World Health Organization

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Artificial intelligence is reshaping health systems: state of readiness across the WHO European Region

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Abstract

Artificial intelligence (AI) is transforming health systems, reshaping how care is planned, delivered and governed. This report presents the first assessment of AI integration into health systems across the whole of the WHO European Region, based on findings from the 2024–2025 survey on AI for health care. It examines national strategies, governance models, legal and ethical frameworks, workforce readiness, data governance, stakeholder engagement, private sector roles and the uptake of AI applications. Drawing on insights from 50 Member States, the report explores how countries are navigating opportunities and challenges, highlighting emerging trends, gaps and practices to guide policy-makers towards coherent, ethical and people-centred approaches to AI in health care.

Keywords

ARTIFICIAL INTELLIGENCE; DIGITAL HEALTH; HEALTH INFORMATION SYSTEMS

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Contents

Foreword

This report presents the first regional assessment of artificial intelligence (AI) in health.

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AI is no longer confined to the pages of future forecasts. Its profound and accelerating rise is already transforming health systems across the WHO European Region. From triaging patients and analysing diagnostic images to enhancing national health surveillance and shaping precision public health, AI is now at work in clinics, hospitals and ministries across our Region. In recent years, AI has shifted from a theoretical tool to a real-time companion in health care delivery. This report captures that shift. It reflects both the promise of AI and the nuanced decisions Member States are making to ensure that progress does not come at the cost of safety, rights or inclusion.

Based on an in-depth Member State survey, the report examines six key thematic pillars for AI governance and uptake: national strategies, legal frameworks, data governance, adoption barriers, alignment with health system needs and trust building. Together, these dimensions trace the contours of a Region in transition – diverse in its contexts but united in its determination to harness AI for the public good. They highlight both impressive strides and persistent gaps. From countries that are pioneering legal requirements for generative AI to others just beginning to establish health data hubs, the report reveals a tapestry of progress that is both inspiring and instructive.

Yet this is not a time to rest on our laurels. The report reveals that only 8% of our Member States have issued a national health-specific AI strategy – an urgent reminder that ambition must be matched with concrete action. The gaps in legal accountability, uneven investments in workforce development and emerging risks of exclusion underscore the need for continued vigilance, cooperation and learning. Equity must remain our guiding principle, ensuring that the benefits of AI extend not only across Member States but also within them, reaching all communities regardless of geography, income or digital capacity.

With the publication of this report, I invite us to reflect, engage and act. We must work collectively to ensure that AI in health delivers on its promises, ensuring the best quality care for our populations. For this reason, AI for health and health systems is a central priority under the new European Programme of Work, with a strong focus on developing a roadmap for the ethical, secure and sustainable use of AI. These efforts align with the Programme's broader digital health agenda, which aims to improve digital health literacy, build public trust, strengthen regional coordination and multisector collaboration, and empower primary care.

Ultimately, this report is not only a testament to what has been achieved but also a map for what must come next. It is a living narrative of ambition and accountability: a joint effort by Member States to navigate the opportunities and challenges of AI in health systems with purpose, equity and foresight. The WHO Regional Office for Europe stands ready to support Member States on this path through guidance, partnership and shared learning. I, therefore, welcome you to explore this report as a tool, a touchstone and an invitation to shape a future in which AI strengthens, rather than fragments, the vision of health for all.

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Abbreviations

AI	artificial intelligence
AI Act	European Union Artificial Intelligence Act
COVID-19	coronavirus disease
EHDS	European Health Data Space
EHR	electronic health record
EU	European Union
EU27	European Union Member States in February 2020
GDPR	General Data Protection Regulation
LMM	large multimodal model
NHS	National Health Service (United Kingdom)

Executive summary

Artificial intelligence (AI) is rapidly reshaping the way health systems operate, influencing how health care is planned, delivered and governed across the WHO European Region. This report is based on findings from the 2024–2025 survey on AI for health care and provides the first Region-wide assessment of the current position and orientation of Member States in terms of policies, regulations, strategies, data governance and the adoption of new initiatives and standards, as well as workforce preparedness.

The survey was administered by the WHO Regional Office for Europe between June 2024 and March 2025 and captured collaborative input from national experts on ethics, governance and implementation practices. Data were compiled, validated and analysed descriptively. This work was undertaken within the broader framework of the *Regional digital health action plan for the WHO European Region (2023–2030)*.

At a time when AI is transitioning from experimental pilot projects to real-world applications, this report aims to equip decision-makers with the evidence needed to navigate opportunities and challenges, ensuring that AI serves people, protects their rights and strengthens health systems. By capturing emerging trends, regional gaps and promising practices, it aims to guide investments, foster collaboration and support governments in developing ethical, transparent and people-centred approaches to AI in health.

All 53 Member States of the WHO European Region received the survey, and 50 chose to participate: a 94% response rate. The report and its findings are based on these responses.

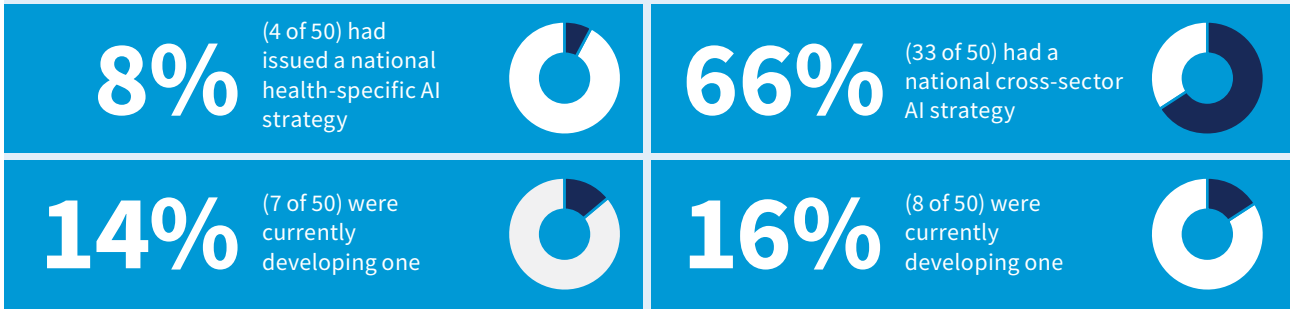
Findings

The report's key findings are organized into six sections, corresponding to the survey's themes:

- the navigators: steering AI strategy and oversight for health systems
- the change-makers: stakeholder engagement and workforce development
- the guardrails: legal, policy and guideline structures for AI in health
- the backbone: health data governance for trustworthy AI
- the catalysts: leveraging AI for health requirements
- the gatekeepers: tackling adoption barriers.

The navigators: steering AI strategy and oversight for health systems

Box E1. The navigators: key findings



National AI strategies provide the blueprint for Member States' visions and objectives to guide responsible development and deployment of AI in health care. These strategies vary in structure and ambition, ranging from stand-alone and health-specific strategies to those embedded within broader digital health agendas or integrated into cross-sectoral frameworks. The survey examines the status of national AI health strategies across the WHO European Region, detailing how Member States develop, oversee and implement strategies, either as dedicated AI for health plans, embedded within digital health agendas or integrated into broader cross-sector frameworks.

Regional context and trends

A small number of Member States have developed or are in the process of developing, health-specific AI strategies, while many others have adopted or are actively advancing cross-sectoral AI strategies. Oversight and implementation of AI strategies are typically managed by existing government agencies, either through a single agency or shared across multiple agencies. A less common approach involves establishing entirely new, independent bodies to lead this work. While cross-sectoral strategies offer broad oversight and consistency across domains, they often lack the specificity necessary for addressing health system priorities. Conversely, health-specific strategies enable more targeted governance and faster implementation, but if there is not effective coordination there is a risk of regulatory fragmentation, inconsistencies in standards and duplicative oversight.

Areas for action include:

- developing and/or updating national strategies, whether health-specific or cross-sectoral, that set a clear vision aligned with health priorities and integrate with broader development plans; and
- setting time-bound objectives with robust monitoring and evaluation frameworks to track progress and ensure accountability.

The change-makers: stakeholder engagement and workforce development

Box E2. The change-makers: key findings

72% (36 of 50) engaged stakeholders, primarily through focus groups (46%; 23 of 50), the most involved parties were government actors, health care providers and AI developers, the least involved were patient associations and the broader public

24% (12 of 50) offered in-service AI training

20% (10 of 50) offered preservice training

42% (21of 50) created new professional roles for AI and data science expertise in health

Engaging patients, public associations and clinicians throughout the AI life cycle is critical to ensure relevance, ethical grounding and social acceptance. Stakeholder engagement, private investment mobilization, cross-border cooperation and workforce development strengthen trust and ensure the integration of inclusive, ethical AI.

Regional context and trends

Across the Region, most Member States have taken steps to engage stakeholders in shaping the use of AI in health. These consultations are conducted predominantly through focus groups and tend to centre on government actors, health care providers and AI developers. Patient associations and the wider public remain significantly underrepresented in these processes, highlighting a gap in inclusive engagement.

Limited engagement carries the risk of producing tools that fail to meet real-world needs, reduce adoption or exacerbate inequities. Similarly, gaps in workforce training can lead to overreliance on AI, erosion of clinical judgement and challenges in critically evaluating outputs. Addressing these gaps requires integrating stakeholder perspectives into design and governance while building competencies to safely and effectively operate AI-enhanced care models.

Opportunities for education and training on AI also remain limited. Few Member States have integrated AI-related content into preservice or in-service training, leaving many health professionals without the skills and knowledge required to navigate AI-enabled care models. In addition, fewer than half of Member States have established new professional roles dedicated to AI and data science expertise within their health systems, underscoring a critical need to strengthen workforce capacity for the digital future of health care.

Areas for action include:

- involving end users, the public and industry in codesign and coregulation processes to identify ethical concerns, enhance accountability and build trust;
- creating platforms and facilitating dialogues that enhance transparency around data sharing and promote culturally sensitive AI applications to empower individuals to make informed decisions about their own care and data; and

- Integrating AI-related content into preservice curricula, in-service training and continuing professional development to equip the health workforce with a solid understanding of AI benefits, risks and ethical considerations.

The guardrails: legal, policy and guideline structures for AI in health

Box E3. The guardrails: key findings

46% (23 of 50) assessed gaps in existing laws and policies related to AI systems in the health sector

8% (4 of 50) had developed liability standards for AI in health

54% (27 of 50) had established regulatory agencies to assess and approve AI systems

6% (3 of 50) had introduced legal requirements for generative AI systems in health care

The legal environment for AI in health is in a state of transition, evolving rapidly yet remaining fragmented and uneven. Accelerating technological change is outpacing existing frameworks, generating uncertainty around liability, risk management and compliance. The survey examined the existence, scope and enforcement of national statutes, regulations and guidance for the development, use and oversight of AI in health across the WHO European Region. The responses highlighted strengths, gaps and opportunities for alignment and responsible innovation.

Regional context and trends

Progress on legal and regulatory responses to AI in health remains uneven across Member States. While many are actively assessing legal gaps, the development of new health sector-specific AI laws remains relatively rare. Only a small number have issued health-specific AI ethical guidelines, with some currently developing them and others yet to introduce any. Existing efforts tend to focus on addressing specific legal and ethical risks, such as providing practical guidance on data protection impact assessments and integrating ethics by design. Minimum standards most often focus on implementing data accountability practices, whereas postmarket monitoring and surveillance of AI products are far less common.

AI policy priorities across the Region have generally centred on procuring, developing and using AI systems in the health sector, while addressing adverse impacts on individuals or collectives and establishing liability standards remain limited. Despite growing concerns about the environmental footprint of generative AI systems, legal requirements for developers to address these impacts are still uncommon. Over half of Member States reported having one or more regulatory agencies responsible for assessing and approving AI systems in health but fewer had agencies tasked with monitoring adoption and use. Encouragingly, cross-country regulatory collaboration is beginning to emerge, with several Member States sharing knowledge and resources to strengthen AI governance in the health sector.

In some cases, sparse health-specific legislation may overlap or conflict with broader AI regulations. Additionally, the lack of clear standards for liability can make clinicians hesitant to rely on AI or, conversely, overly reliant, thereby increasing patient safety risks. Cross-border care and applications beyond

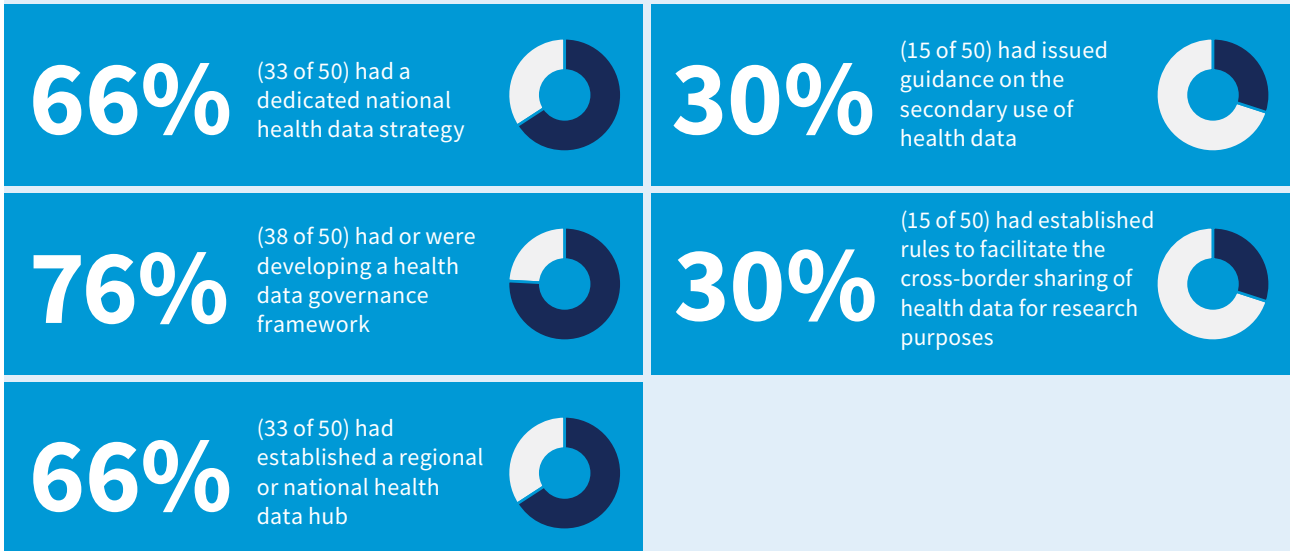
traditional health settings further complicate oversight, blurring the line between regulated clinical tools and loosely governed wellness products and leaving potential gaps in accountability and protection.

Areas for action include:

- establishing clear responsibilities for developers, clinicians, data providers and institutions, with mechanisms for timely redress and accountability when AI systems cause harm, thus ensures that every actor in the AI life cycle understands their obligations, that liability is transparent and that patients and health systems are protected through accessible channels for remediation and enforcement; and
- ensuring that stakeholders understand key AI components, such as data sources, algorithms, decision-making processes and limitations, while respecting proprietary rights and validating safety, reliability and real-world effectiveness through prospective trials before deployment to clinical practice and broader health system use; integrating ethical guidelines and incentivizing responsible design by embedding ethical, legal and technical standards into precertification programmes and encouraging developers to adopt safety-by-design, and human-rights-by-design, approaches from the outset to deliver trustworthy AI systems and accelerate their adoption across diverse health care systems.

The backbone: health data governance for trustworthy AI

Box E4. The backbone: key findings



Data sharing and accessibility are essential for effective AI governance and functionality. Health data hubs and connected electronic health records provide the standardized, secure access needed for AI training and interoperability. The survey examined the level of maturity in health data governance across Member States, including national data strategies, governance architectures and the creation of shared data hubs. Policies that facilitate responsible secondary use of health data, cross-border data exchange and collaboration with industry were identified as were advances, gaps and priority actions necessary to support the ethical and practical deployment of AI in health care systems.

Regional context and trends

Across the Region, many Member States have made significant progress in developing national health data strategies and establishing governance frameworks. A substantial number have also established regional or national health data hubs, forming the core infrastructure for health data management. However, certain areas of data governance are still lagging, including guidance on the secondary use of health data for public-interest research, rules for cross-border data sharing and frameworks for collaboration with private companies on public-interest health research. Without addressing these gaps, AI initiatives risk producing technically advanced tools that do not fully meet clinical or public health needs.

Areas for action include:

- aligning health data governance with international standards to protect individual rights, including informed consent, transparency and independent oversight;
- ensuring special protection for vulnerable groups and promoting public participation in data-sharing decisions;
- setting high standards for health data hubs by requiring precise consent procedures, demonstrable public benefit in data-sharing agreements and good-practice networks to guide equitable design and roll out across the Region; and
- developing guidance for the secondary use of health data in public-interest research and establishing clear rules to enable secure and ethical cross-border data sharing.

The catalysts: leveraging AI for health requirements

Box E5. The catalysts: key findings

52% (26 of 50) identified priority areas for AI in health; only just over half of these had allocated funding for their implementation

Top priorities for AI in health care

98% (49 of 50) cited improving patient care;

90% (45 of 50) cited increasing efficiency

92% (46 of 50) cited reducing workforce pressure;

Use of AI

64% (32 of 50) reported having AI-assisted diagnostics

50% (25 of 50) used AI in chatbots for patient support

Strategic planning and operational investment in AI for health care must go hand in hand for AI initiatives to reach their full potential. The survey examined how Member States prioritize AI applications and engage the private sector, and it assessed the current uptake of AI tools, highlighting their potential impact and alignment with health system objectives.

Regional context and trends

Around half of Member States have identified priority areas where national AI initiatives could deliver the greatest benefits to their health systems and population health. Examples where current AI applications in health systems align with immediate national priorities include patient care, improving health outcomes and reducing pressure on the health care workforce. AI-assisted diagnostics can help to minimize clinician workloads, while chatbots support patient engagement and autonomy. However, only a subset of Member States has allocated dedicated funding to support implementation, highlighting a persistent gap between strategic intent and operational investment. Improving patient care and health outcomes is the leading driver for adopting AI technologies, closely followed by the need to reduce pressure on the health care workforce. AI-assisted diagnostics stands out as the most common application, with nearly two thirds of Member States leveraging AI to enhance imaging and detection. Conversational chatbots for patient assistance are also widely used, with half of Member States reporting their integration in care. Nonetheless, potential risks must also be addressed, including biased or low-quality outputs, automation bias, erosion of clinician skills, reduced clinician–patient interaction and inequitable outcomes for marginalized populations.

Areas for action include:

- aligning AI applications with population and patient interests, as well as national health goals, communicating transparently capabilities, conditions and limitations;
- strengthening funding mechanisms, creating implementation roadmaps and ensuring integration of AI tools into existing health system workflows;
- establishing accreditation and certification and implement standards for developers and mandating independent pre- and postdeployment impact assessments; and
- monitoring AI systems continuously to detect bias, performance drift and potential harms.

The gatekeepers: tackling adoption barriers

Box E6. The gatekeepers: key findings

Barriers to adoption of AI in health care

86% top barrier — **legal uncertainty**, reported by 43 out of 50 Member States

78% second barrier — **financial affordability**, reported by 39 out of 50 Member States

Key policy enablers for widespread adoption of AI in health care

92% liability rules (46 out of 50 Member States)

90% guidance on transparency, verifiability and explainability (45 out of 50)

Despite its promise, AI's impact on health outcomes is often challenged by regulatory uncertainty, ethical challenges, unclear oversight and financial barriers. The use of AI outside formal health care settings, including commercial and consumer-facing tools, blurs oversight boundaries. Financial barriers – including high infrastructure costs, ongoing workforce training, limited reimbursement and subscription fees for advanced AI systems – constrain adoption, particularly in smaller or resource-limited health care systems. Together, these barriers may perpetuate inequities and slow the realization of AI's potential.

Regional context and trends

Across Member States, the adoption of AI in health care faces significant challenges, with legal uncertainty emerging as the most frequently reported barrier, followed closely by financial constraints. Despite these challenges, there is a broad consensus on the policy measures that could facilitate the uptake of AI. Nearly all Member States viewed clear liability rules for manufacturers, deployers and users of AI systems as a key enabler. Similarly, guidance that ensures transparency, verifiability and explainability of AI solutions is considered essential for building trust in AI-driven outcomes.

Areas for action include:

- leveraging regulatory sandboxes to enable regulators, developers and health institutions to collaborate in real-world but lower-risk settings, allowing early identification of safety, ethical and performance issues while fostering innovation under regulatory oversight before widespread deployment;
- evaluating AI solutions against non-AI alternatives (such as established decision-support systems or other digital health tools);
- ensuring alignment with ethical and human rights standards prior to adoption;
- clearly defining which health care responsibilities remain public versus those delegated to private actors; and
- ensuring that public–private partnerships operate transparently, with public disclosure of agreements, and that individual and community rights are upheld by securing ownership or access to AI technologies.

Conclusions and way forward

Based on the findings from the survey, suggestions on next steps are made that summarize key insights and offer potential future policy actions for Member States.

AI in health will only reach its full potential through shared learning, regulatory alignment and sustained investment. By combining evidence, ethics and innovation, Member States can shape a future where AI advances equitable, safe and people-centred health systems. The WHO Regional Office for Europe stands ready to facilitate this collective effort.

1. Overview: exploring the impact of artificial intelligence on health systems

In the WHO European Region, artificial intelligence (AI) is driving a new wave of digital transformation, reshaping health care delivery, management and innovation across diverse settings and health system contexts. The *Regional digital health action plan for the WHO European Region 2023–2030* (Digital Health Action Plan) *(1)* remains highly relevant in the context of AI and its integration into health systems. It provides a strategic framework to help Member States to leverage digital technologies, including AI, to improve health outcomes while tailoring investments to the specific needs of their health systems. A central pillar of the Digital Health Action Plan is its commitment to equity, solidarity and human rights. This is particularly critical for the ethical deployment of AI, ensuring that technological advances do not deepen existing inequalities or undermine patient rights *(1,2)*. However, given the digital divide across and within Member States, knowledge and technology transfer is essential for ensuring equitable access to AI and to prevent the deepening of existing health inequities. Effective transferability of AI is also critical to ensure that tools can be effectively adapted and implemented to suit diverse health systems and resource levels among Member States.

