World Health Organization

European Region

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

Co-funded by the European Union

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Abstract

Artificial intelligence (AI) is transforming how health systems across the European Union (EU) function and how health care is delivered; with the momentum generated by the EU's adoption of the first comprehensive AI law, the world is now looking to the region for guidance in navigating this new era of AI in health. This report provides a focused assessment of AI readiness within EU health systems, drawing on insights from the 2024–2025 survey on AI for health care in the WHO European Region. It examines national AI strategies, legal and ethical frameworks, data governance, stakeholder engagement, workforce preparedness and the integration of AI applications across health services. The report explores how EU Member States are approaching both the opportunities and the challenges of AI, highlighting emerging directions in strategic planning, regulatory alignment, capacity-building and the responsible deployment of AI in health care.

Keywords

ARTIFICIAL INTELLIGENCE; DIGITAL HEALTH; HEALTH INFORMATION SYSTEMS; EUROPEAN UNION

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Contents

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The main authors of the report were Hanna Dunning (WHO consultant, March 2025 to August 2025), Nicholas Letchford (WHO consultant, March 2025 to December 2025), Nagui Salama (WHO consultant, March 2025 to December 2025) and Keyrellous Adib (WHO Regional Office for Europe).

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For further information please contact the WHO Data, Artificial Intelligence and Digital Health Unit (EUDigitalHealth@who.int).

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Abbreviations

AI	artificial intelligence
AI Act	European Union Artificial Intelligence Act
EHDS	European Health Data Space
EHR	electronic health record
EU	European Union
GDPR	General Data Protection Regulation

Executive summary

In the rapidly evolving landscape of artificial intelligence (AI) in health care, 2025 marks a defining moment for the WHO European Region and particularly for the European Union (EU). With the adoption in the EU of the first comprehensive AI legislation, global attention is turning to the EU for inspiration, guidance and lessons learned in navigating this new frontier in digital health. The *Regional digital health action plan for the WHO European Region 2023–2030* 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.

This report draws on the 2024–2025 survey on AI for health in the WHO European Region, offering a focused lens on the EU. All 53 Member States of the WHO European Region received the survey, and 50 chose to participate (a 94% response rate), including all 27 EU Member States. This report highlights where EU Member States currently stand in terms of policy frameworks, regulatory approaches, strategic priorities, data availability and AI adoption trends and barriers. It also gives an overview of the current AI training offered to the health workforce as well as how key stakeholders are being engaged in the development of AI policy and strategies.

National AI strategies

National AI strategies are essential to ensure AI technologies are deployed safely, transparently, inclusively and accountably. They define the vision, direction and coordination mechanisms needed to maximize benefits while managing risks. Cross-sectoral strategies provide broad alignment but may lack the health-specific focus needed for effective implementation. In contrast, health-specific AI strategies enable targeted governance and faster deployment but risk regulatory fragmentation, inconsistent standards and limited cross-border interoperability. Box E1 gives the key findings for national AI strategies.

Box E1. National AI strategies: key findings

11% (3 of 27) have a health-specific AI strategy

85% (23 of 27) have implemented a cross-sectoral AI strategy

15% (4 of 27) are currently developing one

7% (2 of 27) are currently developing one

Box E1 contd.

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

52% (13 of 25) have assigned oversight to multiple agencies

Regional context and trends

A few EU Member States have developed or are developing health-specific AI strategies, while many others focus on cross-sectoral AI strategies. Although most Member States have adopted a national cross-sectoral AI strategy, many strategies remain in early stages of revision or lack a clear definition of AI. Oversight and implementation typically rely on existing government agencies, with fewer countries establishing entirely new, independent bodies.

Areas for action include:

- regularly revising both cross-sectoral and health-specific strategies to reflect evolving health system priorities, technological advances and sustainability goals, while ensuring inclusive stakeholder engagement; and
- clarifying oversight responsibilities by designating responsible entities to implement AI strategies, ensuring accountability, coordination and continuity across sectors with time-bound objectives.

Stakeholder engagement and health workforce development

Effective implementation of AI in health systems requires meaningful engagement of stakeholders and targeted capacity-building of health professionals to ensure that AI solutions are ethical, contextually relevant and socially accepted. By engaging a range of viewpoints, Member States can foster trust, inform policy-making and help to ensure that AI technologies align with health care goals and serve the wider public good. Box E2 gives the key findings for stakeholder engagement and workforce development.

Box E2. Stakeholder engagement and health workforce development: key findings

81% (22 of 27) engage stakeholders, primarily through focus groups (64%; 14 of 22)

26% (7 of 27) have made stakeholder consultation insights publicly available

Most consulted were

91% (20 of 22) government actors

77% (17 of 22) academic institutions

Box E2 contd.

82% (18 of 22) health care providers

Least consulted were

18% (4 of 22) the broader public

Professional training

26% (7 of 27) offer in-service AI training

15% provide both in-service and preservice training

22% (6 of 27) offer preservice training

48% (13 of 27) have created new professional roles for AI and data science expertise in health

Regional context and trends

The majority of EU Member States have engaged stakeholders in shaping AI in health care, primarily through focus groups, with consultations tending to involve government actors, health care providers and academic institutions. However, patient associations are far less frequently consulted and even more rarely is the broader public consulted. Training opportunities for health care professionals to strengthen AI skills remain limited, both in preservice and in-service training, and fewer than half of EU Member States have created new professional roles for AI and data science expertise within their health systems.

Areas for action include:

- embedding inclusive and early engagement that involves health professionals, patients, developers and researchers from the start to integrate ethical considerations, ensure context-specific solutions and adopt coregulation models that balance innovation with independent oversight and accountability; and
- enhancing workforce AI competencies by integrating AI training into education and professional development and offering tiered programmes on AI fundamentals, ethics, data governance and clinical integration.

Legal and regulatory landscape for AI in health

Legal and regulatory contexts currently differ in form and scope across the EU. The regulatory context for AI in health across EU Member States is examined, with a focus on eight key areas: regulatory approaches to governing AI systems, ethical and legal regulations, minimum standards for AI governance, policy focus to regulating specified AI areas targeted by national strategies, legal liability standards, regulations relating to generative AI, institutional oversight, and cross-country regulatory collaboration. Box E3 gives the key findings for the legal and regulatory landscape around AI in health.

Box E3. Legal and regulatory landscape for AI in health: key findings

7% (2 of 27) have issued guidance for manufacturers and users on applying existing liability regimes to AI

48% (13 of 27) have implemented data accountability practices as a minimum standard for AI governance in health

56% (15 of 27) have plans to align legal liability standards with upcoming EU legislation

22% (6 of 27) have issued practical guidance on ethics by design for AI systems in health

Regional context and trends

Progress on legal and regulatory responses to AI in health varies across EU Member States. Many Member States are currently assessing legal gaps, but developing new AI laws specifically for the health sector remains less common. Only two EU Member States have issued health-specific AI ethical guidelines, with some actively working on them; however, the majority have yet to introduce any such guidelines. Efforts tend to focus on addressing specific legal and ethical risks, such as practical guidance on integrating ethics by design and data protection impact assessments. In terms of minimum standards, the most frequent approach involves implementing data accountability practices, whereas postmarket monitoring and surveillance of AI products is less common.

AI policy priorities often 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 impact of generative AI systems, legal requirements for developers to address these issues are still uncommon. Over half of EU Member States reported having one or more regulatory agencies responsible for assessing and approving AI systems in health, although fewer have agencies monitoring adoption and use.

Areas for action include:

- establishing clear liability mechanisms and defining clear responsibilities for developers, clinicians, data providers and institutions, supported by mechanisms for timely redress and accountability when AI systems cause harm;
- promoting ethical AI by design by developing and disseminating practical, sector-specific guidance on integrating ethics by design into AI systems for health to ensure responsible development, deployment and alignment with patient safety and rights; in line with the EU's Artificial Intelligence

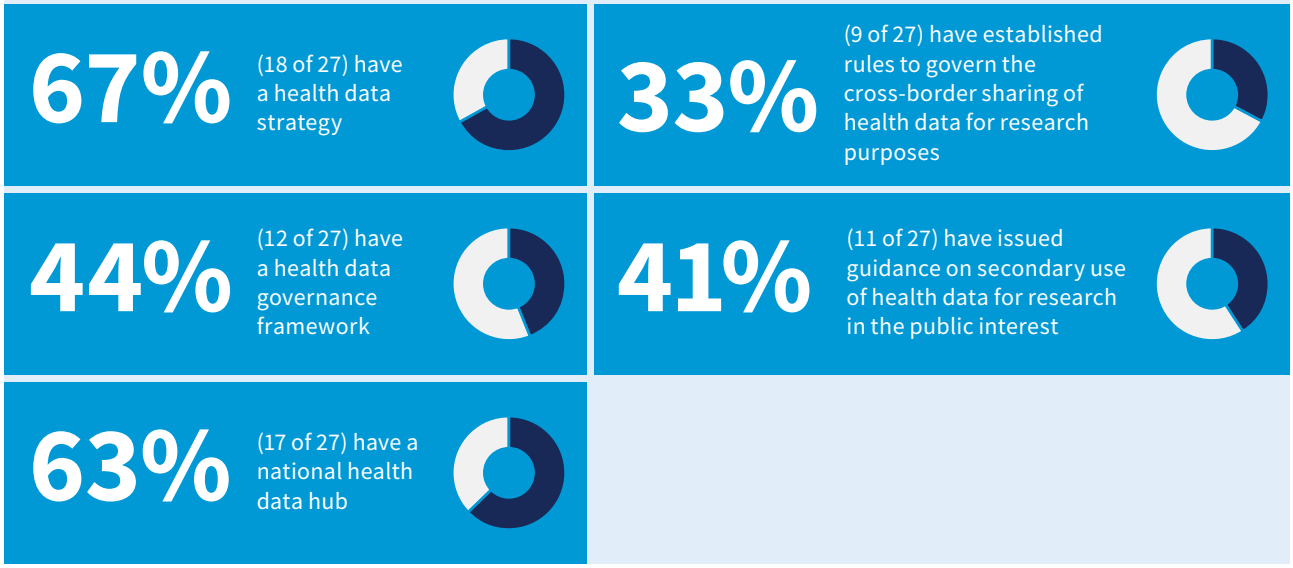
Act; such guidance should emphasize data-related obligations to ensure that AI systems are trained and validated on high-quality, representative datasets that generalize well across diverse environments; and

- supporting adoption of ethical AI through incentives such as grants for ethically designed AI solutions and/or labelling or certification programmes that recognize tools meeting high ethical and safety standards, complemented by precertification programmes and continuous performance monitoring.

Health data governance

High-quality, interoperable health data are foundational for the development and validation of meaningful AI applications in health. National approaches to health data governance are either through dedicated health data strategies or by embedding health data priorities within overarching national data strategies. Additionally, national health data hubs are becoming a cornerstone of national digital health infrastructure, enabling the secure aggregation, management and reuse of health data for research, innovation and system improvement. Countries that lack data hubs risk falling behind. It is important to note the introduction of the European Health Data Space (EHDS) regulation, which will provide an EU-wide framework for the use and reuse of health data from March 2029. The upcoming EHDS may have influenced national efforts in health data governance, with some countries pausing or slowing initiatives in anticipation of alignment with the forthcoming EU-wide framework. Box E4 gives the key findings for health data governance.

Box E4. Health data governance: key findings



Regional context and trends

The majority of EU Member States have adopted dedicated health data strategies, while others are integrating health priorities into overarching data policies. Most Member States also have a national health data hub or are in the process of developing one. Regarding secondary data use and data sharing, a small group of Member States are leading the way by adopting comprehensive policies that enable both domestic and international data flows while maintaining strong protections. Although the EU shows

higher rates of policies supporting data sharing for public-interest research than seen in the wider WHO European Region, the majority of Member States still lack rules and frameworks to facilitate this exchange.

Areas for action include:

- preparing for the implementation of the EHDS framework by ensuring that Member States implement the governance and technical aspects needed by March 2029 for its successful introduction;
- ensuring that all stakeholders involved are timely informed and adequately engaged so that they are ready to comply with obligations deriving from the introduction of EHDS and prepared to explore the opportunities it will enable, in particular with regards to the development and validation of AI solutions in health; and
- expanding the establishment of best-practice networks to ensure equitable AI integration across the EU.

AI opportunities and applications

AI is reshaping health care across the WHO European Region, with advancements in diagnostics genomics, radiology, pathology, remote patient care and disease prevention. The current uptake of these AI tools varies not only in which applications are being used but also in the maturity of the applications. Identifying national priorities and allocating funding for the development, testing, implementation and evaluation of AI ensures that these advancements are in alignment with health system objectives. Box E5 gives the key findings for AI opportunities and applications.

Box E5. AI opportunities and applications: key findings

59% (16 of 27) identified priority areas for AI in health; only 63% of these (10 of 16) have allocated funding for implementation

Drivers of AI innovation

100% (27 of 27) considered improving patient care a major or moderate driver

89% (24 of 27) considered increasing efficiency a major or moderate driver

96% (26 of 27) considered reducing workforce pressure a major or moderate driver

Use of AI

74% (20 of 27) use AI-assisted diagnostics

63% (17 of 27) use conversational platforms (chatbots) for patient assistance

Regional context and trends

The majority of EU Member States have identified key areas where AI technologies are expected to deliver significant value to health systems and population health; however, less than two thirds of those have allocated specific funding for the development, testing and deployment of AI technologies. Across the EU there is consensus on the drivers of AI development and consistent ranking of strategic opportunities suggests a common understanding of AI's potential in health. Member States in the EU reported higher levels of AI adoption and a more mature application of AI in health care compared with the wider WHO European Region. AI-assisted diagnostics stands out as the most commonly reported use, with nearly three quarters of Member States leveraging AI technologies to enhance imaging and detection, for example in radiology, dermatology or ophthalmology. Conversational chatbots for patient assistance were also widely adopted, with two thirds the countries reporting use.

Areas for action include:

- ensuring context-specific AI design by developing AI systems tailored to clearly defined, reliable and context-appropriate tasks that strengthen health system capacity, protect patient interests and align with national health goals – capabilities, limitations and operational conditions should be transparently communicated to all stakeholders;
- creating a centralized catalogue of verified AI solution by establishing an EU-wide, regularly updated platform categorizing validated AI tools by functionality, specialty, performance and operational context, supported by health care institutions, AI developers and Member States to guide safe and equitable adoption; and
- introducing structured accreditation and certification processes to ensure developers integrate evolving ethical, legal and regulatory considerations into AI design, deployment and monitoring.

Barriers and policy enablers for AI adoption in health systems

AI has the potential to enhance patient care, improve system efficiency and accelerate medical modernization; however, the path to widespread integration is not without challenges and barriers. To overcome those barriers, many proposed policy enablers have been explored that align with developments in the EU's Artificial Intelligence Act and reflect key areas of focus, such as legal clarity, ethical frameworks, data governance and accountability mechanisms. Box E6 gives the key findings for barriers and policy enablers for AI in health systems.

Box E6. Barriers and policy enablers for AI adoption in health systems: key findings

Barriers to adoption of AI in health care

41% (11 of 27) rated financial affordability as a barrier of major importance

0% No Member State rated environmental impact as of major importance

Box E6 contd.

Key policy enablers for widespread adoption of AI in health care

63% (17 of 27) cited guidance on transparency, verifiability and explainability of AI solutions to ensure trust in outcomes as having a major positive impact

56% (15 of 27) cited accountability and liability rules for manufacturers, deployers and users applicable to AI systems in health as having a major positive impact

Regional context and trends

Across the EU, the adoption of AI in health care faces significant challenges, with financial affordability emerging as the most frequently reported barrier, followed by legal uncertainty and data quality and standards. Markedly the environmental impact of AI was not considered a major barrier by any EU Member State. Despite the challenges, there is broad consensus on the policy measures that could facilitate AI uptake. Over half of the EU Member States view guidance that ensures transparency, verifiability and explainability of AI solutions as essential for building trust in AI-driven outcomes. Similarly, liability rules for manufacturers, deployers and users of AI in health care is considered a key policy enabler.

