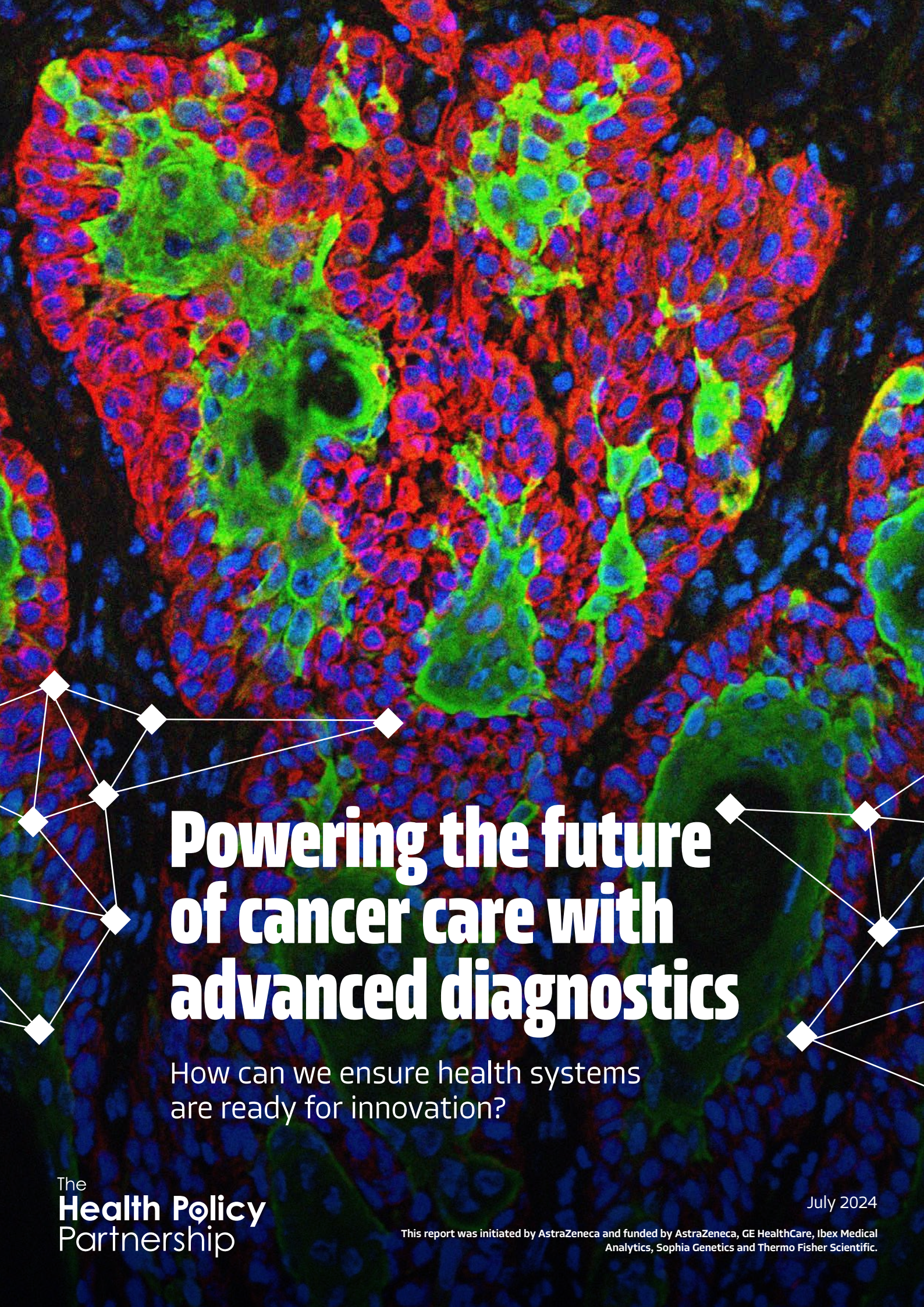

Powering the future of cancer care with advanced diagnostics

How can we ensure health systems are ready for innovation?

The Health Policy Partnership

July 2024

This report was initiated by AstraZeneca and funded by AstraZeneca, GE HealthCare, Ibex Medical Analytics, Sophia Genetics and Thermo Fisher Scientific.

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Cover image: Skin cancer cells, Markus Schober and Elaine Fuchs, The Rockefeller University

About this report

The report was drafted by Shannon Boldon, Esther Shackleton and Jody Tate of The Health Policy Partnership (HPP), and co-authored by the members of the project's Steering Committee:

- Anne-Marie Baird, Senior Research Fellow at Trinity College Dublin, Ireland; President of Lung Cancer Europe, Switzerland
- Petros Christopoulos, Professor of Medicine at Heidelberg University, Germany; Head of Scientific Coordination for the Thoracic Oncology Program in the Thoraxklinik at Heidelberg University Hospital, Germany
- Tony Collier, Vice Chair and Trustee of Tackle Prostate Cancer, United Kingdom
- Laura Cortesi, Director of Oncological Genetics at Modena University Hospital, Italy
- Eva Jolly, Chief Coordinating Officer at Karolinska Comprehensive Cancer Centre, Sweden
- Mark Lawler, Associate Pro-Vice-Chancellor and Professor of Digital Health at Queen's University Belfast, United Kingdom; Scientific Director of the Health Data Research Hub for Cancer (DATA-CAN), United Kingdom; Co-Lead of the European Cancer Organisation's Special Networks
- Zorana Maravic, Chief Executive Officer of Digestive Cancers Europe, Belgium
- Parker Moss, formerly Chief Partnership Officer at Genomics England, United Kingdom; now Executive Vice President at Exscientia, United Kingdom
- Frédérique Penault-Llorca, Professor of Pathology at the University of Clermont-Ferrand, France; Director of Centre Jean Perrin UNICANCER; Deputy Director of the Molecular Imaging and Theranostic Strategies (IMoST) Research Unit, Clermont-Ferrand, France; and President of the Immuno-oncology Group at UNICANCER, France; Deputy President of UNICANCER Group, France; President of AFAQAP (French Association for Quality Assurance in Pathology); President of the Immuno-oncology group at UNICANCER R&D, France
- Federico Rojo, Head of the Pathology Department, Leader of the Molecular Pathology Laboratory, Senior Physician in Pathology, and Scientific Director of the Biobank at Fundación Jiménez Díaz (FJD) University Hospital, Spain
- Heinz-Peter Schlemmer, Head of the Radiology Department at the German Cancer Research Center, Germany; Professor of Radiodiagnostic Oncology at the Medical Faculty of the University of Heidelberg, Germany
- Annemiek Snoeckx, Associate Professor at the University of Antwerp, Belgium; Chair of the Radiology Department at the Antwerp University Hospital, Belgium