The Digital Health Action Plan calls for robust governance and leadership in the digital health transformation process. This involves setting evidence-informed norms, strengthening national capacities and digital literacy, fostering collaboration and knowledge exchange and identifying scalable, patient-centred innovations that will shape future health systems. The Digital Health Action Plan also emphasizes the importance of high-quality health data, supported by modern classifications and secure interoperable digital infrastructure, as the foundation for responsible AI deployment *(1)*. Moreover, building a digitally competent health workforce is a core priority. Health professionals must be equipped with the knowledge and skills to safely and effectively use AI tools in clinical and public health settings. Finally, the Digital Health Action Plan underscores the importance of data usage to support AI-driven innovation in diagnostics, treatment and health system optimization. By incorporating AI into its broader vision for digital transformation, the Digital Health Action Plan aims to support resilient, inclusive and future-ready health systems across the Region *(1,2)*.

As part of fulfilling the objectives and actions set out in the Digital Health Action Plan, the WHO Regional Office for Europe sought to take a snapshot of this evolving landscape through the 2024–2025 survey on artificial intelligence for health care. This report compiles the insights, experiences and strategies of Member States identified in the survey, offering a glimpse into their ambitions, experiments and thoughtful regulations.

This report is not just a collection of survey findings; it reflects a region in motion. It explores how Member States are developing policies, enacting regulations and crafting national strategies to harness the promise of AI while safeguarding health equity, ethics and patient safety. Targeted at a wide range of stakeholders – including governments, policy-makers, international organizations, academia, AI developers, health professionals and the public – this report is designed to provide a background to the survey findings, presenting them in detail as it explains their broader implications and outline areas for action. Grounded in data and brought to life through case studies of various country examples, the report highlights the varied ways in which AI could be leveraged to build more people-centred, resilient and sustainable health systems across the WHO European Region in the future.

1.1 What is AI?

There are several definitions of AI related to its numerous uses; these focus generally on the core capabilities of AI systems such as processing inputs, inferring patterns, adapting to achieve objectives and producing outputs such as predictions, recommendations or decisions. The absence of a universally accepted definition of AI is largely the result of varied interpretations across countries, contexts and organizations. Moving towards more consistent definitions will help to ensure clarity and fairness in regulation, even if certain use cases are exempted.

The survey (and this report more broadly) adopts the WHO definitions outlined in Box 1.

Box 1. WHO definitions of AI

- AI is a branch of computer science, statistics and engineering that uses algorithms or models to perform tasks and exhibit behaviours such as learning, making decisions and making predictions *(2)*.
- An AI system is a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments. AI systems are designed to operate with varying levels of autonomy *(2)*.
- The subset of AI known as machine learning allows computer algorithms to learn through data, without being explicitly programmed, to perform a task *(3)*. So-called large language models are a further subset of machine learning, trained on vast amounts of textual data in order to understand, generate and respond to human language *(2)*. According to WHO, these models have shown potential in health applications such as patient communication, decision support and summarizing clinical information *(2)*.

1.2 AI for health: transforming care and policy

Since the mid 2010s, AI has begun to subtly, yet profoundly, transform the health sector. From clinical decision support and diagnostic imaging to public health surveillance and health system management, AI is reshaping how care is delivered, how data are interpreted and how resources are allocated *(4,5)*. In the WHO European Region, these shifts have prompted a growing focus on policies and regulation to guide the ethical, equitable and effective use of AI in health care. Member States are working to ensure that AI

applications align with core health values, such as transparency, accountability and human oversight, while also addressing risks such as bias, privacy breaches and widening inequalities *(2)*.

The growing influence of AI in health care across the WHO European Region came into sharp focus amid the coronavirus disease (COVID-19) pandemic. AI technologies became invaluable in managing the crisis by enhancing the speed and accuracy of diagnostics, forecasting disease spread and optimizing health system responses. In several countries, AI-driven tools have supported the real-time analysis of large health datasets to inform decision-making, allocate resources efficiently and monitor public health trends *(6)*. For example, Italy and the United Kingdom used AI to triage patients, predict clinical deterioration and support radiological assessments of lung imaging, thus helping to relieve pressure on overstretched hospitals during the COVID-19 pandemic *(7,8)*. These applications underscore how AI has contributed not only to emergency responses but also to maintaining ongoing continuity of care during times of acute disruption.

The COVID-19 pandemic demonstrated the transformative potential of AI while highlighting the need for robust governance to ensure its responsible use. It also highlighted significant disparities between Member States concerning their capacity to leverage these technologies. Some Member States, particularly those with well-established digital health infrastructures and robust data governance frameworks, were able to quickly integrate AI into their pandemic response. These Member States used AI to enhance diagnostics, optimize resource allocation and improve patient management. In contrast, several other Member States, often with less-developed digital ecosystems, struggled with data fragmentation, lack of skilled personnel and insufficient regulatory frameworks. This limited their ability to fully benefit from AI applications *(6,9)*. This digital divide raises important questions about equity in AI adoption, as the disparities observed during the pandemic may persist and exacerbate existing health inequities in the Region *(10)*.

1.3 WHO's guidance in shaping the pathway to integrate AI into health care

WHO has taken a proactive role in guiding the integration of AI into health care, aiming to enhance health outcomes while upholding safety, ethics and equity. In June 2021 WHO published a landmark report titled *Ethics and governance of artificial intelligence for health*, which highlighted the transformative potential of AI in advancing diagnosis, treatment, health research and public health initiatives *(2)*. The Report stressed that the benefits of AI can only be fully realized when ethics and human rights are embedded in its design, implementation and use. It identified critical ethical challenges and proposed six guiding principles to ensure that AI technologies are developed and applied responsibly within the health sectors *(2)*.

- Human autonomy: humans should always retain control over clinical decisions. Users must understand the AI system and the system should ensure privacy and confidentiality.
- Human well-being, safety and public interest: AI systems should not cause mental or physical harm. Strong safety regulations and ongoing quality control measures must be put in place.
- Transparency, explainability and intelligibility: the AI system must be understandable by both developers and users. Sufficient information should be made available to enable meaningful public debate on whether the AI system should be used. The system should also be explainable to those it is presented to, according to their understanding.
- Responsibility and accountability: AI systems should be used by trained professionals. Both patients and health care providers should be able to assess the system and there must be human supervision and mechanisms in place to redress individuals adversely impacted by the system.

- Inclusiveness and equity: the AI system should be free from bias and there must be a process for evaluating and reporting any identified biases.
- Responsiveness and sustainability: AI systems must be adaptable to changes in human behaviour and health care needs, ensuring long-term effectiveness and relevance.

Furthering these efforts, WHO has continued to provide specific guidance on emerging AI technologies. In October 2023, WHO released the *Regulatory considerations on artificial intelligence for health*, which outlined key regulatory priorities to ensure the safety and effectiveness of AI systems *(3)*. Another major focus has been generating evidence for AI-based medical devices, emphasizing the need for rigorous testing, validation and transparency to establish trust in their performance and reliability *(3)*. WHO also provided initial guidance on large language models, recognizing their potential to transform areas such as clinical decision-making and patient communication, while highlighting risks such as misinformation and bias *(2)*. These efforts underscore WHO's commitment to fostering trust in AI technologies and ensuring their equitable, effective and responsible application in health care settings. WHO has also catalogued key strategic considerations that countries could consider as part of their national AI strategies for health *(3)*.

- Documentation and transparency: AI system development should include prespecified, traceable documentation of medical purpose, datasets, standards, metrics and deviations, with record-keeping proportional to risk.
- Risk management and life-cycle approach: AI systems should follow a total product life-cycle approach, including development, postmarket surveillance and change management, incorporating risk mitigation for threats such as bias and cybersecurity.
- Intended use and validation: clear documentation of an AI system's intended use and training data characteristics is essential, along with external analytical validation using independent, representative datasets.
- Clinical validation: validation requirements should be risk based, with randomized clinical trials for high-risk tools and prospective real-world validation for others, followed by rigorous postmarket monitoring.
- Data quality: developers must ensure data quality supports the AI system's purpose, using careful design and testing to detect and correct bias, errors and poor-quality data early.

1.4 The 2024–2025 survey on AI for health in the WHO European Region

This survey represents the first comprehensive effort to collect data on the current status of AI in health care, as well as its challenges and opportunities across the WHO European Region. The survey was intended to generate insights into regulatory and policy developments, identifying barriers to the adoption of AI technologies and assessing the state of AI adoption and priority areas among Member States. Additionally, the survey explored stakeholder engagement, collaborative initiatives and training programmes essential for supporting AI integration. This current effort addresses current research and use of AI, including the maturity of its current application across Member States; for example, whether AI was being used in a specific context informally, in a pilot phase or was established in ongoing use in clinical establishments for at least 2 years.

As the first initiative of its kind, the results collected will be invaluable for policy-makers, providing a robust evidence base with which to inform the development of governance frameworks, address adoption challenges and ensure that AI technologies are aligned with the specific needs of health systems.

Information at the Member State level is available in the country profiles accompanying this report (https://iris.who.int/handle/10665/383485).

1.5 Structure of the report

Chapter 2 outlines the methods used and discusses the report's limitations.

The findings from the 2024–2025 survey on AI for health in the WHO European Region are organized into six sections in Chapter 3. Each section is started with an infographic highlighting the findings in that area and the results are illustrated by case studies from Member States.

Section 3.1. The navigators: steering AI strategy and oversight for health systems. This examines national AI strategies for health, exploring how Member States integrate AI through standalone health-specific strategies, digital health strategies or broader cross-sector frameworks.

Section 3.2. The change-makers: stakeholder engagement and workforce development. Stakeholder engagement, private investment, cross-border collaboration and workforce development to strengthen trust and ensure inclusive, ethical AI integration are explored.

Section 3.3. The guardrails: legal, policy and guideline structures for AI in health. This section reviews regulatory frameworks, assessing laws, policies and guidelines shaping AI development, deployment and oversight and identifies gaps and opportunities for harmonization.

Section 3.4. The backbone: health data governance for trustworthy AI. The maturity of health data governance is evaluated, including strategies, frameworks and data hubs, highlighting policies for responsible data use, cross-border sharing and private-sector collaboration.

Section 3.5. The catalysts: leveraging AI for health requirements. This section analyses how Member States prioritize health system needs, adopt AI applications, engage private actors and align AI initiatives with objectives such as improving patient care and outcomes.

Section 3.6. The gatekeepers: tackling adoption barriers. The last section of the findings identifies the main legal, financial and ethical challenges slowing AI adoption in health care and explores strategies to overcome them.

The final chapter summarizes the key insights and outlines priority actions to advance ethical, equitable and effective AI adoption in health systems across the WHO European Region.

2. Methods and approach

The WHO Regional Office for Europe initiated the survey on AI for health in June 2024, and it remained open until March 2025. Two versions of the survey were provided: a digital version for widespread online access and a paper version for those Member States requesting a traditional medium. Recognizing language diversity, the instructions and questions were available in both English and Russian.

All Member States were formally invited to take part in the survey and each was recommended to nominate a national survey coordinator. The coordinators' roles were crucial in identifying relevant national digital health and AI experts and ensuring their views and responses were recorded in the survey. Of the 53 Member States, 50 chose to participate, a response rate of 94%. Three Member States did not respond and were excluded from the analysis (Bosnia and Herzegovina, Monaco, and Turkmenistan). Some questions were dependent on Member States' responses to other questions, such as if they have a (cross-sector/sector-agnostic) national AI strategy, or if they have adopted a definition for what an AI system constitutes. In such instances, Member States that did not respond positively to the initial question would be excluded from the number of respondents from which reporting percentages were computed. The analytical process was handled by staff and consultants from the WHO Regional Office for Europe.

For the purposes of this report, references to Europe and the European Region denote the WHO European Region. In order to identify further trends, the data were also analysed based on additional subregional groupings (Table 1) and European Union (EU) Member States in February 2020 (EU27).[1] It is important to clarify that the United Kingdom's survey responses represent only England.

Lastly, this report also includes various case examples of AI systems in practice. These case examples were collected as a follow-up request from the survey respondents after the completion of the main survey. The purpose was to give examples of successful applications of AI systems in different national settings.

1 From 1 February 2020, EU27 refers to the 27 remaining EU Member States after the United Kingdom exited the EU.

Table 1. Member States by subregion within the WHO European Region

WHO subregion	Member State
central Asia	Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, Uzbekistan
western Asia	Armenia, Azerbaijan, Cyprus, Georgia, Israel, Türkiye
eastern Europe	Belarus, Bulgaria, Czechia, Hungary, Poland, Republic of Moldova, Romania, Russian Federation, Slovakia, Ukraine
northern Europe	Denmark, Estonia, Finland, Iceland, Ireland, Latvia, Lithuania, Norway, Sweden, United Kingdom
southern Europe	Albania, Andorra, Bosnia and Herzegovina, Croatia, Greece, Italy, Malta, Montenegro, North Macedonia, Portugal, San Marino, Serbia, Slovenia, Spain
western Europe	Austria, Belgium, France, Germany, Luxembourg, Monaco, Netherlands (Kingdom of the), Switzerland

Note: for Member States of the WHO European Region, geographical subregions are as defined by the United Nations Statistics Division and used in all United Nations publications and databases. Official WHO Member State names are also used as short names but names may vary across all the data sources used. In the case of the western Asian subregion, only those Member States that are part of the WHO European Region were considered (others are part of the WHO Eastern Mediterranean Region and are excluded as not being within the remit of this report) *(11)*.

2.1 Limitations and strengths

This report has several limitations. The survey's terminology was necessarily broad, allowing for country-specific interpretations. The validity of responses depends on the expertise of national coordinators and subject-matter experts. Given the fast-moving nature of AI governance, some findings may outdate quickly. Additionally, the categorization of subregions is based on geographical proximity and does not necessarily reflect similar political, economic or health system contexts.

Nevertheless, the report has notable strengths, including a broad geographical and thematic scope, participation of government-embedded respondents, documentary corroboration of submissions and triangulation across multiple stakeholders, all of which enhance the completeness and credibility of the evidence.

3. Findings: insights into AI for health and health systems

3.1 The navigators: steering AI strategy and oversight for health systems

Highlights box 1. The navigators

AI strategy

8% (4 of 50) have issued a national health-specific AI strategy

14% (7 of 50) are currently developing one

66% (33 of 50) have a national cross-sector AI strategy in place

16% (8 of 50) are currently developing one

Member States with a cross-sector national AI strategy either in place or in development

78% (32 of 41) identified the health sector as a key area where AI is expected to have significant impact

46% (19 of 41) assigned oversight to one or more existing government agencies or bodies; and

12% (5 of 41) created a new government agency specifically for overseeing AI implementation

This section presents key findings from the survey on the current state of national AI strategies. It assesses the models and concepts for AI strategies that Member States are exploring and how such strategies are implemented, governed and overseen. There are two main subsections:

- overview of national AI strategies, action plans and policies explores the different forms national health-related AI strategies can take – such as sector-specific (a stand-alone health-focused) strategy or a cross-sectoral (domain-agnostic) digital health strategy; and
- oversight and implementation of national AI strategies, which examines how these strategies are governed, monitored and operationalized, including the role of regulatory bodies and multistakeholder involvement.

A national AI strategy in health can be defined as a high-level, government-endorsed document or framework that outlines a country's vision, principles, priorities and concrete steps for the research, development, governance and deployment of AI systems in the health sector. These strategies often, but not always, provide a foundation for policy coordination, legal oversight, capacity-building and stakeholder engagement.

The form and governance of a national AI strategy vary significantly, shaped by national priorities, institutional capacity, legal systems and the maturity of health and digital infrastructures. Member States differ not only in whether they have adopted strategies specific to AI but also in how they are structured and implemented. An AI strategy can be issued as a separate stand-alone document specific to the health sector, components of broader digital health strategies or integrated within cross-sector or domain-agnostic frameworks that prioritize the application of AI in the health sector *(12)*.

Health-specific AI strategies enable tailored governance, targeted investments and faster implementation, directly addressing clinical, ethical and privacy concerns. However, they risk regulatory fragmentation and reduced interoperability across sectors. In contrast, cross-sectoral strategies promote unified standards, shared infrastructure and cost efficiency but may slow implementation due to the need for broader coordination.

The implementation approaches that Member States have taken to oversee and implement AI strategies also varies significantly across the Region. For example, Finland's AuroraAI programme is a centralized Government authority that sets national priorities and standards *(13)*. Germany has established the Plattform Lernende Systeme, a multistakeholder governance network that engages academia, civil society and the private sector in the strategy process *(14)*. Recognizing these different implementation approaches is critical to understanding how Member States define and implement AI policy objectives in the health sector.

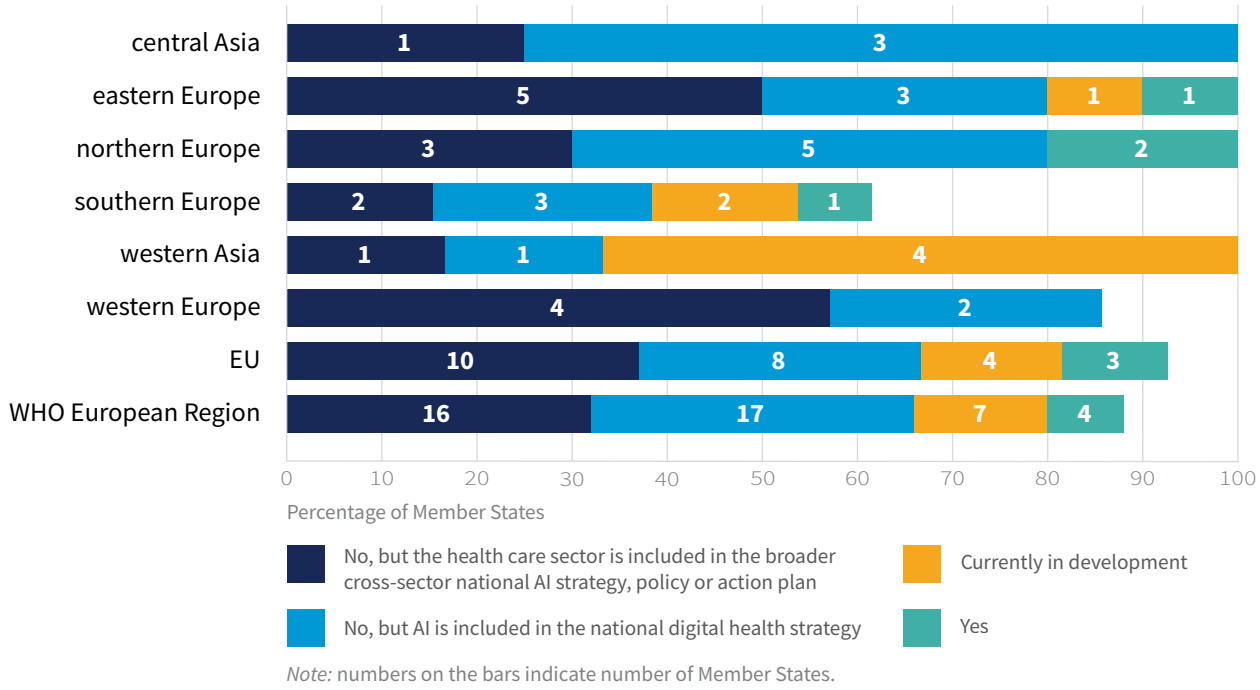
3.1.1 Findings

Overview of national AI strategies, action plans and policies: health-focused AI strategies

Of the 50 responding Member States, only 8% (four) have a national health-specific AI strategy that is already published (Fig. 1). An additional 14% (seven) are currently developing a health-specific AI strategy. A further 32% (16) have a national cross-sector AI strategy of which health is a part and 34% (17) have included AI in their national digital health strategy but have not published a separate health-specific AI strategy. Another 12% (six) reported not having a health-related AI strategy.

From the subregional perspective, it is notable that southern Europe has the highest proportion of Member States without a national AI strategy for the health sector (38%, five out of 13). Across the EU27, a pattern similar to the wider WHO European Region emerged, with 37% (10) reporting the inclusion of the health sector in their national cross-sector AI strategy and 30% (eight) with AI as part of their digital health strategy.

Fig. 1. National strategies, policies, action plans or equivalent for AI in the health sector

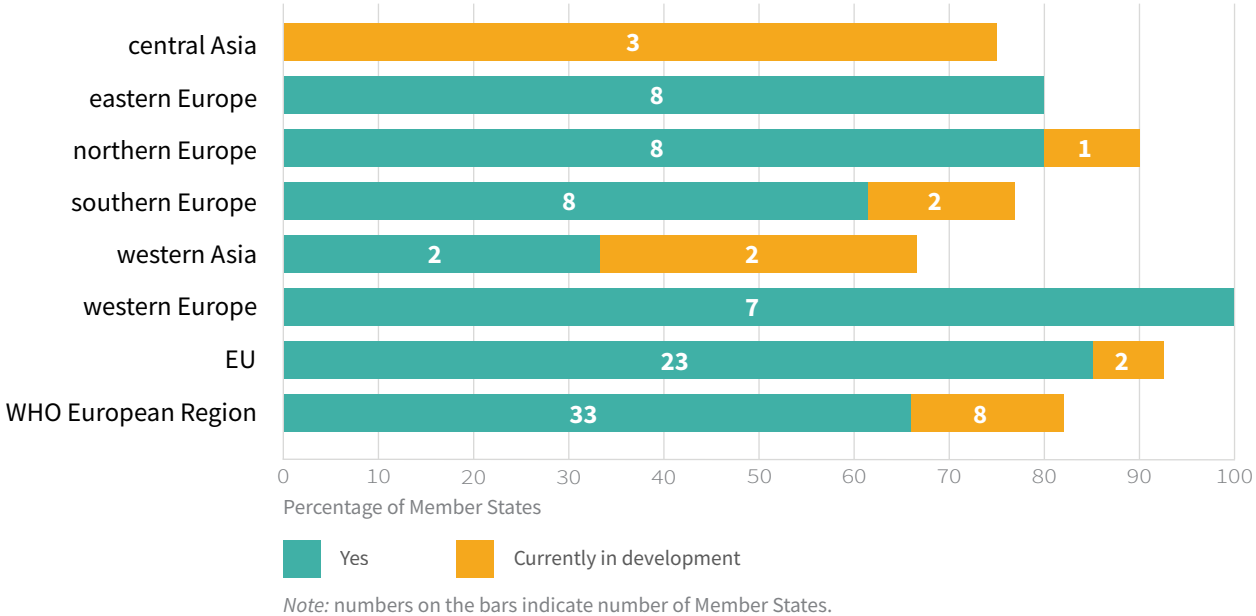


Note: numbers on the bars indicate number of Member States.

Overview of national AI strategies, action plans and policies: domain-agnostic AI strategies

Regionally, 66% of the responding 50 Member States (33) had a cross-sector national AI strategy and 16% (eight) are currently developing such a strategy. Another 16% (eight) reported not having a cross-sector AI strategy. Western Europe, with 100% (all seven Member States), eastern and northern Europe, each with 80% (eight out of 10), and southern Europe, with 62% (eight out of 13), lead in this regard among the subregions with a current national, cross-sector AI strategy (Fig. 2). A similar pattern is seen in the EU, with 85% of Member States (23 out of 27) reported having a national cross-sector AI strategy.