Areas for action include:

- implementing regulatory sandboxes and assurance laboratories by establishing flexible, controlled environments to test AI technologies, enabling real-time learning and adaptive legal frameworks; assurance laboratories in leading health facilities may conduct local performance testing, assess real-world impact and monitor postdeployment use with anonymized, ethically sourced data;
- assessing cost–effectiveness and supporting high-priority AI and evaluating AI technologies against traditional methods to ensure alignment with clinical, regulatory, infrastructural and human rights standards; providing consolidated funding, grants and subsidies would accelerate development, piloting and deployment, particularly for smaller or resource-limited settings;
- strengthening liability and accountability frameworks by assigning responsibility for adverse outcomes through updated liability frameworks covering product, personal, input and data donor liability and ensuring frameworks address causal responsibility, objective liability, retrospective harm and mechanisms for vicarious liability to safeguard patients and support accountable AI use; and
- balancing AI benefits with environmental impact and evaluate the carbon and water footprint of AI models, including considering the indirect health impacts of AI-related emissions and weighing the trade-offs between AI-driven health gains and potential climate-related health risks to ensure responsible deployment that minimizes harm.

1. Introduction

1.1 Definitions of artificial intelligence

Artificial intelligence (AI) encompasses a wide range of applications, leading to multiple definitions. Most definitions emphasize the core capabilities of AI systems – such as processing inputs, identifying patterns, adapting to achieve specific goals and generating outputs such as predictions, recommendations or decisions. The lack of a universally accepted definition is largely due to the diverse ways AI is interpreted across countries, contexts and organizations.

The survey and this report adopt the definitions used by the European Union (EU) and WHO as outlined in Box 1.

Box 1. Definitions of AI

The EU defines an AI system as "a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations or decisions that can influence physical or virtual environments" *(1)*.

WHO defines AI as 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)*.

The subset of AI known as machine learning allows computer algorithms to learn through data, without being explicitly programmed, to perform a task *(3)*. Large language models are a further subset of machine learning that are trained on vast amounts of textual data to understand, generate and respond to human language *(4)*.

1.2 The EU approach to governing AI

The governance of AI in the EU is built on a comprehensive framework designed to balance innovation with fundamental rights, safety and trust. Central to this approach are key instruments such as the EU's Artificial Intelligence Act (AI Act), which establishes a risk-based regulatory framework *(5)*; the broader European health data strategy, which supports innovation and interoperability; the European Health Data Space (EHDS) *(6)*; and the General Data Protection Regulation (GDPR), which safeguards data privacy and individual rights *(7)*.

1.3 The AI Act

The AI Act, adopted in June 2024, represents the world's first comprehensive legal framework specifically regulating AI *(5)*. Its primary objective is to ensure that AI systems developed and deployed within the EU are safe, ethical and respect fundamental rights *(8)*. Legislation builds on earlier EU initiatives, such as the 2020 White Paper on AI, and aims to foster trustworthy AI that supports innovation while safeguarding public interest. Particularly relevant to the health care sector, the AI Act fills regulatory gaps left by existing frameworks such as the Medical Device Regulation *(9)*, which do not fully address the complexities of AI driven medical technologies *(10)*.

A cornerstone of the AI Act is its risk-based approach, which categorizes AI systems into four tiers: unacceptable, high, limited and minimal risk. In health care, most AI applications – such as diagnostic tools, triage systems and clinical decision support – are classified as high risk due to their potential impact on patient safety and outcomes *(8)*. Starting in August 2026 and following a transition period of 2 years (or in some cases 3 years), high-risk AI systems will be required to meet a comprehensive set of obligations. These include measures for risk management, data quality and governance, logging and traceability, technical documentation, transparency, and human oversight, as well as ensuring accuracy, robustness and cybersecurity *(11)*. This approach is designed to mitigate risks such as algorithmic bias, lack of explainability and data privacy concerns. The AI Act is expected to significantly influence the future of digital health in Europe by promoting innovation within a clear ethical and legal framework, ultimately enhancing patient care and trust in AI technologies *(10)*.

1.4 The EU European strategy for data

The EU European strategy for data *(12)* prioritizes putting people first and European rights values in the digital age, aiming to harness data as a key driver of economic growth, innovation and societal progress. It envisions a single market for data to enhance Europe's global competitiveness and data sovereignty through Common European Data Spaces. The strategy is supported by the Data Governance Act, which promotes trusted data sharing, and the Data Act, which unlocks industrial data for economic benefit *(12)*. Looking ahead, the forthcoming Data Union Strategy (expected in 2025) will build on this foundation to boost AI innovation, streamline data rules and strengthen cross-border data use and international data flows *(12)*.

1.5 The EHDS

The EHDS is a dedicated digital framework aimed at advancing health care across the EU by creating a unified ecosystem of rules, standards, infrastructure and governance for the secure cross-border exchange of, use and reuse of health data. Its core objectives are to empower individuals with enhanced digital access to and control over their personal health data – both within their home countries and across EU borders; create a single market for electronic health record (EHR) systems; and enable the secure, efficient reuse of health data for research, innovation, policy-making and regulatory purposes *(13)*.

The adoption of the EHDS Regulation in March 2025 initiated a 2-year period during which the European Commission will adopt key implementing acts to define the detailed rules necessary for operationalizing the Regulation. By 2029 substantial parts of the EHDS Regulation are expected to become applicable across EU Member States, particularly concerning the exchange of priority health data categories and the rules for the secondary use of health data *(14)*.

1.6 Data protection (GDPR) in the AI era

The GDPR, enacted by the EU in 2018, is a legal framework designed to protect individuals' personal data and privacy. It establishes strict rules for how organizations collect, process and store personal data, with particular emphasis on transparency, accountability and individual rights *(7)*. Although AI is not specifically addressed in the text of the GDPR, many of its provisions are directly applicable to AI systems. These principles are particularly relevant in the context of AI, which often relies on large datasets to train algorithms and make automated decisions *(15)*.

In the health care sector, the intersection of GDPR and AI is particularly significant. AI tools used to assist in screening for diseases such as cancer require access to vast amounts of patient data to function effectively. Under GDPR, health care providers must obtain explicit consent from patients before using their data and must ensure that any data used is either anonymized or strictly necessary for the intended purpose. While GDPR provides a strong foundation for ethical AI development, further guidance and sector-specific standards are needed to support innovation while safeguarding individual rights *(15)*.

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

The 2024–2025 survey represents the first comprehensive effort to assess the status, challenges and opportunities of AI in health care across the Region. It provides insights into regulatory developments, adoption levels, stakeholder engagement and training needs, offering valuable evidence to guide policy-makers in shaping governance frameworks and supporting effective AI integration in health systems.

Information for Member States of the Region is available in the country profiles accompanying this report *(16)*.

1.8 Structure of the report

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

The relevant findings for the EU 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.

Section 3.1. National AI strategies. This section reviews how EU Member States are developing, governing and implementing AI strategies through stand-alone plans, integration into digital health strategies or broader cross-sectoral frameworks.

Section 3.2. Stakeholder engagement and health workforce development. Stakeholder engagement, private investment, cross-border collaboration and workforce development across the EU are explored.

Section 3.3. Legal and regulatory landscape for AI in health. This section reviews the EU's regulatory context, national laws and guidelines shaping AI development and oversight while identifying gaps and opportunities for greater harmonization.

Section 3.4. Health data governance. The maturity of health data governance across the EU is evaluated, focusing on strategies, frameworks and data hubs, while highlighting policies enabling responsible data use, cross-border sharing and collaboration with the private sector.

Section 3.5. AI opportunities and applications. This section analyses how EU Member States identify health system priorities and adopt AI solutions to ensure alignment with EU health objectives and improved outcomes.

Section 3.6. Barriers and policy enablers for AI adoption in health systems. The last section identifies the key challenges to AI adoption in EU health care systems and highlights policy enablers to accelerate responsible implementation.

The final chapter summarizes key insights and outlines priority actions to promote ethical, equitable and effective AI adoption in health systems across EU Member States.

2. Methods and approach

The WHO Regional Office for Europe initiated the 2024–2025 survey on AI for health in the WHO European Region in June 2024. The survey period remained open until March 2025. Two formats 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 53 Member States of the WHO European Region were formally invited to partake 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 in the survey. Three Member States did not respond and were excluded from the analysis, giving a response rate of 94% for the Region; however, all 27 Member States from the EU completed it. Some questions were dependent on Member States' responses to other questions, such as if they have a (cross-sector/sector-agnostic) national AI strategy in place or if have they adopted a definition for what constitutes an AI system. In these instances, Member States that did not respond affirmatively to the initial question would be excluded from the number of respondents from which percentages were computed. The analytical process was handled by staff and consultants from the WHO Regional Office for Europe.

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.

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. Results

3.1 National AI strategies

National AI strategies in EU Member States are summarized in Highlights box 1.

Highlights box 1. National AI strategies

AI strategy

11% (3 of 27) have a health-specific AI strategy

15% (4 of 27) are currently developing one

85% (23 of 27) have implemented a cross-sectoral AI strategy

7% (2 of 27) are currently developing one

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

32% (8 of 25) have revised their national AI strategy

52% (13 of 25) assigned oversight to multiple agencies with shared responsibility

80% (20 of 25) have identified health as a key sector impacted by AI

8% (2 of 25) created a new government agency for overseeing AI implementation

This section presents key findings on the current state of national AI strategies across the EU. It examines the models and concepts EU Member States have adopted, as well as how these strategies are implemented, governed and overseen. The section is organized into two main subsections:

- overview of AI strategies explores the various forms national AI strategies can take, such as cross-sectoral versus sector-specific approaches and whether health-related AI is addressed through stand-alone plans or embedded within broader digital health strategies; and
- oversight and implementation of national AI strategies examines how these strategies are governed, monitored and operationalized, including the roles 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 defines a country's vision, principles, priorities and concrete steps for the research, development, governance and deployment of AI in the health sector. These strategies often, but not always, provide a basis for policy coordination, legal oversight, capacity-building and stakeholder engagement, although their form and governance vary depending on national priorities, institutional capacity, legal systems and the maturity of health and digital infrastructures. Strategies may be stand-alone health-specific documents, integrated within digital health strategies or part of broader cross-sectoral frameworks. Health-specific strategies allow tailored governance, targeted investment and faster implementation, while cross-sectoral approaches enhance interoperability, shared infrastructure and efficiency but may require more complex coordination.

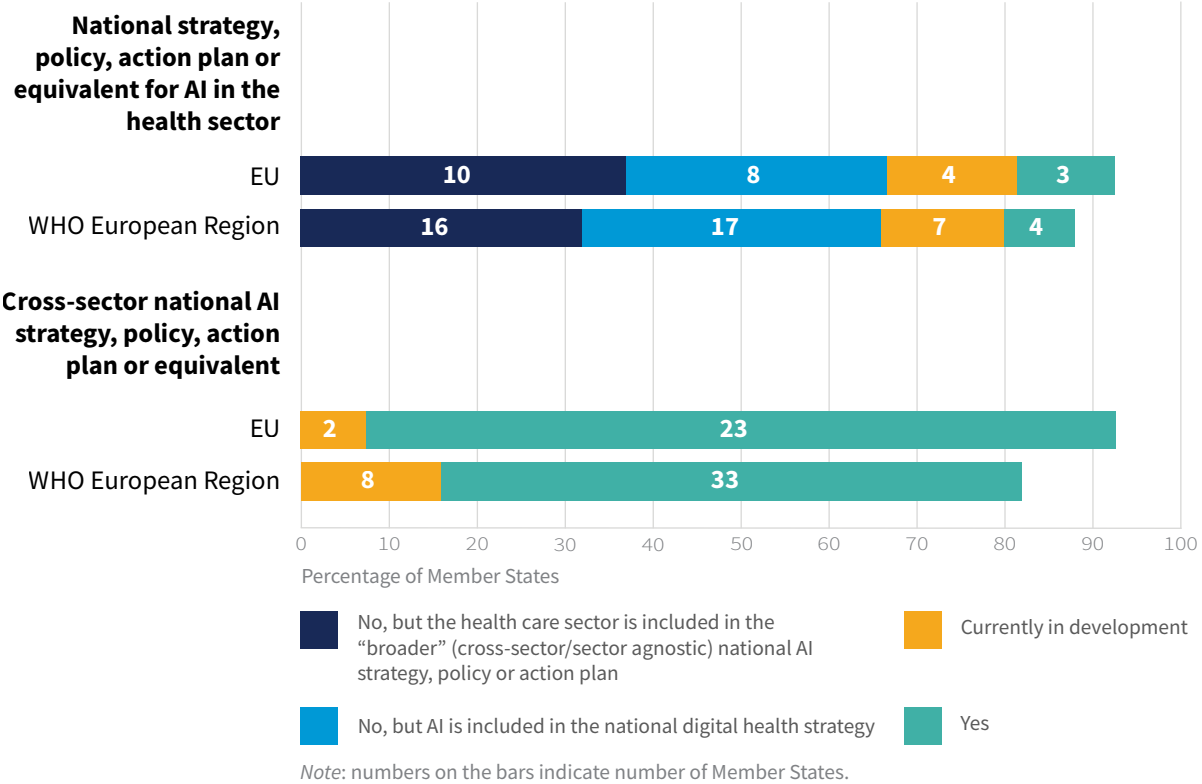
3.1.1 Findings

Overview of national AI strategies

Across the EU, 11% of Member States (three of 27; Finland, Slovakia and Sweden) have a national AI strategy for the health sector (Fig. 1). A further 15% (four of 27; Cyprus, Czechia, Italy and Spain) indicated that this is under development. However, instead of developing a specific AI strategy for the health sector, it was far more common to either include AI in a national digital health strategy (30%; eight of 27) or to include the health sector in a cross-sectoral AI strategy (37%; 10 of 27).

Similar patterns were observed across the WHO European Region where only 8% of Member States (four of 50) reported having a national AI strategy for the health sector. A further 14% of Member States (seven of 50) reported such a strategy was currently being developed. Meanwhile, 34% of Member States (17 of 50) had chosen to include AI in their national digital health strategy and 32% (16 of 50) had included the health sector in their cross-sectoral national AI strategy.

Fig. 1. National AI strategies in the EU and WHO European Region



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

As shown in Fig. 1, 85% of EU Member States (23 of 27) have implemented a national cross-sectoral AI strategy, with an additional 7% (two of 27; Croatia and Estonia) currently developing one. In contrast, across the wider WHO European Region, 66% of Member States (33 of 50) reported having a cross-sectoral AI strategy in place, while 16% (eight of 50) indicated that such a strategy is under development.

Across the EU, 68% of Member States (17 of 25) with a national cross-sectoral AI strategy or strategies under development reported having a definition of what constitutes an AI system. In terms of strategy revisions and updates, 32% (eight of 25) have revised their AI strategy since 2019 and another 32% (eight of 25) are in the process of revising or plan to do so soon. Notably, 80% (20 of 25) identified the health sector as a key area expected to be significantly impacted by AI.

