EU HEALTH POLICY PLATFORM THEMATIC NETWORK 2024

Advancing Precision Medicine for Europe's Cancer Patients with AI-powered Imaging

Addressing public health area 3 "Unlocking the power of artificial intelligence against cancer"

Joint Statement

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Background and Introduction

Each year in Europe 2.7 million people are diagnosed with cancer and 1.3 million lose their lives due to this disease. If no further action is taken, the number of people newly diagnosed will increase to more than 3.2 million by 2040[1]. Over the past decade, cancer treatment has seen significant advancements, with new medicines offering potential cures and prolonged survival even in advanced cases. However, these treatments come with high costs, raising concerns about affordability and equitable access to quality care. To address these issues, we urgently need to transform **healthcare**. Digital transformation[2] of healthcare has the potential to enhance precision medicine by maintaining high standards of care while also ensuring affordability. The implementation of AI-powered digital tools that lead to increased involvement of patients and their families in the management of their disease outside traditional hospital settings may shift the healthcare system from hospital-based to community-based care. AI-powered prediction models of treatment response and outcome that also incorporate patients' socioeconomic and lifestyle data can offer personalised guidance for cancer patients and survivors, helping them to manage and prevent their illness across their lifespan.

Alongside this shift, rapid advancements in diagnostic technologies present unprecedented opportunities for precision medicine in cancer, delivering the right treatment at the right time to the right patient. Anatomical and functional Imaging is currently able to provide localised information on the presence of cancer, tumour burden and biology. Imaging information can be quantified (imaging biomarkers, radiomics) and automatically extracted with AI solutions enabling AI-powered data-driven analyses. The development of AI-powered solutions for precision medicine holds tremendous promise in keeping healthcare accessible and maintaining costs sustainable. The integration of imaging, other diagnostic data (tissue, fluid, molecular, endoscopic and clinical data) for the development of multimodal AI-powered clinical prediction models of outcome will provide physicians with tools for more accurate treatment decision-making and patients with tools for better patient shared decision-making. This will allow us to fully leverage the strengths and potential of AI algorithms in such a context.

The terms health data and medical images are applied throughout this statement in the context of both primary and secondary use. Primary use of health-related data and medical images refers to the utilisation in immediate patient care. Here, AI tools could play a crucial role in enhancing how medical imaging can be used to benefit the patient, improve diagnostic accuracy, optimise

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[1] European Cancer Information System https://ecis.jrc.ec.europa.eu

[2] Mario Draghi outlines his plan to make Europe more competitive, The Economist, https://www.economist.com/by-invitation/2024/09/09/mario-draghi-outlines-his-plan-to-make-europe-more-competitive (accessed on 21 October 2024)

workflows, and support personalised care, ultimately improving patient outcomes. The secondary use of such data will however also be crucial to drive innovation – most importantly by leveraging vast amounts of imaging and derived data. New AI tools could potentially be developed for automating data integration and analysis, supporting the detection of subtle abnormalities, and predicting disease progression with greater precision. After thorough local testing and fine-tuning, emphasis needs to be placed on how to best integrate such tools into clinical practice, ensuring that they are user-friendly, continuously reliable, explainable, and compatible with existing technologies, IT infrastructure and regulatory requirements. This would enhance the value of imaging and might democratise access to high-quality diagnostics across diverse healthcare settings.

Despite impressive recent developments in both cancer care and AI, overall digitisation of healthcare is lagging behind in many Member States. Bringing advanced diagnostic technologies together to the benefit of patients' outcome and society at large comes with many challenges. These include technological hurdles such as infrastructure development, data quality and interoperability; the need for a robust regulatory framework and rigorous testing; the need for trust-building among patients, healthcare providers and scientists; resources to generate the evidence in order to incorporate valuable AI solutions in clinical practice guidelines; accredited AI training programmes for healthcare professionals; support from policymakers and hospital executives and, last but not least, the willingness and means of different key stakeholders to collaborate effectively. This is no small feat and will require concerted efforts by various stakeholders, especially in overcoming challenges with only limited incentive at first sight.

This Joint Statement reflects the views of a broad range of stakeholders on how to better integrate AI-powered imaging with other diagnostic and clinical data, with the aim of bringing integrated diagnostics into the clinic.

Relation to EU policy areas and synergies with ongoing/planned EU health and digital actions

The Joint Statement is directly related to **Europe's Beating Cancer Plan**, in particular the **European Cancer Imaging Initiative**[3] and its flagship project **EUCAIM**[4], which has collaborated closely on the development of the statement and serves as a pioneer and good practice example for many of the proposed actions.