Fig. 2. Cross-sectoral national AI strategies, policies, action plans or equivalent



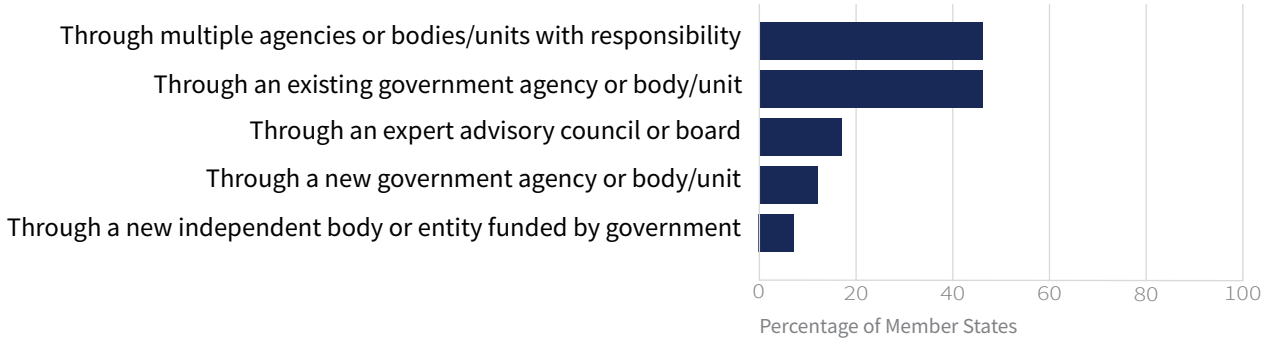
Note: numbers on the bars indicate number of Member States.

Of the 41 Member States that have a cross-sector national AI strategy or are developing one, 68% (28) have adopted a definition for what constitutes an AI system and 78% (32) have identified the health sector as a key area where AI is set to have a significant impact. In total, 29% of the 41 Member States (12) have revised and updated their strategy since 2019 and a further 39% (16) are either currently revising or plan to revise the strategy soon.

Oversight and implementation of national AI strategies

Member States across the WHO European Region took a varied approach to the implementation and operation of national AI initiatives within the health sector. The two most common approaches, each reported by 46% of Member States (19 out of 41), involved assigning implementation and execution responsibility either (i) to an existing government agency or (ii) by distributing it across multiple responsible agencies (Fig. 3). This approach, while commonly used across all subregions, was not the only mode Member States used to implement national AI initiatives. An expert advisory council was also established in 17% of Member States (seven out of 41); 12% of Member States (five out of 41) created an entirely new government agency; and 7% of Member States (three out of 41) created a new independent body funded by the government to fulfil this purpose.

Fig. 3. Oversight of implementation and operation of national AI initiatives in the health sector in the WHO European Region



Across most subregions, national AI strategies are typically implemented through existing government agencies, with northern Europe, western Europe and central Asia showing the highest adoption of this approach. However, many Member States, particularly in northern Europe and central Asia, distribute the oversight responsibility across multiple agencies.

3.1.2 Summary

A small number of Member States have developed, or are in the process of developing, health-specific AI strategies, while many others have adopted or are actively advancing cross-sectoral AI strategies. Oversight and implementation of AI strategies are typically managed by existing government agencies, either through a single agency or shared across multiple agencies, whereas a less common approach involves establishing entirely new, independent bodies to lead this work. While cross-sectoral strategies offer broad oversight and consistency across domains, they can lack the specificity needed for health system priorities. Conversely, health-specific strategies enable more targeted governance and faster implementation but if there is not effective coordination, they risk regulatory fragmentation, inconsistencies in standards and duplicative oversight.

3.2 The change-makers: stakeholder engagement and workforce development

Highlights box 2. The change-makers

72% (36 of 50) have engaged stakeholders, primarily through focus groups (46%; 23 of 50)

28% (10 out of 36) made the insights from their consultations publicly available

Most consulted were

81% (29 out 36) government actors

75% (27 out 36) health care providers

75% (27 out 36) AI developers

Least consulted were

42% (15 out of 36) patient associations

22% (8 out 36); the broader public

Professional training on AI

20% (10 of 50) offered preservice educational opportunities

24% (12 of 50) offered in-service training

42% (21 of 50) created new professional roles for AI and data science expertise in health

This section examines the current approaches and experiences of Member States regarding stakeholder engagement, private investment and health care workforce capacity development. It is divided into the following sections:

- modes of stakeholder engagement examines how Member States are involving stakeholders in shaping the governance and application of AI technologies in health;
- private investment and cross-border partnerships for AI research in health systems explores how partnerships and collaboration are contributing to the development and diffusion of AI solutions; and
- building an AI-ready workforce in health care considers current efforts to train and equip health professionals with the competencies needed to safely and effectively work with AI.

Effective and inclusive collaboration between governments, health professionals, AI developers and public and patient associations is essential to ensure that health care AI is safe, ethical and relevant. Health professionals help to align AI solutions with real clinical and public health needs, while coregulation models and public–private partnerships can balance government oversight with private innovation. The public and patient associations further ensure that AI tools reflect real-world needs by representing patient perspectives, enhancing usability, building trust and monitoring ethical implications, while guiding policies to protect patient rights and serve the public interest. The Council of Europe's *Guide to public debate on human rights and biomedicine (15)* provides relevant guidance on conducting public debates and hearings, emphasizing the importance of inclusive, well-prepared and well-resourced dialogue on complex biomedical and ethical issues.

Building capacity among the health care workforce is central to the WHO European Region strategy for digital health *(1)*, particularly in the context of AI integration. While the WHO Regional digital health action plan for the WHO European Region 2023–2030 emphasizes strengthening digital literacy *(1)*, several Member States still lack pre- or in-service digital health training; among those that do offer training, physicians are often prioritized over other health professionals *(16)*. Beyond technical skills, health care workers also need critical thinking, ethical decision-making and a solid understanding of AI's practical applications and risks. Addressing this requires transforming education to foster interdisciplinary competencies – including data governance, AI fundamentals and communication – supported by a new cadre of educators proficient in both health sciences and AI.

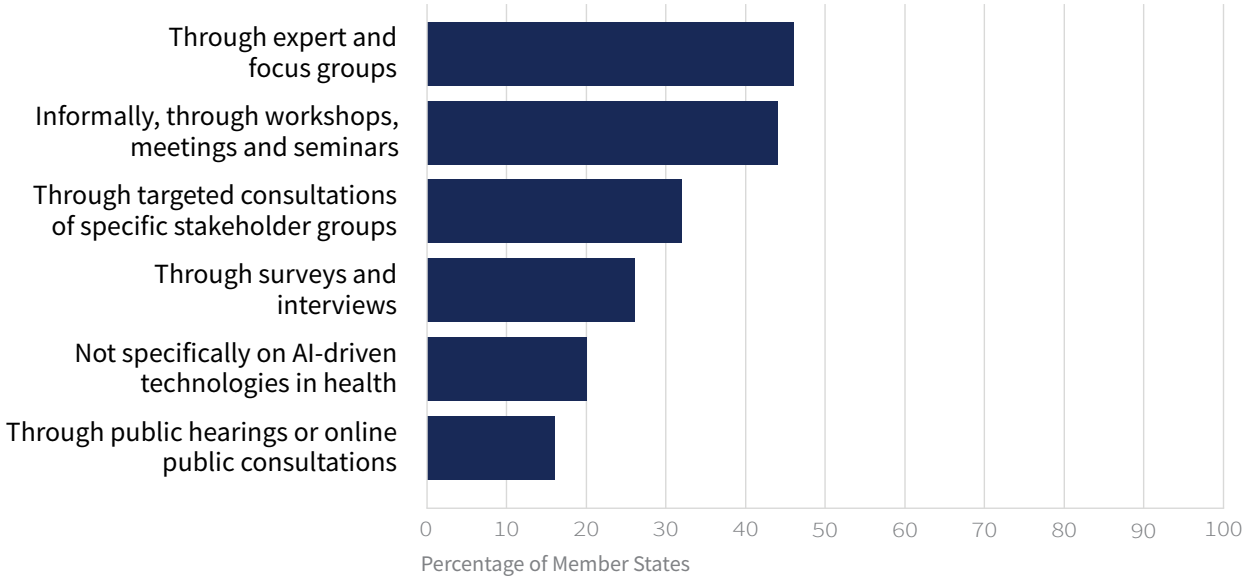
3.2.1 Findings

Modes of stakeholder engagement

Across the WHO European Region, 72% of Member States (36 out of 50) indicated that they had engaged with relevant stakeholders on the application of AI-driven technologies in health systems, in one form or another. Of the Member States who had not conducted any form of stakeholder engagement, 57% (eight out of 14) were planning to engage stakeholders in the future.

As shown in Fig. 4, focus groups (46%, 23 out of 50) and informal meetings, seminars and workshops (44%, 22 out of 50) represented the most common type of stakeholder engagement in Member States. Conversely, consultations for AI-driven technologies not specific to the health sector (20%, 10 out of 50) and public hearings and consultations (16%, eight out of 50) were the least common approaches to stakeholder engagement. For example, Slovakia's Ministry of Health is implementing a project using an AI-assisted radiotherapy planning tool (Case study 1).

Fig. 4. Engagement with relevant stakeholders on the use of AI-driven technologies in health systems



Case study 1. An AI-assisted radiotherapy planning tool in Slovakia

Brief context

The Ministry of Health in Slovakia is implementing a project aimed at improving radiotherapy planning using AI. This initiative aligns with the national strategy to enhance cancer care amid growing cancer incidences, projected to rise by 40% by 2030. The project involves equipping 11 health care providers with software that automates organ-contouring processes during radiotherapy planning, ensuring adherence to modern international standards.

Preparation and planning

The initiative emerged from a thorough evaluation of inefficiencies in the current radiotherapy-planning process. Extensive stakeholder engagement was undertaken, including policy-makers, radiation oncologists and independent experts in oncology. A centralized public procurement process was initiated, emphasizing qualitative assessment criteria:

- expert quality evaluation: 40% weight
- objective evaluation metrics: 10% weight
- functional requirements: 25% weight
- price (via final auction): 25% weight.

Implementation and results

The submission deadline for objections concluded on 23 December 2024. The contracts with the winning bid were then finalized, with key expected outcomes including:

- efficiency: reducing oncologists' time spent on contouring by at least 50%;
- quality: enhancing the precision of radiotherapy plans, leading to improved patient outcomes; and

Case study 1. contd

- accessibility: providing uniform access to advanced AI tools across 11 health care providers in Slovakia.

This project addresses critical challenges, such as the monotony and inefficiency of manual contouring, which occupies 30–50% of radiation oncologists' working hours and thereby contributing to delays in patient care.

Lessons learned and future prospects

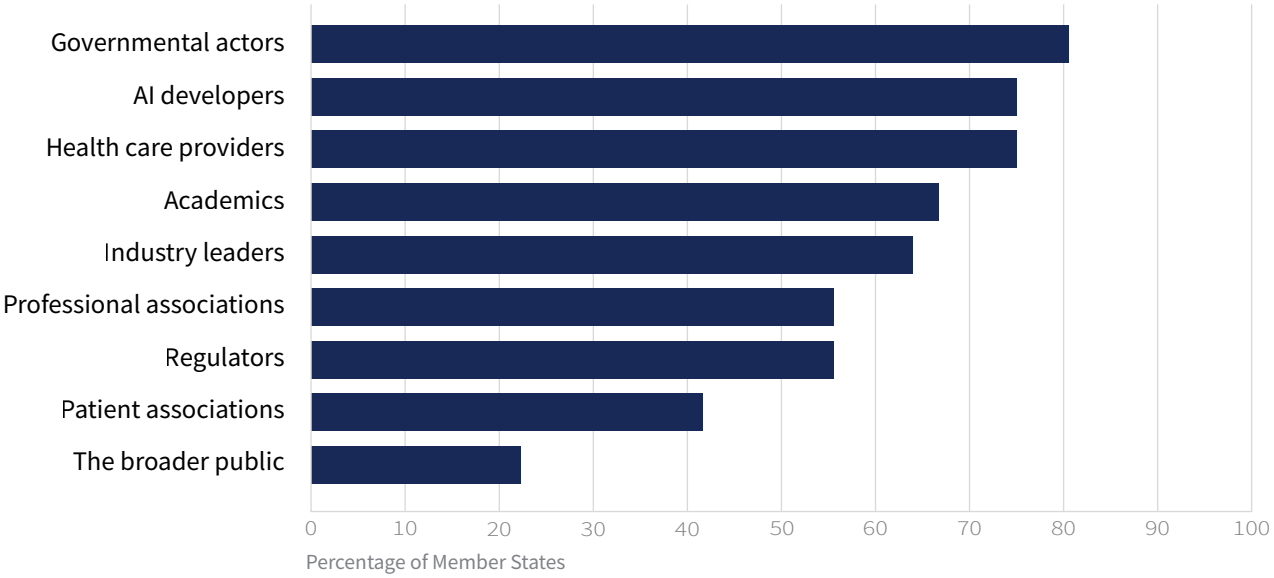
The key lessons so far highlight the value of:

- stakeholder engagement in designing a robust procurement framework; and
- qualitative assessments in procurement to ensure quality and relevance over cost-centric approaches.

Future steps involve monitoring the implementation's impact, collecting user feedback and exploring scalability for additional health care providers. The integration of AI represents a strategic leap towards more efficient, patient-centred oncology care in Slovakia.

As shown in Fig. 5, Member States consulted with a wide range of stakeholders, the most common groups being government actors (81%, 29 out of 36), health care providers (75%, 27 out of 36) and AI developers (75%, 27 out of 36). The least common stakeholders consulted were patient associations (42%, 15 out of 36) and the broader public (22%, eight out of 36). Over half of Member States, 53% (19 out of 36), had consulted more than six different stakeholder groups. Additionally, 28% (10 out of 36) had made the insights from their consultations publicly available.

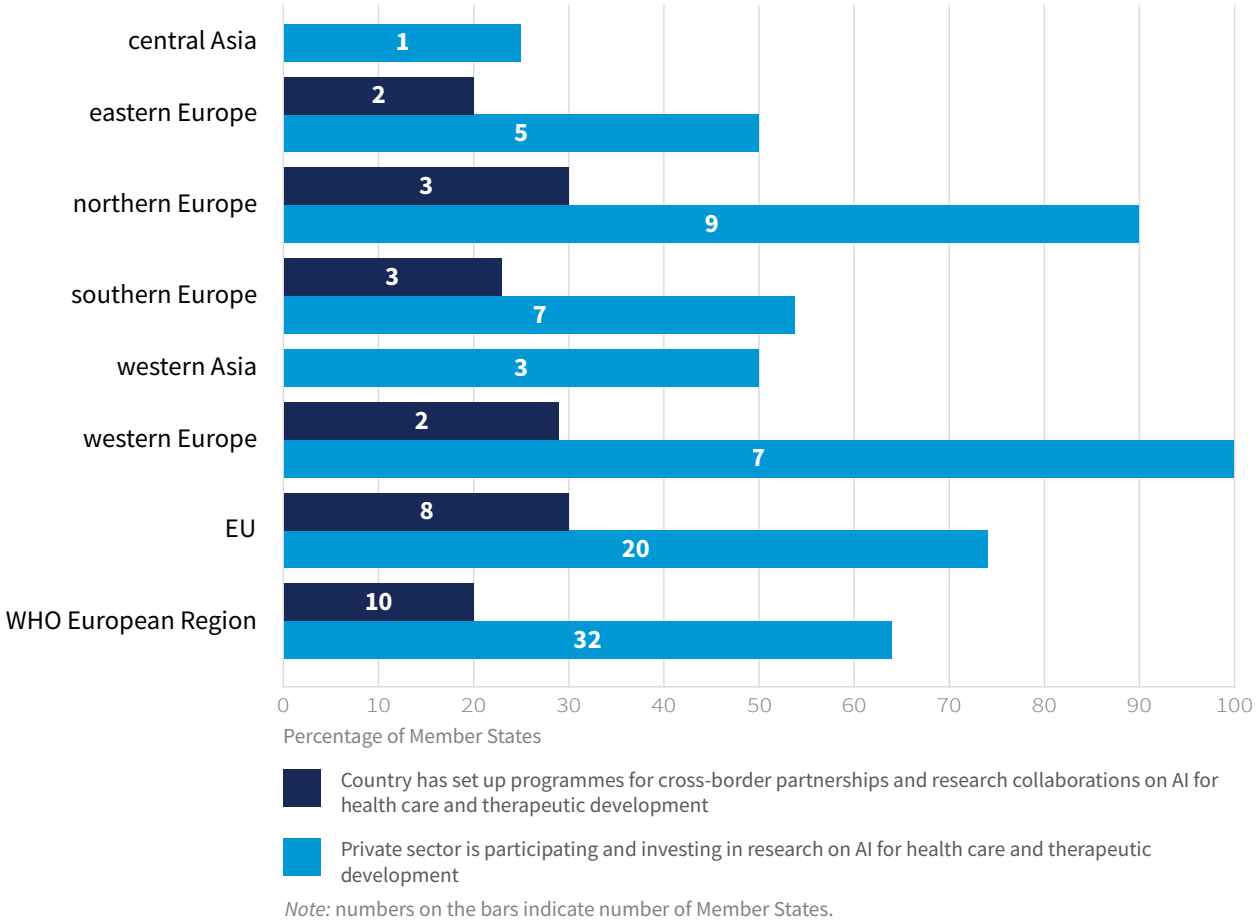
Fig. 5. Stakeholder sectors consulted on the use of AI-driven technologies in health systems



Private investment and cross-border partnerships for AI research in health systems

Private sector participation is crucial for accelerating innovation, scaling AI solutions and translating academic advances into practical applications that improve health outcomes. As shown in Fig. 6, 64% of Member States (32 out of 50) reported private sector investment in AI research for health systems. Cross-border partnerships, by contrast, are far less common, with only 20% of Member States (10 out of 50) indicating that they had established such partnerships. The investment from the private sector has mainly been concentrated in western Europe (100%, all seven Member States) and northern Europe (90%, nine out of 10). Within the EU, 74% (20 of 27) had seen private sector investment in AI research for health (Case study 2).

Fig. 6. Private sector investment and programmes for cross-border partnerships and research collaborations on AI for health care



Note: numbers on the bars indicate number of Member States.

Case study 2. Private sector investment in Finland

Brief context

The new EU European Health Data Space legislation promotes the secondary use of health data while emphasizing the need for strong data privacy, aligning with the focus of the EU Artificial Intelligence Act on data quality and privacy *(17)*. Both regulations prioritize anonymization as a key data privacy method. Historically, data quality has been a challenge in anonymization, but this case study demonstrates that achieving both high data utility and privacy is possible. The study using clinical data

Case study 2. contd

from the control arm of a completed randomized phase II clinical trial and real-world data from Finnish health care data sources *(18)*.

For Bayer AG, the complexity, costs and effort of clinical trials motivated the exploration of innovative technologies. The use of VEIL.AI next-generation data anonymization allowed delivery of high-quality data while maintaining the level of privacy required by the General Data Protection Regulation (GDPR).

Objective and preparation

The project aimed to integrate Finnish real-world data and Bayer's randomized clinical trial data to build an external control arm.

The key partners were:

- Bayer AG, which provided strategic direction and funding
- VEIL.AI, next-generation data anonymization using VEIL.AI Anonymization Engine AI software
- MedEngine for data analytics
- Findata, the Finnish Social and Health Data Permit Authority.

Implementation and results

Real-world data from Finnish health registers and hospital data lakes (around 3300 records) were brought into a Findata secure operating environment, where (after pseudonymization and cleaning) VEIL.AI carried out data anonymization, providing row/subject level output. VEIL.AI also anonymized Bayer's randomized clinical trial data within the Bayer data environment.

VEIL.AI's next-generation anonymization technology ensured the data retained high utility while meeting GDPR requirements. Findata verified the anonymization, approving the outcome as "GDPR-free" and permitting transfer to Bayer, Germany.

High-quality anonymization of legacy randomized clinical trial data and the possibility of integrating these with real-world data enable new opportunities such as:

- creation of external control arm
- enhanced trial efficiency, faster patient recruitment and improved statistical power
- secondary use of clinical trial data.

Key achievements and future prospects

The future clinical trials project demonstrated the transformative potential of integrating high-quality anonymized data with clinical trials.

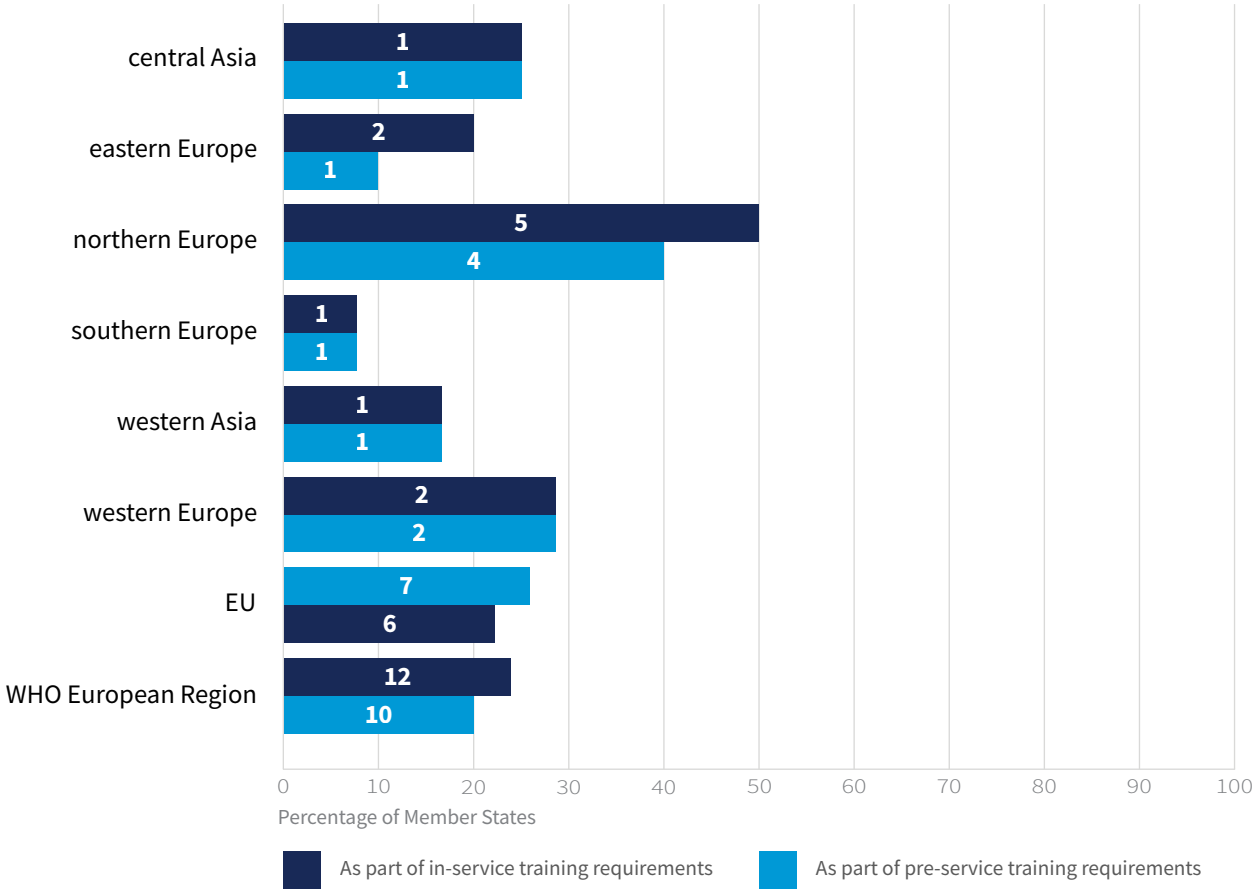
> *This is a significant achievement. In our study, we could draw the same conclusions from anonymized data as from traditional pseudonymized, individual-level research data.*
>
> *Jussi Leinonen, Strategic Project Lead at Bayer*

Notably, this marks the first instance of row-level anonymized health data being approved for transfer from a secure operating environment.