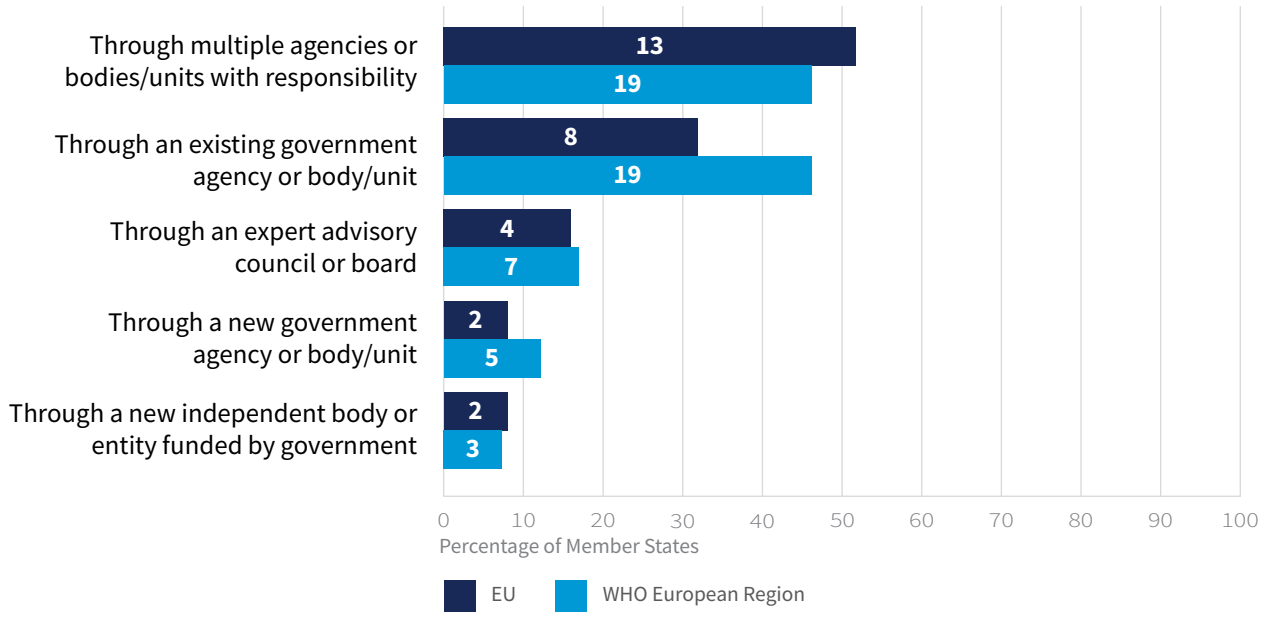
Similar patterns were observed across the wider WHO European Region: among 41 Member States with a national cross-sectoral AI strategy in place or under development, 68% (28) reported having defined AI systems, 29% (12) having revised their strategy, 39% (16) being in the process of revising or planning revisions, and 78% (32) recognizing health as a priority area for AI impact.

Oversight and implementation of national AI strategies

The most common approach to oversight and implementation of national AI strategies across the EU was through multiple agencies with shared responsibility, reported by 52% of Member States (13 of 25) (Fig. 2). This was followed by oversight through an existing government agency, indicated by 32% (eight of 25). Other approaches were far less common: 8% of Member States (two of 25) reported oversight by a new government agency, 16% (four of 25) by an expert advisory council and 8% (two of 25) by a new independent entity funded by the government.

Across the WHO European Region, the two most common oversight models were equally split between existing government agencies and multiple agencies with responsibility, each reported by 46% of Member States (19 of 41). Similar to the EU, other models were much less frequently reported: 12% of Member States (five of 41) indicated oversight by a newly established government agency, 17% (seven of 41) through an expert advisory council and just 7% (three of 41) through a new independent government-funded entity.

Fig. 2. Oversight of implementation and operation of national AI initiatives in the health sector



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

3.1.2 Summary

A few EU Member States have developed or are developing health-specific AI strategies, while many others are focusing on cross-sectoral AI strategies. Although most Member States have adopted a national cross-sectoral AI strategy, many remain in early stages of revision or lack a clear definition of AI. Oversight and implementation typically rely on existing government agencies, with fewer countries establishing entirely new independent bodies.

Cross-sectoral strategies provide broad oversight and promote consistency across domains but may not address specific health system priorities or clinical needs. Health-specific strategies allow for targeted governance, tailored regulation and faster implementation, yet without coordination, they risk regulatory fragmentation, inconsistent standards and duplicative oversight. Such fragmentation can hinder cross-border collaboration, limit interoperability and slow the adoption of AI tools requiring national or international alignment.

3.2 Stakeholder engagement and health workforce development

Stakeholder engagement and workforce development in EU Member States are summarized Highlights box 2.

Highlights box 2. Stakeholder engagement and health workforce development

81% (22 of 27) engaged relevant stakeholders in shaping AI governance in the health sector, most often through expert focus groups

74% (20 of 27) reported private sector investment in AI health research, reinforcing the need for clear regulatory frameworks to manage innovation risks

26% (7 of 27) made stakeholder consultation insights publicly available to support transparent and accountable AI policy-making

30% (8 of 27) established cross-border partnerships for AI in health, underscoring the growing relevance of harmonized EU-wide regulatory approaches

Most consulted were

91% (20 of 22) government actors

77% (17 of 22) academic institutions

82% (18 of 22) health care providers

Least consulted were

18% (4 of 22) the broader public

Highlights box 2 contd.

Professional training

26% (7 of 27) offer in-service training

15% (4 of 27) provide both in-service and preservice training

22% (6 of 27) offer preservice training

48% (13 of 27) had created new professional roles for AI and data science expertise in health

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

- modes of stakeholder engagement examines how EU 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 government agencies, health professionals, AI developers and public and patient associations is essential for the safe, ethical and relevant deployment of AI in health care. Health professionals play a key role in ensuring AI solutions address real clinical and public health needs, while public and patient associations provide critical input on usability, ethical considerations and patient rights. By incorporating diverse perspectives, these collaborations enhance trust, guide policy development and ensure that AI technologies serve both health care objectives and the broader public interest.

Private investment and cross-border partnerships also play a critical role in AI readiness. For example, Austria's involvement in the EHDS pilot and the EU-funded Testing and Experimentation Facility for Health AI *(17)* initiative demonstrates how Member States are leveraging public–private collaborations to support safe AI innovation. The initiative brings together stakeholders from multiple EU countries to test and validate trustworthy AI applications in health, helping to align ethical principles with real-world deployment *(18).* By taking stock of national practices across the EU, this section aims to provide a roadmap for how ethical governance, inclusive processes and long-term capacity-building can support the safe, equitable and effective use of AI in health systems.

Building capacity within the health care workforce is a cornerstone of the WHO European Region digital health strategy, particularly regarding AI integration. Although the WHO *Regional digital health action plan 2023–2030* emphasizes strengthening digital literacy *(19)*, many Member States still lack preservice or in-service digital health training and existing programmes often prioritize physicians over other health professionals. Beyond technical skills, health care workers require critical thinking, ethical decision-making and a strong understanding of AI's practical applications and risks. Achieving this necessitates transforming education to develop interdisciplinary competencies, including data governance, AI fundamentals and communication, supported by a new cadre of educators proficient in both health sciences and AI.

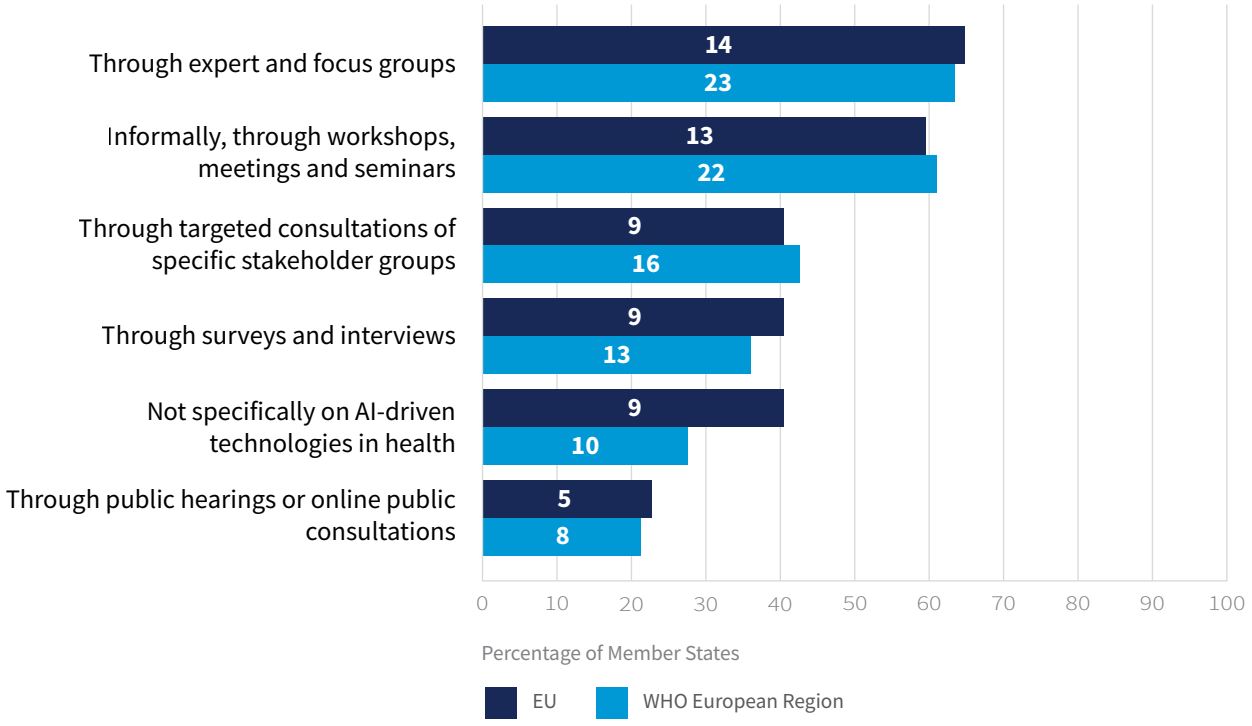
3.2.1 Findings

Modes of stakeholder engagement

Among EU Member States, 81% (22 of 27) reported engaging relevant stakeholders in the integration of AI into health systems. As shown in Fig. 3, the most commonly used method was expert focus groups, reported by 64% of Member States (14 of 22), followed closely by informal meetings such as workshops and seminars, cited by 59% (13 of 22). Public hearings were the least used method, adopted by only 23% of Member States (five of 22): Cyprus, Estonia, France, Lithuania and Netherlands (Kingdom of the). Among the five EU Member States that had not yet conducted stakeholder engagement activities, 60% (three; Czechia, Luxembourg and Portugal) indicated plans to do so in the future.

Across the broader WHO European Region, 72% of Member States (36 of 50) reported having undertaken some form of stakeholder engagement in relation to AI in health. The most frequently used approaches were focus groups (64%, 23 of 36) and informal meetings such as workshops and seminars (61%, 22 of 36). Meanwhile, cross-sectoral AI consultations (28%, 10 of 36) and public hearings (22%, eight of 36) were among the least utilized forms of engagement. Of the 14 Member States that had not yet carried out engagement activities, 57% (eight of 14) reported plans to do so in the future.

Fig. 3. Engagement with relevant stakeholders on the use of AI-driven technologies in health systems



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

For EU Member States, the most commonly consulted stakeholder groups were government actors, with 91% of Member States (20 of 22) reporting that they have consulted stakeholders, followed by health care providers (82%, 18 of 22) and academic institutions (77%, 17 of 22) (Table 1). Engagement with the broader public was much less common, reported by only 18% of Member States (four of 22; Denmark, Estonia, France and Netherlands (Kingdom of the)). Additionally, 32% of EU Member States that had engaged stakeholders (seven of 22) made the insights from their stakeholder consultations publicly available. These results are aligned with the findings of stakeholder engagement in the wider WHO European Region.

Table 1. Stakeholder groups that EU Member States have engaged with on the use of AI-driven technologies in health systems

Member State	Governmental actors	Health care providers	Academics	Industry leaders	Regulators	Patient associations	Professional associations	AI developers	Broader public
Austria	✓	✓	✓	✓	✗	✓	✓	✓	✗
Belgium	✓	✓	✗	✓	✗	✓	✗	✓	✗
Bulgaria	✓	✓	✗	✓	✓	✓	✓	✗	✗
Croatia	✓	✓	✓	✓	✓	✗	✓	✓	✗
Cyprus	✓	✓	✓	✓	✗	✓	✗	✗	✗
Denmark	✓	✓	✓	✓	✓	✓	✓	✓	✓
Estonia	✓	✓	✓	✓	✓	✓	✓	✓	✓
Finland	✓	✓	✓	✓	✓	✓	✓	✓	✗
France	✓	✓	✓	✓	✓	✓	✓	✓	✓
Germany	✓	✗	✓	✓	✗	✓	✓	✓	✗
Greece	✓	✗	✓	✓	✓	✗	✗	✗	✗
Hungary	✓	✓	✓	✗	✓	✗	✓	✓	✗
Italy	✓	✗	✓	✗	✗	✗	✗	✗	✗
Latvia	✗	✓	✓	✓	✓	✓	✓	✗	✗
Lithuania	✓	✓	✓	✗	✓	✓	✗	✓	✗
Malta	✓	✓	✓	✗	✓	✗	✗	✓	✗
Netherlands (Kingdom of the)	✓	✓	✓	✓	✓	✓	✗	✓	✓
Poland	✓	✓	✓	✓	✓	✓	✓	✓	✗
Slovakia	✓	✓	✗	✗	✓	✗	✓	✗	✗
Slovenia	✗	✓	✗	✓	✗	✗	✗	✗	✗
Spain	✓	✓	✓	✓	✓	✗	✓	✗	✗
Sweden	✓	✗	✗	✗	✗	✗	✗	✗	✗

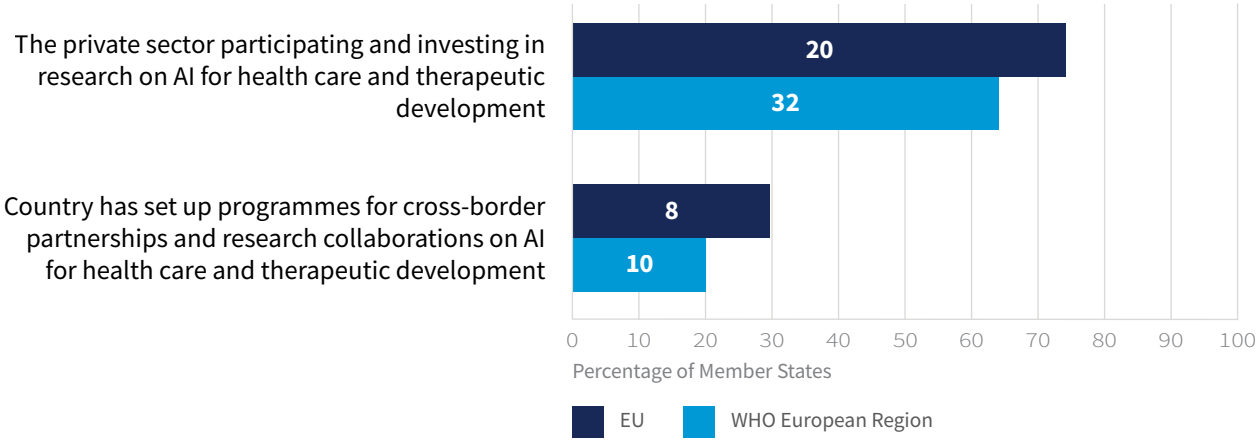
✓ — Yes

✗ — No

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

As shown in Fig. 4, 74% of EU Member States (20 of 27) reported private sector investment in AI research within the health sector. The broader WHO European Region reflects this pattern, with 64% of Member States (32 of 50) reporting private sector investment in AI research in the health sector. However, cross-border partnerships and research collaborations remain limited, although somewhat more common than in the wider WHO European Region: 30% of EU Member States (eight of 27) indicating that they have established such collaborations whereas 20% (10 of 50) in the Region have done so.

Fig. 4. Private sector investment and programmes for cross-border partnerships and research collaborations on AI for health care



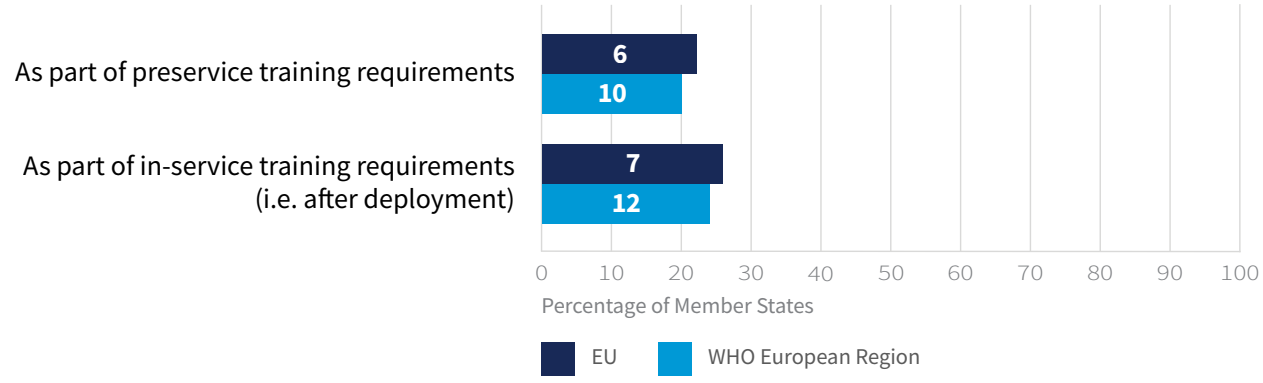
Note: numbers on the bars indicate number of Member States.

