficiency in both access to and development of these technologies. This is essential to safeguard against future restrictions or geopolitical disruptions that could compromise Europe's ability to deliver innovative and equitable AI solutions for cancer patients.***

The *Harnessing AI for Cancer Care in Europe: Opportunities, Challenges, and Policy Recommendations* is authored and published at a time in which significant debate is taking place among the institutions of the EU about the future Multiannual Financial Framework 2028-34, and the pivot towards a 'Competitiveness Agenda' that it heralds. Indeed, the European Commission's proposal for the Multiannual Financial Framework (MFF) 2028–2034 reflects a strategic emphasis on AI as a cornerstone for Europe's future competitiveness, resilience, and technological sovereignty. AI is prominently featured across various funding initiatives, particularly within the Horizon Europe programme and the proposed European Competitiveness Fund. With a proposed doubling of Horizon Europe's budget to €175 billion, it will be of critical importance that the prospective large EU investments in the field of AI in the future are well considered, long term, and deliver on anticipated results.

Furthermore, under the new MFF proposals, Member States are required to develop National Plans that align with EU priorities. Approximately €865 billion is earmarked for these plans, encompassing areas such as infrastructure, digitalisation, and health. Member States must draft plans detailing reforms and investments in line with EU priorities, including digitalisation and health. The new 'National Plans' facility appears a natural mechanism by which all EU member states might address gaps in their digital health data infrastructures as well as ensure their health professional workforce gains the skills they need to fully engage with the opportunities presented by AI's application to cancer care.

The below table summarises some recommendations from the European Cancer Organisation to decision-makers on the MFF.

| Proposed funding programme in the new MFF | Means by which this programme can support the application of AI to cancer care |
|---|---|
| **Horizon Europe (€175 billion – part of the EU Competitiveness Fund)** | • Sustain and renew the EU Research Mission on Cancer, with clear remit to advance Europe as a global leader in AI and cancer research<br>• Maintain and elevate EUCAIM as an internationally exceptional resource for the sharing and utilisation of cancer images across borders. |

| | |
|---|---|
| **Other elements of the Competitiveness Fund of which €51.5 billion is directed towards digital leadership; €22.6 billion is directed towards Health, Biotechnology, Agriculture, & Bioeconomy; and, €26.2 billion is provided towards Clean Transition and Industrial Decarbonisation** | • Within the Digital Leadership component - Support the development of the European Health Data Space as a central (and globally unique) tool to fuel AI's application in cancer care.<br>• Within the Health, Biotechnology, Agriculture, & Bioeconomy component – Support the development of novel approaches to AI's application in fields of cancer care and control, including prevention, screening and early detection.<br>• Within the Clean Transition and Industrial Decarbonisation – develop and implement new solutions to reduce the carbon footprint associated to the use of AI in cancer, health and other sectors. |
| **National Plans (€865 billion)** | • Give explicit guidance and encouragement to EU Member States on the use of National Plan funding to address major gaps in country-level health and oncology data collection and utilisation<br>• Support EU member states at addressing national level skills gaps and shortages as constraints to the deployment of AI to cancer care and control |
| **Global Europe (€200 billion allocation)** | • Enable EU Neighbourhood and Accession countries to participate within key EU projects on AI and cancer, including connecting to the European Health Data Space |
| **Education and Youth (Erasmus+) (€49 billion)** | • Creation of bespoke pan-European training and education opportunities for the application of AI to cancer care<br>• Support the maintenance and enhancement of currently developed EU training and education projects such as TRANSITION and DigiCanTrain. |

Furthermore, as the EU seeks to ensure the fullest return on investment from the deployment of such funds, it should be referenced that the Research Policy Network of the European Cancer Organisation is actively considering if more developed and longer-term means of coordination of funding is required. A recent Green Paper on Optimising EU Investment in Cancer Research is inviting views on the prospect of bringing into being a new European Cancer Institute to oversee and help coordinate EU investments in cancer research. Such an approach could assist in the overall efforts to make Europe a global leader in the application of AI in cancer care and control by ensuring long-term approach, guided in accountable fashion by experts in the field, and with the full involvement and advice from stakeholder communities. More information here: **www.europeancancer.org/green-paper-cancer-research**

## To meet these challenges, ECO recommends:

- Full deployment of EU MFF related funding to establish a political goal for global leadership by Europe in AI's application for cancer care.
- Consideration to the need for a European Cancer Institute, or similar body, to oversee a fully coordinated and long-term approach to achievement of such a goal.

# 7. Conclusions and Summary of Recommendations

The adoption of artificial intelligence in cancer care across Europe presents unprecedented opportunities for improving patient outcomes, efficiency, and innovation. However, realising these benefits requires careful attention to trust, ethics, legal clarity, patient involvement, professional skills, data quality, and regulatory oversight. Harnessing AI effectively in oncology demands a coordinated, Europe-wide approach that aligns national and EU-level policies, ensures transparency and accountability, and embeds patient-centred principles throughout. By addressing these challenges systematically, Europe can not only enhance cancer care but also establish itself as a global leader in the safe, ethical, and effective use of AI in healthcare.