Building an AI-ready workforce in health care

Fig. 7 shows the percentage of Member States that offer in-service (for professionals who are already engaged or deployed) and preservice (in education or training) opportunities to develop AI skills for health and health-related professionals. Only a quarter of Member States across the WHO European Region (24%, 12 out of 50) have in-service training opportunities for health and health-related professionals to develop a solid AI skills base. Preservice training opportunities are only available in 20% of Member States (10 out of 50). Additionally, 28% of Member States (14 out of 50) offer either type of training, with only eight (16%) offering both.

Fig. 7. Educational or training opportunities for health and related professionals

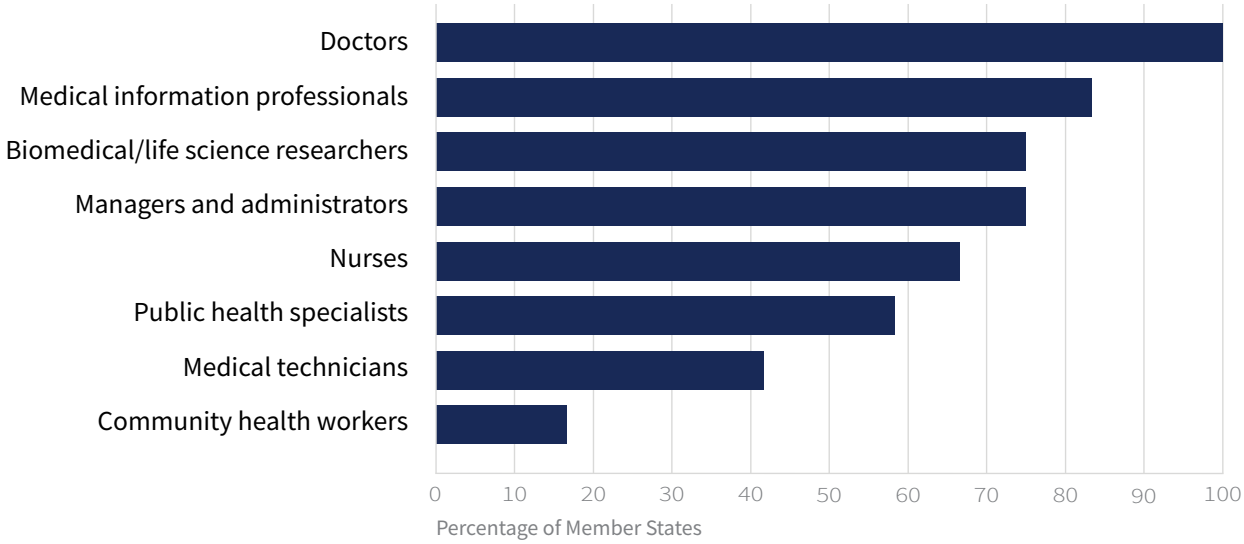


Note: numbers on the bars indicate number of Member States.

Northern Europe has the highest rates of offering both types of training, with 40% (four out of 10) offering preservice training and 50% (five out of 10) offering in-service training. In contrast, southern Europe and western Asia had the lowest training rates, with 15% (two out of 13) and 17% (one out of six) offering in-service or preservice training, respectively. In the EU, the training rates are similarly low: 22% (six out of 27) for preservice training and 26% (seven out of 27) for in-service training.

Fig. 8 shows the percentage of professional groups that have been offered in-service training. All 12 Member States offered in-service training to doctors (100%), closely followed by medical information professions (83%, 10 out of 12). The least common professions to receive in-service training were medical technicians (42%, five out of 12) and community health workers (17%, two out of 12). A third of Member States (33%, four out of 12) offered training to six or more different professions, while 42% (five out of 12) had offered training to four or fewer professions. Additionally, 42% of Member States (21 out of 50) reported that they had created new professional roles and opportunities for people with in-depth knowledge of data science and AI in the health sector.

Fig. 8. Health professionals that have been offered in-service training opportunities for AI



3.2.2 Summary

Across the Region, most Member States have taken steps to engage stakeholders in shaping the use of AI in health. These consultations are conducted predominantly through focus groups and tend to centre on government actors, health care providers and AI developers. However patient associations and the wider public remain significantly underrepresented in these processes, highlighting a gap in inclusive engagement.

Limited engagement risks producing tools that fail to meet real-world needs, reduce adoption or exacerbate inequities. Similarly, gaps in workforce training can lead to overreliance on AI, erosion of clinical judgement and challenges in critically evaluating outputs. Addressing these gaps requires integrating stakeholder perspectives into design and governance while building competencies to safely and effectively operate AI-enhanced care models.

Opportunities for education and training on AI also remain limited. Few Member States have integrated AI-related content into preservice or in-service training, leaving many health professionals without the skills and knowledge required to navigate AI-enabled care models. In addition, fewer than half of Member States have established new professional roles dedicated to AI and data science expertise within their health systems, underscoring a critical need to strengthen workforce capacity for the digital future of health care.

3.3 The guardrails: legal, policy and guideline structures for AI in health

Highlights box 3. The guardrails

46% (23 of 50) assessed gaps in existing laws and policies that relate to AI systems in the health sector

54% (27 of 50) had established one or more regulatory agencies to assess and approve AI systems in health

46% (23 of 50) had implemented data accountability practices as a minimum standard for AI governance in the health sector

8% (4 of 50) had developed liability standards or guidance for manufacturers and users of AI in health

6% (3 of 50) had introduced legal requirements specifically for generative AI systems in the health sector, despite growing concerns about risks such as misinformation and bias

This section provides a comprehensive overview of how Member States across the WHO European Region have formulated laws, regulations, policies and guidelines related to AI. The section is structured into eight subsections:

- national regulatory approaches to governing AI systems outlines Member States' approaches to introducing laws and policies relating to AI and their broad categories;
- ethical standards and legal regulations for AI examines safeguards to ensure responsible use;
- minimum standards for AI governance explores baseline requirements for safety, transparency and liability;
- policy focus for AI regulation considers procurement, certification and limited accountability measures;
- legal liability standards for AI systems addresses liability in case of harm, malfunction or unintended consequences;
- regulations relating to generative AI focuses on emerging challenges from large multimodal models (LMMs);
- regulatory agencies responsible for approving and adoption of AI systems maps institutional roles; and
- cross-country regulatory collaboration highlights efforts to harmonize approaches and foster cooperation.

Several legislative and policy instruments exist to govern the development and use of AI among Member States. The Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and Rule of Law (Framework Convention on AI), opened for signatures on 5 September 2024, is the first-ever international legally binding treaty in this field. This treaty aims to ensure that activities within the life-cycle of AI systems are fully consistent with human rights, democracy and rule of law, while being conducive to technological progress and innovation. As of June 2025, 16 parties were signatories to the Framework Convention on AI, including the EU.

Some Member States rely heavily on so-called hard law – formal legislation comprising of legally binding rules and standards – while others emphasize soft law – mechanisms such as guidelines, voluntary codes of conduct and ethical frameworks. For example, the EU Artificial Intelligence Act (AI Act) *(17)*, provisionally agreed in 2023 and entered into force in August 2024, introduces binding obligations for developers and deployers of high-risk AI systems, including AI-based medical devices and certain other systems used for health purposes, alongside transparency requirements for Generative AI models such as LMMs *(19)*. The AI Act also sets rules for generative AI: a category of AI technologies wherein algorithms are trained on datasets that can be used to generate new content, such as text, images or video *(2)*. In contrast, countries such as Estonia *(20)* and Switzerland *(21)* are exploring adaptive governance models that prioritize innovation while promoting ethical AI through nonbinding guidance. This distinction is not as clear cut, however; provisions on general-purpose AI models in the AI Act similarly rely on nonbinding Codes of Practice (Box 2) *(22)*.

Box 2. The AI Act

The EU proposed AI Act can significantly impact the health care sector by promoting the responsible and safe use of AI in health care.

The draft Act acknowledges that AI comes with complex challenges that can potentially threaten fundamental rights and user safety. To address these concerns, the Act adopts a risk-based approach.

It categorizes AI systems into four levels of risk, which helps to determine the level of regulation that should be applied to AI systems.

- Unacceptable risk: AI systems that pose an unacceptable risk, such as those using manipulative techniques, exploiting vulnerable groups, engaging in social scoring or employing real-time remote biometric identification for law enforcement, will be banned.
- High risk: AI systems with the potential to negatively impact safety or fundamental rights will require thorough assessment before entering the market and continuous monitoring during their life-cycle; this would include items such as medical devices and systems used in health care.
- Limited risk: AI systems, such as chatbots, emotion recognition systems and biometric categorization systems, have limited risk but they are still subject to a limited set of transparency obligations to inform users and allow users to make informed decisions.
- Low risk: AI systems presenting only low or minimal risk can be developed and used without additional legal obligations. However, the AI Act encourages providers to voluntarily apply mandatory requirements meant for high-risk AI systems, promoting responsible and safe AI usage in health care.

Legislation is critical for international alignment, alongside technical standards and governance frameworks. National strategies outline country priorities and goals and further illustrate the need for alignment between countries. For example, the EU's Product Liability Directive is an example of legislation to modernize liability rules in the digital age. Effective from December 2024, the Directive expands the definition of "product" to include software, AI systems and digital files, ensuring that victims can claim compensation for damages caused by defective products, including psychological harm and data loss. The Product Liability Directive extends liability to various economic operators within the EU, including importers and online platforms, particularly when manufacturers are based outside the EU, and it mandates increased transparency through evidence disclosure and publication of court judgements. Member States are required to transpose the Directive into national law by December 2026.

Regulatory ecosystems on AI must include robust frameworks that address key technical, governance, ethical and legal elements, such as minimum safety and transparency standards, certification processes and liability rules *(22,23)*. For example, Austria has introduced the "Trusted AI" certification through TÜV Austria *(24)*, which independently verifies the quality and suitability of AI applications, including those in health care, ensuring they meet established safety and efficacy. These initiatives reflect a growing recognition that regulatory clarity is essential for both accountability and innovation.

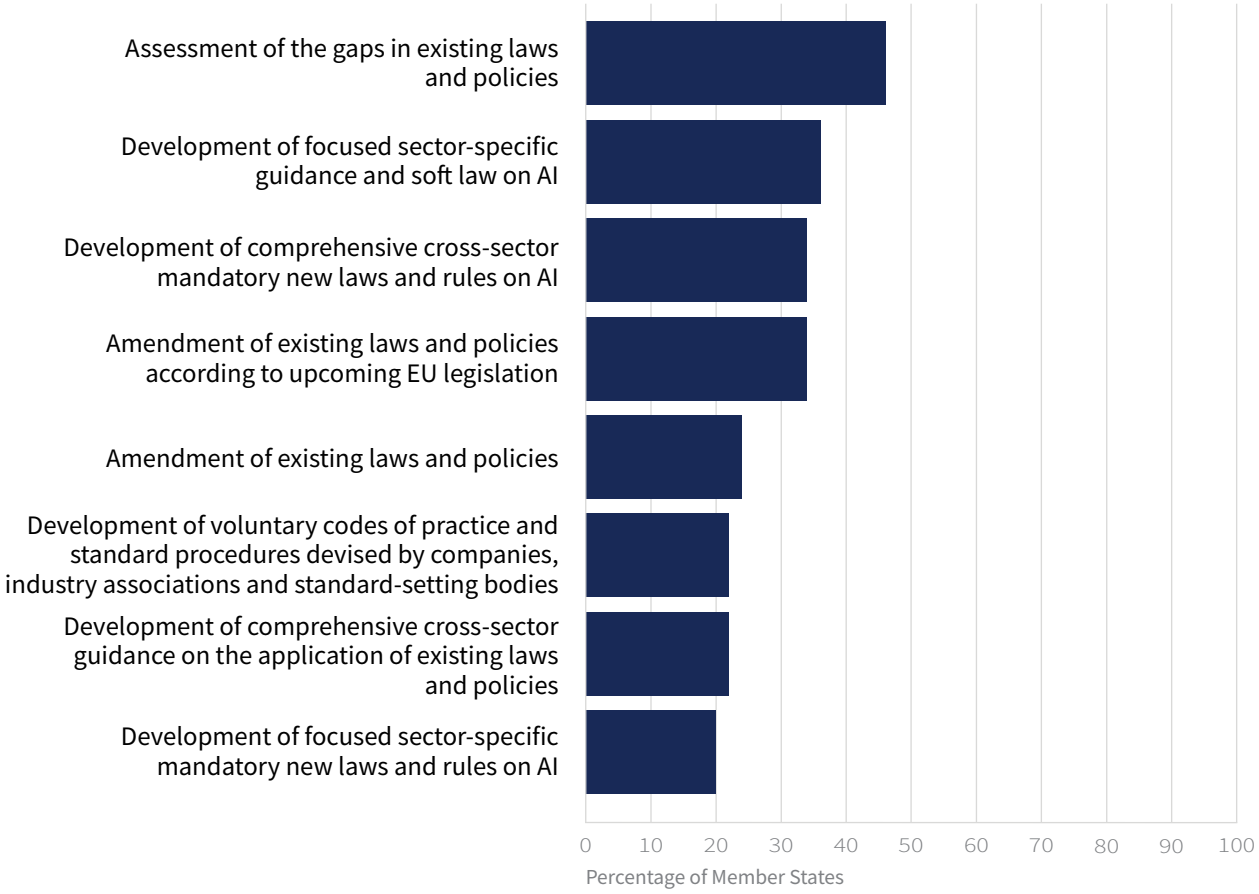
Alongside regulatory clarity, the capacity of institutions and specific supervisory authorities relating to AI is a concern. While the regulation of AI-driven medical devices is an evolving area, the Czechia State Institute for Drug Control is actively developing frameworks to assess and approve AI-driven medical devices, ensuring they comply with national and EU regulations *(25)*. In Poland, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products *(26)* is enhancing its capacity to evaluate AI applications in health care, working alongside national ethics boards and procurement agencies. Mapping these roles and building institutional capacity will be critical to ensuring that AI technologies are rigorously assessed and equitable before reaching patients and providers. Capturing the nuance of regulation on AI is essential. Regulation not only mitigates risk but also fosters responsible innovation, public trust and equitable access. Without safeguards, AI systems may perpetuate bias, harm patients or undermine rights. Yet overly strict or fragmented rules can hinder innovation and access. Striking the right balance requires clear liability standards, public consultation and cross-border regulatory cooperation.

3.3.1 Findings

National regulatory approaches to governing AI systems

Member States across the WHO European Region have taken numerous and varied approaches to governing the development, deployment and use of AI systems in the health sector. As shown in Fig. 9, 46% of Member States (23 out of 50) assessed gaps in existing laws and policies that relate to AI systems in the health sector. Other common approaches used by Member States were to develop new cross-sector laws for AI (34%, 17 out of 50). Developing health sector-specific guidance and ethical principles for AI was reported in 36% of Member States (18 out of 50). The least common approaches were to develop cross-sector guidance on the application of existing laws (22%; 11 out of 50), new voluntary codes of practice (22%; 11 out of 50) and new health-sector specific laws for AI (20%; 10 out of 50).

Fig. 9. Approaches to developing legislative measures or other provisions to govern the development, deployment and use of AI systems in the WHO European Region



Two of the 50 responding Member States (4%) reported having taken all seven approaches listed in Fig. 9. However, most reported focusing on a single approach (14 Member States), while three reported to have taken other approaches not listed in the questionnaire. The diversity of approaches indicates that AI governance is still evolving and Member States could benefit from sharing best practices and exchanging experiences on the benefits and limitations of different approaches to governing AI in the health sector.

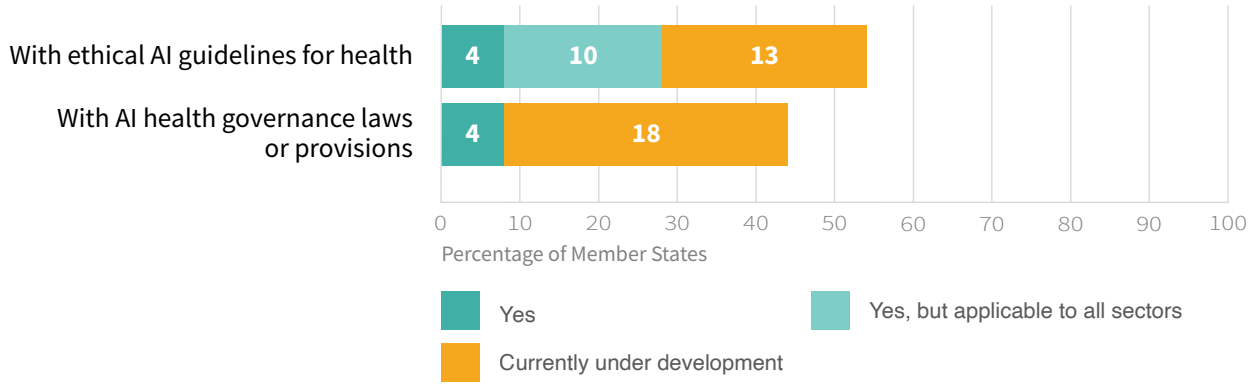
Approaches to AI governance in the health sector vary across subregions. Assessing gaps in existing laws is common in western Asia (67%; four out of six), western Europe (57%; four out of seven) and eastern Europe (50%; five out of 10), while developing new cross-sector laws is more frequent in southern Europe (46%; six out of 13), western Asia (50%; three out of six) and central Asia (50%; two out of four). Within the EU, the most common approaches were to assess gaps in existing laws and policies (44%, 12 out of 27), develop health-specific guidance and ethical principles for AI (37%, 10 out of 27) and amend existing laws according to upcoming EU legislation (37%, 10 out of 27). However, all EU Member States will necessarily need to adopt the AI Act as a regulation.

Ethical standards and legal regulations for AI

Development of laws, policies and ethical guidelines is an important component of national AI governance. These instruments help to clarify roles and responsibilities, address ethical risks and ensure accountability in both cross-sectoral and health-specific applications of AI. While most Member States reported either developing new guidance, laws or voluntary codes and standards or amending or reviewing existing ones, 8% (four out of 50) have issued specific legislation for the governance and oversight of AI in the health

sector, as shown in Fig. 10. Another 36% (18 out of 50) reported that such legislation is currently under development.

Fig. 10. Legislative measures or provisions for AI governance and guidelines to address the ethical implications arising from the development and use of AI

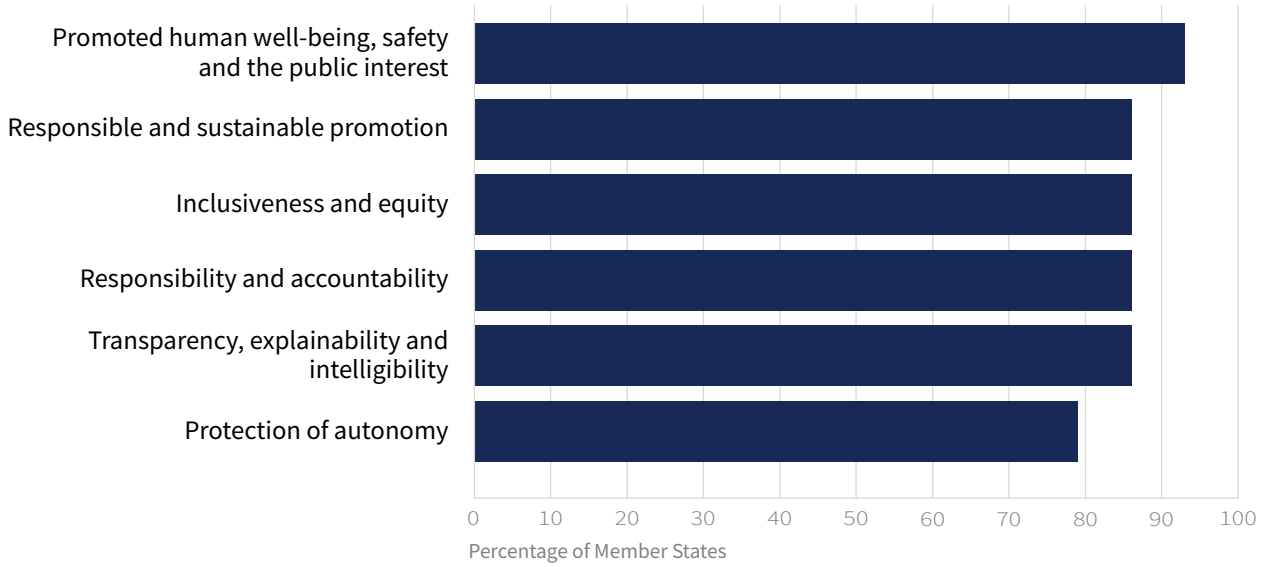


Note: numbers on the bars indicate number of Member States.