Building an AI-ready workforce in health care

In-service training to support health and related professionals in building AI expertise was reported by 26% of EU Member States (seven of 27), while preservice training was offered by 22% (six of 27) (Fig. 5). Both types of training are available in 15% of Member States (four of 27; Belgium, Denmark, Estonia and Finland). Additionally, 15% (four of 27; Cyprus, Czechia, Latvia and Malta) reported plans to introduce both in-service and preservice training in the future.

A similar pattern emerges across the WHO European Region: 24% of Member States (12 of 50) reported providing in-service training, while just 20% (10 of 50) reported providing preservice training. In total, 28% of Member States in the Region (14 of 50) offered either in-service or preservice training, with 16% (eight of 50) providing both. These figures highlight a general need to scale up training opportunities to equip the health workforce with the necessary AI skills.

Fig. 5. Educational opportunities for health and health-related professionals



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

The seven EU Member States offering in-service training (Austria, Belgium, Denmark, Estonia, Finland, Hungary and Spain) have most commonly extended it beyond doctors to nurses (71%, five Member States), administrators (71%, five Member States), researchers (71%, five Member States) and medical information professionals (71%, four Member States) (Table 2). These were not necessarily the same four Member States for each group, highlighting variation in training priorities across the EU. The least

frequently trained group were community health workers, included in only 29% of Member States (two of seven; Denmark and Spain). While one of the seven Member States (14%), Austria, provided training to just three professional categories, two of the seven (29%), Denmark and Spain, reported offering in-service training to all eight professional groups surveyed. In addition, 48% of EU Member States (13 of 27) reported the creation of new professional roles and career paths for individuals with specialized skills in AI and data science to support the health sector.

Table 2. Professional groups offered in-service training opportunities across EU Member States

Member State	Doctors	Nurses	Managers and administrators	Biomedical/ life science researchers	Medical information professionals	Medical technicians	Public health specialists	Community health workers
Austria	✓	✓	✗	✗	✗	✓	✗	✗
Belgium	✓	✗	✗	✓	✓	✗	✓	✗
Denmark	✓	✓	✓	✓	✓	✓	✓	✓
Estonia	✓	✓	✓	✓	✗	✓	✓	✗
Finland	✓	✓	✓	✗	✓	✗	✗	✗
Hungary	✓	✗	✓	✓	✓	✗	✗	✗
Spain	✓	✓	✓	✓	✓	✓	✓	✓

✓ — Yes

✗ — No

Similar findings were observed in the wider WHO European Region. All 12 Member States that currently provide in-service training reported offering it to doctors (100%) and a majority (83%; 10 of 12) included health information specialists. However, fewer countries reported training medical technicians (42%, five of 12) or community health workers (17%, two of 12). One third of these countries (33%, four of 12) offered training to six or more professional groups, while 42% (five of 12) trained four or fewer. Additionally, 42% of all Member States (21 of 50) reported creating new roles for individuals with advanced AI and data science expertise to support digital transformation in the health sector.

3.2.2 Summary

The majority of Member States have engaged stakeholders in shaping AI in health care, primarily through focus groups, with consultations tending to involve government actors, health care providers and academic institutions. However, patient associations and even more so the broader public are far less frequently consulted. Training opportunities for health care professionals to strengthen AI skills remain limited, both in preservice and in-service training, and fewer than half of EU Member States have created new professional roles for AI and data science expertise within their health systems.

Engaging patients, public associations and health care professionals throughout the AI life-cycle is critical to ensure relevance, ethical grounding and trust. Limited stakeholder 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. Closing these gaps requires embedding stakeholder insights into both the design and governance of AI systems, while simultaneously strengthening workforce capabilities to ensure safe, effective and contextually appropriate use of AI in health care.

3.3 Legal and regulatory landscape for AI in health

The key features of the legal and regulatory landscape around AI in health are given in Highlights box 3.

Highlights box 3. Legal and regulatory landscape for AI in health

7% (2 of 27) issued guidance for manufacturers and users on applying existing liability regimes to AI

48% (13 of 27) implemented data accountability practices as a minimum standard for AI governance in health

56% (15 of 27) have plans to align legal liability standards with upcoming EU legislation

22% (6 of 27) issued practical guidance on ethics by design for AI systems in health

Across the EU, regulatory strategies differ in form and scope. Some countries, such as France and Germany, have developed comprehensive national AI strategies with sector-specific components for health, while others integrate AI regulation into broader digital health or innovation frameworks *(18).* Formal legislation, such as the EU Medical Device Regulation *(9)* and the GDPR *(20)*, occurs alongside so-called soft law mechanisms such as guidelines, ethical codes and voluntary standards. For example, Finland has issued national ethical principles for AI promoting fairness, transparency and accountability *(21)*, while Netherlands (Kingdom of the) is establishing regulatory sandboxes and adaptive experimentation environments to test AI systems under real-world conditions.

This section provides a comprehensive overview of how EU Member States have developed laws, regulations, policies and guidelines related to AI. It is organized into eight subsections:

- regulatory approaches to governing AI systems describes how EU countries design and implement legal and institutional structures to govern AI in health, including centralized and decentralized models;
- ethical and legal regulations for AI examines how Member States incorporate principles such as transparency, accountability and human rights into their AI strategies and legal systems;
- minimum standards for AI governance outlines common technical and procedural requirements for AI systems, including life-cycle management, documentation and validation;
- policy focus for AI regulation specifies areas targeted by national strategies to regulate AI and identifies the thematic priorities of national AI policies in health, such as procurement, certification, auditing and public engagement;
- legal liability standards for AI systems explores how countries are addressing responsibility and redress mechanisms when AI tools fail or cause harm;
- regulations relating to generative AI highlights emerging approaches to managing risks and transparency obligations for general-purpose AI models, including large language models;
- institutional oversight and regulatory agencies examines the agencies responsible for approving AI systems across EU Member States and the roles played by health and digital authorities; and
- cross-country regulatory collaboration reviews initiatives and mechanisms for regulatory alignment and cooperation at the EU level, including joint assessments, data spaces and harmonized standards.

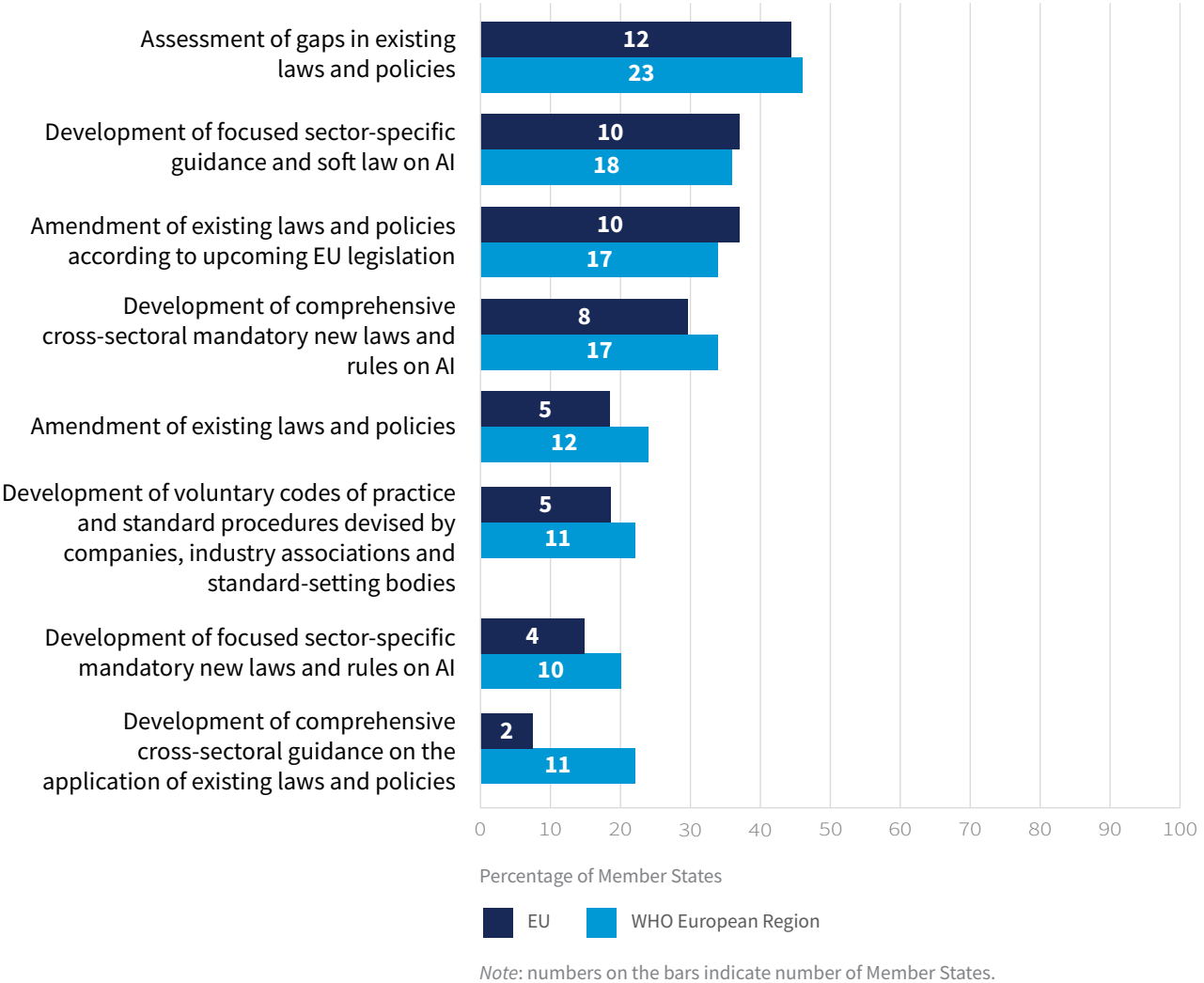
3.3.1 Findings

Regulatory approaches to governing AI systems

Across the EU, the most common approach to governing the development, deployment and use of AI systems was assessing gaps in existing laws and policies, reported by 44% of Member States (12 of 27) (Fig. 6). Other commonly reported approaches included amending existing laws in line with upcoming EU legislation (37%, 10 of 27) and developing health-specific guidance and ethical principles for AI systems (37%, 10 of 27). The least common approach, reported by only 7% of EU Member States (two of 27, Belgium and Italy), was the development of cross-sector guidance on the application of existing laws and policies.

Similar patterns were observed across the broader WHO European Region. The most frequently reported approach was also the assessment of gaps in existing laws and policies, reported by 46% of Member States (23 of 50). This was followed by the development of sector-specific guidance and ethical principles for AI systems (36%, 18 of 50) and developing comprehensive, mandatory cross-sectoral legislation for AI (34%, 17 of 50). Less common approaches included creating new mandatory health-specific legislation for AI systems (24%, 12 of 50), comprehensive cross-sectoral guidance on applying existing laws (22%, 11 of 50) and voluntary codes of practice or standard procedures developed by industry actors or standard-setting bodies (22%, 11 of 50).

Fig. 6. Approaches for legislative measures or other provisions to govern the development, deployment and use of AI systems

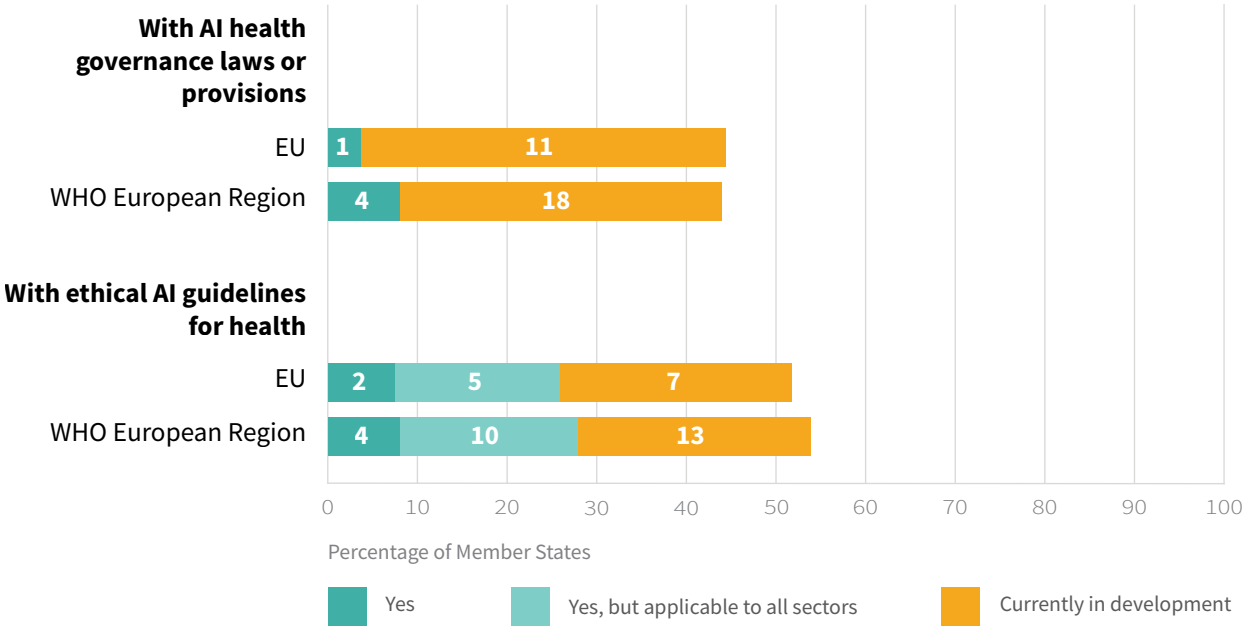


Note: numbers on the bars indicate number of Member States.

Ethical and legal regulations for AI

Although most EU Member States indicated that they are either creating new guidance, laws or voluntary codes and standards or updating existing ones, only one Member State, Belgium, has reported having implemented such legislation; an additional 41% (11 of 27) reported that they were developing such legislation (Fig. 7). Similarly, when looking at the wider WHO European Region, 8% (four of 50) have enacted specific legislation focused on the governance and oversight of the AI sector and an additional 36% (18 of 50) reported that such legislation is currently in development.