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Foreword

Without urgent action, the number of people dying from cancer in Europe will continue to rise. In 2022, there were 1.3 million cancer-related deaths in Europe, a 2.4% increase on 2020.[1] Global estimates suggest that, during the 21st century, cancer will surpass cardiovascular disease to become the leading cause of premature death.[2] This highlights the immediate need for earlier and more accurate diagnosis, and more effective treatments for all cancers.

While cancer outcomes are improving for some people, many others continue to face a poor outlook. People with lung, pancreatic and liver cancer, for example, are among those who face a particularly poor prognosis.[1] People with a cancer diagnosed at a late stage also face especially poor outcomes. For example, only 10% or fewer people with advanced-stage lung cancer are expected to live for five years or longer.[3] In advanced pancreatic cancer that is metastatic (meaning it has spread to other parts of the body), fewer than 5% of people will survive for three years or more.[4]

Advanced diagnostics are the basis on which we could see significant improvements in cancer outcomes. They present an opportunity for people with cancer to benefit from improved survival and quality of life due to more accurate and earlier diagnosis coupled with more effective, targeted treatments and fewer severe side effects from treatments that are not likely to be effective. Advanced diagnostics may also bring health system efficiencies by reducing the use of treatments that would be ineffective for an individual, and offering greater automation of diagnostic tools and clinical workflows – potentially freeing up time from an already overburdened workforce.

Health systems in Europe will not be able to realise the full benefits of advanced diagnostics unless all people have access to them and not just those who are fortunate enough to receive their care at a specialist centre. Policy- and decision-makers across Europe must recognise the pivotal role that advanced diagnostics could play in improving cancer outcomes, and act now to ensure all people with cancer can benefit from new and emerging innovations.

Signed by
Members of the Steering Committee

Executive summary

Advanced diagnostics have the potential to transform outcomes for people with cancer. Historically, diagnosis and treatment of cancer have been based on the location of a tumour and its stage. But increasingly sophisticated diagnostic approaches are now allowing researchers and healthcare professionals to understand cancer in much greater depth.[5,6] This more detailed understanding of each person's cancer can help healthcare professionals diagnose cancer earlier and more accurately, reducing the chance of incorrect diagnosis or a diagnosis being missed,[7] and allowing for the selection of treatments that target specific biological pathways. This approach, known as precision medicine, has the potential to:[8,9]

- improve the effectiveness of treatment
- reduce the chance of someone being exposed to severe side effects from treatments that would not be effective for them
- allow healthcare professionals to monitor in real time how well treatment is working – in case a different approach might be more effective.

Health systems could see efficiencies and cost savings from the widespread implementation of advanced diagnostics for cancer. Cancer-related costs may be reduced due to fewer ineffective treatments being delivered and the reduced need to manage severe side effects.[10-12] Some advanced diagnostics would allow cancers to be diagnosed earlier, which might also bring savings.[13] Furthermore, technologies such as those that use artificial intelligence could support the optimisation of clinical workflows.[14,15]

Advanced diagnostics comprise a range of technologies that are not yet widely available in clinical practice. These include technologies that provide more precise images of a tumour or cancer cells, more in-depth information on the molecules within cancer cells, and more powerful data and analytical tools. While these technologies hold great promise, they are largely available only in research settings and/or specialist hospitals.

As advanced diagnostics become more widely available, existing barriers could become more pronounced. Complex regulatory and reimbursement pathways may be slowing down the availability of new technologies and disincentivising investment and innovation; inadequate infrastructure and workforce capacity are limiting the ability to deliver increasingly complex diagnostic techniques; and low awareness of the role and benefits of diagnostics among people with cancer could limit their use.[16-19] These issues are contributing to widespread variation in diagnostic practices across Europe and could ultimately be contributing to inequalities in cancer outcomes.[20-23] Such inequalities must be understood and addressed to avoid their widening when advanced diagnostics become available in health systems.

Securing the benefits of advanced diagnostics relies on health systems being ready to adopt them in a way that provides equal access for all people with cancer. While full system adoption of advanced diagnostics will take time, this report provides some concrete recommendations to help health systems prepare. We have identified five priority areas where policymakers should take action:

1. Adapt regulatory pathways to support the rapid assessment and uptake of advanced diagnostics.
2. Develop innovative approaches to reimbursement and funding that support equitable access to advanced diagnostics.
3. Improve the efficiency and equity of diagnostic and care pathways.
4. Address gaps in workforce numbers and expertise to ensure that advanced diagnostics can be implemented at scale.
5. Build awareness and trust in advanced diagnostics among people with cancer and the wider public.

Why health systems must prepare for advanced diagnostics

Ziad M. El-Zaatari, Science Photo Library

Benefits for people with cancer

Advanced cancer diagnostics are enabling researchers and healthcare professionals to understand the complex nature of cancer in more detail than ever before. The use of advanced diagnostics – which are currently available only in research and/or specialist hospital settings – is supporting an evolution in cancer diagnosis. This means diagnosis is moving from being based solely on the type and stage of cancer towards including the precise determination of a cancer's location, size, and molecular and genetic characteristics.[5 6]

Throughout this report, terms highlighted in blue are hyperlinked to the glossary.