Separately, ethical guidelines have been issued by 8% of Member States (four out of 50) to address the ethical implications of developing and using AI specifically within the health sector; 26% of Member States (13 out of 50) noted that ethical guidelines are currently being developed and 20% (10 out of 50) indicated they have developed cross-sector guidelines for the development and use of AI but not specific to the health sector. In contrast, 38% of Member States (19 out of 50) reported that they have not introduced any ethical guidelines, whether specific to the health sector or not.

As shown in Fig. 11, of the 14 Member States that issued ethical guidelines (to the health sector and other sectors), 93% (13) focused on human well-being, safety and the public interest. Other principles such as (i) transparency, explainability and intelligibility, (ii) responsibility and accountability, (iii) inclusiveness and equity, and (iv) responsible and sustainable promotion of AI were also common topics, addressed by 86% of Member States (12). Protection of autonomy was mentioned the least, yet still prominently discussed by 79% of Member States (11 out of 14), and 71% of Member States (10 out of the 14) indicated that they addressed all six principles in their respective ethical guidelines.

Fig. 11. Principles covered in the ethical guidance



When developing an AI strategy for health, it is important to assess potential legal and ethical risks that AI systems pose to patients and the public *(27)*. While some Member States have taken steps to address these risks, there is a significant gap and 60% of Member States (30 out of 50) have not issued any practical guidance on managing these risks.

As shown in Fig. 12, the most common approach, used by 20% of Member States (10 out of 50), was to issue practical guidance on data protection impact assessments relating to AI systems. The second most common approach, reported by 16% of Member States (eight out of 50), was to issue practical guidance on ethics by design, defined by the European Commission as the incorporation of ethical principles into the development process to allow ethical issues to be addressed as early as possible and followed up closely throughout research activities *(28)*, while 8% of Member States (four out of 50) issued five or more practical guidance or ethical checklists to assess the potential legal risks.

Fig. 12. Practical guidance for assessing possible legal and ethical risks of AI systems to patients and the public

Member States that issued practical guidance on data protection impact assessments were mostly concentrated in southern Europe (31%, four out of 13). Southern Europe also had the most Member States that issued specific practical guidance on ethics by design (38%, five out of 13). Similarly, the most common approach in the EU was to issue practical guidance on ethics by design (22%, six out of 27).

Case study 3 outlines the use of AI-based technology to provide faster and more accurate breast cancer screening while maintaining ethical standards.

Case study 3. The National Mammography Screening Reporting System in Türkiye

The National Mammography Screening Reporting System supports Türkiye's equitable and transparent approach in its health care strategy by integrating AI-based technologies into breast cancer screening processes. This system ensures that women aged 40–69 years have access to free mammography screening services, providing equal opportunities for all individuals. AI algorithms facilitate the detection of abnormalities in breast tissue and automate the breast imaging, reporting and data system classification, reducing the workload of radiologists and accelerating health care services.

AI applications in health care services in Türkiye are regulated under the Personal Data Protection Law and the guidelines of the Ministry of Health. In the mammography AI project, patient privacy and data security have been prioritized and data have been anonymized to train AI models.

Ethical principles and security measures have been adhered to during the breast imaging-reporting and data system classification and patient prioritization processes.

The National Screening Mammography Reporting System adopts responsible data governance policies to train AI algorithms. Mammography data collected at cancer early diagnosis, screening and education centres are stored in a centralized system and anonymized. This data management approach ensures patient privacy while providing the necessary infrastructure for AI algorithms to deliver more accurate results.

The mammography AI project is an example of innovation developed to make breast cancer screening processes faster and more accurate. This project utilizes machine-learning techniques to detect abnormalities in breast tissue and automate the classification.

In cancer early diagnosis, screening and education centres, there is a need to enhance the AI literacy of health care personnel and address their training requirements. These barriers are planned to be overcome through training programmes designed to enable health care workers to understand and effectively utilize AI algorithms.

The mammography AI project is designed to ease the workload of health care professionals while supporting their decision-making processes. The project emphasizes that AI is not intended to replace radiologists but to assist and enhance their decisions. In this context, informational meetings have been organized at the cancer early diagnosis, screening and education centres and efforts are planned to build trust in AI through collaboration with patients and health care professionals.

Minimum standards for AI governance

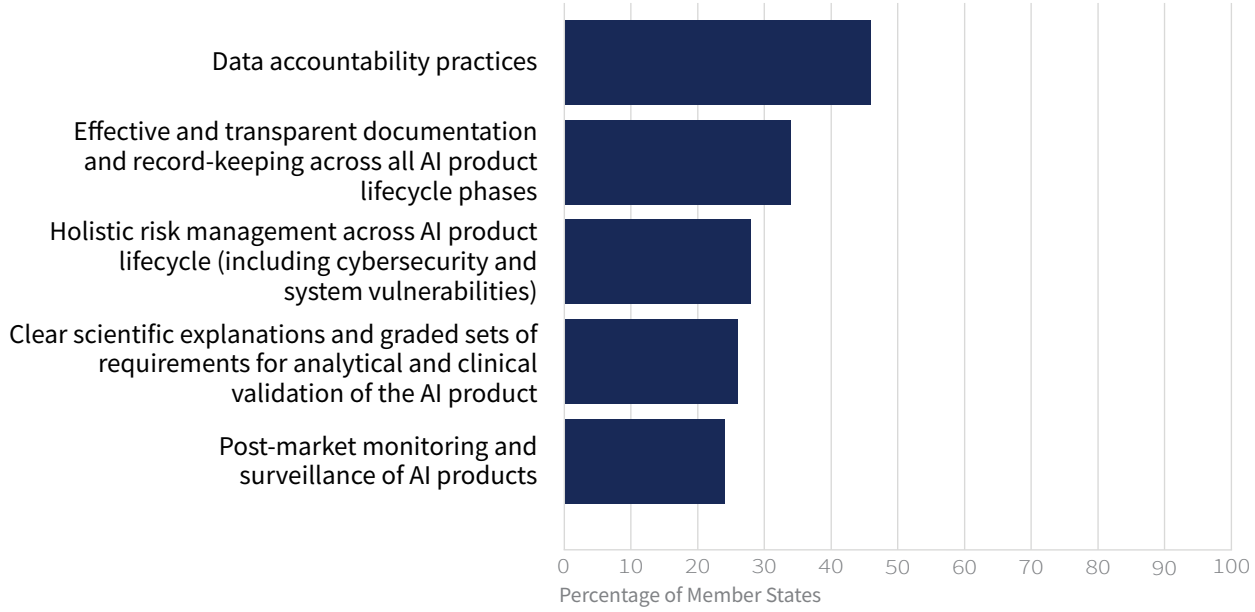
Other regulatory considerations include developing minimum standard requirements in laws, rules, policies and guidelines for governance and oversight of AI within the health sector. The survey provides five separate categories of minimum standard requirements *(3)*:

- effective and transparent documentation and record-keeping across AI product life-cycle phases to facilitate regulatory assessment and auditing;
- data accountability practices to ensure that data are lawfully collected, used and disclosed, taking into account privacy, mitigation of bias and other risks to ensure safety, quality and integrity;

- clear scientific explanations and graded sets of requirements for analytical and clinical validation of the AI product intended for use;
- holistic risk management approach that addresses risks including those associated with cybersecurity threats and the AI system's vulnerabilities throughout the total AI product life-cycle phases; and
- postmarket monitoring and surveillance of AI products.

The most common approach across the WHO European Region is to implement data accountability practices (46%, 23 out of 50 Member States) (Fig. 13). This involves ensuring that data are collected, used and disclosed lawfully. It also includes considering data privacy and addressing other risks to ensure data safety, quality and integrity. Ensuring effective and transparent documentation across all AI product life-cycle phases to facilitate regulatory assessment and auditing was also common among 34% of Member States (17 out of 50).

Fig. 13. Minimum standard requirements in laws, rules, policies or guidelines for governance and oversight of health care



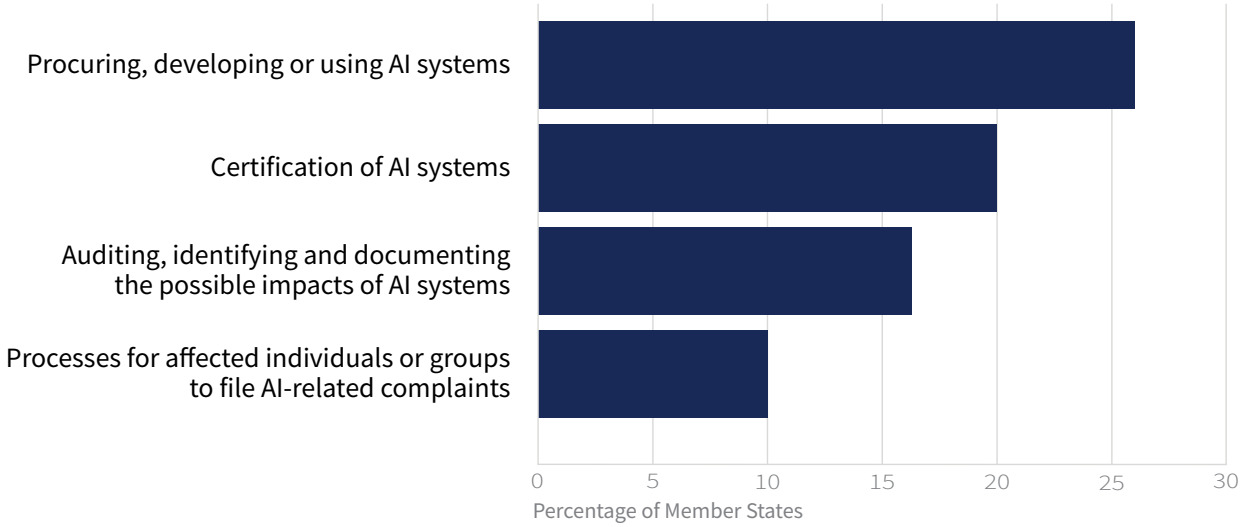
Implementing data accountability practices was most common in western Europe (57%, four out of seven) and southern Europe (54%, seven out of 13), as well as the EU more broadly (48%, 13 out of 27). Similarly, ensuring effective and transparent documentation was also common in western (57%, four out of seven) and southern (38%, five out of 13) Europe.

Policy focus for AI regulation

A crucial component of AI governance is enacting policies to regulate how AI systems are developed and applied. A policy may focus on many different aspects; the most common in the WHO European Region (26%, 13 out of 50 Member States) being procuring, developing and using AI systems in the health sector (Fig. 14). Among several possible responses, certification of AI systems was the second most common policy focus, with 20% of Member States (10 out of 50) reporting such policies had been passed. Policies that focus on either auditing, identifying and documenting possible impacts of AI systems, reported by

16% of Member States (eight out of 50), or on processes for individuals or collectives adversely affected by AI systems to complain, reported by 10% of Member States (five out of 50), were less common.

Fig. 14. Member States approaches to regulating the AI in health care



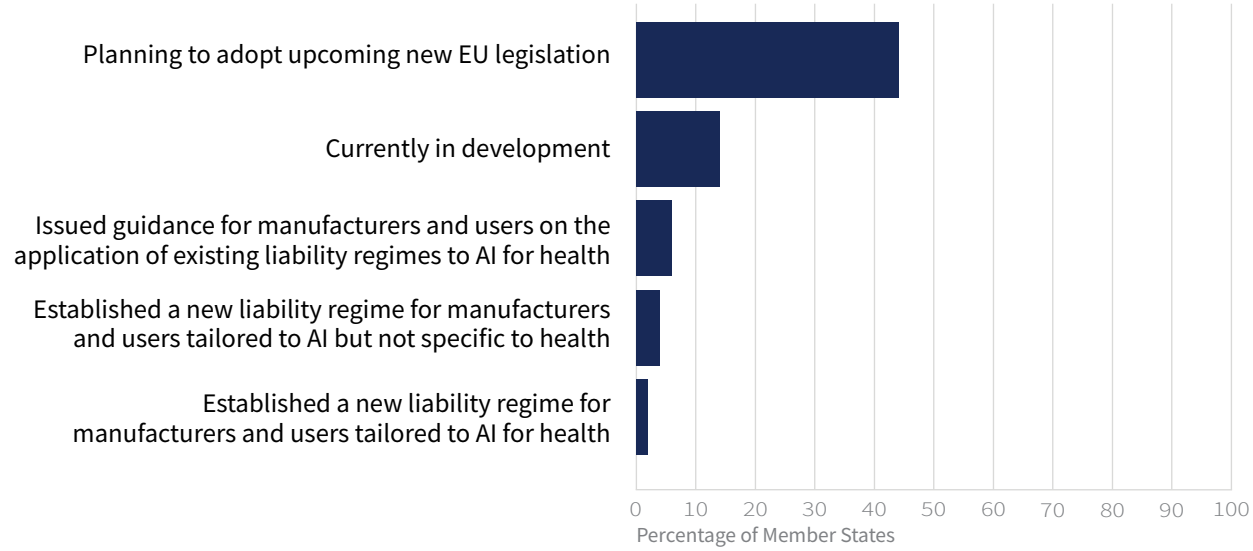
Only 10% of Member States (five out of 50) have enacted three or more different types of AI-related health policy, with most of these countries located in western and northern Europe. In contrast, 64% of Member States (32 out of 50) reported having no policies focused on AI in the health sector or are unsure of whether such policies exist. These Member States are spread primarily across western and central Asia but also in eastern and southern Europe.

Legal liability standards for AI systems

Developing clear legal liability standards is essential to ensure accountability when AI systems cause harm in the health sector. The EU Product Liability Directive already governs medical devices and clinical practice but may not fully address the unique challenges posed by AI, including opacity, adaptivity and complex causality *(29.)* Nonetheless, a separate AI-specific liability law may not be necessary in health care provided current frameworks are interpreted and applied appropriately *(30,31)*. Liability standards, whether new or adapted, play a vital role in defining the responsibilities of manufacturers and users, building trust in AI technologies and protecting patient rights and safety.

Only 8% of Member States (four out of 50) have either developed liability standards for AI for health or have guidance for manufacturers and users on the application of existing liability standards (Fig. 15). Another 14% of Member States (seven out of 50) reported they are currently developing new liability standards specifically for this purpose.

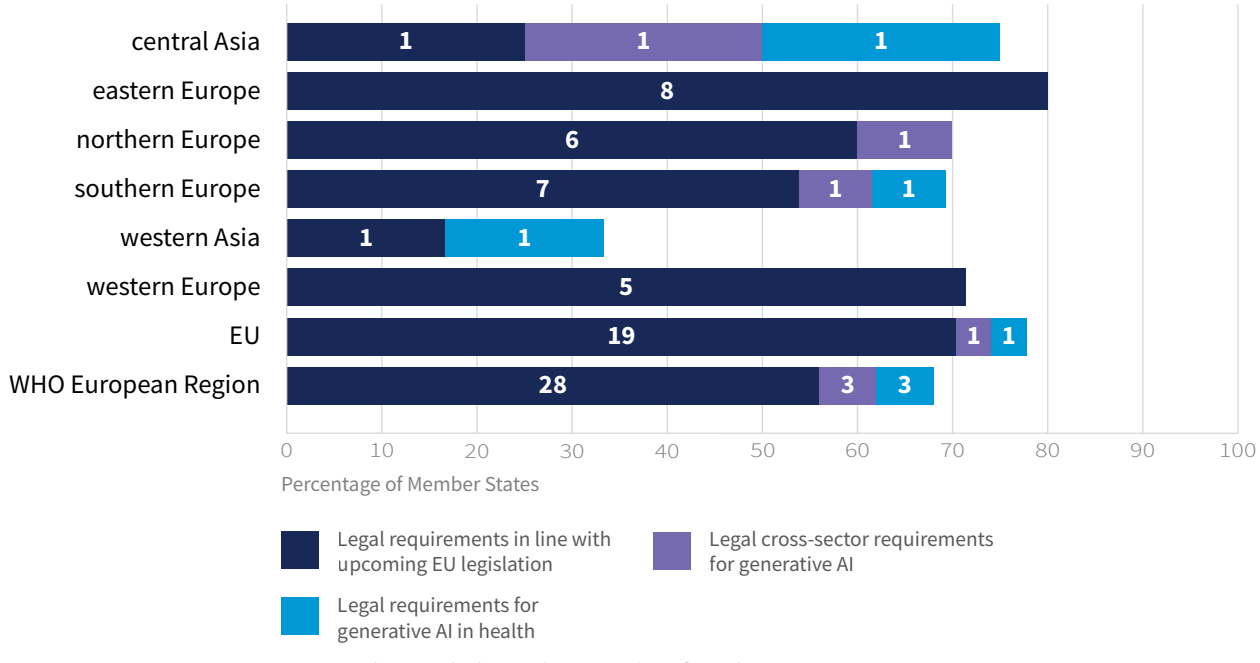
Fig. 15. Legal liability standards establishing legal duties, obligations and responsibilities of manufacturers and users for harms caused by AI systems deployed in health care setting



Regulations relating to generative AI

Introducing specific legal requirements for the use of generative AI systems, including general-purpose LMMs, is crucial to ensure their safe, ethical and accountable deployment in the health sector *(2)*. These models pose risks, such as misinformation, bias and lack of transparency, that require tailored regulatory responses *(2,32)*. Only 6% of Member States (three out of 50) reported having developed legal requirements for generative AI systems specific to the health sector (Fig. 16). Another 6% (three out of 50) have reported the development of legal cross-sector requirements, so not specific to any sector. However, 70% of Member States in the EU (19 out of 27) are preparing for the adoption of new legal requirements in line with upcoming EU legislation.

Fig. 16. Legal requirements and obligations for generative AI system



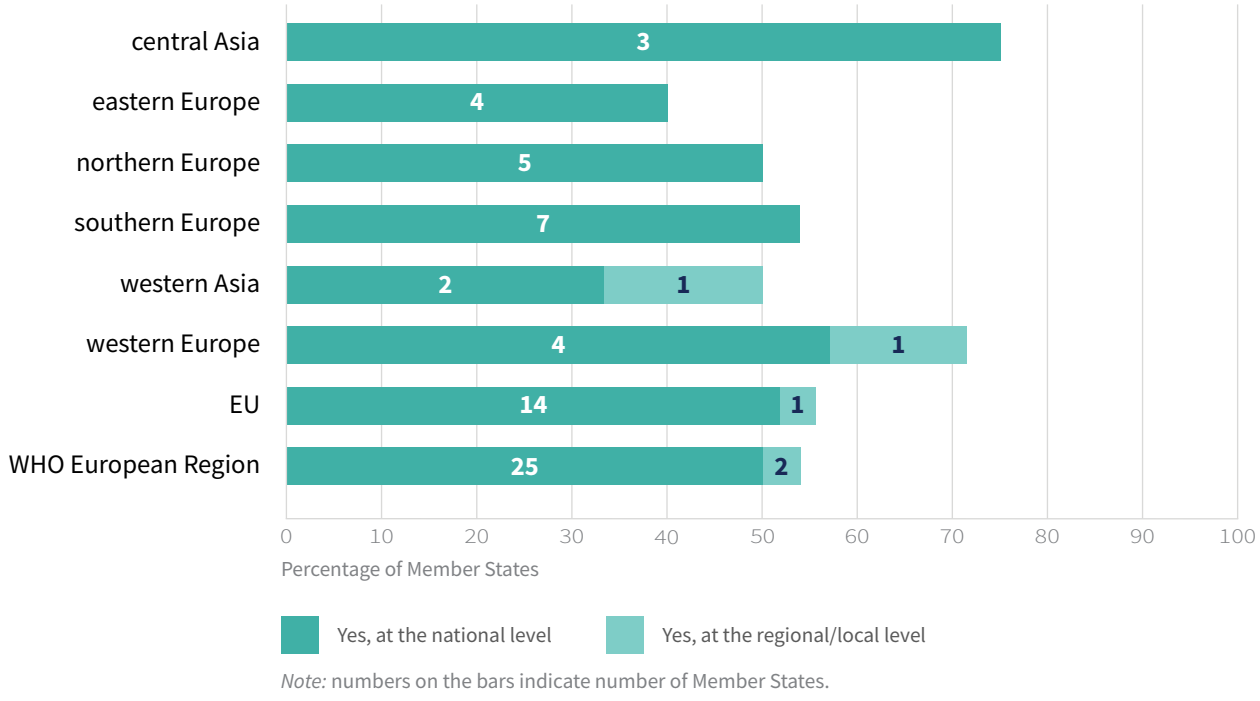
Note: numbers on the bars indicate number of Member States.

The environmental impact of LMMs and other generative AI models is well documented through their significant energy consumption and resource demands *(32,33)*. These models contribute substantially to carbon emissions and water usage, raising sustainability concerns as their deployment scales. Despite the known environmental impact of generative AI systems, only 20% of Member States (10 out of 50) have introduced legal requirements for developers to address such concerns.

Regulatory agencies responsible for the approval and adoption of AI systems

A key element of effective AI governance in health is the establishment of dedicated regulatory agencies with oversight responsibilities *(2)*. These agencies could play a central role in evaluating, approving and monitoring AI systems to ensure safety, efficacy and accountability. Over half of Member States (54%, 27 out of 50) reported having one or more regulatory agencies responsible for assessing and approving AI systems in the health sector, either at the national or subnational level (Fig. 17). In contrast, only 24% of Member States (12 out of 50) have agencies responsible for monitoring the adoption and use of AI in the health sector. A further 26% (13 out of 50) reported that they are developing these agencies.

Fig. 17. Regulatory agencies responsible for assessing and approving AI systems for use in health care



Note: numbers on the bars indicate number of Member States.

The highest percentage of regulatory agencies is found in central Asia (75%; three out of four Member States) and western Europe (71%; five out of seven), alongside 56% of EU Member States (15 out of 27). By contrast, only 40% of Member States in eastern Europe (four of the 10) have established agencies responsible for assessing and approving AI systems. Case study 4 describes the AI Airlock system from the United Kingdom National Health Service (NHS) AI Lab for testing and assessing AI systems in the medical industry.

Case study 4. The AI Airlock system in the United Kingdom

The AI Airlock is a world-leading regulatory sandbox for testing AI as a medical device and is a safe space to examine regulatory challenges using real world products and prototypes.

This initiative, led by the Medicines and Healthcare products Regulatory Agency and supported by the NHS AI Lab, is designed to create a controlled testing environment where developers can rigorously validate AI tools in real-world clinical settings before full-scale deployment, ensuring they meet the NHS standards for safety, efficacy and integration into existing health care workflows *(34)*.

The initiative is intended to gain further understanding of targeted challenges in the development and regulation of AI as a medical device and the consequences of these uses on the current medical device regulatory pathway experienced by innovators.