Fig. 7. Member States with AI governance laws and with ethical AI guidelines



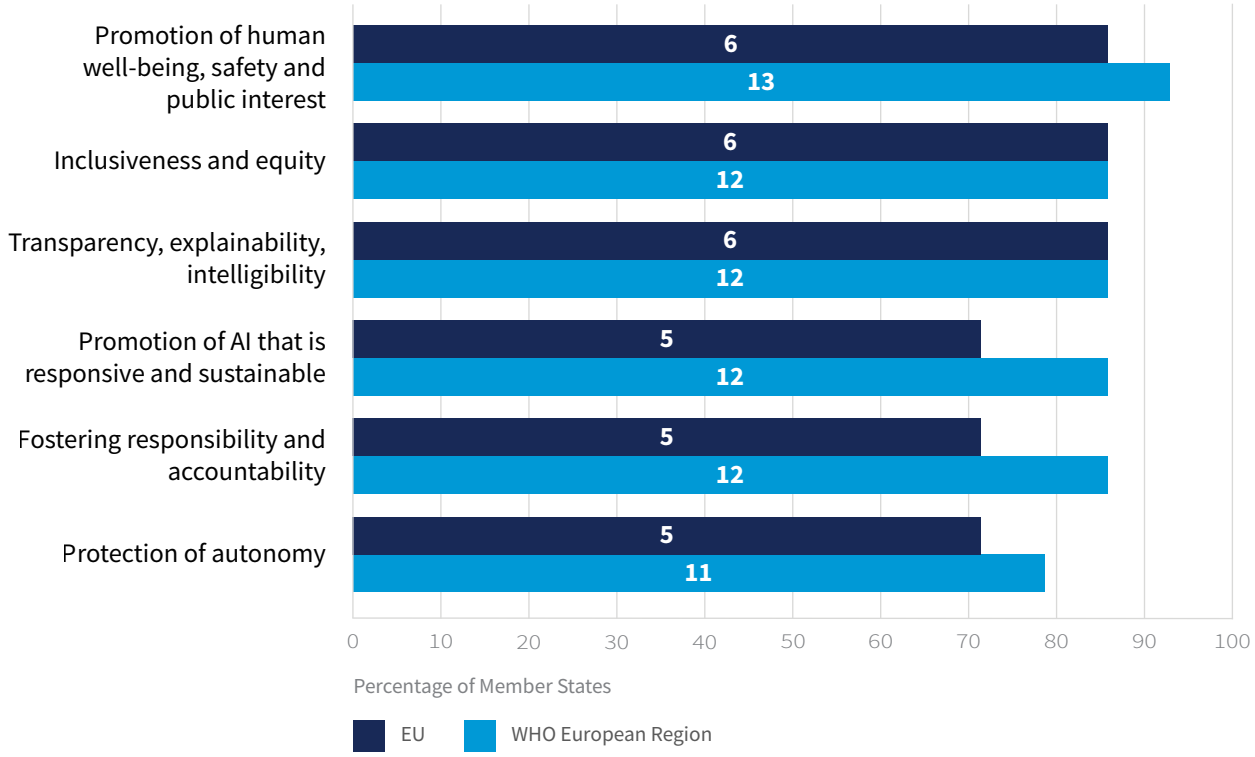
Note: numbers on the bars indicate number of Member States.

Looking now specifically at ethical AI guidelines, 7% of EU Member States (two of 27; France and Italy) indicated they have issued health-specific guidelines to address ethical implications, as shown in Fig. 7. An additional 19% (five of 27) indicated that they have issued cross-sectoral guidelines. A further 26% of Member States (seven of 27) indicated that such guidelines are currently under development. Most Member States though (44%; 12 of 27) reported to have issued no such guidelines nor were they under development.

A similar distribution was seen across the wider WHO European Region with 8% (four of 50) having a health-specific guideline to address ethical implications and an additional 20% (10 of 50) having cross-sectoral guidelines.

Among the seven EU Member States that have issued ethical guidelines, whether specific to health or broader in scope, 86% (six) emphasized the promotion of human well-being, safety and serving the public interest, 86% (six) emphasized inclusiveness and equity and 86% (six) addressed transparency, explainability and intelligibility (Fig. 8). Ethical guidelines for AI in health that addressed all six ethical principles were reported in 57% (four of the seven Member States; France, Italy, Malta and Poland).

Fig. 8. Principles covered by ethical guidelines

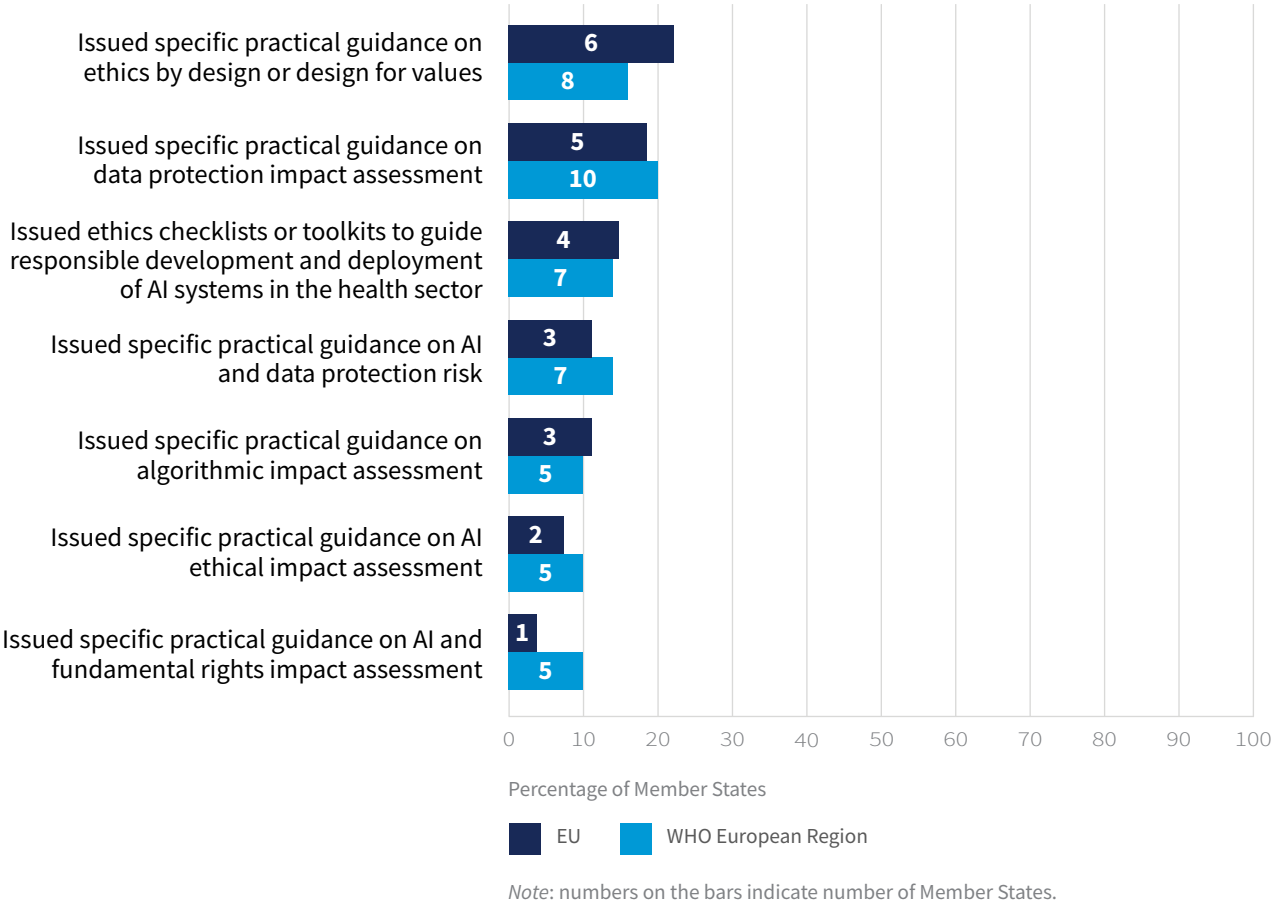


Note: numbers on the bars indicate number of Member States.

Across the EU, the most commonly reported AI policy measure was the issuance of practical guidance on ethics by design, adopted by 22% of Member States (six of 27; Cyprus, Greece, Italy, Netherlands (Kingdom of the), Portugal and Spain) (Fig. 9). This was closely followed by issuing specific guidance on conducting data protection impact assessments, reported by 19% of the 27 Member States (five; Belgium, Greece, Italy, Netherlands (Kingdom of the) and Spain). Less-frequently adopted approaches included issuing practical guidance on AI ethical impact assessments (7%; two Member States; Netherlands (Kingdom of the) and Spain) and on fundamental rights impact assessments (4%; one Member State; Spain).

A similar pattern was observed across the WHO European Region. The most frequently adopted measure, reported by 20% of Member States (10 of 50), was issuing practical guidance on conducting data protection impact assessments. This was followed by issuing guidance on ethics by design, reported by 16% (eight of 50). Only a small proportion of countries (8%, four of 50) had released five or more ethical checklists or guidance documents. In contrast, the majority, 60% of Member States (30 of 50), had not issued any such resources.

Fig. 9. Practical guidance to assess the possible legal and ethical risks of AI systems



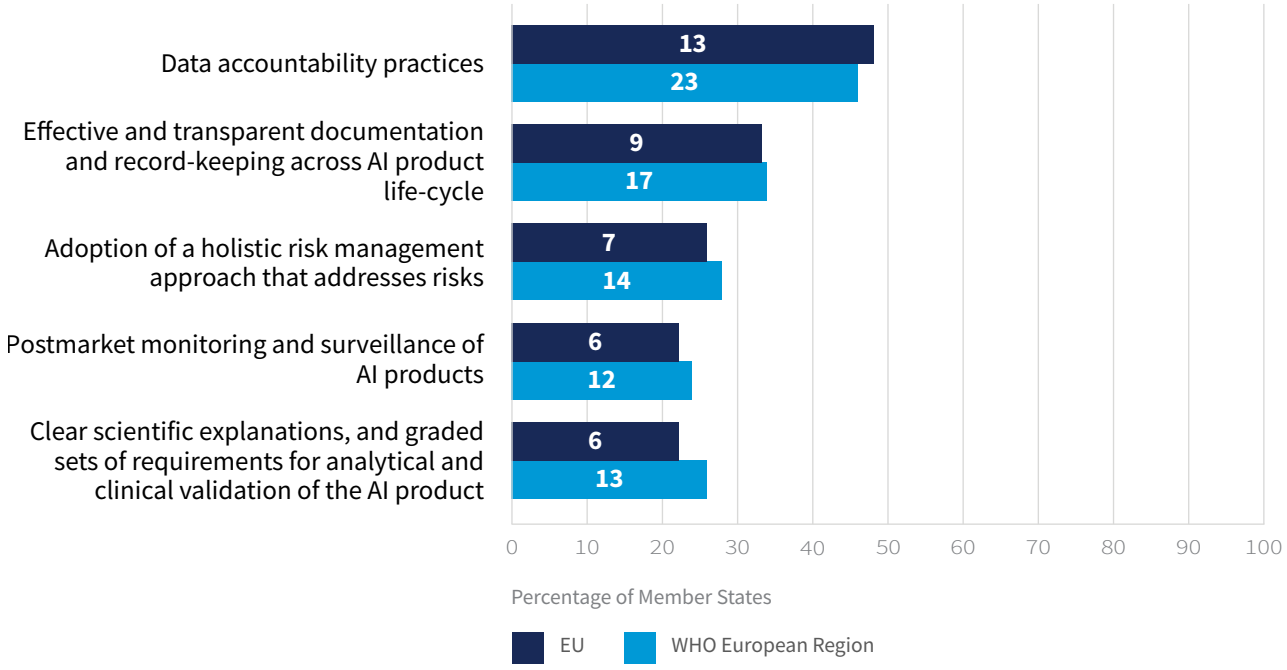
Note: numbers on the bars indicate number of Member States.

Minimum standards for AI governance

Additional regulatory priorities include establishing minimum standard requirements for the governance and oversight of AI in the health sector. These standards can take various forms, depending on national contexts. Across the EU, the most common approach to governing AI systems involves implementing data accountability measures, reported by 48% of Member States (13 of 27) (Fig. 10). These measures are aimed at ensuring that data are lawfully collected, used and shared while safeguarding privacy, minimizing bias and protecting the quality, security and integrity of data. In addition, 33% of EU Member States (nine of 27) reported maintaining clear and transparent documentation throughout all phases of the AI system life-cycle to facilitate regulatory assessment and auditing.

A similar trend is observed across the WHO European Region. Data accountability measures were reported by 46% of Member States (23 of 50), making it the most widespread approach. These measures address key concerns including lawful data use, privacy protection, bias mitigation and risk management. Another commonly adopted measure was maintaining transparent documentation across the AI life-cycle, cited by 34% of Member States (17 of 50), to support regulatory review and audit processes.

Fig. 10. Minimum standard requirements addressed in laws, rules, policies, guidelines for governance and oversight of AI for health



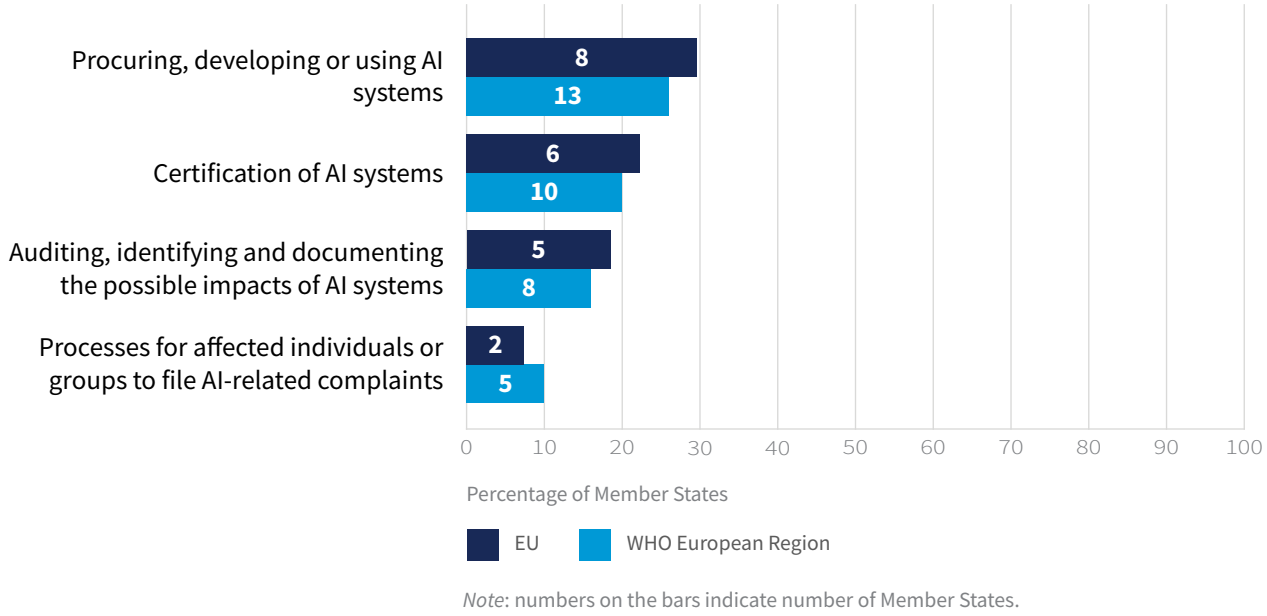
Note: numbers on the bars indicate number of Member States.

Policy focus for AI regulation

A key element of national AI governance is the establishment of policies governing the design and use of AI technologies (Fig. 11). Among EU Member States, the most common focus is on the procurement, development and use of AI in the health sector, reported by 30% of Member States (8 of 27), followed by the certification of AI systems, reported by 22% of Member States (six of 27). Only 7% of Member States (two of 27; France and Spain) reported having established at least three of the policy categories listed, while 44% (12 of 27) had implemented at least one policy category related to the governance of AI in health.

A similar pattern is seen across the broader WHO European Region, with the most common policy focus being the procurement, development and use of AI systems in health settings, reported by 26% of Member States (13 of 50). Certification policies were the next most reported focus, adopted by 20% of Member States (10 of 50). Fewer countries reported having policies for auditing or assessing the impacts of AI systems (16%, eight of 50) or for identifying individuals or groups negatively affected by such systems (10%, five of 50).