With the increasingly precise information provided by diagnostics, healthcare professionals can select highly tailored treatments. This approach is known as precision medicine.[24] While current diagnostic tools are able to collect some information and are already supporting improvements in cancer outcomes for some people, advanced diagnostics could progress this much further.[25 26] This is because they can collect larger and more complex data sets that can provide a more detailed understanding of cancer than ever before, and guide decisions on the most effective treatment.[14 27-29]

Advanced diagnostics could play a pivotal role in improving survival for people with cancer. As advanced diagnostics enter clinical practice, we could see: earlier and more accurate diagnosis, with an associated reduction in incorrect diagnosis or a diagnosis being missed; greater stratification of cancer based on the unique characteristics of a tumour; the selection of more tailored treatment options that are likely to be most effective; and more accurate monitoring of treatment effectiveness.[6 7 30 31] People with cancers that are diagnosed at an earlier

stage tend to be more likely to survive than those whose cancers are diagnosed at a late stage.[32] Advanced diagnostics that are more sensitive and can detect earlier-stage cancers therefore hold great potential in improving the overall chance of someone surviving cancer.[32]

These new diagnostic tools could also contribute to improved quality of life for people with cancer. Use of advanced diagnostics could reduce the risk of people with cancer being exposed to treatments that may be ineffective for them and cause severe side effects, thus increasing the chance that people complete their recommended course of treatment.[30] It may also support a reduction in the need for multiple – potentially invasive – diagnostic procedures such as tissue biopsies.[6 24]

We urgently need new diagnostic tools that detect cancer at an early stage and are also patient-friendly.

ZORANA MARAVIC
Belgium

Improvements for health system efficiency

System-wide healthcare costs could be reduced through the use of advanced diagnostics. While precision medicine approaches may increase the cost of diagnosis and treatment, their use is likely to reduce other health system costs.[30] This is due to factors including fewer ineffective treatments being delivered and less need to manage severe side effects for treatments that would not be effective for that individual.[10-12] In Ireland, for example, it was found that over €50,000 could be saved per person with colorectal cancer by testing people with the cancer for a specific genetic variation and selecting their treatment based on the results. This was largely because healthcare professionals were able to tailor treatment approaches and avoid severe side effects that could have led to the person being hospitalised.[11] By enabling earlier diagnosis, advanced diagnostics could bring cost savings, as earlier-stage cancers are generally less expensive to treat.[13] For example, medical costs for breast cancer diagnosed at an early stage are around 50% lower than for breast cancer diagnosed at a late stage.[33]

50%

lower medical costs for breast cancer diagnosed at an early stage compared with those diagnosed at a late stage

Advanced diagnostics could also bring efficiencies to the way healthcare is delivered. Artificial intelligence (AI)-based technologies could help alleviate the workload of staff reading images such as X-rays, scans or pathology slides, while also supporting the optimisation of clinical workflows.[14 15] AI-assisted pathology can reduce the time it takes pathologists to review samples by over 30%, improve diagnostic accuracy, and reduce the chance of incorrect diagnosis or diagnosis being missed altogether.[7 34] Some advanced imaging technologies could support greater efficiency by enabling healthcare professionals to identify and mark cancer for treatment during surgery, avoiding the need for a subsequent procedure. However, as the use of advanced diagnostics is currently largely restricted to research settings, the evidence of their full economic impact is limited.

30%

reduction in time needed for pathologists to review samples when using AI-assisted pathology

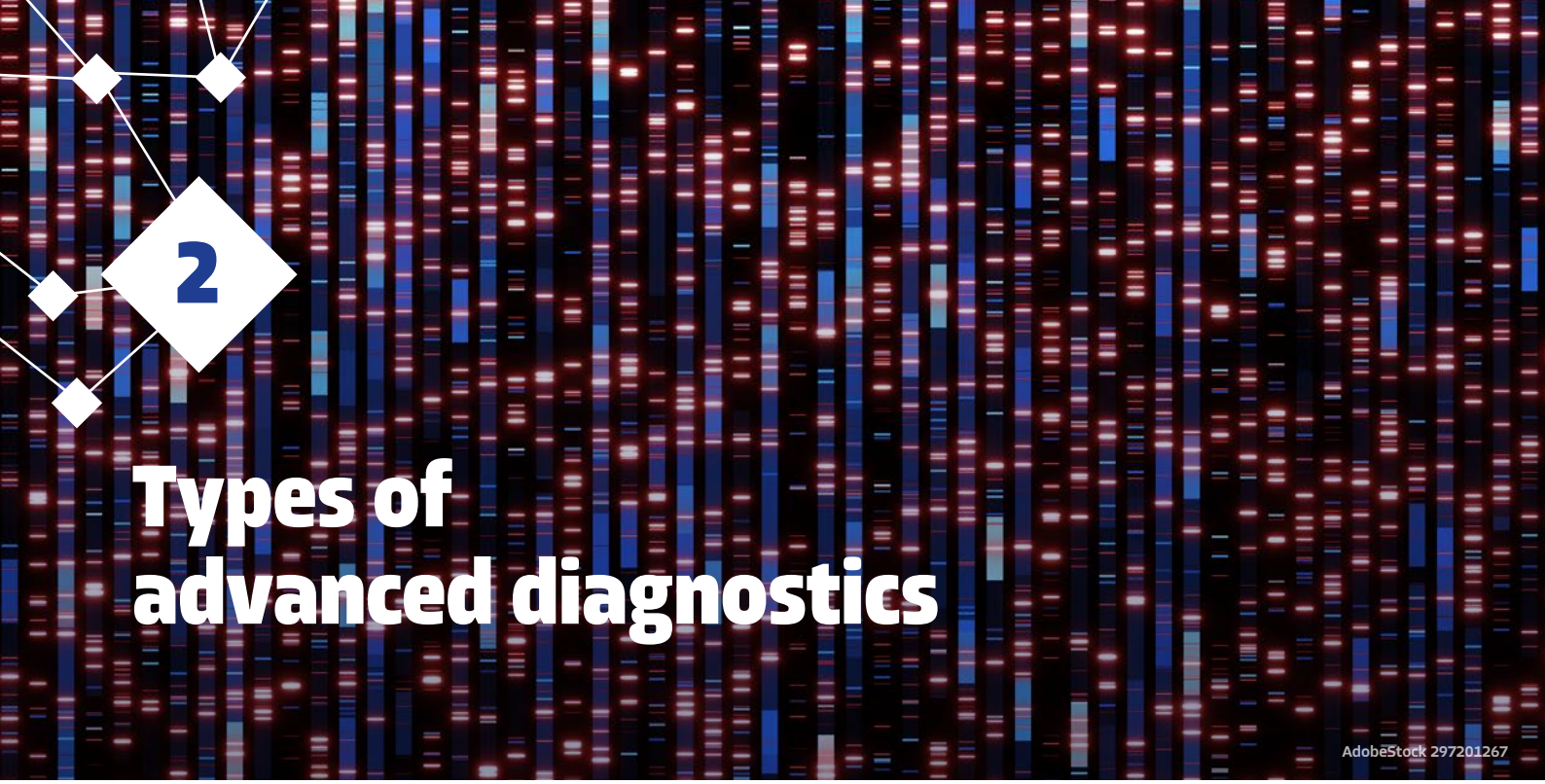
The potential to drive equitable outcomes