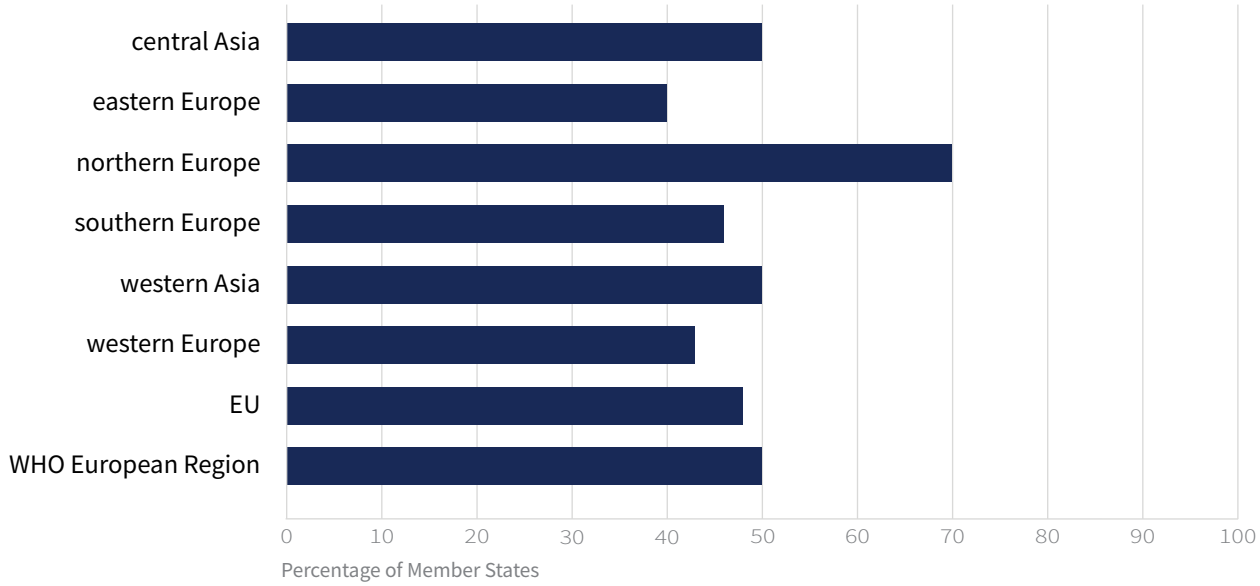
This collaborative project is already underway and will enable further identification of the novel regulatory challenges for AI as a medical device, answer previously unanswered questions and ultimately support safer, earlier access to innovative AI products.

Using real-world products and challenges, the AI Airlock will bring together the expertise of key partners including the United Kingdom Approved Bodies, the NHS and other regulators in the health care space and across Government.

Cross-country regulatory collaboration

Establishing collaborations across jurisdictions allows regulators to share knowledge, resources and best practices, helping them stay aligned with rapid AI developments. Collaborations address cross-border challenges, promotes consistency in standards and accelerates regulatory learning *(2,35)*. Half of Member States (50%, 25 out of 50) reported that they had established collaborations with other Member States to share knowledge and resources on how to best regulate AI systems in the health sector (Fig. 18). The highest percentage of cross-border collaboration has been in northern Europe (70%, seven out of 10). In contrast, only 40% of Member States in eastern Europe (four of the 10) have established such collaborations. Nearly half of Member States in the EU (48%, 13 out of 27) have introduced cross-country regulatory knowledge exchange.

Fig. 18. Established collaborations to share knowledge and resources across jurisdictions



3.3.2 Summary

Progress on legal and regulatory responses to AI in health remains uneven across Member States. While many are actively assessing legal gaps, the development of new health-sector-specific AI laws is still relatively rare. Only a small number of Member States have issued health-specific AI ethical guidelines, with some currently developing them and others yet to introduce any. Existing efforts tend to focus on addressing specific legal and ethical risks, such as providing practical guidance on data protection impact assessments and integrating ethics by design. Minimum standards most often focus on implementing data accountability practices, whereas postmarket monitoring and surveillance of AI products are far less common.

AI policy priorities across the Region generally centre on procuring, developing and using AI systems in the health sector, while addressing adverse impacts on individuals or collectives and establishing liability standards remain limited. Despite growing concerns about the environmental footprint of generative AI systems, legal requirements for developers to address these impacts are still uncommon. Over half of Member States reported having one or more regulatory agencies responsible for assessing and approving AI systems in health, although fewer have agencies tasked with monitoring its adoption and use. Encouragingly, cross-country regulatory collaboration is beginning to emerge, with several Member States sharing knowledge and resources to strengthen AI governance in the health sector.

In some cases, sparse health-specific legislation may overlap or conflict with broader AI regulations. Additionally, the lack of clear standards for liability can make clinicians hesitant to rely on AI or, conversely, overly reliant, increasing patient safety risks. Cross-border care and applications beyond traditional health settings further complicate oversight, blurring the line between regulated clinical tools and loosely governed wellness products and leaving potential gaps in accountability and protection.

3.4 The backbone: health data governance for trustworthy AI

Highlights box 4. The backbone

66% (33 of 50) have adopted a dedicated national health data strategy

76% (38 of 50) have a health data governance framework in place or are currently in the process of developing one

66% (33 of 50) have created a health data hub at the regional or national level

30% (15 of 50) have issued guidance on the secondary use of health data for research in the public interest

30% (15 of 50) have rules in place to facilitate cross-border sharing of health data for research

40% (20 of 50) have established rules, policies and processes to facilitate sharing of health data with private companies for public interest health-related research

This section examines the policy frameworks and processes that shape how health data are governed, collected, shared and utilized across the WHO European Region. It provides an overview of health data governance structures, policies for the secondary use of data and the national health data hubs, which serve as the core infrastructure for health data development. The findings are divided into three sections:

- national health data strategies and governance frameworks outline the various governance approaches and oversight;
- the emergence of health data hubs explores the data sources, financing and utilization of health data hubs; and
- enabling secondary use of health data for public interest health-related research focuses on the policy landscape facilitating health data sharing.

The reuse of high-quality health data from multiple sources is recognized as essential to creating and validating meaningful algorithms and realizing the potential of AI for better health *(2)*. Health data hubs play a pivotal role in enabling the responsible development and deployment of AI in health care. Health data hubs are platforms that can mobilize large and varied volumes of health data and compile and process the data using the platform's considerable computing power in order, for example, to run complex research algorithms.

In several countries these developments are aimed at ensuring participation in the European Health Data Space (EHDS) ecosystem (Box 3). By serving as centralized repositories or platforms, these hubs consolidate disparate health datasets, ensuring their quality, accessibility and interoperability. Since the early 2000s, the data that qualify as health data have expanded dramatically and now include large quantities of personal data from many sources *(2)*. These can include genomic data, medical records or nonhealth-related data that are converted into health data from devices such as smartphones or wearable technology. National health data hubs can also be used for training machine/deep learning models for the purposes of creating clinical AI systems that provide predictive and decision support functions *(16)*.

Box 3. The EHDS

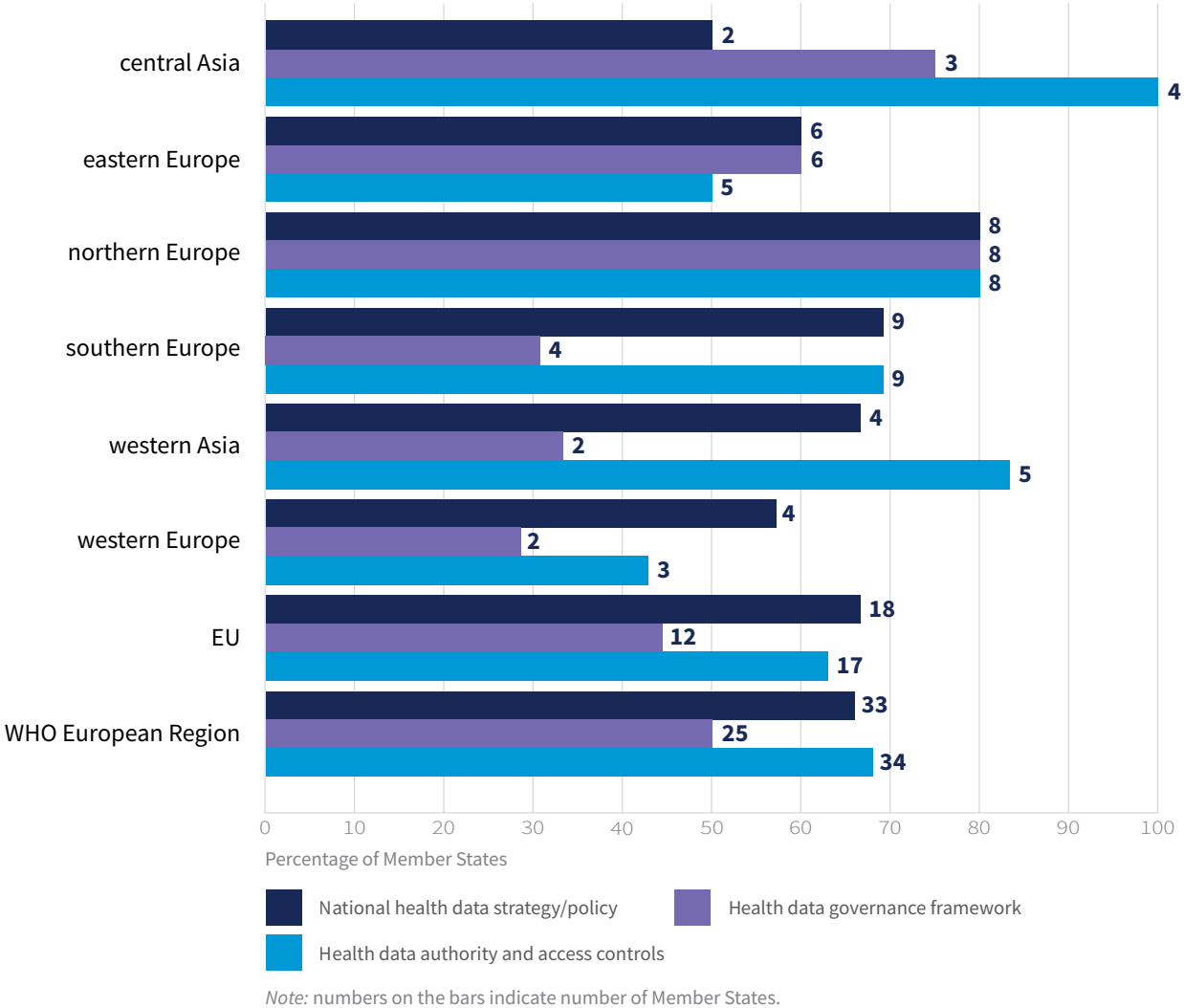
The EHDS is a key pillar of the EU health system and seeks to establish a unified framework for health data sharing across EU Member States *(36)*. By fostering interoperability and facilitating cross-border collaboration, the EHDS can leverage these hubs to drive AI in the context of primary and secondary use of health data, improve health care outcomes and create equitable access to high-quality care throughout Europe. The development of robust national health data hubs will be critical for aligning with the EHDS and maximizing its potential.

3.4.1 Findings

National health data strategies and governance frameworks

As shown in Fig. 19, 66% of Member States (33 out of 50) have a dedicated national health data strategy in place. Additionally, 18% (nine out of 50) have health data included in their national data strategy or policy. Of the 33 Member States that have a national health data strategy in place, 30% (10) have either revised the strategy since adoption or are currently in the process of revising it.

Fig. 19. National health data strategies, frameworks and health data authorities by subregion



Note: numbers on the bars indicate number of Member States.

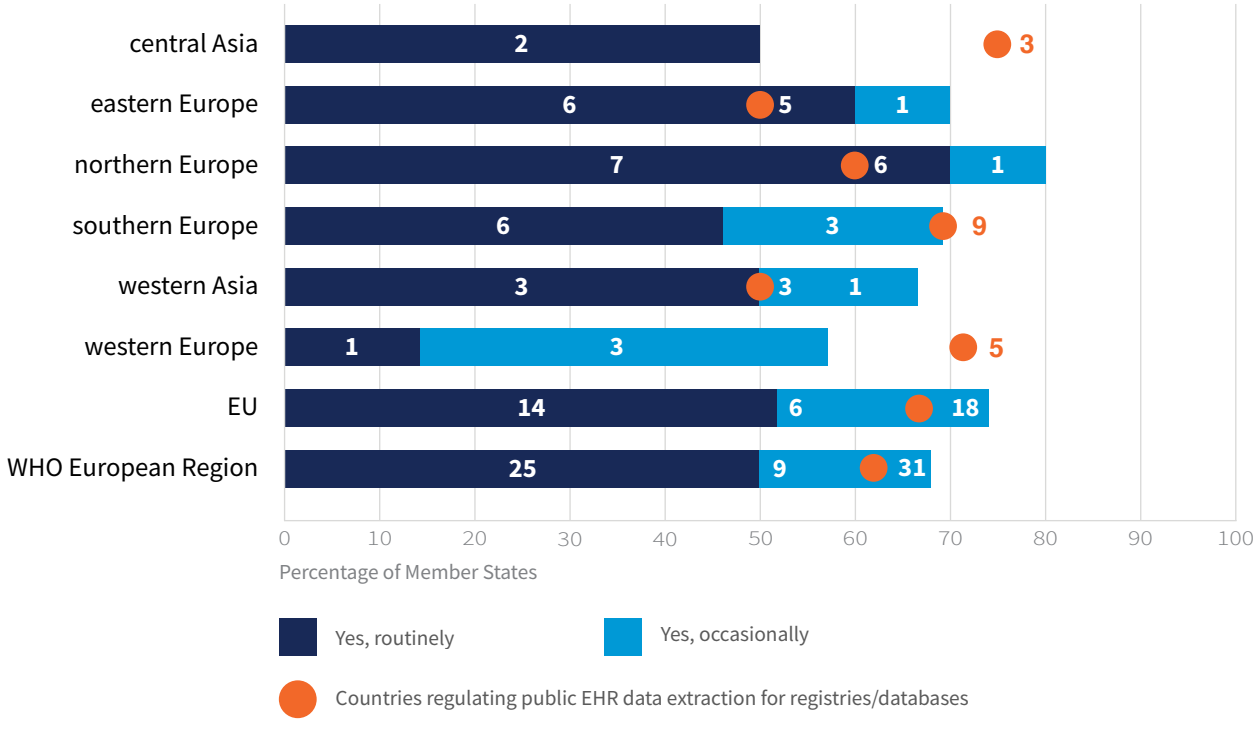
A health data governance framework is in place in 50% of Member States (25 out of 50). This refers to a structured system of laws, policies, procedures and guidelines that govern the collection, storage, use, sharing and processing of health-related data across the health care ecosystem to ensure that health data are handled responsibly, ethically and in accordance with legal requirements. An additional 26% of Member States (13 out of 50) are currently in the process of developing such a framework.

With regard to oversight, 68% of Member States (34 out of 50) have set up a health data authority, which was defined as a body responsible for health data governance and the approval of requests for new dataset creation or dataset access, links or extraction. Of the 13 Member States that reported not having set up a health data authority 12 (92%) reported that they were missing a national health strategy and/or a national health data governance framework, highlighting the importance of a strong health data policy foundation.

At subregional level, 44% of Member States in the EU (12 out of 27) have adopted a health data governance framework, a figure expected to reach 100% once the EHDS is fully implemented. Adoption is lowest in western Europe (29%; two out of seven) and southern Europe (31%; four out of 13), while northern Europe leads with 80% of Member States (eight out of 10) having established frameworks. It is also worth noting that after the EHDS is in effect all 27 EU Member States will need to have set up a health data authority.

As shown in Fig. 20, 62% of Member States (31 out of 50) have laws or policies in place that permit authorities to extract data from electronic health record (EHR) systems for the creation of regional/national registries and databases. These frameworks support critical activities such as public health monitoring, monitoring quality of care and evaluating health system efficiency. Fig. 20 also shows that, in practice, 68% of Member States (34 out of 50) routinely or occasionally extract data from EHR systems to merge into regional, national or subnational registries and databases, demonstrating a strong commitment to leveraging EHR data for broader health system insights.

Fig. 20. EHR data extraction for registries and databases and existence of legal frameworks permitting data extraction

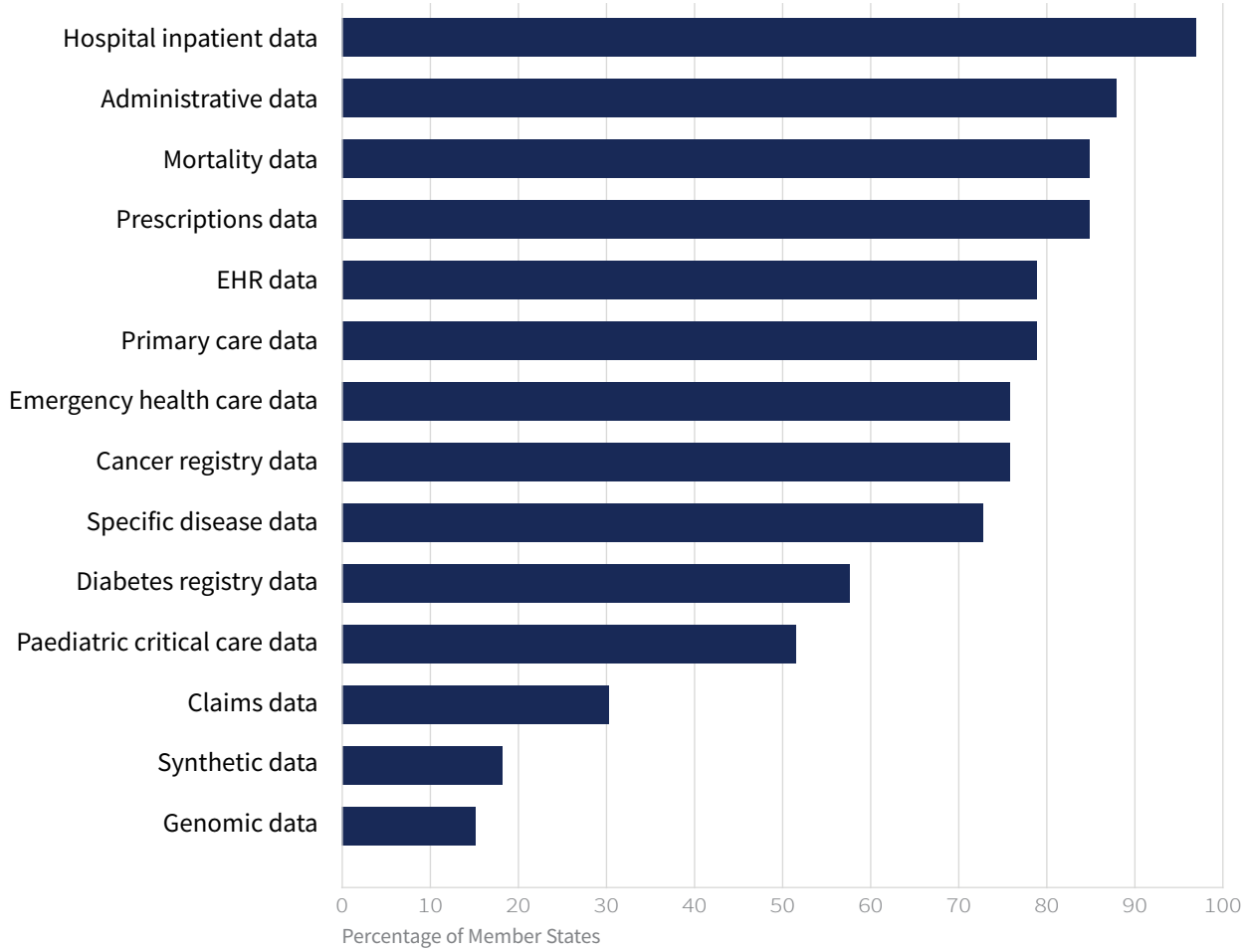


Note: numbers on the bars indicate number of Member States.

The emergence of health data hubs

In the WHO European Region, 66% of Member States (33 out of 50) have created a health data hub at the national or subnational level. An additional 22% of Member States (11 out of 50) reported that they are currently developing one. Fig. 21 shows the data types stored in these health data hubs. Of the 33 Member States that reported having health data hubs, the most common data types are hospital inpatient data (97%; 32 Member States) and administrative data (88%; 29 Member States). Other significant sources include mortality data (85%; 28 Member States) and prescription data (85%; 28 Member States). The least common data types included in health data hubs are synthetic data (18%; six Member States) and genomic data (15%; five Member States).[2]

Fig. 21. Types of data sources included in health data hubs



Although the overall picture of which data are most collected was similar across the subregions, there are some notable differences. Of the five Member States collecting genomic data, three are in eastern Europe. Other data types additionally listed as a data source include birth registry, outpatient data, vaccination records, home care, referrals, reproductive health data, laboratory results and health surveys.

Of the 33 Member States that have a health data hub, the large majority (79%; 26 Member States) responded that it is publicly financed. A combination of public and private financing accounted for 18%

2 Synthetic data are artificial data that are generated from original data and a model that is trained to reproduce the characteristics and structure of the original data *(37)*. Genomic data refer to the complete set of genetic information in an organism, including DNA sequences, RNA transcripts, proteins and epigenetic modifications *(38)*.

of the health data hubs (six Member States) and only one Member State's health data hub was solely privately funded.

To ensure data are collected and formated in a way that supports analysis and exchange, it can be useful to have standard requirements for the creation of health data warehouses (such as a hospital data warehouse). Regionally only 52% of Member States (26 out of 50) are promoting standard requirements for the creation of health data warehouses. In central Asia, all Member States (100%; all four responding) have standard requirements for the creation of health data warehouses, which is notably higher than the average in the EU (44%; 12 out of 27).

Enabling secondary use of health data for public interest health-related research

Member States reported diverse conditions under which health data from national or subnational sources are made accessible for research in the public interest. Data availability and accessibility of health data vary across the Region (Table 2). Anonymization of data is the most common requirement, reported by 82% of Member States (27 out of 33), ensuring privacy while enabling large-scale analysis. Additionally, 64% of Member States (21 out of 33) share data only following the approval from designated bodies, such as ethics committees, to ensure data access aligns with legal and ethical standards.