Fig. 11. Policy focus for industry AI regulation



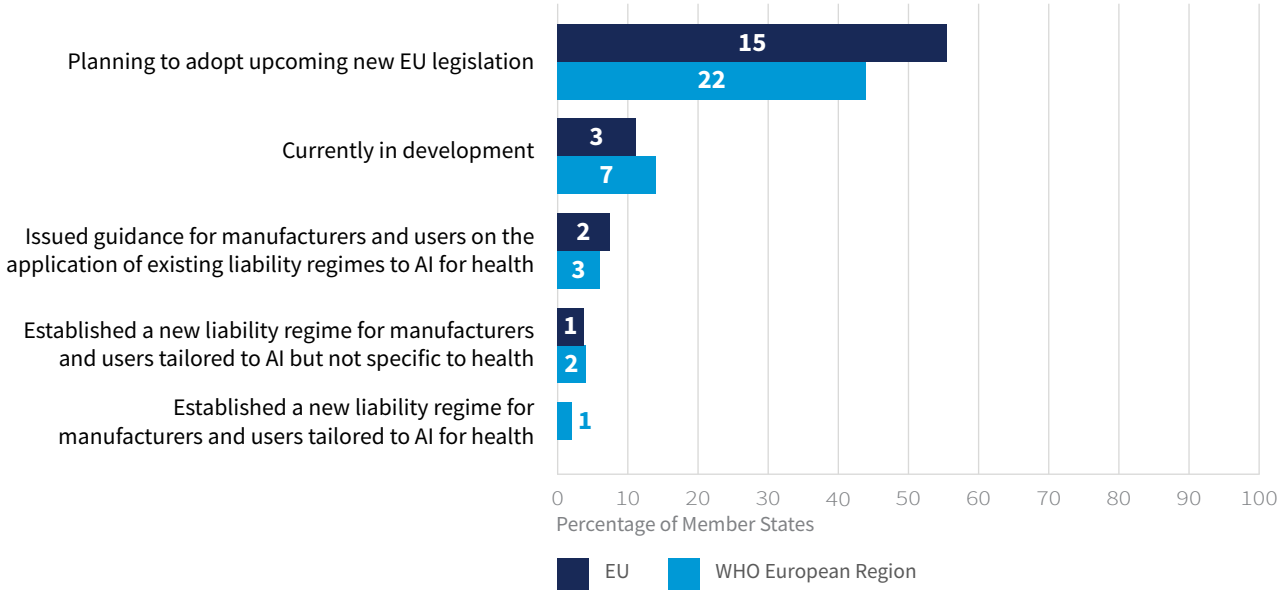
Note: numbers on the bars indicate number of Member States.

Legal liability standards for AI systems

Establishing clear legal standards for liability is crucial to ensure accountability when AI systems cause harm within the health sector. Such standards help to define the roles and responsibilities of both developers and users, foster trust in AI technologies and safeguard patient rights and well-being. Currently, 56% of EU Member States (15 of 27) reported having plans to align legal liability standards with upcoming EU legislation (Fig. 12). In contrast, only 11% (three of 27; Bulgaria, Italy and Latvia) reported that they are currently developing dedicated legal liability standards. Other approaches remain limited: 7% of Member States (two of 27; Spain and Sweden) have issued guidance for manufacturers and users on applying existing liability regimes to AI, while just one Member State (4%), Belgium, has established a new AI-specific liability framework.

Similarly, across the broader WHO European Region, only 8% of Member States (four of 50) have introduced either dedicated liability frameworks for AI or issued guidance on how existing liability laws apply to AI. A further 14% (seven of 50) are currently developing new liability standards to address the unique challenges posed by AI technologies.

Fig. 12. Legal liability standards establishing legal duties, obligations and responsibilities of manufacturers and users regarding harms caused by AI systems deployed in health care



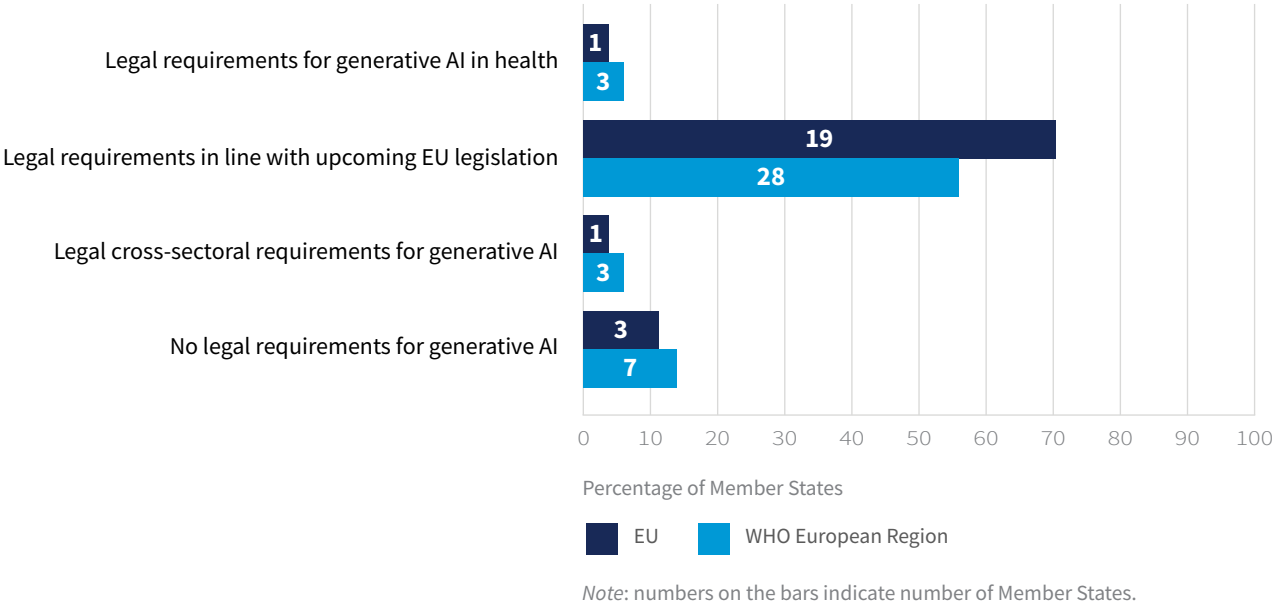
Note: numbers on the bars indicate number of Member States.

Regulations relating to generative AI

The majority of EU Member States, 70% (19 of 27), reported plans to introduce specific legal requirements and obligations for the use of generative AI systems in the health sector that align with forthcoming EU legislation (Fig. 13). In contrast, only one Member State (4%; Latvia) has enacted legal requirements that are cross-sectoral and not specific to the health sector.

A similar pattern is observed across the wider WHO European Region. Currently, 6% of Member States (three of 50) have implemented legal provisions specifically addressing the use of generative AI in health, while an additional 6% have introduced broader cross-sectoral legislation not limited to a single domain.

Fig. 13. Legal requirements and obligations for generative AI systems



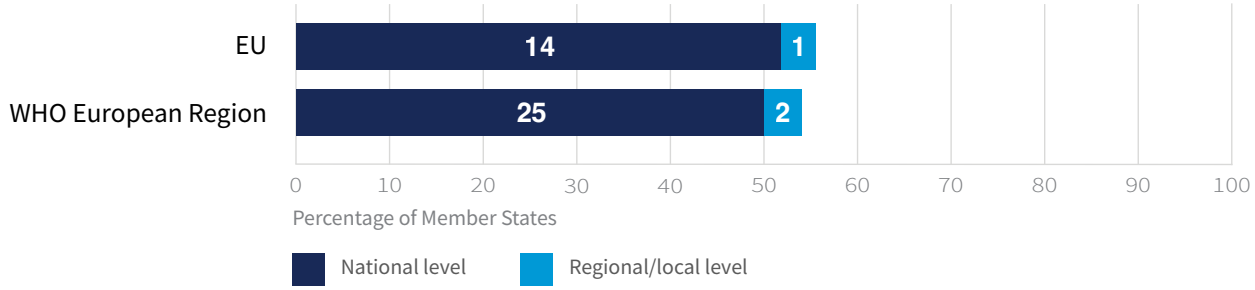
Note: numbers on the bars indicate number of Member States.

The environmental footprint of large multimodal models and other generative AI systems is well established, particularly because of their high energy consumption and intensive resource use. These technologies significantly contribute to carbon emissions and water consumption, prompting growing concerns about their sustainability as adoption increases. Nevertheless, 22% of Member States in the EU (six of 27) and only 20% of Member States (10 of 50) in the WHO European Region have implemented legal obligations requiring developers to mitigate these environmental impacts.

Institutional oversight and regulatory agencies

An essential component of strong AI governance in the health sector is the creation of dedicated regulatory bodies tasked with oversight functions. These institutions are crucial for reviewing, authorizing and supervising AI systems to ensure they are safe, effective and accountable. As shown in Fig. 14, 56% of EU Member States (15 of 27) reported having one or more agencies, either at the national or subnational level, responsible for evaluating and approving AI systems in the health sector. This reflects a similar trend in the wider WHO European Region, where 54% of Member States (27 of 50) reported having at least one agency responsible for evaluating and approving AI technologies in health. This highlights the growing institutional focus on predeployment oversight of AI technologies in health. However, fewer Member States in the Region have extended this oversight to the postdeployment phase: only 24% (12 of 50) currently have agencies monitoring the actual implementation and use of AI in health settings. An additional 26% (13 of 50) noted that such oversight bodies are currently in development.

Fig. 14. Regulatory agencies responsible for assessing and approving AI systems for use in health care

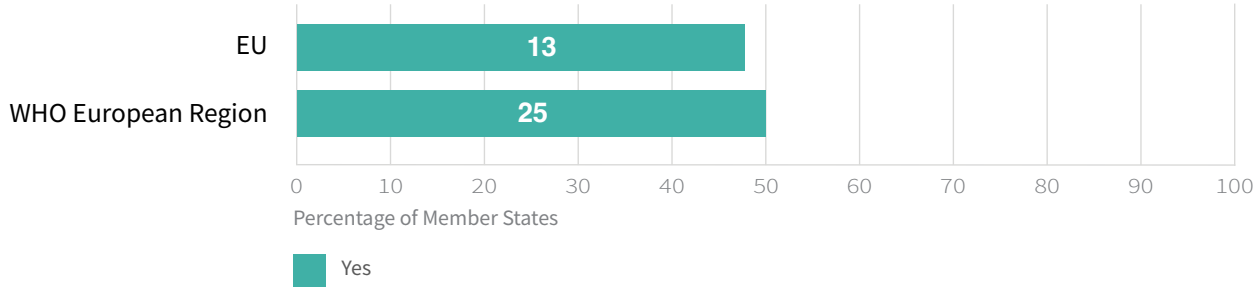


Note: numbers on the bars indicate number of Member States.

Cross-country regulatory collaboration

Forming partnerships across jurisdictions enables regulators to exchange expertise, pool resources and adopt best practices, helping them to keep pace with the fast-evolving AI landscape. These collaborations help to tackle cross-border issues, foster harmonization of standards and speed up the process of regulatory learning. Nearly half of EU Member States (48%, 13 of 27) reported having established such partnerships with other countries to share insights and resources on regulating AI systems in the health sector (Fig. 15). Likewise, 50% of the WHO European Region Member States (25 of 50) have established similar cross-country partnerships.

Fig. 15. Established collaborations to share knowledge and resources across jurisdictions



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

3.3.2 Summary

Across EU Member States, progress on legal and regulatory responses to AI in health varies. Many are currently assessing legal gaps, while developing new AI laws specifically for the health sector remains less common. Two EU Member States have issued health-specific AI ethical guidelines; although some reported actively working on them, the majority have yet to introduce them. Efforts have tended to focus on addressing specific legal and ethical risks, such as practical guidance on integrating ethics by design and on data protection impact assessments. In terms of minimum standards, the most frequent approach involves implementing data accountability practices; by comparison, postmarket monitoring and surveillance of AI products is less common.

AI policy priorities often centre on procuring, developing and using AI systems in the health sector, while efforts to address adverse impacts on individuals or collectives and establish liability standards remain limited. Despite growing concerns about the environmental impact of generative AI systems, legal requirements for developers to address these issues are still uncommon. Over half of EU Member States reported having one or more regulatory agencies responsible for assessing and approving AI systems in health, although fewer have agencies monitoring adoption and use.

The legal environment is evolving but remains fragmented and uneven. Only a few Member States are developing dedicated legal liability standards, while the majority are planning to adapt to upcoming EU legislation. Rapid technological change challenges existing frameworks, creating uncertainty around liability, risk management and compliance. In some cases, sparse health-specific legislation may overlap or conflict with broader AI regulations. 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 Health data governance

The key features of health data governance across the EU are given in Highlights box 4.

Highlights box 4. Health data governance

67% (18 of 27) have a national health data strategy or policy

33% (9 of 27) have set rules for cross-border sharing of health data for research

44% (12 of 27) have a health data governance framework

41% (11 of 27) have issued guidance on secondary use of health data for research in the public interest.

63% (17 of 27) have a health data hub at national level

This section explores the evolving policy frameworks and governance mechanisms that underpin the collection, sharing and secondary use of health data across the EU. It is divided into three subsections:

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

High-quality and interoperable health data are foundational to the development and validation of meaningful AI applications in health *(2)*. Health data hubs play a pivotal role in this ecosystem, serving as centralized platforms that aggregate diverse datasets, ensure data quality and enable secure access for research and innovation. By mobilizing extensive computing resources and facilitating the responsible use of data, these hubs support the development of advanced algorithms and AI tools that can enhance clinical decision-making and improve health outcomes.

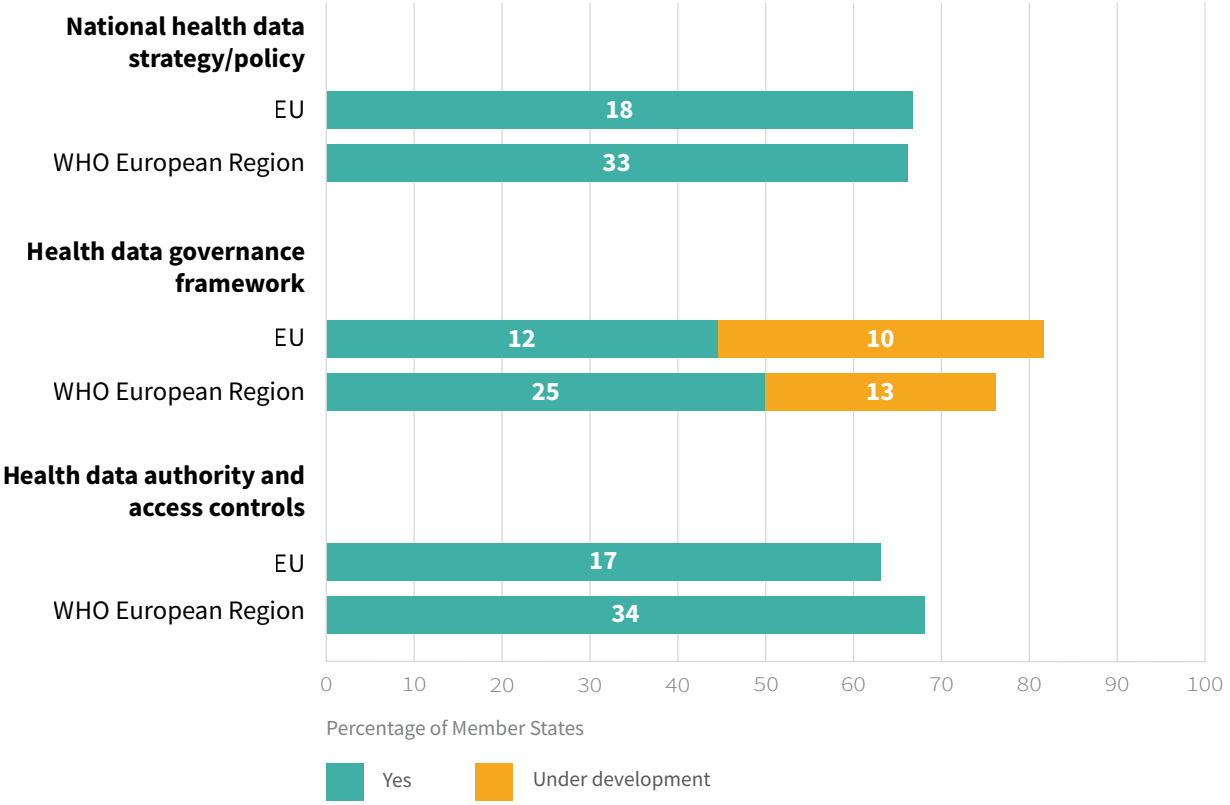
The secondary use of health data holds significant promise across a range of domains, including patient safety, regulatory compliance, quality improvement, public health surveillance, research and evidence-informed policy-making. National health data hubs also provide the infrastructure necessary to train machine learning and deep learning models, enabling the development of predictive and decision-support systems tailored to clinical contexts. However, persistent challenges such as unstructured data formats, limited interoperability and cross-border data integration continue to hinder the full realization of these benefits.