A range of barriers limit access to existing diagnostics, contributing to inequalities in cancer outcomes across Europe. Countries with the highest rates of cancer-related deaths – such as Poland, Slovakia and Hungary – also have poorer access to diagnostic technologies.[1 26 35 36] Even in countries considered to have generally good access to healthcare, such as France and Germany, around 25–50% of people with non-small-cell lung cancer do not receive guideline-recommended tests at diagnosis.[21 37] Furthermore, rates of cancer-related deaths are higher among people with lower levels of education and those who live in rural areas; the population groups are also less likely to have access to early diagnosis and effective treatments than people with higher levels of education or those who live in urban areas.[38 39]

To ensure all people with cancer in Europe can benefit, health systems must be ready to implement advanced diagnostics. Policymakers must learn from the challenges that are driving inequalities in access to current diagnostics, to avoid these inequalities continuing or even worsening when advanced diagnostics become widely available.

need to acknowledge existing inequities in currently available diagnostics and be sure not to replicate them with future advancements.

ANNE-MARIE BAIRD
Ireland



Advanced molecular technologies

Liquid biopsy is a minimally invasive diagnostic approach that could provide a more holistic view of a person's cancer than traditional tissue biopsy. Liquid biopsy can collect molecular information from multiple cancer sites simultaneously, including from cancer cells that have become detached from a main tumour and spread to other parts of the body – something that a tissue biopsy cannot do.[40 41] Because liquid biopsies are less invasive and therefore easily repeatable, they are more practical than tissue biopsies.[41] This could especially benefit people who are considered high risk for a surgical procedure, those whose tumours are relatively inaccessible, and the 15–20% of cases where a sample from a tissue biopsy is insufficient for diagnostic testing.[42 43] Liquid biopsy can be more sensitive than some other diagnostic tools, detecting a cancer relapse on average 3–5 months earlier than a scan.[44 45] It can also be cost-effective and, in some cases, cost saving.[46] When used to predict the type of tumour a person has, liquid biopsy could save the health system in England £58,000 for every 100 people with brain tumours.[47] Liquid biopsy holds great potential but, in order to see it used widely, more data are needed to demonstrate its role in improving patient survival and to understand how cost-effective it is.[40 41 48]

Other advanced molecular approaches are being developed that could further enhance the sensitivity and speed of analysis of samples from liquid and tissue biopsies. Third-generation squencing (TGS) allows healthcare professionals and researchers to analyse long strands of genetic code in real time so they can comprehensively map cancer-related changes. In the future, TGS could be used to guide clinical decisions.[27 49 50] It could also provide healthcare professionals with results much more

…id biopsy reduces the need for invasive tissue retrievals and remains sensitive, even for patients without radiologic evidence of disease. We need to generate more prospective evidence and secure its reimbursement so that all people with cancer can benefit from it .

PETROS CHRISTOPOULOS
Germany

easily and quickly than current approaches.[49] Another approach, known as epigenomics, seeks to identify the specific patterns across the genome as normal cells become cancer cells.[51] This approach could be more sensitive and accurate than other molecular approaches, even at a very early stage.[52-54] It can also produce very precise data on where the cancer cells originated, to ensure the right treatment is selected.[55 56] This could bring additional benefits to people with cancer as it requires only a very small sample, which may limit the need for multiple biopsies.[56]

Advanced imaging technologies

Innovations in imaging techniques are supporting earlier and more accurate diagnosis of cancer. Many long-standing imaging techniques, such as magnetic resonance imaging (MRI) and positron emission tomography (PET), have seen significant advances in recent years, leading to a new generation of imaging technologies with the highest specificity and sensitivity to date.[6 29] Total-body PET scans, for example, offer the potential for 40-fold greater sensitivity than traditional PET scans.[57 58] They also offer improved ability to detect cancers that may have spread, and reduce the time needed for each scan, significantly lessening a person's exposure to radiation.[59 60] Multiparametric MRI (mpMRI) can produce a more detailed picture of cancer than previous imaging technologies and more easily distinguish between cancerous and non-cancerous tumours.[61] This could allow more than 25% of people with suspected prostate cancer to avoid a tissue biopsy.[61] Hybrid imaging systems that combine different technologies in a single scanner (e.g. PET-CT and PET-MRI) can also provide a more accurate diagnosis than when used individually.[29]

25%

of people with suspected prostate cancer could avoid tissue biopsy with the use of mpMRI

Alongside these advancements, a range of new technologies that improve the accuracy and sensitivity of imaging results are in development. Some of these technologies (such as nanoparticle-based imaging) can be used to obtain clearer images of tumours, supporting healthcare professionals to better target treatment to specific cancer cells and monitor how that treatment is delivered.[62 63] In addition, molecular imaging probes are being developed, including tracers that are tailored to a person based on the genomic profile of their tumour; such tracers can create imaging data that is higher quality, and improve the accuracy of diagnosis.[6]

Combining advanced imaging technologies with molecular information from liquid biopsies could allow us to see significant advances in personalised screening, diagnosis and treatment.