Table 2. Health data hub data accessibility for research by subregion

	Anonymization of data (%)	Approval by designated body (%)	Data subject consent (%)	Pseudonymization of data (%)	Noncommercial exploitation (%)	Limited to public sector researchers (%)
central Asia	67	100	33	0	33	33
eastern Europe	86	14	57	43	14	29
northern Europe	100	71	86	71	43	14
southern Europe	78	78	22	56	44	22
western Asia	75	50	25	0	25	0
western Europe	67	100	67	100	100	33
EU	82	53	47	65	41	29
WHO European Region	82	64	48	48	39	21

Percentage of Member States in region

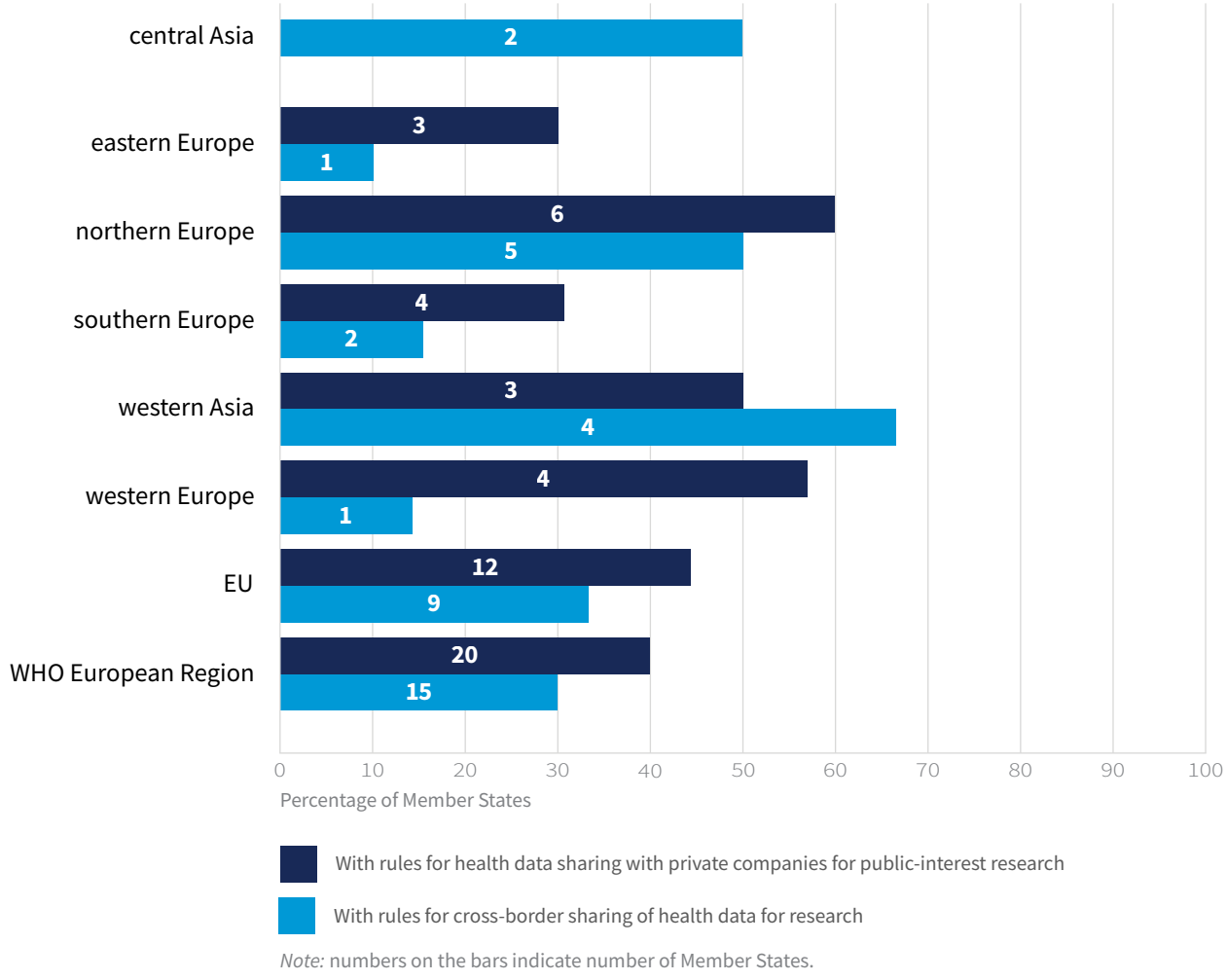
0 10 20 30 40 50 60 70 80 90 100

Guidance on the secondary use of health data for public interest and research ensures ethical, secure and effective use. However, only 30% of Member States (15 out of 50) have issued such guidance. Examples of secondary uses for public interest include health service management, risk stratification, financial and national clinical audit, research and public health surveillance.

When it comes to sharing health data with private companies for public interest health-related research, 40% of Member States (20 out of 50) have established rules, policies and processes to facilitate these

collaborations (Fig. 22). Cross-border sharing of health data for research presents another area of concern, with only 30% of Member States (15 out of 50) having rules in place to facilitate such exchanges. In northern Europe 60% of Member States (six out of 10) had established rules, policies or procedures for health data sharing with private companies for research, the highest among the subregions. Cross-border data sharing was highest in western Asia where 67% of Member States (four out of six) had adopted rules, more than double the regional average.

Fig. 22. Policies for health data sharing for research with private companies and policies for cross-border sharing



Note: numbers on the bars indicate number of Member States.

3.4.2 Summary

Across the Region, many Member States have made significant progress in developing national health data strategies and establishing governance frameworks. A substantial number have also established regional or national health data hubs, forming the core infrastructure for health data management. However, certain areas of data governance are still lagging, including guidance on the secondary use of health data for public-interest research, rules for cross-border data sharing and frameworks for collaboration with private companies on public-interest health research. Without addressing these gaps, AI initiatives risk producing technically advanced tools that do not fully meet clinical or public health needs.

3.5 The catalysts: leveraging AI for health requirements

Highlights box 5. The catalysts

52% (26 of 50) had identified key areas where national AI initiatives could bring the greatest benefit to the health system and population health; only 54% of these Member States (14 out of 26) have allocated funding to support implementation

Priorities driving the use AI technology

98% (49 of 50) reported improving patient care and health outcomes as the top priority

92% (46 of 50) reported reducing pressure on the health care workforce as second highest

Use of AI

64% (32 of 50) reported using AI-assisted diagnostics, making it the most common application of AI in health care

50% (25 of 50) used conversational platforms (chatbots) for patient assistance

AI technologies in health care have already led to significant advancements in drug discovery, genomics, radiology, pathology and prevention *(2)*. This section provides an overview of the AI priorities and snapshot of AI application in health care across the WHO European Region. It is divided into the following sections:

- AI strategic priority initiatives and their funding outlines what priorities have been identified;
- opportunities driving development, testing or use of AI in health in order to better understand the motivations advancing new technology; and
- common applications and uses of AI in health care explores the current application and maturity of AI.

The integration of AI into health care offers transformative potential for improving health system efficiency, advancing medical research and enhancing population health outcomes. To realize these benefits, governments must pinpoint areas where AI technologies can have the greatest impact and allocate funding to support their development and implementation. These steps are critical to ensuring that AI-driven technologies are not only innovative but also aligned with national health priorities and can address pressing health care challenges.

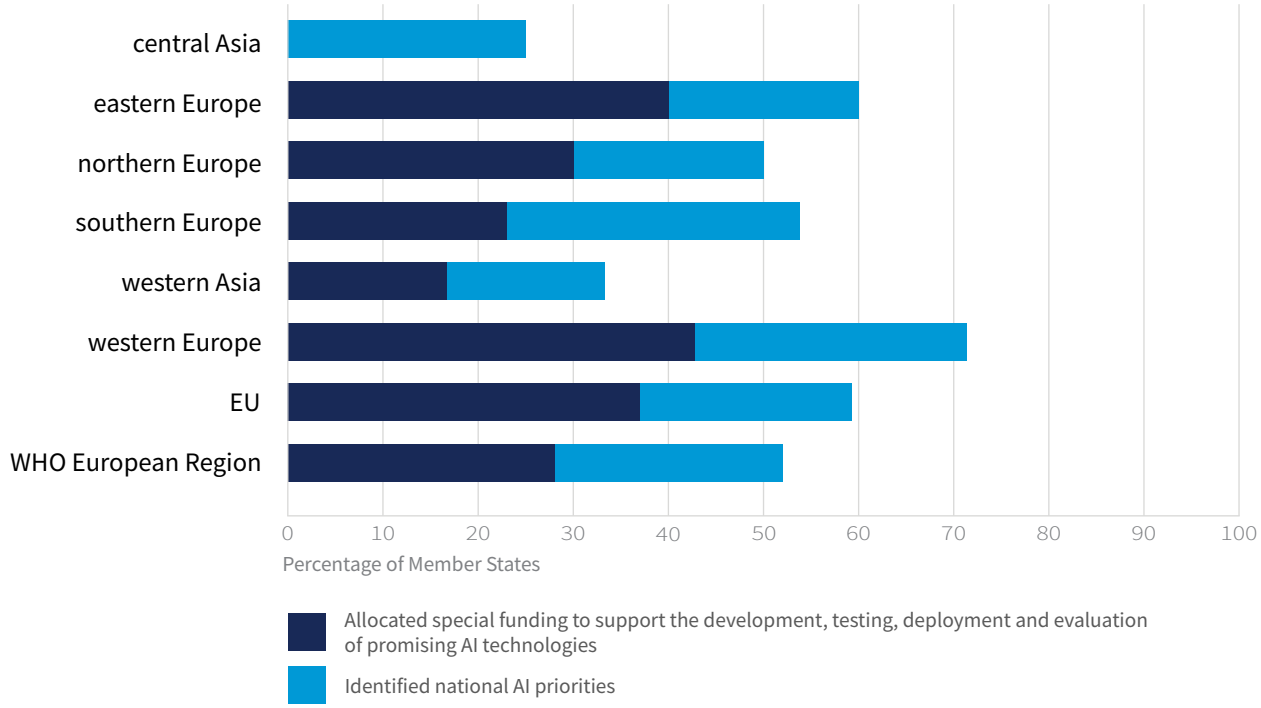
3.5.1 Findings

AI strategic priority initiatives and their funding

Around half of the responding Member States (52%; 26 out of 50) have identified areas of implementation and operation of national AI initiatives where AI-driven technologies have the potential to bring the greatest benefit to their country's health system and population health. The most common responses from the prioritization include diagnostics, imaging, pathology, mental health, analysing health data, administrative support, health workforce planning and patient screening.

Of the 26 Member States that have identified priority areas, 54% (14) have allocated special funding to support the development, testing, deployment and evaluation of promising AI technologies. As Fig. 23 illustrates, there is a gap between national AI prioritization having taken place and allocation of special funding across the entire region. The private sector was participating and investing in research on AI for health care and therapeutic development in 64% of Member States (32 out of 50).

Fig. 23. National AI priorities and allocated funding

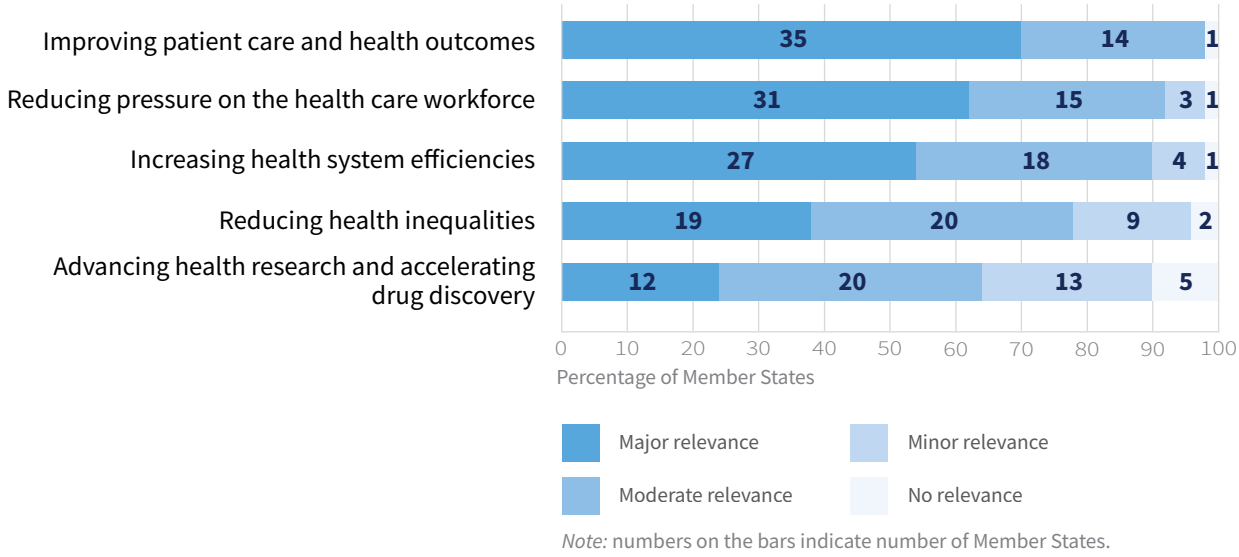


There are notable subregional differences. In western Europe, 71% of Member States (five out of seven), the highest of any subregion, identified priority areas whereas only 25% of Member States (one out of four) in central Asia did so.

Opportunities driving development, testing or use of AI in health

Member States rated five different opportunities created by AI development to understand the motivation driving development, testing or use of AI in health. Fig. 24 presents the overview of regional responses showing that improving patient care and health outcomes was the most relevant, with 98% of Member States (49 out of 50) rating it as of major or moderate relevance. Reducing pressure on the health care workforce was the second highest ranked opportunity, with 92% of Member States (46 out of 50) rating it as major or moderate relevance. Increasing health system efficiencies was also highly relevant, with 90% of Member States (45 out of 50) selecting major or moderate relevance.

Fig. 24. Opportunities driving development, testing or use of AI in health



Note: numbers on the bars indicate number of Member States.

The results were also broken down by subregion to explore differences in opportunity relevance across the WHO European Region. Table 3 indicates the percentage of Member States that selected an opportunity as of major relevance, giving insight into top priorities. The top opportunity selected as of major relevance by all subregions except one was improving patient care and health outcomes (see Case study 5 as an example from the United Kingdom). In eastern Europe, reducing pressure on the health care workforce was the top driver, with 60% of Member States (six out of 10) selecting it. Although only 24% of Member States (12 out of 50) selected advancing health research and drug discovery as a major relevant driver, 50% of Member States (five out of 10) in northern Europe did. This indicates that while all subregions are focused on addressing immediate health challenges, improving quality of care and reducing pressure on the health care workforce, northern Europe is also prioritizing longer-term investments in health through research and innovation.

Table 3. Major relevant AI opportunities by subregion

	Improving patient care and health outcomes (%)	Reducing pressure on the health care workforce (%)	Increasing health system efficiencies (%)	Reducing health inequalities (%)	Advancing health research and accelerating drug discovery (%)
central Asia	100	100	50	50	25
eastern Europe	30	60	40	30	20
northern Europe	90	90	70	50	50
southern Europe	77	38	69	38	23
western Asia	67	33	17	33	0
western Europe	71	71	57	29	14
EU	70	67	56	37	22
WHO European Region	70	62	54	38	24

Percentage of Member States in region

0	10	20	30	40	50	60	70	80	90	100

Case study 5. The Artificial Intelligence in Health and Care Award in the United Kingdom

The NHS Artificial Intelligence in Health and Care Award aimed to benefit patients by combining the power of AI with the expertise of the NHS to improve health and care outcomes. AI technology designed to assist in the treatment and diagnosis of strokes is a priority for the NHS AI Lab. One of the technologies funded by the AI Award was e-Stroke/Brainomix 360, an AI imaging software for driving treatment decisions and designed around the patient pathway *(39)*. Brainomix 360 was utilized in 37 hospitals across five NHS stroke networks in a 13-month period. Statistics for the largest stroke AI network in the United Kingdom (with a population of over 9 million) showed that in the first 3 months of its implementation, the number of thrombectomies performed rose over 280% (from 93 to 256) and patients achieving independence afterwards rose from 34% to 55%. A survey of 39 stroke clinicians who had used Brainomix 360 showed that the majority found the AI technology made treatment decision-making faster, identifying eligible patients easier and improved communicating the details of treatment with other sites.

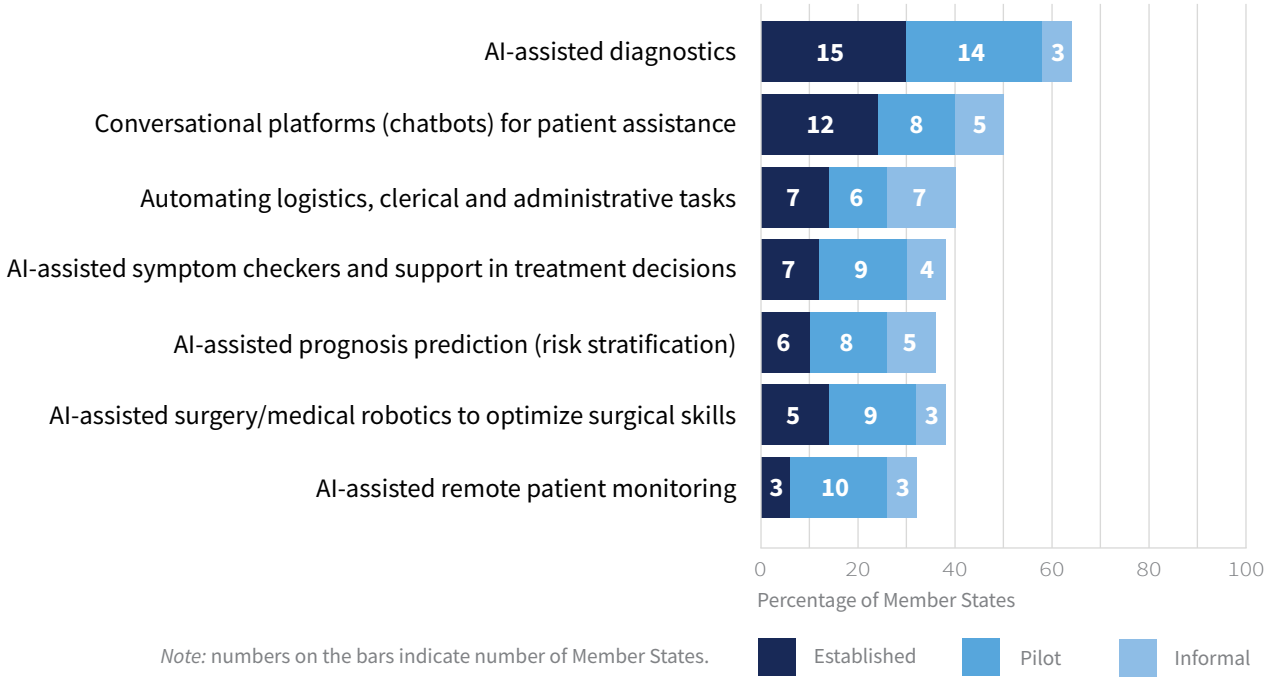
After this successful initial roll out and testing phase, Brainomix 360 has now been deployed in every stroke ward in NHS hospitals across the United Kingdom and is improving patient outcomes in many locations. The process has also provided valuable lessons about the implementation of AI in general, such as focusing on the clinical need and the patient pathway. The value of ongoing support, user-led education and shared learning, as well as a focus on building confidence in AI technology and its use, was also apparent.

Common applications and uses of AI in health care

The most common applications of AI in health care and their level of developmental maturity are presented in Fig. 25. The categories used for maturity of the application were:

- informal: early adoption in a few clinical establishments in the absence of formal processes and policies;
- pilot: testing and evaluating the use in a few clinical establishments for given situations; and
- established: ongoing use in clinical establishments for a minimum of 2 years and planned to continue for at least 2 more years.

Fig. 25. Overview of most common AI applications and maturity ranking in the WHO European Region



Note: numbers on the bars indicate number of Member States.

Across the WHO European Region, there was a wealth of developing and developed AI applications assisting health care professionals. The most common AI application was AI-assisted diagnostics (in, for example, radiology, dermatology or ophthalmology) used by 64% of Member States (32 out of 50) , with 30% (15 out of 50) considering it established. An additional 34% of Member States (17 out of 50) are currently piloting or informally using AI-assisted diagnostics.

The second most common application of AI in health care was conversational platforms (chatbots) for patient assistance, which was used by 50% of Member States (25 out of 50), with 24% (12 out of 50) considering it established. An additional 26% of Member States (13 out of 50) are currently piloting or informally using AI conversational platforms for patient assistance. Chatbots have a variety of applications ranging from symptom assessment, scheduling appointments or medication reminders to support patient care *(40)*.

Another commonly used application of AI in health care is to automate logistics and administrative tasks, with 40% of Member States (20 out of 50) using it and with 14% of Member States (seven out of 50) considering it established; 38% of Member States (19 out of 50) are using AI-assisted surgery robotics, with 14% (seven out of 50) considering it established. AI-assisted symptom checkers are used in 38% of Member States (19 out of 50), with 12% (six out of 50) considering it established.

A less commonly used application includes AI-assisted prognosis prediction, with 36% of Member States (18 out of 50) indicating use, with 10% (five out of 50) considering it established. Finally, AI-assisted remote patient monitoring is used by 32% of Member States (16 out of 50), with 6% (three out of 50) considering it established.

Case study 6 describes the use of AI to improve detection of colorectal cancer in Hungary, where a shortage of pathologists had led to delays in diagnosis and worsened patient outcomes. This project highlights how AI-driven innovations can systematically enhance health care delivery and create scalable, sustainable tools for addressing critical health needs.

Case study 6. Use of AI in colorectal cancer screening in Hungary

Colorectal cancer is a significant public health issue in Hungary, which has one of the highest incidence and mortality rates globally. Approximately 9000 new cases and over 5000 deaths occur annually, making it the second most common cause of cancer-related deaths in the country. A critical challenge in addressing colorectal cancer is the shortage of pathologists, which leads to delays in diagnosis and worsens patient outcomes. Innovative solutions such as AI-driven diagnostic tools are urgently needed to assist pathologists, reduce their workload and improve diagnostic efficiency.

The AI project began with the digitalization of 200 haematoxylin–eosin stained whole-slide images of colorectal biopsies using a 3DHistech Pannoramic 1000 Digital Slide Scanner, generating high-resolution data for AI development *(41)*. The images were annotated for 10 relevant pathological classes, including adenocarcinoma, low-grade dysplasia and high-grade dysplasia, by pathology residents and were validated by board-certified pathologists to ensure accuracy. A convolutional neural network (ResNet50) was trained on these annotated image patches to classify pathological conditions, with a focus on multilabel classification tasks. The model achieved strong performance, particularly for frequent conditions such as normal and low-grade dysplasia, with area-under-the-curve scores ranging from 0.73 to 0.98; this significantly improved diagnostic precision and recall. This AI tool reduced pathologists' workload by identifying critical regions for review, enabling faster and more accurate diagnoses while addressing the challenge of a global pathologist shortage.