3.4.1 Findings

National health data strategies and governance frameworks

As shown in Fig. 16, 67% of EU Member States (18 of 27) have adopted a national health data strategy or policy. Notably, the majority of these strategies or policies (78%; 14 of 18) were introduced after 2020, reflecting a growing recognition of the strategic importance of health data in digital health transformation. An additional 19% of Member States (five of 27) have integrated health data governance within broader national data strategies, aligning closely with the WHO European Region average of 18% (nine of 50).

Fig. 16. Percentage of national health data strategies, frameworks and health data authorities in the EU and WHO European Region



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

In terms of governance frameworks, 44% of EU Member States (12 of 27) currently have a formal health data governance framework, while a further 37% (10 of 27) are in the process of developing one. Although the current EU average remains below that of the broader WHO European Region (50%), the completion of ongoing initiatives is expected to bring the EU in line with or potentially above, regional benchmarks.

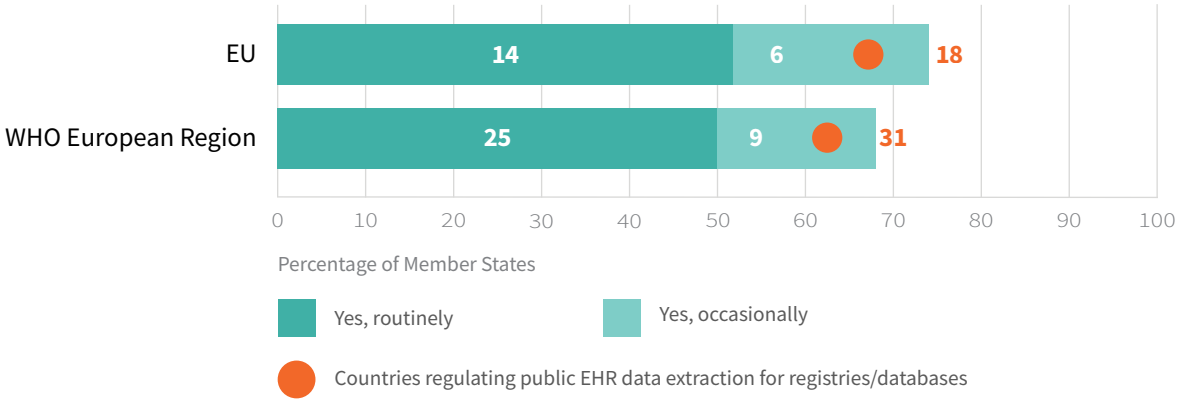
Health data authorities have also emerged as key institutional actors in this space, with 63% of EU Member States (17 of 27) having an established a national health data authority, slightly below the WHO European Region average of 68% (34 of 50). All such authorities within the EU operate at national level, underscoring the importance of centralized oversight in ensuring data quality, security and ethical use.

The EHDS is set to transform health data governance across the EU by providing a unified technical and governance framework for the secure sharing and use of health data across Member States, empowering individuals and enabling data-driven innovation in health care.

Its implementation is expected to harmonize national health data governance structures, ensuring that all EU Member States operate under consistent standards. By improving access to high-quality and interoperable health datasets, the EHDS will accelerate the development and validation of trustworthy AI tools for clinical and public health applications.

As shown in Fig. 17, 67% of EU Member States (18 of 27) have so far enacted laws or policies that authorize public authorities to extract data from EHR systems for the development of regional, local or national registries and databases. These mechanisms are essential for monitoring health conditions, assessing quality of care and evaluating health system performance. In contrast, three Member States (Cyprus, Romania and Sweden) reported the absence of formal policies permitting such data extraction. Nevertheless, in practice, data are still occasionally or routinely extracted in these countries, highlighting a gap between policy and operational realities.

Fig. 17. Frequency of 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 EU

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, for example in order to run complex research algorithms. A national health data hub has been established by 63% of EU Member States (17 of 27). An additional 22% of EU Member States (six of 27) are currently in the process of developing one. At the broader WHO European Region level, 66% of Member States (33 of 50) reported having a health data hub at either the national or regional level.

Health data hubs vary significantly in terms of the breadth and depth of data sources they integrate. Table 3 provides an overview of the inclusion of 14 commonly used data sources across national health data hubs in the EU. While none of the 17 Member States with health data hubs includes all 14 data sources, Czechia and Estonia have achieved the highest level of integration, each incorporating 12 of these 14 data sources. Belgium and Finland follow closely, including 11 data sources, while Austria and Spain only include four each of the 14 data sources in their national hubs.

Table 3. Data sources included in national health data hubs

Member State	Hospital inpatient data	Prescription data	Administrative data	Mortality data	EHR data	Emergency health care data	Cancer registry data	Primary care data	Specific disease data	Diabetes registry data	Paediatric critical care data	Claims data	Synthetic data	Genomic data
Austria	✓	✗	✗	✓	✗	✗	✓	✗	✓	✗	✗	✗	✗	✗
Belgium	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓
Bulgaria	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗
Czechia	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗
Estonia	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓
Finland	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗
France	✓	✓	✓	✓	✗	✗	✓	✗	✓	✓	✗	✓	✗	✗
Hungary	✓	✓	✓	✓	✓	✓	✗	✓	✗	✗	✓	✗	✗	✗
Italy	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✗	✗	✗
Latvia	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✗	✗	✗	✓
Lithuania	✓	✓	✗	✗	✓	✓	✗	✓	✗	✗	✗	✗	✗	✗
Malta	✓	✗	✓	✓	✓	✓	✓	✗	✓	✗	✗	✗	✗	✗
Poland	✗	✓	✗	✗	✓	✗	✗	✗	✗	✗	✗	✗	✓	✗
Portugal	✓	✓	✓	✓	✓	✓	✗	✓	✗	✗	✓	✗	✗	✗
Slovakia	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗
Slovenia	✓	✓	✓	✗	✓	✗	✓	✗	✗	✗	✗	✗	✗	✗
Spain	✓	✗	✓	✗	✗	✗	✗	✓	✗	✗	✗	✗	✓	✗

✓ — Yes

✗ — No

The composition of data sources within national health data hubs varies significantly across EU Member States, reflecting differing priorities, capacities and stages of development. Among the 17 Member States with a health data hub, the most commonly included source is hospital inpatient data, featured in 94% (16 of 17), followed by prescription data, included in 82% (14 of 17). EHRs, administrative data and mortality data are each integrated by 76% (13 of 17) of EU Member States.

Less commonly included data sources highlight areas for potential expansion. Synthetic data and claims data are present in only 24% of health data hubs (four of 17), while genomic data are the least represented, included in just 18% (three of 17). The countries currently incorporating genomic data into their national hubs are Belgium, Estonia and Latvia.

In terms of funding models, the vast majority of national health data hubs – 88% (15 of 17) – are publicly funded. Finland and Italy are exceptions in that funding is drawn from a mix of public and private sources.

Secondary use of health data for public-interest health-related research

Anonymization is the most commonly required condition for accessing health data for research purposes (Table 4). It is mandated by 82% of EU Member States with a national health data hub (14 of 17), mirroring the WHO European Region average of 82% (27 of 33). Pseudonymization is also a widely used safeguard, required by 65% of EU Member States (11 of 17).

Table 4. Conditions under which data in health data hubs are available for research by Member States

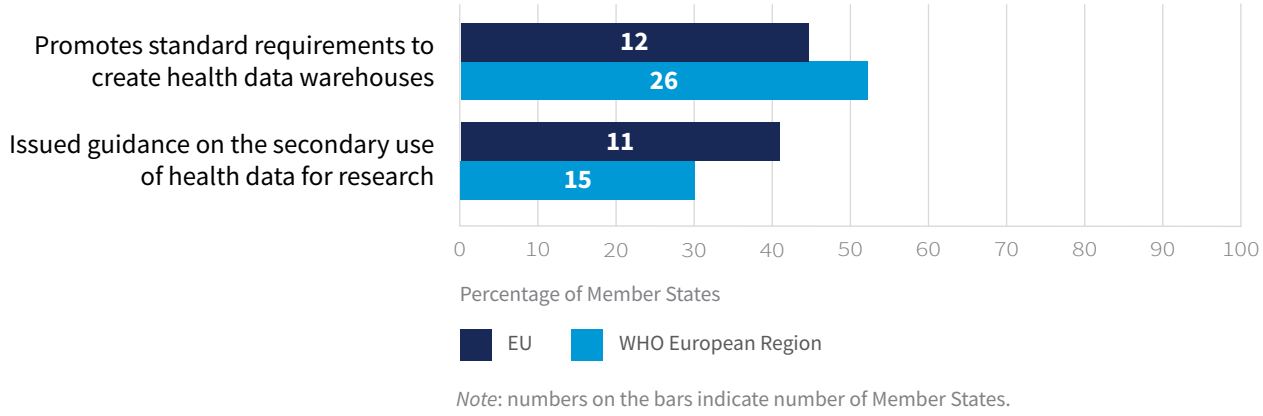
Member State	Anonymization of data	Pseudonymization of data	Approval by designated body	Data subject consent	Noncommercial exploitation	Limited to public sector researchers
Austria	✓	✓	✓	✗	✓	✓
Belgium	✓	✓	✓	✓	✓	✗
Bulgaria	✓	✗	✗	✗	✗	✗
Czechia	✓	✓	✓	✓	✗	✗
Estonia	✓	✓	✓	✓	✗	✗
Finland	✓	✓	✓	✗	✓	✗
France	✗	✓	✓	✓	✓	✗
Hungary	✓	✗	✗	✓	✗	✓
Italy	✓	✗	✓	✗	✗	✗
Latvia	✓	✗	✗	✓	✗	✗
Lithuania	✓	✓	✗	✓	✗	✗
Malta	✓	✓	✓	✗	✗	✗
Poland	✓	✗	✗	✓	✗	✗
Portugal	✗	✗	✗	✗	✗	✓
Slovakia	✓	✓	✗	✗	✓	✓
Slovenia	✗	✓	✗	✗	✓	✗
Spain	✓	✓	✓	✗	✓	✓

✓ — Yes

✗ — No

As shown in Fig. 18, 41% of EU Member States (11 of 27) have issued formal guidance to facilitate the use of these data, which exceeds the average for the WHO European Region of 30% (15 of 50). These guidelines play a critical role in clarifying legal and ethical parameters, promoting transparency and fostering trust among data providers and users.

Fig. 18. Policies promoting requirements for data warehouses and guidance on secondary use of health data for research

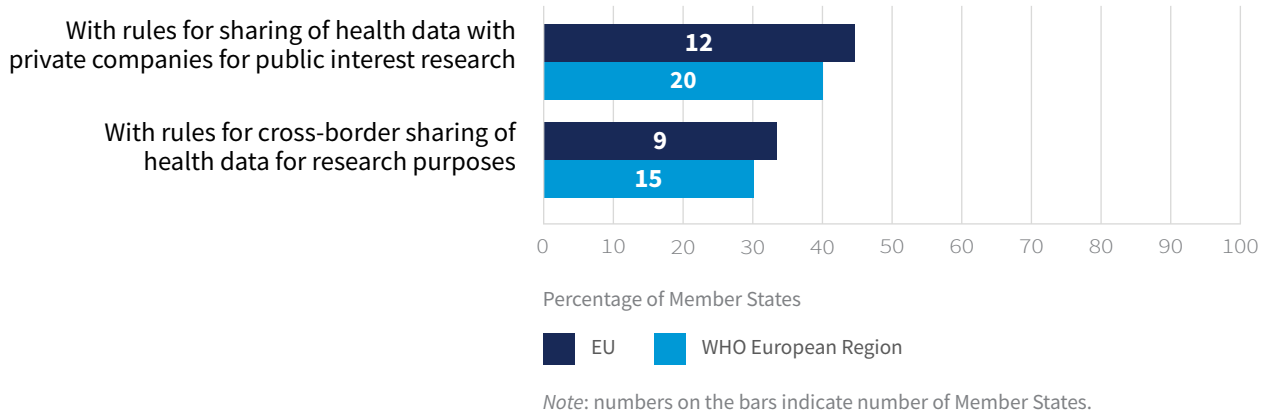


Note: numbers on the bars indicate number of Member States.

In parallel, 44% of EU Member States (12 of 27) reported actively promoting standard requirements for the creation of health data warehouses. While this figure is slightly below the average for the WHO European Region of 52% (26 of 50), it reflects a growing recognition of the need for harmonized infrastructure to support secure, scalable and interoperable data environments.

Cross-border data sharing is a critical enabler of collaborative research and innovation across the EU; 33% of EU Member States (nine of 27) have established national rules to govern the cross-border sharing of health data for research purposes. This is slightly above the average for the WHO European Region of 30% (15 of 50), reflecting the EU's growing emphasis on data interoperability and regional cooperation (Fig. 19). Efforts to support the secondary use of health data for research in the public interest are gaining momentum across the EU.

Fig. 19. 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.

In addition, 44% of EU Member States (12 of 27) have implemented rules, policies and processes to facilitate the sharing of health data with private sector entities for health-related research in the public interest. This also exceeds the average in the WHO European Region of 40% (20 of 50), underscoring the EU's commitment to fostering responsible public–private collaboration in health innovation.

Seven Member States (Croatia, Czechia, Denmark, Estonia, Finland, Germany and Sweden) have adopted both cross-border data-sharing rules and frameworks for engaging with private companies. These countries exemplify more comprehensive approaches to enabling secure, ethical and impactful data use across sectors and borders.

3.4.2 Summary

The majority of EU Member States have adopted dedicated health data strategies, while others are integrating health priorities into overarching data policies. Most Member States also have a national health data hub or are in the process of developing one. Regarding secondary data use and data sharing, a small group of Member States are leading the way by adopting comprehensive policies that enable both domestic and international data flows while maintaining strong protections. Although the EU shows higher rates of policies supporting data sharing for public-interest research compared with the wider WHO European Region, the majority of Member States still lack rules and frameworks to facilitate this exchange. If these barriers are not addressed, AI initiatives risk producing technically sophisticated solutions that fail to meet the practical needs of clinical care and public health.

3.5 AI opportunities and applications

Highlights box 5 outlines key opportunities and applications for AI in health across EU Member States.