HEINZ-PETER SCHLEMMER
Germany

Novel approaches to imaging are supporting pathologists to more accurately and efficiently diagnose cancer. Digital pathology involves digitising tissue samples on glass slides. This reduces the need for physical infrastructure by enabling cloud-based storage of slide images;[14] one study in the US found that the implementation of digital pathology could

save a large academic centre USD$1.3 million over five years.[64]
3D pathology is an emerging approach to tissue analysis that combines digital and computational approaches that offer the potential for greater accuracy.[65]

Data-driven technologies

AI can be used to support earlier and more accurate cancer diagnosis. Its potential benefits could include enhancing image quality, automatically detecting and segmenting tissues, and extracting important information on the features of a tumour from imaging data.[66-68] These benefits can reduce errors and provide healthcare professionals with reliable and comprehensive data more quickly.[66-69] AI is also expected to reduce the chance of incorrect diagnosis or a diagnosis being missed.[7 70] It can also be used to guide treatment plans.[66]

could be saved over five years at a large academic centre with the use of digital pathology

AI is having a tangible impact on the work of pathologists. Approaches such as computational pathology (CPATH) combine digital pathology with AI to analyse a combination of tumour information.[14] This approach could improve diagnostic accuracy, reduce analysis time, and improve the efficiency of clinical workflows.[14] CPATH has also demonstrated the potential to more consistently and efficiently identify people who could benefit from specific treatments. For example, it can detect high levels of the HER2 protein, which may indicate an aggressive but potentially treatable form of breast cancer.[71 72] CPATH allows this information to be collected as accurately as manual analysis, but 50% faster.[73] Several CPATH-based technologies are already approved for use in Europe, although a range of challenges need to be addressed to ensure their widespread adoption in clinical practice.[74-76]

CPATH is faster than manual analysis by

50%

Combining data from molecular- and imaging-based advanced diagnostics could provide a more precise characterisation of each cancer and therefore guide treatment decisions more effectively than a single approach. This multimodal approach combines complementary data from various diagnostic methods and clinical data, allowing healthcare professionals to comprehensively assess cancer characteristics, stage and behaviour, and make more effective treatment decisions.[28 29 77 78] One study of people with lung cancer found that a multimodal approach combining genetic, pathology and radiology data outperforms approaches relying on just one commonly used molecular test by 19% when predicting how someone with non-small-cell lung cancer will respond to a particular treatment.[28]

Using a multimodal approach to predict lung cancer treatment was found to outperform using a single molecular test by

19%

3

How health systems can prepare for advanced diagnostics

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Advanced diagnostics have the capacity to transform cancer care, but only if health systems make them available to those who need them. To ensure that policymakers are adequately prepared for the introduction of advanced diagnostics, lessons must be learnt from the existing barriers and challenges that limit access to current diagnostics. By addressing these issues, we could see improved and more equitable cancer outcomes and greater health system efficiency. This could also support greater innovation in Europe by addressing the high levels of uncertainty that manufacturers currently face, which are limiting investment in diagnostic technologies that could benefit people with cancer in the region.[19]

[people with cancer] hear about new technologies, which give us hope, but they take too long to become available. We need to ensure these technologies are available quicker, so we can close the gap between the hype and the hope.

TONY COLLIER
United Kingdom

Adapting regulatory pathways to support the rapid assessment and uptake of advanced diagnostics

Making regulatory assessments fit for purpose

Existing regulatory frameworks are unable to accommodate the adaptive nature of emerging technologies, especially those that use AI. AI-based technologies continually learn and evolve to be increasingly precise, but regulatory assessments do not reflect this because they take place at a single point in time.[79 80]

There is a need, therefore, for innovative and flexible regulatory approaches. Such approaches should reflect the adaptiveness of emerging technologies while ensuring their safety, effectiveness and accuracy.[19 81] For example, the 'regulatory sandbox' model allows innovators to test new products under regulators' supervision before they enter clinical

Testing novel products under supervision: the regulatory sandbox model

Regulatory sandboxes provide a framework to allow innovators to test new products under regulatory supervision. Under this model, existing regulatory requirements are relaxed or adapted for a limited time and under certain conditions.[86]

Although there are very few examples of regulatory sandboxes in practice, their implementation will be boosted through the €60-million, five-year programme Testing and Experimentation Facility for Health AI and Robotics (TEF-Health).[87] The programme, funded by the European Union (EU) and the Digital Europe Programme, was established in 2023 and began implementation in early 2024.[88] TEF-Health comprises a network of facilities that will allow small- and medium-sized enterprises to test, validate and certify novel AI and robotics approaches in four areas, including cancer.[82 86 89]

Although TEF-Health is at the very early stages of implementation, and its impact is not yet clear, the project is expected to:[85]

- facilitate faster transfer of technology from research to clinical practice
- support the creation of standardised testing protocols and certifications that will be made available to innovators in the future
- increase public confidence in new technologies
- improve efficiency and reduce duplication by improving cooperation between innovators and regulators.