Additionally, the integration of AI into existing health care systems was planned to complement current workflows, ensuring compatibility with EHR and regulatory compliance. The outcomes include improved colorectal cancer screening through earlier detection and grading of lesions, better resource utilization due to faster diagnosis times, and the establishment of a scalable AI framework that could be applied to other medical conditions. This approach not only improved patient outcomes by enabling timely interventions but also provided a cost-effective solution to the challenges of Hungary's health care system.

There was large variation in AI application across the subregions (Table 4). Northern Europe had the highest rates of AI application in most of the categories including AI-assisted diagnostics (100%, 10 out of 10), chatbots for patient assistance (90%, nine out of 10) and automating logistics and administrative tasks (80%, eight out of 10). Western Europe was the leader of AI-assisted remote patient monitoring, with 57% of Member States (four out of seven) applying it.

Table 4. Percentage of Member States by subregion currently using the most common applications of AI technology for health

	AI-assisted diagnostics (%)	Conversational platforms (chatbots) for patient assistance (%)	Automating logistics, clerical and administrative tasks (%)	AI-assisted symptom checkers and support in treatment decisions (%)	AI-assisted prognosis prediction (risk stratification) (%)	AI-assisted surgery/medical robotics to optimize surgical skills (%)	AI-assisted remote patient monitoring (%)
central Asia	50	50	0	50	25	25	25
eastern Europe	50	40	20	40	40	30	40
northern Europe	100	90	80	70	50	40	40
southern Europe	54	31	31	15	23	54	15
western Asia	50	33	33	17	33	17	17
western Europe	71	57	57	43	43	43	57
EU	74	63	59	48	48	41	41
WHO European Region	64	50	40	38	36	38	32

Percentage of Member States in region

0	10	20	30	40	50	60	70	80	90	100

Out of the 50 Member States reporting, 15 (30%) provided information on additional applications of AI in health care and their maturity. Established projects included the use of AI for planning diets, summarizing EHRs, to support health and social care management and policy-making, and dictation tools to support speech to text. Some examples of ongoing pilots included rare disease data collection, analysis of secure messaging with patients to help health professionals to answer messages more efficiently, and general practitioners and psychologists using generative AI systems and early neurological deviation detection. There were also examples of informal projects exploring the role of AI in public health surveillance, drug development, language translation during patient consultation and in designing platforms to enhance the workflow of mental health practitioners.

3.5.2 Summary

Around half of Member States have identified priority areas where national AI initiatives could deliver the greatest benefits to their health systems and population health. Examples where current AI applications in health systems align with immediate national priorities include patient care, health outcomes and reducing pressure on the health care workforce. AI-assisted diagnostics can help to reduce clinician workloads, while chatbots support patient engagement and autonomy. However, only a subset of Member States has allocated dedicated funding to support implementation, which highlights a persistent gap between strategic intent and operational investment. Improving patient care and health outcomes is the leading driver for adopting AI technologies, closely followed by the need to reduce pressure on the health care workforce. AI-assisted diagnostics stands out as the most common application, with nearly two thirds of Member States leveraging AI to enhance imaging and detection. Conversational chatbots for patient assistance are also widely used, with half of Member States reporting their integration in care.

Nonetheless, potential risks must also be addressed, including biased or low-quality outputs, automation bias, erosion of clinician skills, reduced clinician–patient interaction and inequitable outcomes for marginalized populations.

3.6 The gatekeepers: tackling adoption barriers

Highlights box 6. The gatekeepers

Main barriers for widespread adoption of AI in health care

86% (43 out of 50) cited legal uncertainty as a major or moderately important barrierand

78% (39 out of 50) cited financial affordability as a major or moderately important barrier

Main policy enablers for widespread adoption of AI in health care

92% (46 out of 50) cited clear liability rules for manufacturers, deployers and users applicable to AI systems in health care as of a major or moderately positive impact

90% (45 out of 50) cited guidance on transparency, verifiability and explainability of AI solutions to ensure trust in outcomes as a major or moderately positive impact

This section explores the existing barriers and the potential of various policy actions. It is divided into two sections:

- barriers to widespread adoption of AI in the health sector examines the obstacles to implementing AI-driven technology; and
- policy enablers of AI adoption in the health sector explores which policy actions would have the greatest positive impact.

Health care systems face a range of barriers to integrating AI, including legal, regulatory, financial, infrastructural and cultural challenges. These obstacles span uncertainties around legal compliance and data quality, as well as gaps in infrastructure and workforce capacity, highlighting the complexity of implementing AI in practice and the need for coordinated, comprehensive solutions.

Additionally, targeted legislative, policy and guidance measures can help to mitigate these barriers. Many of these actions align with developments in EU legislation and focus on areas such as legal clarity, ethical frameworks, data governance and accountability mechanisms. Prioritizing these measures can create an enabling environment that supports innovation while ensuring safety, trust and equity in the use of AI technology.

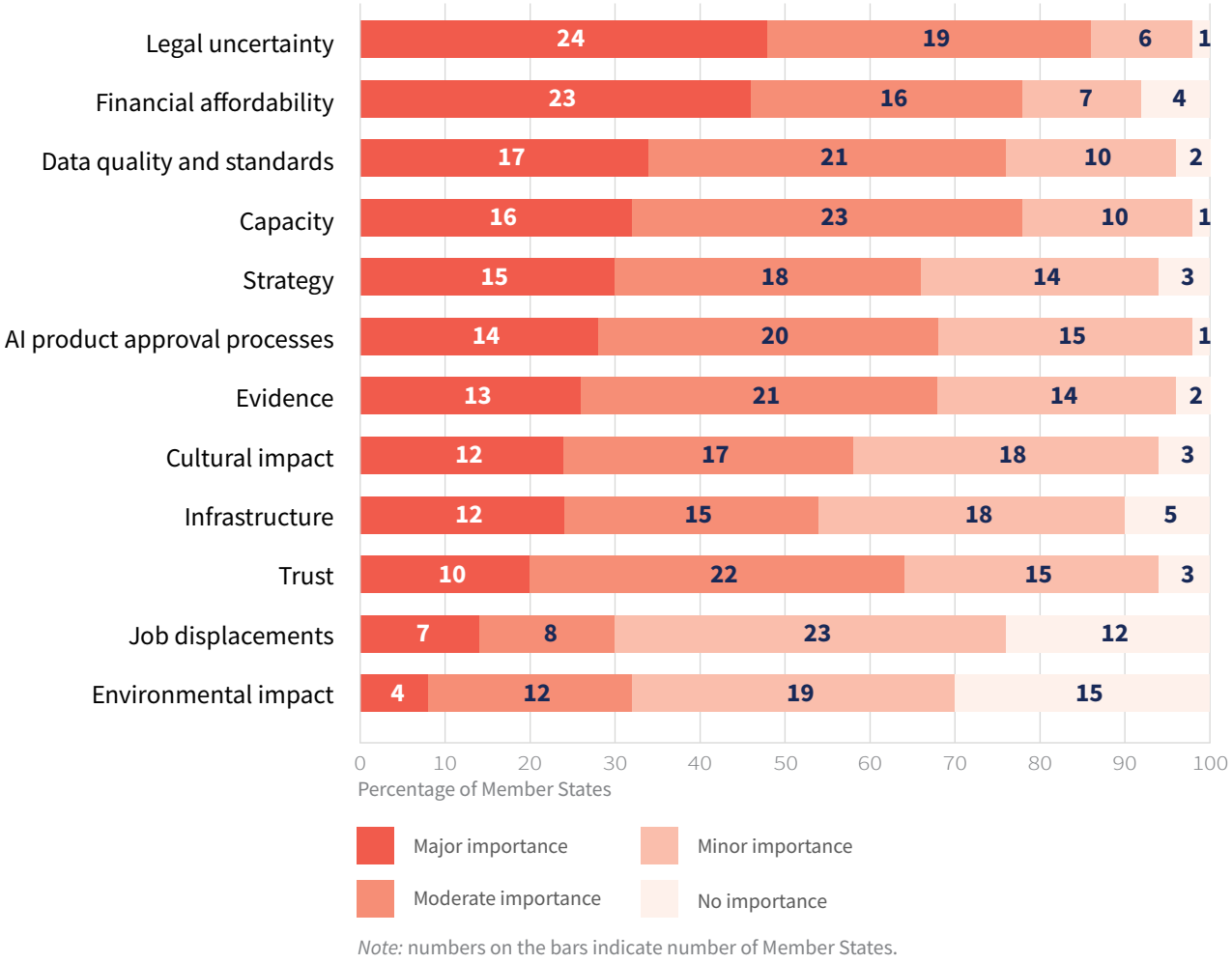
3.6.1 Findings

Barriers to widespread adoption of AI in the health sector

Twelve specific barriers to AI adoption were rated by Member States on a scale ranging from "no importance" to "major importance", allowing for a nuanced understanding of the obstacles faced by health care systems.

Legal uncertainty was identified as the most significant challenge, with 48% of Member States (24 out of 50) rating it a major barrier and an additional 38% (19 out of 50) viewing it as moderately important (Fig. 26). Financial affordability was also ranked as the second most important barrier, with 46% of Member States (23 out of 50) rating is as a major barrier and an additional 32% (16 out of 50) rating it as moderately important.

Fig. 26. Importance of barriers to AI implementation



Note: numbers on the bars indicate number of Member States.

There were variations between the subregions and how Member States rated the importance of the 12 barriers (Table 5). Western Asian Member States rated data quality and standards as the most important barrier and also put a high level of importance on capacity, trust, the cultural impact and legal uncertainty.

Table 5. Importance of barriers to AI adoption by subregion

	Legal uncertainty (%)	Financial affordability (%)	Data quality and standards (%)	Capacity (%)	Strategy (%)	AI product approval processes (%)	Evidence (%)	Cultural impact (%)	Infrastructure (%)	Trust (%)	Job displacements (%)	Environmental impact (%)
central Asia	75	50	25	25	50	25	25	50	0	25	25	0
eastern Europe	30	40	30	20	30	0	20	10	20	10	20	10
northern Europe	40	60	30	30	30	30	20	0	40	10	0	0
southern Europe	77	46	38	38	46	46	23	46	23	31	15	8
western Asia	67	50	67	50	17	33	50	50	50	50	33	33
western Europe	0	43	14	29	0	29	29	0	0	0	0	0
EU	33	41	33	26	26	26	26	22	22	11	11	0
WHO European Region	48	46	34	32	30	28	26	24	24	20	14	8

Percentage of Member States in region

0	10	20	30	40	50	60	70	80	90	100

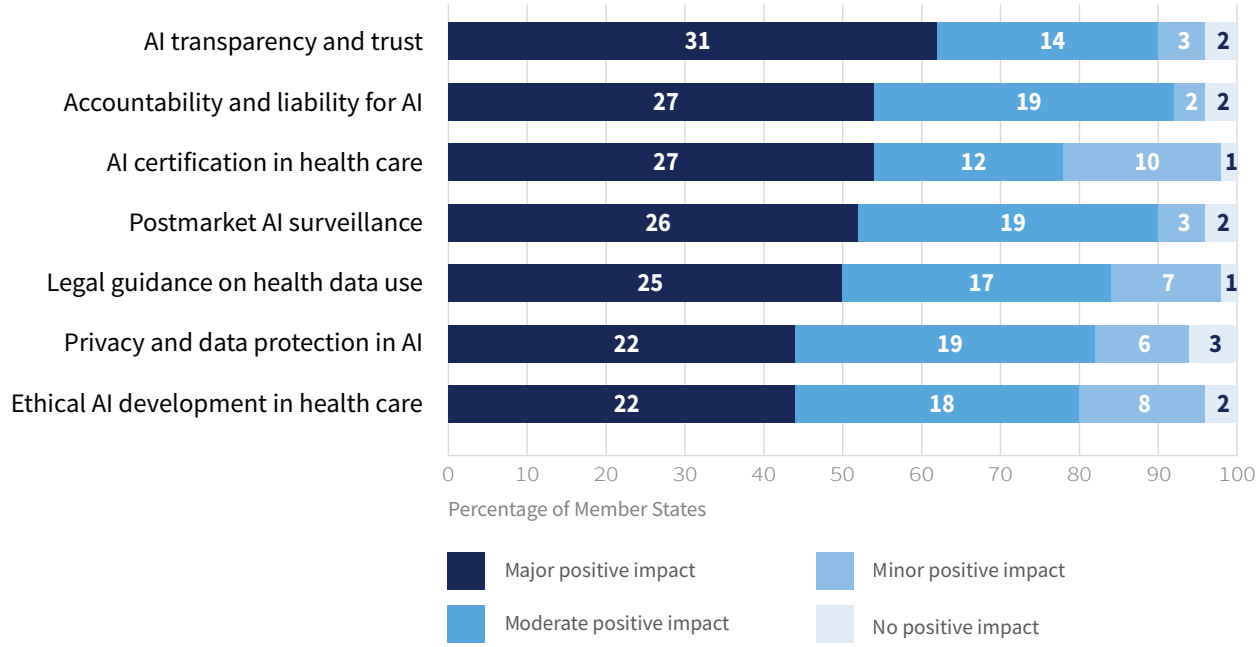
Policy enablers of AI adoption in the health sector

Seven enabling policy options were rated, which provided valuable insights into how adoption of AI in health care can be accelerated. Enablers were rated on a scale ranging from "no positive impact" to "major positive impact", offering a clear understanding of the perceived importance of each measure.

Guidance on transparency, verifiability and explainability of AI solutions to ensure trust in outcomes was rated as having a major positive impact by 62% of Member States (31 out of 50) and as having a moderate positive impact by 28% (14 out of 50) (Fig. 27). Similarly, accountability and liability rules for manufacturers, deployers and users applicable to AI systems in health care was rated as having major positive impact by 54% of Member States (27 out of 50) and as having a moderate positive impact by 38% (19 out of 50).

Policies and guidance on the ethical development and use of AI in health care was rated the least impactful policy option; however, 44% of Member States (22 out of 50) rated it as having a major positive impact and 36% (18 out of 50) rated it as having a moderately positive impact.

Fig. 27. Impact of proposed legislative options on adoption of AI in health care



Note: numbers on the bars indicate number of Member States.

In central Asia, the highest perceived impact was identified as coming from certification of AI systems to be developed and used in health care and therapeutic environments. Conversely this was rated the lowest impact option by Member States in western Europe (Table 6).

Table 6. Impact of proposed legislative options on adoption of AI in health care by subregion

	AI transparency for trust (%)	Accountability and liability for AI (%)	Postmarket AI surveillance (%)	Legal guidance on health data use (%)	Ethical AI development in health care (%)	Privacy and data for AI (%)
central Asia	75	75	50	50	25	25
eastern Europe	50	50	50	60	30	40
northern Europe	80	60	70	60	70	70
southern Europe	62	54	62	54	46	62
western Asia	67	67	33	33	50	33
western Europe	43	29	29	29	29	0
EU	63	56	52	56	41	44
WHO European Region	62	54	52	50	44	44

Percentage of Member States in region

0	10	20	30	40	50	60	70	80	90	100

3.6.2 Summary

Across Member States, the adoption of AI in health care faces significant challenges, with legal uncertainty emerging as the most frequently reported barrier, followed closely by financial constraints. Despite these challenges, there is broad consensus on the policy measures that could facilitate AI uptake. Nearly all countries viewed clear liability rules for manufacturers, deployers and users of AI systems as a key enabler. Similarly, guidance that ensures transparency, verifiability and explainability of AI solutions was considered essential for building trust in AI-driven outcomes.

4. The way forward for AI in health care

Across the WHO European Region, AI has begun to shift how care is planned, delivered and governed, promising more efficient services, improved patient outcomes and reduced pressures on overburdened health workforces. However, as the 2024–2025 survey on AI for health care has revealed, this promise is balanced by significant challenges, gaps and uncertainties that must be carefully navigated.

National strategies for AI for health are still evolving in many Member States. Some have developed health-specific strategies, while others rely on broader cross-sectoral AI plans. Each approach presents distinct advantages and risks: cross-sectoral strategies promote consistency across domains but may overlook the specific needs of health care systems, whereas health-specific strategies offer tailored guidance but risk fragmentation if not effectively coordinated. Moving forward, the Region requires strategies that are both visionary and practical with clear, measurable objectives that are aligned with broader health and digital development agendas.

No AI strategy can succeed without the people it affects. Stakeholder engagement emerges as a critical enabler. However, across the Region, patients, the public and even many health professionals are often underrepresented in AI discussions. Their voices are essential, not only to ensure relevance and trust but also to surface ethical considerations that might otherwise be overlooked.

Building a capable health workforce is critical for the successful integration of AI in health care. However, many Member States lack structured plans and programmes to support workforce development. Health care professionals need training that extends beyond technical skills, fostering critical thinking, ethical judgement and a strong understanding of AI's practical risks and benefits. Establishing new professional roles, promoting interdisciplinary education and ensuring continuous learning will be essential to prepare the workforce for this AI-driven transformation.

Additionally, legal, ethical and regulatory frameworks are the guardrails that keep AI safe and trustworthy. Many Member States have begun adapting existing laws and creating regulatory bodies, but gaps remain, particularly in liability, certification and standards for new technologies such as generative AI. Clear rules and accountability mechanisms will help to protect patients, guide clinicians and provide developers with the certainty they need to innovate responsibly.

Effective health data governance is the backbone of trustworthy AI. Well-governed, accessible and secure health data are essential for training AI systems, enabling interoperability and supporting research. However, persistent gaps in data sharing, cross-border collaboration and public engagement risk limiting AI's potential or producing solutions misaligned with clinical and public health needs. Closing these gaps will require harmonized governance frameworks and stronger regional collaboration to enable the secure and responsible secondary use of health data.

The growing adoption of AI for diagnostics and patient support highlights the need for sustainable funding to cover critical areas such as infrastructure costs, ongoing workforce training and subscription fees for advanced AI systems. Persistent financial barriers hinder implementation, particularly in smaller

or resource-limited health systems. Maximizing impact requires prioritizing targeted investments, securing dedicated funding streams and clear reimbursement mechanisms that ensure equitable access to AI solutions across all health systems.

Together, the Member States of the WHO European Region, with support from the WHO Regional Office for Europe, are forging a path forward on a journey that blends strategy with people-centred design, robust governance, ethical oversight and practical deployment. The following highlights key areas of action and considerations drawn from the findings presented in this report.

- **The navigators: steering AI strategy and oversight for health system**
    - Develop and/or update national strategies, whether health-specific or cross-sectoral, that set a clear vision aligned with health priorities and integrate with broader development plans.
    - Set time-bound objectives with robust monitoring and evaluation frameworks to track progress and ensure accountability.
    - Ensure strategies involve stakeholders across sectors and provide mechanisms for sustainability and adaptation to technological advancements.
    - Assign management, oversight and implementation of AI strategies to a well-established government agency or multiple agencies rather than temporary structures, to ensure continuity, accountability and sustained execution.

- **The change-makers: stakeholder engagement and workforce development**
    - Involve end users, the public and industry in codesign and coregulation processes to identify ethical concerns, enhance accountability and build trust.
    - Create platforms and dialogues that improve transparency around data sharing and promote culturally acceptable AI applications.
    - Integrate AI-related content into preservice curricula, in-service training and continuing professional development to equip the health workforce with a solid understanding of AI benefits, risks and ethical considerations.
    - Ensure ongoing training for relevant stakeholders to stay informed on evolving ethical, legal and regulatory requirements, embedding these considerations throughout the AI design life-cycle.

- **The guardrails: legal, policy and guideline structures for AI in health**
    - Establish clear responsibilities for developers, clinicians, data providers and institutions, with mechanisms for timely redress and accountability when AI systems cause harm. This ensures that every actor in the AI lifecycle understands their obligations, that liability is transparent and that patients and health systems are protected through accessible channels for remediation and enforcement.
    - Ensure stakeholders understand key AI components, such as data sources, algorithms, decision-making processes and limitations, while respecting proprietary rights; validate safety, reliability and real-world effectiveness through prospective trials before deployment to clinical practice and broader health system use.
    - Integrate ethical guidelines and incentivize responsible design by embedding ethical, legal and technical standards into precertification programmes. Encourage developers to adopt safety- and human-rights-by-design approaches from the outset to deliver trustworthy AI systems and accelerate adoption across diverse health systems.

- Expand postmarket surveillance and establish mechanisms for ongoing monitoring of AI products in health to ensure safety, effectiveness and adherence to standards.
- Invest in regulatory agencies tasked with both approving and monitoring AI in health and promote cross-country knowledge-sharing to improve governance practices.

- **The backbone: health data governance for trustworthy AI**
  - Align health-data governance with international standards to protect individual rights, including informed consent, transparency and independent oversight.
  - Ensure special protections for marginalized groups and promote public participation in data-sharing decisions.
  - Set high standards for health data hubs by requiring precise consent procedures, demonstrable public benefit in data-sharing agreements and good-practice networks to guide equitable design and rollout across the Region.
  - Define clear rules for data access, consent and benefit-sharing, including collaborations with the private sector, while ensuring public benefit, transparency and protection of individual rights.
  - Develop guidance for the secondary use of health data in public-interest research and establish clear rules to enable secure and ethical cross-border data sharing.

- **The catalysts: leveraging AI for health requirements**
  - Align AI applications with patient interests and national health goals, communicating capabilities, conditions and limitations transparently.
  - Strengthen funding mechanisms, create implementation roadmaps and ensure integration of AI tools into existing health system workflows.
  - Implement standards for developers and mandate independent pre- and postdeployment impact assessments.
  - Monitor AI systems continuously to detect bias, performance drift and potential harms.
  - Perform pre- and postdeployment assessments guided by international standards, independently audited, with results publicly available.

- **The gatekeepers: tackling adoption barriers**
  - Leverage regulatory sandboxes to enable regulators, developers and health institutions to collaborate in real-world but lower-risk settings, allowing early identification of safety, ethical and performance issues while fostering innovation under regulatory oversight prior to widespread deployment.
  - Evaluate AI solutions against non-AI alternatives (e.g. established decision-support systems or other digital health tools) and ensure alignment with ethical and human rights standards prior to adoption.
  - Ensure that public–private partnerships operate transparently with public disclosure of agreements, uphold individual and community rights by securing ownership or access to AI technologies, and clearly define which health care responsibilities remain public and which are delegated to private actors.

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