To achieve this, Harnessing AI for Cancer Care in Europe is suggesting a set of recommendations across different areas:

### 1. Standards for Accountability, Transparency, and Clinical Validation

- Establish clear national standards for AI tools in cancer care, informed by ASCO's six guiding principles.
- Develop specialty-specific validation frameworks for AI algorithms.
- Implement robust post-market surveillance systems for ongoing monitoring.
- Ensure standards are publicly communicated and co-created with oncology professionals and patient advocates.

### 2. Ethical AI Adoption

- Allocate EU budget (2028–34) funding to support implementation of EU Ethics Guidelines for Trustworthy AI.
- Promote environmentally sustainable AI practices.
- Support countries in improving inclusiveness and representativeness of health and oncology data systems.

### 3. EU-Level AI Certification and Trust

- Develop a voluntary EU product certification scheme for AI tools in health and cancer care.
- Model the scheme on existing data protection and cybersecurity certification mechanisms.
- Ensure certification increases transparency and explainability of AI models.

### 4. Legal Liability Clarity

- Clarify legal liabilities for healthcare professionals and hospital directors deploying AI.
- Provide plain-language summaries, explanations of legal terms, and case law learnings.
- Encourage collaboration between regulatory agencies, trade associations, and companies on corporate liability.

### 5. Patient and Citizen Participation

- Secure patient and caregiver representation in national and EU decision-making bodies related to AI in cancer care.
- Examples include the European Health Data Space Management Board, EU digital health funding boards, the EU Research Mission on Cancer, and EMA advisory structures.

### 6. AI Literacy for Healthcare Professionals

- Invest in pan-European AI training initiatives (e.g., DigiCanTrain, TRANSiTION, INTERACT-EUROPE 100).
- Adopt measurable EU-level AI literacy goals; e.g., by 2035, at least 50% of healthcare and oncology professionals should feel informed and confident in AI use.

### 7. Regulatory Guidance and Monitoring

- Provide clear EU guidance and independent reporting on GDPR and AI Act implementation.

- Include strong stakeholder input from clinicians and patient representatives.
- Use reporting to drive continuous regulatory improvement, balancing privacy and innovation.

### 8. Data Quality and Bias Mitigation

- Use mechanisms like the European Health Data Space to harmonise health and cancer data infrastructures.
- Upgrade cancer registry systems to ensure fully representative datasets.
- Support countries in making necessary investments through EU funding mechanisms.

### 9. Strategic Investment and Coordination

- Deploy EU MFF funding to establish Europe as a global leader in AI for cancer care.
- Consider creating a European Cancer Institute or similar body to coordinate long-term AI initiatives in oncology.

# Annex: Glossary

| | |
|---|---|
| **Agentic AI** | AI that can make autonomous decisions |
| **Bias** | Systematic error or unfairness in AI outputs |
| **Chatbots** | AI programmes that simulate human conversation |
| **Deep Learning (DL)** | Machine learning using multi-layered neural networks |
| **Digitalisation** | Converting processes or data into digital form |
| **Digitation** | Creating digital data from analog sources |
| **Explainability** | Clarity on how AI makes decisions |
| **Federated Learning** | Machine learning trained across multiple devices without centralising data |
| **Few-Shot Learning** | AI learning from very few examples |
| **Fine-Tuning** | Adjusting a pre-trained model for a specific task |
| **Foundation Model** | Large AI model trained on broad data, adaptable to many tasks |
| **Generative AI** | AI that creates new content |
| **HIP Learning** | Hierarchical, Interpretable, and Probabilistic learning (structured AI approach) |
| **Interoperability** | Ability of systems to work and exchange data together |
| **LLMs (Large Language Models)** | AI models trained to understand and generate language |
| **Machine Learning (ML)** | AI technique where models learn from data |
| **Neural Network** | Computing system inspired by brain neurons for pattern recognition |
| **Non-LLMs** | AI models not specifically focused on language |
| **Overfitting** | When a model performs well on training data but poorly on new data |
| **Predictive AI** | AI that forecasts outcomes or trends |
| **Radiomics** | Extraction of large amounts of features from medical images |
| **Supercomputer** | Extremely powerful computer for complex calculations |
| **Trustworthiness** | Reliability and safety of AI systems |
| **Virtual Human Twins** | Digital replicas of humans for simulation or analysis |
| **Wearable AI** | AI integrated into wearable devices for monitoring or assistance |
| **Zero-Shot Learning** | AI solving tasks without having seen examples during training |

To learn more about these terms and other AI and oncology related terms and phrases, we recommend consulting the Living Glossary for AI in Medicine, developed by the International AI in medicine Education Working Group[33].

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