TEF-Health will also support the implementation of the recent EU AI Act, which calls for at least one regulatory sandbox for AI in each Member State.[87]

practice (*Case study 1*).[82 83] This approach could reduce the time it takes for a product to become available, encourage investment in innovation by allowing for real-world testing while reducing regulatory uncertainty, and support the development of clearer regulatory requirements and tools for use by innovators in the future.[84 85]

Facilitating implementation of the In Vitro Diagnostic Medical Devices Regulation (IVDR)

Recent regulatory changes in the EU aim to improve the safety and quality of diagnostic devices, but the changes are leading to bottlenecks and delays. IVDR is an EU-level regulatory framework for diagnostics that comes with more stringent requirements for manufacturers to demonstrate and document safety and clinical effectiveness.[90] But its implementation is being hampered by bottlenecks that prevent people with cancer from accessing the diagnostics – and, consequently, the treatments – they need.[18 91] There are not enough notified bodies

(organisations designated by the EU to approve diagnostics), nor guidance and frameworks for manufacturers on the approval process.[19 91 92] These challenges pose a risk to the availability of current diagnostics and, if left unaddressed, could affect the availability of advanced diagnostics. Access to diagnostics used in clinical trials for new cancer treatments in Europe is already seeing a negative impact; it is estimated that up to 27,400 people with cancer will be affected by delays in access to clinical trials.[92]

Strengthened infrastructure, guidance and frameworks to support IVDR's implementation could help ensure manufacturers meet the new regulatory requirements while avoiding unnecessary delays. MedTech Europe, which represents medical technology companies, has highlighted the urgent need for structural changes to the regulatory system.[93] These include making the notified bodies approval system more efficient and adding an 'innovation principle' that allows for fast-track approval pathways for urgent medical need.[93] The European Commission should reflect on these aspects as it prepares for an upcoming evaluation of IVDR.[94]

27,400 people with cancer will be affected by delays in access to clinical trials

Developing innovative approaches to reimbursement and funding that support equitable access to advanced diagnostics

Ensuring health technology assessment frameworks capture the full value of advanced diagnostics

The dynamic nature of cutting-edge technologies, especially those that use AI, creates new challenges for health technology assessment (HTA) bodies. Technologies are often assessed immediately after approval, before data that provide a fuller picture of long-term effectiveness and impact are available.[95] As noted previously in relation to regulatory requirements, this is a challenge for technologies that use AI and are designed to learn and improve.[95] Furthermore, HTAs may not capture broader aspects of value such as a technology's contribution to equitable outcomes in populations with high unmet needs.[96]

HTA frameworks need to be agile and capture the full clinical, societal and economic value of advanced diagnostics. Frameworks and assessments must adapt for advanced diagnostics, especially those that use AI, to reflect their complex and evolving nature.[95] They could draw from emerging frameworks in innovative cancer treatments that have extended the window of evidence generation for reimbursement decisions to take into account factors that are important to people with cancer and to society.[96]

Rethinking funding models

Public funding is often inadequate for the cancer diagnostics that are currently available. The budgets that governments allocate for diagnostics vary but are very often below what is actually needed.[19] This is recognised as a major barrier preventing access to the diagnostics that are currently available.[26 97]

Innovative models that involve risk-sharing offer one possible solution to address reimbursement-related concerns. Models that shift the risk towards the manufacturer until enough evidence has been collected may help overcome some of the challenges associated with reimbursement for advanced diagnostics.[98] Although these models are mostly theoretical at this point, there are examples from other disease areas (*Case study 2*) that could be adapted and applied to support widespread access to advanced diagnostics.

Applying a subscription-based reimbursement model for hepatitis C

In 2016, Australia committed AUD$1.2 billion over five years to a subscription model for hepatitis C treatment.[99] This model is a finance-based (i.e. not based on performance or value), risk-sharing approach to reimbursement.[100] In return for this guaranteed funding, pharmaceutical companies provided an unlimited amount of direct-acting antiviral treatments for hepatitis C.[99]

This has led to major health and economic benefits:

- Between 2016 and 2030, Australia is projected to benefit from AUD$6.17 billion in economic productivity gains, which will yield a net economic benefit of AUD$5.70 billion.
- Australia is on track to reduce the hepatitis C infection rate by 23% (15,700 cases), and deaths are projected to decrease by 46% (8,500 deaths) between 2016 and 2030.

With a fixed budget of AUD$1 billion, Australia is esimated to treat 93,400 more people with hepatitis C using this reimbursement model than traditional pay-per-packet pricing.[101]

Providing optimal funding for diagnostics is key, and realising that high-quality diagnostics can be cost saving must also be considered. Health budgets are often siloed, meaning there is little motivation for one area of the health service to fund diagnostics when cost savings may benefit another domain. We need a more holistic approach to cancer care which puts patients firmly at the centre.

MARK LAWLER
United Kingdom

Innovative solutions to funding are necessary to support the availability of advanced diagnostic tools and need to be supported by policy.

ANNEMIEK SNOECKX
Belgium

Improving the efficiency and equity of diagnostic and care pathways

Building efficient testing infrastructure and pathways

Gaps in infrastructure and inefficient testing pathways can lead to disparities in access and long delays in receiving results. In many European countries, underdeveloped infrastructure leads to unequal access to laboratory tests and imaging equipment.[36 102] Tissue samples taken during a biopsy often have to follow complex pathways for testing, potentially involving numerous facilities.[103] This can contribute to delays in receiving test results that could support treatment selection.[103 104]

Clear and efficient referral and testing pathways could ensure people with cancer have timely access to personalised treatments. Referral systems and testing pathways must be improved to ensure people with cancer can access best-practice care, regardless of whether the facility where they receive their care has the necessary infrastructure on site.[17] Locally based pathways with point-of-care testing may be appropriate for some technologies and could bring efficiencies while reducing delays in receiving results.[17] Whole-genome sequencing at initial diagnosis could also streamline testing, providing a 'one-stop shop' for biomarker testing upfront, as opposed to multiple single-gene tests.[105]

…need to adapt our infrastructure to build efficiency, improve turnaround times for test results and ensure greater communication between clinics and laboratories.