EUCAIM is a project co-funded by the European Commission under the Digital Europe programme that will establish a pan-European digital federated infrastructure of FAIR (Findable, Accessible, Interoperable, and Reusable) anonymised cancer images from real-world data. The infrastructure ensures data sovereignty for providers and offers a platform, including an Atlas of Cancer Images, to develop and benchmark AI tools for precision medicine. It addresses the fragmentation of existing cancer image repositories and serves clinicians, researchers, and innovators by providing validated clinical decision-making systems to support diagnosis, treatment, and predictive medicine and defines legal frameworks for data management in compliance with EU legislation. EUCAIM offers a midterm atlas of >60 million annotated cancer images from >100,000 patients, a continuously growing infrastructure based on observational studies at hospitals (real world data from hospital data spaces and screening programmes) and an AI-platform to develop reproducible – and, ideally, explainable image-based AI models in

[3] https://digital-strategy.ec.europa.eu/en/policies/cancer-imaging (accessed on 11 November 2024)

[4] https://cancerimage.eu/ (accessed on 11 November 2024)

oncology. Hence, EUCAIM will impact clinical pathways in radiology and oncology with evidence-based use of imaging biomarkers and imaging panels identifying the right treatment to the right patients, in many different oncologic situations.

In order to ensure sustainability of the infrastructure, EUCAIM plans to create a European Digital Infrastructure Consortium (EDIC) that aligns with its objectives, providing secure and accessible digital infrastructures, enhancing the Union's industry and economy, ensuring General Data Protection Regulation (GDPR) compliance, and supporting the secondary use of health data.

EUCAIM is being developed in an evolving legal landscape, carefully addresses the heterogeneous national health data regulations, and is aligned with the Data Governance Act (DGA), the European Data Act (EDA), as well as with the recently adopted European Health Data Space (EHDS) Regulation and the AI Act, which are also extremely relevant for the scope of this Joint Statement.

The Joint Statement also ties in with the EU's digital health policies to harness the potential of digital technologies to improve healthcare delivery, patient outcomes, and health system efficiency as well as relevant elements of the EU's Digital Decade Policy (infrastructure development, capacity building, ehealth).

As regards health actions next to EUCAIM, other health data space infrastructure projects, in particular the Genomic Data Infrastructure (GDI) project are of relevance when it comes to advancing data integration and interoperability.

Also, EU Cancer Mission projects (such as EOSC4Cancer[5], CCI4EU[6], ECPDC[7], EUonQoL[8]), EU actions on cancer screening (such as the SOLACE, TOGAS, PRAISE-U projects, as well as EDITH – Building the European Virtual Human Twin) and the Joint Actions by Member States in relevant areas including TEHDAS (Towards the European Health Data Space) and EUCanScreen, the new Joint Action on implementing screening for lung, prostate, gastric and other cancer types, are relevant for the scope of this Joint Statement.

The signatories of this joint statement have defined the following common vision:

Vision

- Advance precision medicine for Europe's cancer patients and contribute to the full implementation of Europe's Beating Cancer Plan (in particular its flagship project EUCAIM), the EU Cancer Mission, and the EU's digital health policies.
- Bring integrated diagnostics into the clinic by linking AI-powered imaging and radiomics biomarkers with other diagnostic and molecular data.
- Promote the development of accurate AI-powered integrated diagnostic models providing healthcare providers with accurate predictors of treatment outcome.
- Improve patient outcomes while keeping cancer care affordable and accessible by enhancing personalised and effective treatment strategies.

[5] https://eosc4cancer.eu/ (accessed on 11 November 2024)
[6] https://cci4eu.eu/ (accessed on 11 November 2024)
[7] https://www.hidih.org/projects/epcdc (accessed on 11 November 2024)
[8] https://euonqol.eu/ (accessed on 11 November 2024)

- Guarantee equity in access to AI solutions, knowledge, research, and state-of-the-art care for patients from different socio-economic, gender and age groups, contributing to an improved quality of life and living conditions for citizens and patients across Europe.
- Enhance the secondary use of health data to amplify the impact and reproducibility of imaging biomarker innovations, particularly within cancer research institutions and collaborative networks, including national cancer data nodes, health data access bodies and cancer mission hubs.

Call for Action

To achieve their defined vision, the signatories of this Joint Statement have formulated and committed to a range of actions to facilitate AI-powered precision medicine in cancer care and identified areas where the EU institutions, research community and Member States are called to action.

In particular, the undersigned organisations call upon the new European Commission and European Parliament as well as EU Member States to develop and implement robust implementation guidance for the new European legislations (above all the AI Act and EHDS) in close interaction with all relevant stakeholders. This is crucial to ensure legal clarity and practicable approaches while minimising lost resources and research efforts, allowing Europe's patients to benefit from technological advances, to strengthen Europe's leadership role in AI in the medical sector, and to support continuous innovation in the field, overcoming the risk of hindering innovation. Furthermore, the signatories of this Joint Statement call for adequate consideration and support within the 10th Framework Programme to allow further advancing precision medicine for Europe's cancer patients through collaborative research, increased use of both existing and new infrastructures for research and innovation, and incentivised data sharing practice.

1. **Review and validate existing literature for the most promising AI-powered predictive biomarkers such as imaging (radiomics), laboratory, pathology, molecular and fluid biomarkers**

   While many promising studies have been published on a variety of imaging biomarkers for all possible cancer entities, little is known if and how these biomarkers could indeed be used clinically, with a specific clinical impact, as some of these methods suffer from reproducibility and scalability issues. This is due to a variety of factors, including the fact that new research is more incentivised and rewarded compared to validation and clinical translation[9]. The signatories of this Joint Statement will therefore engage with their respective research communities to stimulate such action and carry out systematic reviews to collect and organise evidence which then will be published and should inform

[9] Markowetz F. (2024) All models are wrong and yours are useless: making clinical prediction models impactful for patients. *Npj Precision Oncology* (https://www.nature.com/articles/s41698-024-00553-6)

future research. Similarly, the signatories encourage their research communities to focus on clinical validation studies to further strengthen the evidence on potentially relevant biomarkers, thus facilitating clinical translation. Ultimately these research efforts should help to better identify needs for funding and clinical effectiveness studies.

2. Consider AI-powered imaging in in-vivo clinical cancer trials

There is increasing evidence for the potential value of relevant biomarkers for predicting treatment efficacy. Biomarkers such as ctDNA, genomic or of immune tumour microenvironment are already being incorporated in clinical trials. Molecular markers such as the mismatch repair status of colorectal cancer are strong predictors for response to immunotherapy and part of the standard workup of colorectal cancer. In other cancer types, genomic structural alterations of tumour tissues may be either predictive of response to many drugs or prognostic of patients' outcome. Furthermore, some of these genomic alterations may be predictive of presence of driver germline gene variants which themselves predispose to cancer. Imaging already plays a central role in the management of cancer patients; however, so far, its use has been mostly limited to assessing and monitoring tumour burden. There is compelling evidence showing the potential of AI-powered imaging biomarkers such as CT body composition[10] for predicting outcome, and a multitude of AI-powered tools for imaging biomarker extraction already exist. Yet studies incorporating imaging biomarkers in in-vivo clinical trials and in screening programmes are crucial to understand the real value of including AI-powered imaging in the treatment pathway. The signatories of this Joint Statement therefore call on the European cancer research community including industry to consider imaging biomarkers to be incorporated in in-vivo clinical cancer trials and on the EU institutions to suggest stronger interdisciplinarity in any cancer-related funding measures as these could help identify predictors of outcome (e.g. differential accumulation of pharmaceuticals in adipose tissue, sarcopenia as objective measure of frailty, etc.).

3. Improve the results of cancer screening programmes by AI-powered imaging

AI plays an increasingly important role in evolving areas of screening, especially where imaging-based procedures are used. Screening is vital for both population and individual health, helping detect diseases early in at-risk, asymptomatic individuals or individuals studied for any other unrelated issues. Democratising the use of AI for cancer screening may decrease social determinants of inequities in screening implementation and improve access to these programmes. Based on recent studies, AI may enhance screening also by improving diagnostic accuracy and reducing the burden on healthcare providers, helping to optimise early disease detection and outcomes. In addition, AI tools in screening programmes can reduce diagnostics invasiveness (e.g. avoidance of contrast

[10] Maurya AK et al. (2024) Body Composition Analysis Techniques and Its Application in Oncology: A Review. Nutrition and Cancer (https://www.tandfonline.com/doi/full/10.1080/01635581.2024.2353942)

agents), making imaging less time-consuming and less expensive. The signatories of this Joint Statement therefore call on the European cancer research community to consider imaging biomarkers to be evaluated in screening programmes, both opportunistic (use of AI to detect cancer in any single imaging study performed for whatever reasons) and on target populations (such as for breast, lung, and prostate).

4. **Ensure interdisciplinary stakeholder engagement in the development and implementation of strategies for multimodal AI-powered clinical decision support**

   Advancing precision medicine and bringing imaging and multimodal AI-powered solutions into clinical routine requires not only domain expertise but also a collaborative spirit. The knowledge about advancements in digital technology and biomarker development resides with the experts. Cancer organisations, research institutes and European collaborative networks, including national cancer data nodes, health data access bodies (HDABs) and cancer mission hubs should include in their governing bodies the key stakeholders; medical professionals (including radiologists, nuclear medicine physicians and oncologists), patient representatives, (imaging and data) scientists (including medical physicists), ethicists, lawyers, policymakers and industry partners. Together they should identify and monitor best practices to understand if, how and where multimodal AI-powered solutions can enhance reproducible and accurate precision medicine. This will ensure a broadly supported implementation of AI-powered solutions in daily management of cancer patients. The signatories of this Joint Statement therefore encourage European cancer organisations, research institutes and EU networks to ensure interdisciplinarity in their governing bodies.