LAURA CORTESI
Italy

Improving digital infrastructure and data-sharing standards

The use of advanced diagnostics may be hampered by technical and legal challenges associated with compiling often disparate data sets. Pooling clinical, pathological, genomic and imaging data sets from different institutions and/or countries is an ongoing challenge; significant investment and months of laborious extraction and annotation may be required before analysis can begin.[77 106 107] This is further complicated by a lack of effective methods for extracting data from electronic health records, incompatible data formats, a lack of standardised cancer terminology for coding data, and a shortage of tools for harmonising and combining data sets.[107] Legal barriers can also pose a challenge for data sharing across borders. The EU General Data Protection Regulation (GDPR) – which was designed to protect people's privacy – could stifle patient-oriented collaborative research and international data sharing if implemented without careful planning.[108]

Barriers to sharing data across the country is a barrier to diagnostic innovation.

FEDERICO ROJO
Spain

Innovative models and frameworks for data sharing across countries in Europe could support the faster adoption of advanced diagnostics. The European Cancer Imaging Initiative (ECII) was launched in 2023 as part of Europe's Beating Cancer Plan.[109] One element of ECII involves creating a Europe-wide infrastructure for sharing cancer images – addressing

Enabling large-scale data sharing to support the use of AI in cancer care

The EUropean Federation for CAncer IMages (EUCAIM) is a digital infrastructure designed to facilitate the optimisation of AI and high-performance computing in cancer care.[112 113] It enables large-scale data sharing within the bounds of GDPR.[112 114 115] EUCAIM is funded by the Digital Europe Programme, receiving more than €18 million.[113]

The first trial of EUCAIM will build on pre-existing, real-world, de-identified imaging data sourced from research repositories from the Artificial Intelligence for Health Imaging Network.[112 116] The researchers, clinicians and innovators using these data will have access to a cross-border, secure data infrastructure and will be able to develop clinical decision-making tools that can support cancer diagnosis and treatment.[112 116] It is hoped the trial will demonstrate a proof of concept for how mass data sharing can be executed, while preserving the data sovereignty of providers and people with cancer.[112 113 116]

By the end of the project, more than 100,000 cases will be available to clinicians and researchers, as well as at least 50 algorithms.[112] These data will be shared via TEF-Health (see *Case study 1*), meaning small- and medium-sized operators will be able to use these data to test their technologies.[112]

key barriers to data sharing and making cancer images more accessible (*Case study 3*).[110 111] By broadening the pool of available data, researchers may be able to develop more accurate diagnostic tools to guide more appropriate clinical decisions.

Addressing gaps in workforce numbers and expertise to ensure advanced diagnostics can be implemented at scale

Boosting workforce capacity to meet evolving needs

Existing workforce challenges could pose a threat to delivering advanced diagnostics. The demand for cancer services is outpacing workforce capacity, and this strain is expected to worsen.[117] The specialist workforce required to deliver advanced diagnostics – including, but not limited to, pathologists and bioinformaticians – is experiencing acute shortages.[118] This contributes to testing delays and long waiting times for results.[117 119] At the same time, it is difficult for healthcare professionals to keep up to date given the speed of technological progress.[120]

Targeted recruitment, upskilling of staff and leveraging potential efficiencies could address gaps in the workforce. Understanding which specific cancer professionals need to be recruited to deliver advanced diagnostics in clinical practice will be critical. The European Cancer Organisation has recommended an EU-level study to assess mid- and long-term skills gaps in oncology.[18] As the skills needed to implement advanced diagnostics evolve, staff education and training will be important.[120] Workforce challenges could also be mitigated by the optimisation of workflows and the greater use of tools that support healthcare professionals to take appropriate clinical decisions based on an individual's test results.[117]

Diagnostics are advancing all the time. We need to train clinical staff in a systematic and ongoing way on how to implement the new technologies as they become available.

EVA JOLLY
Sweden

Building awareness and trust in advanced diagnostics among people with cancer and the wider public

Communicating the benefits of advanced diagnostics

People with cancer need an understanding of the role of advanced diagnostics to make informed decisions about their own care. This includes information on what genomic tests are for and their potential implications.[16] Simple educational tools – such as videos and infographics – can equip people with the knowledge they need to discuss and make decisions about their treatment with their healthcare professional, leading to true shared decision-making.[121] However, research has found that people with cancer, and the wider public, have limited awareness of precision medicine, which could be a barrier to its use.[16]

Healthcare professionals must ensure patients are engaged and empowered in decisions around their care. This means patients must be informed so that they can understand why a test may be needed and what the results mean.

FATIMA CARDOSO
Portugal

Efforts to raise awareness about advanced diagnostics must pay particular attention to socioeconomically disadvantaged and minority ethnic groups. Testing rates are lower in socioeconomically disadvantaged populations than in other populations,[21] which could be contributing to inequitable outcomes. In addition, there is evidence that suggests people from minority ethnic backgrounds may be less willing to use precision medicine (including advanced diagnostics) in their care and may have more concerns about its use than people from non-minority backgrounds.[122–124] This suggests a need for policymakers, patient advocacy organisations and healthcare professionals to collaborate in developing studies, engaging in dialogues and creating policies that aim to understand and address barriers among these groups, and to build trust and support.[17 125 126]

Recommendations for policy change

National-level policy- and decision-makers must act now to 'futureproof' health systems by improving their readiness to adopt advanced diagnostics. At the same time, European-level institutions, including the European Commission and its funded initiatives, have the ability to create a more supportive environment that facilitates innovation, addresses inequalities and supports national-level implementation of advanced diagnostics. This would advance the EU's policy objectives in relation to beating cancer, addressing inequalities, the digitalisation of healthcare, and innovation.

To make this vision become a reality, five priority actions have been identified. By making these changes (see page 22), policy- and decision-makers could ensure that health systems are ready for the widespread adoption of advanced diagnostics when they become available. This would allow innovation to become accessible more quickly, ultimately supporting improved outcomes and quality of life for all people with cancer in Europe.