5. **Develop a comprehensive strategy for research on innovative AI-powered solutions that have the potential to impact patient outcomes**

   A strategy must be developed to guide high-quality research throughout the entire lifecycle of AI tools – from initial development and validation to their translation and implementation in clinical practice. Rigorous training, validation, and testing – using retrospective, prospective and at times simulated data – are critical to the success of AI tools. Large and representative (pseudo-)anonymised datasets of high quality are essential for training AI models effectively, enabling them to perform reliably across various tasks. The development and validation of multimodal AI solutions introduce additional complexity, requiring the integration of diverse data sources, such as environmental, population, clinical, molecular and imaging data. Furthermore, AI technology must be validated in real-world settings, considering the diversity of patient populations and the wide range of clinical conditions, as well as a possible change in performance of the AI model over time. The use of anonymised data may come at a cost, especially when linking to longitudinal outcomes and long-term follow-up is necessary to understand how specific predictions apply to distinct risk groups and tumour entities. Lastly, a widespread adoption of effective AI-powered solutions in clinical practice can

only be ensured when such clinical decision support tools are incorporated into clinical practice guidelines.

The signatories of this Joint Statement call on stakeholder groups and organisations to develop a research strategy that spans the entire AI development pathway, from innovation to validation in real-world settings, translation and clinical practice implementation. They also urge the EU to support research (including Health Technology Assessment – HTA, translational research and post-market surveillance strategies) aimed at developing and validating innovative, multimodal AI tools, but also at assessing their relevant risks and thus ensuring improved patient outcomes, and call upon Member States for a harmonised implementation of the new HTA Regulation to improve and accelerate patient access to innovative diagnostic and potentially lifesaving digital technologies.

6. Enhance data quality and infrastructure in healthcare and research institutions to leverage AI-powered multimodal solutions

To harness the potential of AI/data-powered multimodal solutions in cancer care, it is essential to enhance data quality and infrastructure in healthcare and research institutions across the EU. This requires a multifaceted approach to at least some level of standardisation as well as to data management and integration. Integrating diverse data types, including imaging, molecular, and clinical data, from various sources necessitates robust interoperability across different systems, repositories, and institutions. A key component of this infrastructure is the implementation of advanced health data warehouses, both at hospitals and research environments. These repositories are designed to store and integrate large volumes of structured and unstructured data from multiple sources. Establishing common standards for health data acquisition, storage, collection, and annotation is crucial to ensure consistency and reliability in AI model development and implementation. Concerning imaging data, minimising inconsistencies in image acquisition protocols and developing techniques for harmonised image biomarker extraction after acquisition are crucial steps to ensure that AI-powered imaging tools can be effectively integrated into real-world clinical practice and research. The reproducibility of AI-powered prediction models will be improved by establishing consensus guidelines on image acquisition (e.g., on spatial and contrast resolution) specific for the organ and disease being evaluated. The establishment of quality assurance programmes will ensure continuous monitoring and refining of both imaging protocols and harmonisation techniques. Data standards should address not only formats but also quality metrics, metadata requirements, and privacy safeguards. Furthermore, healthcare and research institutions need support to upgrade their IT infrastructure to handle large-scale data processing and storage securely. The maturity level of hospital data warehouses varies widely across the EU, with some institutions having advanced systems capable of real-time analytics, while others are still in the early stages of implementation. Addressing these disparities and promoting the adoption of standardised, interoperable data storage practices is crucial for the successful and equitable implementation of AI-powered solutions in healthcare.

The signatories of this Joint Statement therefore call on the European health professional societies (including ESR) and the European research community to develop a strategy and guidance for data quality and harmonisation in biomarker extraction. The signatories also call on the EU, its Member States and funding bodies to support healthcare and research institutions in enhancing their overall data management capabilities. This includes not only generating high-quality, standardised datasets which are interoperable to the EEHRxF[11], but also implementing robust data governance frameworks, upgrading data storage and processing infrastructure, and adopting interoperable data systems.

7. Improve the coordination and accessibility of health data for AI development and validation in Europe

The development and validation of multimodal AI-powered solutions in healthcare requires access to vast amounts of quality data. Currently, data collection, retention, access and usage practices are often unclear and inconsistent across different institutions and Member States, for a great part hindering the progress of each step required for successful AI research – from development to implementation and post-market surveillance. The EHDS presents a promising opportunity to address these challenges by creating a common framework for health data sharing across the EU, both for primary use in healthcare provision and secondary use for research. However, there are still significant hurdles to overcome, including harmonising data protection regulations across Member States, ensuring ethical use of data while building AI-powered solutions for clinical use involving industry partners, and maintaining public trust. The EHDS will need to balance the needs of researchers and innovators with the rights and privacy of patients, while also considering the diverse legal and ethical landscapes across Member States.

The EHDS must be structured to ensure that Health Data Access Bodies (HDABs) have the capability to access, organise, and structure data effectively to meet the comprehensive needs of researchers. EUCAIM, as a possible EDIC Authorised Participant, will have to be linked with other existing HDAB initiatives in an interoperable way.

Similarly, existing health data repositories across Europe can be interconnected to enhance data accessibility and usability for AI research and development. To facilitate this integration, an identifier should be created to link datasets and enable the connection of different datasets related to the same research study, even if the data is stored in different locations or formats. This identifier should be compatible with and integrated into existing research databases, institutional repositories (e.g., where research outputs are stored), and platforms used by funding agencies. This would make it much simpler to track, manage, and access research data across various systems and platforms, to link research studies across Europe, and it would potentially also allow linking of long-term outcomes.

[11] https://health.ec.europa.eu/ehealth-digital-health-and-care/eu-cooperation/ehealth-network_en

The signatories of this Joint Statement call on the European Commission to connect the EHDS and HDABs with the related professional societies and EUCAIM to discuss metrics of data quality. Moreover, we urge the EU to establish appropriate links with EU-funded initiatives, such as EHDS-related governance and implementation actions, the Health Data Analytics and Benchmarking initiative, the European Network of Cancer Registries, as well as relevant European Research Infrastructure Consortia (ERICs) and EDICs to foster integration and ensure the success of these efforts. We emphasise the need for continuous dialogue between policymakers, researchers, healthcare providers, and patient organisations to ensure that the EHDS evolves to meet the changing needs of AI-powered healthcare innovation while upholding the highest standards of data protection and ethical use.

Furthermore, the signatories call on the EU to support research projects to discuss how to link and connect personal data stored in different repositories, keeping safety and security aspects within the GDPR, and to define a European governance framework to oversee the issuance, management, and maintenance of interoperability and identifiers. The signatories recognise the value of integrating European platforms such as EUCAIM into research and innovation actions to leverage its standardised imaging data platform and federated network. This will enhance the development and validation of AI tools, ensuring that these innovations are aligned with European regulatory standards and are collaboratively refined across a network of diverse clinical environments.

8. Ensure seamless integration of AI-generated results into clinical workflows

The successful translation and implementation of AI-powered solutions in healthcare extend well beyond the development and validation phases. A critical, often overlooked challenge is the deployment and integration of AI-generated results into existing clinical workflows. While much attention has been given to data quality and interoperability for AI development, the final step of delivering AI insights to healthcare professionals in a user-friendly manner remains problematic. Many healthcare institutions struggle with fragmented IT systems that lack standardised interfaces and platforms for incorporating AI outputs. This leads to inefficiencies, potential errors, and resistance from healthcare professionals who find it cumbersome to access and interpret AI-generated results within their established routines. The lack of uptake or absence of uniform standards for integrating AI outputs across different vendor platforms and hospital information systems further complicates this issue, potentially limiting the real-world impact of even the most advanced AI-powered algorithms.

The signatories of this Joint Statement therefore call on the European health professional societies (including ESR) and the European research community to prioritise the development and adoption of standards-based interoperability for end-user IT systems in hospitals, specifically focusing on the implementation of common data models and the integration of AI-generated results. We call on the EU to incentivise healthcare institutions and IT vendors to adopt these standards through targeted funding initiatives and regulatory measures.

9. Establish clear guidelines and frameworks for regulatory compliance of AI-powered solutions in clinical care

The use of AI-powered solutions in clinical practice, while presenting opportunities for improved cancer care, also introduces challenges. It can be foreseen that development in AI technology will further accelerate and therefore regulatory frameworks will need to keep up with technological advancements.

The recently passed EU AI Act aims to address these issues by establishing a risk-based approach to AI regulation, with medical AI-powered applications likely to fall under high-risk categories. This risk-based approach necessitates the development of robust risk assessment methodologies specific to AI in healthcare. These should consider not only technical risks but also potential impacts on patient outcomes and health equity. However, the practical implementation of these regulations in healthcare remains unclear, particularly regarding clinical validation, human oversight, and liability. The AI Act's intersection with existing medical device regulations adds another layer of complexity, also meaning increasing efforts and resources on the end-user side.

The signatories of this Joint Statement therefore call on the EU to expedite the development of clear, comprehensive healthcare-specific guidance for regulatory compliance of AI-powered solutions in clinical care. Engagement with regulatory bodies is required to align AI evaluation processes with existing regulatory requirements, thus facilitating smoother integration of evidence-based reliable AI-powered clinical decision-making solutions into guidelines.