1 Adapt regulatory pathways to support the rapid assessment and uptake of advanced diagnostics.

- **Redesign regulatory frameworks for advanced diagnostics to allow for their adaptive nature,** and support the widespread adoption of regulatory sandboxes.
- **Ensure the upcoming evaluation of the IVDR considers key aspects of the legislation that are leading to bottlenecks and uncertainty.** This includes assessing efficiency and developing a fast-track assessment pathway for priority technologies.

2 Develop innovative approaches to reimbursement and funding that support equitable access to advanced diagnostics.

- **Establish HTA frameworks that assess and recognise the full value of diagnostics** for people with cancer and for society.
- **Adopt risk-sharing models for the funding of advanced diagnostics** to facilitate their smoother and more rapid integration into care pathways.

3 Improve the efficiency and equity of diagnostic and care pathways.

- **Ensure testing and referral pathways for advanced diagnostics are clear, efficient and supported** by appropriate infrastructure.
- **Facilitate the sharing of data between institutions and across borders** while ensuring data privacy through the use of innovative data-sharing frameworks.

4 Address gaps in workforce numbers and expertise to ensure that advanced diagnostics can be implemented at scale.

- **Identify and address gaps in the specialist workforce needed to implement advanced diagnostics** while ensuring their expertise is updated to keep pace with rapidly evolving technologies.

5 Build awareness and trust in advanced diagnostics among people with cancer and the wider public.

- **Collaborate with patient associations and civil society in developing research and policies that aim to improve awareness of and trust in advanced diagnostics.** These should specifically address the concerns and needs of traditionally underserved groups.

Glossary

3D PATHOLOGY: An emerging approach to tissue analysis in which large samples are imaged using 3D microscopy instead of slides, and examined in high resolution and in combination with computational tools including artificial intelligence (AI).[127]

ADVANCED DIAGNOSTICS: A range of technologies, many of which are currently available only in research and clinical trial settings. These include: advanced imaging techniques, which provide images of a tumour or cancer cells; advanced molecular diagnostics, which provide information on the molecules within cancer cells; enhanced data and analytical tools; and the combined use of these technologies.

ARTIFICIAL INTELLIGENCE (AI): A field of science concerned with building computers and machines that can perform advanced functions such as reasoning, learning and acting in a way that would traditionally require human intelligence.[128] AI is able to process a scale of cancer-related data that exceeds that which humans are capable of analysing.[128]

BIOMARKER (CANCER): A measurable molecular indicator that provides information on the risk and occurrence of cancer, or on patient outcomes.[129]

CHARACTERISATION: Determination of the diagnosis stage and prognosis of the tumour regarding survival, which allows healthcare professionals to predict the response of a cancer to specific treatments.[6]

COMPUTATIONAL PATHOLOGY (CPATH): The computational analysis of information extracted from digital pathology whole-slide images in combination with other data, typically using AI-based algorithms.[14 130]

DETECTION: The process of identifying the particular area of interest within an image, allowing for the characterisation of a tumour.[6]

DIGITAL PATHOLOGY: The process of digitising tissue samples on slides using whole-slide scanners.[14 130]

EPIGENOMICS: The study of how local genome activity is changed without changes to the DNA sequence (known as epigenetics).[51]

GENOMIC: The study of DNA and genes.[131]

HYBRID IMAGING SYSTEMS: Systems that can combine different types of images obtained in one scanner to create multimodal systems; examples include the hybrid positron emission tomography (PET) and magnetic resonance imaging (MRI) scanner, which uses advanced imaging workflows and image analysis.[29]

IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (IVDR): EU legislation that sets out requirements for the certification of medical devices. A key feature is the requirement that 80–90% of devices undergo a conformity assessment by a certified institution.[91]

LIQUID BIOPSY: A minimally invasive diagnostic procedure that collects bodily fluids (e.g. blood, saliva, urine) for analysis to provide an indication of disease status, and monitor response to treatment.[6 48]

MOLECULAR IMAGING PROBE: An agent used to visualise, characterise and quantify biological processes in living systems. One type of molecular imaging probe is a tracer.[132]

MONITORING: Observing how successful a treatment is by assessing how the tumour develops in order to determine whether a different treatment should be selected.[6]

MULTIMODAL: Approaches that involve the analysis of data from various diagnostic techniques (such as imaging, genomics and pathology) to assess characteristics, stage, behaviour and treatment response.[28 29 77 78]

MULTIPARAMETRIC MRI (MPMRI): A specific type of MRI scan that produces a more detailed picture of cancer than standard MRI. It supports cancer detection and risk classification.[133 134]

NANOPARTICLE-BASED IMAGING: Improves the contrast of tumours in an image, making it easier to analyse.[135]

PATHOLOGY: A medical specialty that is considered part of laboratory medicine. Pathology contributes to the diagnosis of diseases through identifying the cause and severity of disease, and monitoring treatments using samples from the body (e.g. blood, urine, tissues, cells). In addition, pathologists also perform post-mortem examinations and autopsies.[136]

PRECISION MEDICINE: An approach to selecting treatment based on information about differences in people's genes, environment and lifestyles.[8] Some people refer to this approach as personalised medicine, although these terms are considered to be slightly different.[30]

THIRD-GENERATION SEQUENCING (TGS): Enables the analysis of long strands of DNA or RNA.[137]

TISSUE BIOPSY: A test in which a doctor takes a small amount of tissue from the area in the body where cancer is suspected. The tissue is then sent to a laboratory and examined by a pathologist.[138]

TOTAL-BODY POSITRON EMISSION TOMOGRAPHY (TOTAL-BODY PET): A type of scan that allows for the entire body to be imaged simultaneously, and faster than traditional techniques, with less exposure to radiation.[60]

TRACER: A substance that is introduced to the body of a patient during an imaging scan and allows healthcare professionals to visualise cancer; a form of molecular imaging probe.[6 139]

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