10. Integration of AI technology in healthcare: building trust, literacy and ensuring safety and transparency

Challenges for successful implementation of AI-powered technologies in healthcare lie not only in the technology itself, but in changing mindsets to accept and trust these digital tools. Besides a thorough assessment of its clinical effectiveness, cost-effectiveness and regulatory compliance, there should be a better understanding and confidence in AI systems. Patients may have concerns about privacy, data usage, and the reliability of AI-assisted diagnosis. Providing clear and transparent information on AI models' inner working (i.e., explainability) with transparent information on benefits and limitations would address potential fears and concerns while helping to build trust among both professional and patient communities. This should include the establishment of patient engagement programmes in the AI development process. Healthcare professionals, while recognising the potential of AI, often lack comprehensive training in digital health and AI literacy, further leading to hesitation in incorporating AI-tools and results into their clinical practice. For scientists and institutions, we advocate for the creation of incentives to contribute to data sharing platforms and promote open science practices. Open science will contribute to building trust and acceptance among healthcare providers and scientists by objectively demonstrating robustness and reliability of AI solutions. We emphasise the need for a comprehensive strategy to provide accredited training in

digitalisation and AI for healthcare professionals at all levels, including both practising clinicians and medical students.

The signatories of this Joint Statement call on patient associations, cancer organisations, healthcare providers, technology developers, and policymakers to participate in a transparent dialogue and develop strategies on how to build trust and competence in AI technologies across all stakeholder groups.

Guidance and incentives to foster data altruism, i.e. voluntary health data sharing by individuals and organisations for public interest, such as scientific research, are needed and should be developed in cooperation with a wide range of stakeholders, including data altruism organisations, European health professional societies, public and private institutions, as well as patient organisations, and a platform for best practice sharing should be established.

The signatories of this Joint Statement furthermore call on the European Commission to support research into explainability and social sciences and humanities (SSH) aspects of AI tools and training of professionals.

Closing statement (summary table)

Action	The signatories of this Joint Statement call on:
1. Review and validate existing literature for the most promising AI-powered predictive biomarkers such as imaging (radiomics), laboratory, pathology, molecular and fluid biomarkers	• research communities to act and carry out systematic reviews to collect and organise evidence, which should inform future research • research communities to focus on clinical validation studies to further strengthen the evidence
2. Consider AI-powered imaging in in-vivo clinical cancer trials	• the European cancer research community, including industry to consider imaging biomarkers to be incorporated in in-vivo clinical cancer trials • the EU institutions to suggest stronger interdisciplinarity in any cancer-related funding measures
3. Improve the results of cancer screening programmes by AI-powered imaging	• the European cancer research community to consider imaging biomarkers to be evaluated in screening programmes, both opportunistic and on target populations
4. Ensure interdisciplinary stakeholder engagement in the development and implementation of strategies for multimodal AI-powered clinical decision support	• cancer organisations, research institutes, European collaborative networks (including National Cancer Data nodes, HDBAs and Cancer Mission hubs) to ensure interdisciplinarity and include key stakeholders; medical professionals (including radiologists, nuclear medicine physicians and oncologists), patient representatives, (imaging and data) scientists, ethicists, lawyers, policymakers and industry partners in their governing bodies
5. Develop a comprehensive strategy for research on innovative AI-powered solutions that have the potential to impact patient outcomes	• Stakeholder groups and organisations to develop a research strategy that spans the entire AI development pathway, from innovation to validation in real-world settings and clinical practice implementation • the EU to support research aimed at developing and validating innovative, multimodal AI tools as well as at assessing their relevant risks • Member States for a harmonised implementation of the new HTA Regulation to improve and accelerate patient access to innovative diagnostic and potentially lifesaving digital technologies
6. Enhance data quality and infrastructure in healthcare and research institutions to leverage AI-powered multimodal solutions	• European health professional societies (including ESR and EANM) and the European research community to develop a strategy and guidance for data quality and harmonisation in biomarker extraction • the EU, its Member States and funding bodies to support healthcare and research institutions in enhancing their overall data management capabilities

7. Improve the coordination and accessibility of healthcare data for AI development and validation	• the European Commission to connect the EHDS and HDAB with the related professional societies and EUCAIM to discuss metrics of data quality; to establish appropriate links with EU-funded initiatives, such as EHDS-related governance and implementation actions, the Health Data Analytics and Benchmarking initiative, the European Network of Cancer Registries, as well as relevant ERICs and EDICs, to foster integration and ensure the success of these efforts • policymakers, researchers, healthcare providers, and patient organisations to be in constant dialogue to ensure that the EHDS evolves to meet the changing needs of AI-powered healthcare innovation • the EU to support research projects to discuss how to link and connect personal data stored in different repositories, keeping safety and security aspects within the GDPR and to define a European governance framework to oversee the issuance, management, and maintenance of interoperability and identifiers; to recognise the value of integrating European platforms such as EUCAIM into research and innovation actions to leverage its standardised imaging data platform and federated network.
8. Ensure seamless integration of AI-generated results into clinical workflows	• the European health professional societies (including ESR and EANM) and the European research community to prioritise the development and adoption of standards-based interoperability for end-user IT systems in hospitals, specifically focusing on the implementation of common data models and the integration of AI-generated results. • the EU to incentivise healthcare institutions and IT vendors to adopt these standards through targeted funding initiatives and regulatory measures.
9. Establish clear guidelines and frameworks for regulatory compliance of AI-powered solutions in clinical care	• the EU to expedite the development of comprehensive healthcare-specific guidance for regulatory compliance of AI-powered solutions in clinical care and engage regulatory bodies to align AI evaluation processes with existing regulatory requirements, thus facilitating smoother integration of evidence-based reliable AI-powered clinical decision-making solutions into guidelines.
10. Integration of AI technology in healthcare: building trust and ensuring safety and transparency	• patient associations, cancer organisations, healthcare providers, technology developers and policymakers to participate in a transparent dialogue and develop strategies on how to build trust and competence in AI technologies, to give guidance and incentives to organisations, health professionals, public and private institutions to foster data altruism. • the European Commission to support research into explainability and social sciences and humanities (SSH) aspects of AI tools and training of professionals.

Signatories of the Joint Statement

European medical/scientific societies

1. European Society of Radiology (ESR)
2. Cardiovascular and Interventional Radiological Society of Europe (CIRSE)
3. European Association of Nuclear Medicine (EANM)
4. European Association of Urology (EAU)
5. European Cancer Organisation (E.C.O.)
6. European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)
7. European Federation of Organisations for Medical Physics (EFOMP)
8. European Federation of Radiographer Societies (EFRS)
9. European Organisation for Research and Treatment of Cancer (EORTC)
10. European Respiratory Society (ERS)
11. European Society of Cardiovascular Radiology (ESCR)
12. European Society for Hybrid, Molecular and Translational Imaging (ESHI^{MT})
13. European Society for Magnetic Resonance in Medicine and Biology (ESMRMB)
14. European Society of Neuroradiology (ESNR)
15. European Society of Paediatric Radiology (ESPR)
16. European Society of Surgical Oncology (ESSO)
17. European Society of Musculoskeletal Radiology (ESSR)
18. European SocieTy for Radiotherapy and Oncology (ESTRO)
19. European Society of Urogenital Radiology (ESUR)
20. European Society of Medical Imaging Informatics (EuSoMII)

Comprehensive cancer centres and universities in Europe

21. American College of Greece-Research Center (ACG)
22. Department of Radiology and Nuclear Medicine and the board of Amsterdam UMC
23. German Cancer Research Center (DKFZ)
24. German Center of Lung Research (DZL)
25. Erasmus MC, University Medical Center Rotterdam
26. Fondazione Policlinico Universitario Agostino Gemelli IRCCS
27. Groupe Hospitalier Mutualiste de Grenoble (GHM)
28. German Oncology Center
29. Hospital Clinic of Barcelona
30. Hospital Universitario y Politécnico La Fe – Instituto de Investigación Sanitaria La Fe (La Fe University and Polytechnic Hospital – La Fe Health Research Institute)
31. Dept. of Precision Medicine, Maastricht University
32. Medical University of Gdánsk
33. The Netherlands Cancer Institute (NKI)
34. Oslo Cancer Cluster
35. Oslo University Hospital (OUS)

36. Sapienza – University of Rome
37. University of Heidelberg
38. University of Cyprus
39. University of Zagreb School of Medicine
40. Vall d'Hebron Institute of Oncology (VHIO)
41. Vilnius University Faculty of Medicine

Patient organisations

42. ESR Patient Advisory Group (ESR PAG)
43. Cancer Patients Europe (CPE)
44. European Lung Foundation (EFL)
45. Lung Cancer Europe (LuCE)

National radiology societies

46. German Roentgen Society (DRG)
47. Estonian Society of Radiology (ERU)
48. Maltese Association of Radiologists and Nuclear Medicine Physicians (MARNMP)
49. Polish Medical Society of Radiology (PLTR)
50. The Royal College of Radiology of the UK (RCR)
51. Société Française de Radiologie (SFR)
52. Société Luxembourgeoise de Radiologie (SLR)
53. Spanish Society of Radiology (SERAM)
54. Swiss Society of Radiology (SGR-SSR)
55. Portuguese Society of Radiology and Nuclear Medicine (SPRMN)
56. Slovenian Association of Radiology (ZRS)

Other European/(inter)national health stakeholders

57. European Union of Medical Specialists (UEMS)
58. European Academy of Cancer Sciences (EACS)
59. European Imaging Biomarkers Alliance (EIBALL)
60. European Infrastructure for Translational Medicine (EATRIS)
61. Health-RI
62. Hellenic Cancer Society (H.C.S.)
63. International Foundation for Integrated Care (IFIC)
64. Centro Nacional de Dosimetría (INGESA)
65. Instituto Tecnológico de Informática (ITI)
66. Medical Image Computing and Computer Assisted Intervention Society (MICCAI)
67. Multinational Association of Supportive Care in Cancer (MASCC)
68. Asociación Española de Normalización (UNE)
69. Spanish National Research Council / Agencia Estatal Consejo Superior de Investigaciones Científicas (CSIC)

Relevant European projects

70. CGI-Clinics

European industry associations

71. European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)

AI innovators, companies

72. Aigora GmbH
73. contextflow
74. Gruppo Maggioli
75. NTT DATA
76. Quibim
77. radiomics.bio
78. SHINE 2Europe
79. Voronoi Health Analytics

Individuals

80. Priv.-Doz. Dr. med. Adrien Holzgreve, MHBA, Department of Nuclear Medicine, LMU Mun ich University Hospital
81. Rui Amaral Mendes, PhD, FIAOMS, FIAOO, MASCO, member of the Steering Committee of the Department of Bioethics and Artificial Intelligence of the International Chair in Bioethics and researcher of the Cancer subgroup of the Personalised Medicine group of RISE-Health


EU Health Policy Platform


ESR
EUROPEAN SOCIETY
OF RADIOLOGY


EUCAIM
CANCER IMAGE EUROPE


THE AMERICAN COLLEGE OF GREECE
Pierce
Deree
Alba
1875


Amsterdam UMC


dkfz.
GERMAN
CANCER RESEARCH CENTER
IN THE HELMHOLTZ ASSOCIATION
Research for a Life without Cancer


DZL
Deutsches Zentrum für
Lungenforschung


Erasmus MC
University Medical Center Rotterdam


Gemelli
Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Università Cattolica del Sacro Cuore


Groupe Hospitalier
Mutualiste de Grenoble
La Mut' prend soin de vous


German
Oncology
Center


Clínic
Barcelona
UNIVERSITAT DE
BARCELONA


IIS La Fe
Health Research Institute


Maastricht
University


MEDICAL
UNIVERSITY
OF GDAŃSK


NETHERLANDS
CANCER
INSTITUTE
ANTONI VAN LEEUWENHOEK


OSLO CANCER
CLUSTER


OSLO UNIVERSITY HOSPITAL


SAPIENZA
UNIVERSITÀ DI ROMA


UNIVERSITÄT
HEIDELBERG
ZUKUNFT
SEIT 1386


University
of Cyprus


University of Zagreb
School of Medicine


Vall
d'Hebron


Faculty of
Medicine


ESR
EUROPEAN SOCIETY
OF RADIOLOGY
PAG


CANCER
PATIENTS
EUROPE


ELF
EUROPEAN
LUNG
FOUNDATION


Lung Cancer
Europe


DEUTSCHE RÖNTGENGESELLSCHAFT
Gesellschaft für medizinische Radiologie und bildgeführte Therapie e.V.


POLSKIE
LEKARSKIE
TOWARZYSTWO
RADIOLOGICZNE
1925


The Royal College of Radiologists


SFR
SOCIÉTÉ FRANÇAISE
DE RADIOLOGIE
& D'IMAGERIE MÉDICALE


SLR
Société Luxembourgeoise de Radiologie a.s.b.l.


seram
Sociedad Española de Radiología Médica


SGR
SSR
Schweizerische Gesellschaft für Radiologie
Société Suisse de Radiologie
Swiss Society of Radiology


SPRMN


ZDRUŽENJE
RADIOLOGOV
SLOVENIJE


U.E.M.S.
EUROPEAN UNION OF MEDICAL SPECIALISTS
The advocate of medical specialists

EACS
EUROPEAN ACADEMY
OF CANCER SCIENCES

eatris

EIBALL

HELLENIC
CANCER
SOCIETY

health RI
enabling data driven health & life sciences

IFIC
International Foundation
for Integrated Care

ICT TECHNOLOGY CENTRE

The Medical Image Computing
and Computer Assisted
Intervention Society
MICCAI

MASCC
MULTINATIONAL ASSOCIATION OF
SUPPORTIVE CARE IN CANCER
WWW.MASCC.ORG

UNE
Normalización
Española

CSIC

CGI-Clinics
Cancer Genome Interpreter

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European Union
Grant Agreement No. 101057509

COCIR
Advancing Healthcare

aigora

contextflow

GRUPPO
Maggioli

NTT DATA

Quibim

radiomics bio
INSIGHT-BASED DECISION MAKING

SHINE
2Europe

Voronoi
Health Analytics