Highlights box 5. AI opportunities and applications

59% (16 of 27) identified priority areas for AI in health; only 63% of these (10 of 16) have allocated dedicated funding or grants to support implementation

Drivers of AI innovation

100% (27 of 27) considered improving patient care a major or moderate driver

89% (24 of 27) considered increasing efficiency a major or moderate driver

96% (26 of 27) considered reducing workforce pressure a major or moderate driver

Use of AI

74% (20 of 27) use AI-assisted diagnostics

63% (17 of 27) use conversational platforms (chatbots) for patient assistance

AI-driven solutions are evolving rapidly, with many being piloted and integrated into patient care across the EU. This section provides an overview of the AI priorities and snapshot of AI application in health care. It is divided into the following three sections:

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

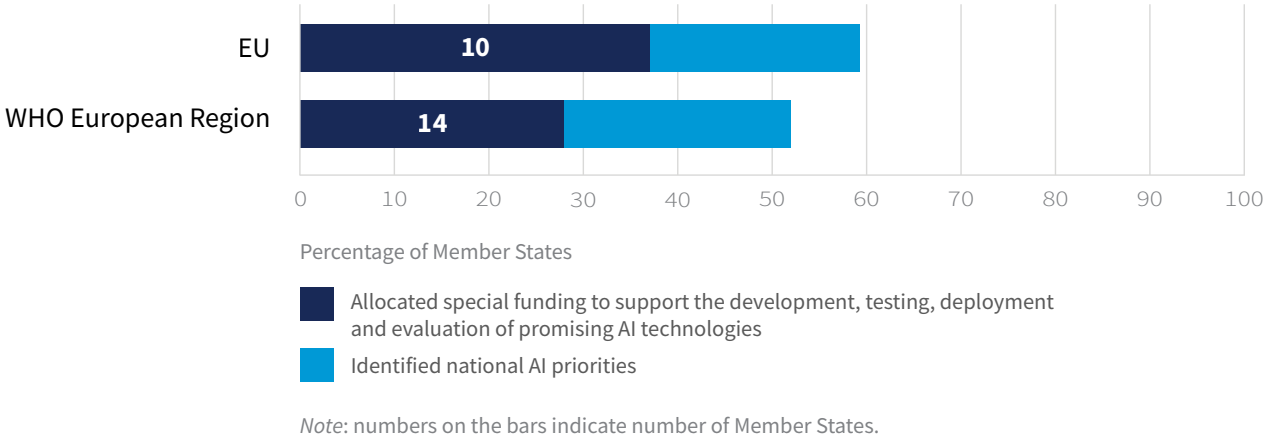
The integration of AI into health systems offers transformative potential. It can improve operational efficiency, accelerate medical research and enhance population health outcomes. To fully realize these benefits, governments must identify high-impact areas for AI application and allocate targeted funding to support the development, deployment and evaluation of these technologies. These steps are essential to ensure that AI innovations are not only cutting edge but also responsive to national health needs and capable of addressing systemic challenges.

3.5.1 Findings

AI strategic priority initiatives and their funding

As shown in Fig. 20, 59% of EU Member States (16 of 27) 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. This is higher than the average for the WHO European Region of 52% (26 of 50). Of the 16 EU Member States that have identified priorities, 63% (10 of 16) have allocated special funding or project grant funding to support the development, testing, deployment and evaluation of promising AI technologies: Belgium, Denmark, France, Hungary, Italy, Lithuania, Netherlands (Kingdom of the), Poland, Romania and Spain.

Fig. 20. Member States that have identified national AI priorities and those that have identified priorities and allocated funding for implementation



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

The most commonly listed priority for applying AI in health care is enhancing patient care and outcomes, including personalized medicine, patient screening and improving the overall health care experience. Closely related is the use of AI for diagnosis, prediction and assisted medical decision-making, such as risk profiling, image analysis and AI-driven services in areas such as medical imaging and telemedicine. Another recurring theme is the optimization and systematization of health care data, emphasizing the need to manage large volumes of data effectively. There is also a strong emphasis on reducing administrative burdens for health care professionals and empowering patients. Finally, the development of a robust AI ecosystem and adherence to regulatory frameworks such as the EU Regulation on the EHDS are recognized as foundational to enabling these advancements.

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. Table 5 presents an overview of regional responses showing that improving patient care and health outcomes was the most relevant, with 100% of EU Member States (27 of 27) saying it is of major or moderate relevance. Reducing pressure on the health care workforce was the second highest ranked opportunity, with 96% (26 of 27) of EU Member States saying it was of major or moderate relevance. This was followed closely by increasing health system efficiencies (89% of Member States; 24 of 27).

Table 5. AI opportunities driving development across the EU

Country	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
Austria	●●●●	●●●●	●●●●	●●	●●
Belgium	●●●●	●●●●	●●●	●●●●	●●●
Bulgaria	●●●	●●●	●●●	●●●	●●
Croatia	●●●●	●●●	●●●●	●●	●●
Cyprus	●●●●	●●●	●●	●●●	●●●
Czechia	●●●●	●●●●	●●●	●●●	●●
Denmark	●●●●	●●●●	●●●●	●●●●	●●●●
Estonia	●●●●	●●●●	●●●●	●●●●	●●●
Finland	●●●●	●●●●	●●●●	●●●	●●●●
France	●●●●	●●●	●●●●	●●●	●●●
Germany	●●●●	●●●●	●●●●	●●●●	●●●●
Greece	●●●●	●●●●	●●●●	●●●●	●●●●
Hungary	●●●	●●●●	●●	●●●●	●●
Ireland	●●●	●●●●	●●●	●●●	●●●
Italy	●●●●	●●●●	●●●●	●●●●	●●●
Latvia	●●●●	●●●	●●●	●●	●
Lithuania	●●●●	●●●●	●●●	●●	●●
Luxembourg	●●●●	●●●●	●●●	●●	●●●
Malta	●●●●	●●●●	●●●●	●●●	●●●
Netherlands (Kingdom of the)	●●●	●●●●	●●●●	●	●●●
Poland	●●●	●●●	●●●	●●●	●●
Portugal	●●●●	●●●	●●●●	●●●●	●●●
Romania	●●●	●●	●●	●●●	●
Slovakia	●●●	●●●●	●●●●	●●●	●●●
Slovenia	●●●	●●●	●●●	●●	●
Spain	●●●●	●●●●	●●●●	●●●●	●●●●
Sweden	●●●●	●●●●	●●●●	●●●●	●●●●

●●●●	●●●	●●	●
Major relevance	Moderate relevance	Minor relevance	No relevance

Other opportunities were less prominent. Reducing health inequities is seen as a major or moderately relevant driver by 74% of EU Member States (20 of 27). Finally, the least relevant driver in the EU is advancing health research and accelerating drug discovery with 63% of Member States (17 of 27) saying it is of major or moderate relevance.

The importance of the various opportunities driving AI development in the EU closely mirrors the trends observed across the broader WHO European Region. The ranking of these opportunities is consistent between the two groups and the proportion of Member States identifying each opportunity as being of major relevance is nearly identical. This alignment suggests a shared understanding of the strategic value of AI for health, reinforcing the potential for coordinated regional approaches to policy, investment and implementation.

Common applications and uses of AI in health care

The most common applications of AI in health care in the EU and their level of developmental maturity are outlined in Table 6. 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 a further 2 years.

Table 6. AI application in health care across the EU

Member State	AI-assisted diagnostics	Conversational platforms (chatbots) for patient assistance	Automating logistics, clerical and administrative tasks	AI-assisted surgery/medical robotics to optimize surgical skills	AI-assisted symptom checkers and support in treatment decisions	AI-assisted prognosis prediction (risk stratification)	AI-assisted remote patient monitoring
Austria	Established	Pilot	Established	Established	Pilot	Pilot	Pilot
Belgium	Pilot	Pilot	–	Pilot	Pilot	–	Established
Bulgaria	–	–	–	–	–	–	–
Croatia	Established	Pilot	Informal	Established	–	Informal	–
Cyprus	–	–	–	–	–	–	–
Czechia	Established	Pilot	Informal	Pilot	Pilot	Pilot	Pilot
Denmark	Established	Established	Established	–	Established	Established	Pilot
Estonia	Established	Established	Established	–	Established	Established	–
Finland	Pilot	Established	Established	Established	Informal	Pilot	Established

Table 6 contd.

Member State	AI-assisted diagnostics	Conversational platforms (chatbots) for patient assistance	Automating logistics, clerical and administrative tasks	AI-assisted surgery/medical robotics to optimize surgical skills	AI-assisted symptom checkers and support in treatment decisions	AI-assisted prognosis prediction (risk stratification)	AI-assisted remote patient monitoring
France	Established	Informal	Pilot	Established	Established	Pilot	Pilot
Germany	–	–	–	–	–	–	–
Greece	–	–	–	–	–	–	–
Hungary	Established	Established	–	–	–	Pilot	Pilot
Ireland	Pilot	Informal	Informal	–	–	–	–
Italy	Informal	Informal	Informal	Informal	Informal	Informal	Informal
Latvia	Pilot	Established	Established	Informal	Pilot	–	–
Lithuania	Established	–	–	–	–	–	–
Luxembourg	Pilot	–	Informal	–	–	–	–
Malta	Pilot	–	Pilot	–	–	–	–
Netherlands (Kingdom of the)	Established	Pilot	Pilot	–	–	Established	Informal
Poland	Pilot	Established	Pilot	Pilot	Informal	Informal	Pilot
Portugal	Established	Established	–	Established	–	–	–
Romania	–	–	–	–	–	–	–
Slovakia	–	–	–	–	Pilot	–	–
Slovenia	–	–	–	–	–	–	–
Spain	Pilot	Established	Established	Established	Pilot	Pilot	Pilot
Sweden	Established	Pilot	Pilot	–	Established	Pilot	–

The most common AI application was AI-assisted diagnostics (e.g. radiology, dermatology or ophthalmology) used by 74% (20 of 27) of EU Member States, with 41% (11 of 27) considering it established. An additional 33% of Member States (nine of 27) reported currently piloting or informally using AI-assisted diagnostics. Application was higher in the EU than in the wider WHO European Region, where 64% (32 of 50) were currently using AI-assisted diagnostics.

The second most common application of AI in health care was conversational platforms (chatbots) for patient assistance, used by 63% (17 of 27) of EU Member States, with 30% (eight of 27) considering it established. An additional 33% of Member States (nine of 27) reported currently piloting or informally using AI conversational platforms for patient assistance. Application of chatbots is also higher on average in the EU than in the wider WHO European Region, where 50% (25 of 50) of Member States are using them.

Another commonly used application of AI in health care is to automate logistics and administrative tasks – used by 59% of Member States (16 of 27) with 22% (six of 27) considering it established. AI-assisted prognosis prediction was being used by 48% of Member States (13 of 27), with 11% (three of 27) considering it established, and AI-assisted surgery robotics was being used by 41% of Member States (11 of 27), with 22% (six of 27) considering it established.

Less commonly used applications include AI-assisted symptom checkers: used in 44% of Member States (12 of 27) with 15% (four of 27) considering it established. Finally, AI-assisted remote patient monitoring is used by 41% of Member States (11 of 27) with 7% (two of 27) considering it established.

At Member State level, Austria, Czechia, Finland, France, Italy, Poland and Spain are putting into practice all seven types of the most commonly used AI applications to various degrees.

Across all seven categories of AI application in health care, EU Member States report higher rates of use compared with the broader WHO European Region. The most pronounced difference is observed in the use of AI for automating logistics and administrative tasks: 59% of EU Member States (16 of 27) report active use in this area compared with just 40% across the WHO European Region (20 of 50). Additionally, the adoption of AI technologies in the EU is generally more established, reflecting a higher level of operational maturity and integration.

3.5.2 Summary

The majority of EU Member States have identified key areas where AI technologies are expected to deliver significant value to health systems and population health; however, less than two thirds of those have allocated specific funding for the development, testing and deployment of AI technologies. Across the EU there is consensus on the drivers of AI development, and consistent rankings of strategic opportunities suggest a common understanding of AI's potential in health. Member States in the EU reported higher levels of AI adoption and a more mature application of AI in health care compared with the wider WHO European Region. AI-assisted diagnostics stands out as the most commonly reported use, with nearly three quarters of countries leveraging AI technologies to enhance imaging and detection. Conversational chatbots for patient assistance were also widely adopted, with two thirds the countries reporting use.

There remains a disconnect between strategic planning and investment, which hinders AI initiatives from achieving their full impact. While challenges exist, it is important to highlight that current uses of AI in national health systems are well aligned with immediate priorities – enhancing patient care, improving health outcomes and alleviating pressure on health care staff. AI-powered diagnostic tools can ease clinicians' workloads, while chatbots contribute to patient engagement and support greater autonomy. Nonetheless, several risks must be proactively managed, including biased or low-quality outputs, automation bias, diminished clinical skills, reduced clinician–patient interaction and the potential for inequitable outcomes among marginalized groups.

3.6 Barriers and policy enablers for AI adoption in health systems

Highlights box 6 summarizes barriers and policy enablers for AI in health systems across the EU.

Highlights box 6. Barriers and policy enablers for AI adoption in health systems

Barriers to adoption of AI in health care

41% (11 of 27) rated financial affordability as a barrier of major importance

33% (9 of 27) rated data quality and standards as a barrier of major importance

33% (9 of 27) rated legal uncertainty as a barrier of major importance; this was notably lower than the average for the WHO European Region of 48% (24 of 50)

0% No Member State rated environmental impact as of major importance

Key policy enablers for widespread adoption of AI in health care

63% (17 of 27) cited guidance on transparency, verifiability and explainability of AI solutions to ensure trust in outcomes as having a major positive impact

56% (15 of 27) cited accountability and liability rules for manufacturers, deployers and users applicable to AI systems in health as having a major positive impact

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

- 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 AI integration, including legal, regulatory, financial, infrastructural and cultural challenges. These obstacles span from uncertainties around compliance and data quality to gaps in infrastructure and workforce capacity, underscoring the complexity of adoption and the need for coordinated, system-wide efforts.

Additionally, targeted legislative, policy and guidance measures can help to mitigate these challenges. Many of these actions align with developments under EU legislations such as the AI Act, focusing on legal clarity, ethical frameworks, robust data governance and clear accountability mechanisms. By prioritizing these measures, Member States can create an enabling environment that supports innovation while ensuring safety, trust and equity in the use of AI technologies.

3.6.1 Findings

Barriers to widespread adoption of AI in the health sector

Twelve specific barriers to AI adoption were rated each on a scale from "no importance" to "major importance". This approach provides a nuanced view of the challenges confronting health care systems as they seek to integrate AI technologies. Table 7 presents an overview of these barriers and how they were rated by Member States across the EU.

Table 7. Importance of barriers to widespread adoption of AI in the health sector in the EU

Country	Financial affordability	Legal uncertainty	Data quality and standards	AI product approval processes	Capacity	Evidence	Strategy	Cultural impact	Infrastructure	Trust	Job displacements	Environmental impact
Austria	●●●	●●●	●●●	●●●●	●●●	●●	●●	●●●	●●●	●●●	●●	●●
Belgium	●●	●●●	●●●	●●●	●●●●	●●	●●●	●●	●●	●●●	●●	●●
Bulgaria	●●	●●●	●	●●	●●●	●●●	●●●	●●●●	●	●●	●	●●●
Croatia	●●●	●●●●	●●	●●●	●●	●●●●	●●●●	●●●●	●●	●●●	●	●●
Cyprus	●●	●●●	●●●●	●●●●	●●●	●●●	●●●	●●●●	●●●	●●●	●●●●	●●●
Czechia	●●●●	●●●	●●●●	●●●	●●	●●●●	●●	●●●	●●●●	●●●	●	●
Denmark	●●●●	●●●	●●	●●●	●●●	●●	●●	●●●	●●●●	●●●	●●	●●
Estonia	●●●●	●●●	●●	●●●	●●●	●●●	●●	●●	●●	●●	●	●
Finland	●●●	●●●	●●	●●●	●●●	●●●	●●●	●●	●●	●●	●●	●●
France	●●●●	●●	●●	●●	●●●●	●●	●●●	●●●	●●	●●●	●●	●●●
Germany	●●●●	●●●	●●●	●●●	●●	●●●●	●	●	●●●	●●	●	●
Greece	●	●●●●	●●●	●●●●	●●●	●●●●	●●●●	●●●●	●	●●●●	●●●●	●
Hungary	●●●	●●●	●●●●	●●	●●	●●●	●●●●	●●	●	●●	●●	●
Ireland	●●●●	●●●●	●●●	●●●	●●●●	●●●	●●●●	●●	●●●●	●●	●●	●●●
Italy	●●●	●●●●	●●●●	●●●●	●●●	●●	●●●●	●●●●	●●●	●●●●	●●●●	●●
Latvia	●●●●	●●●	●●●●	●●●	●●	●●●	●●●	●	●●	●	●●	●
Lithuania	●●●	●●	●●●	●●	●●●	●●	●●	●●	●●	●●	●●	●
Luxembourg	●	●●●	●●●	●●●●	●●	●●●	●●●	●●●	●●	●●●	●●	●
Malta	●●●●	●●●●	●●●●	●●●	●●●●	●●●	●●●	●●	●●●	●●	●●	●●
Netherlands (Kingdom of the)	●●●●	●●●	●●●●	●●	●●●	●●●●	●●	●●	●●●	●●	●●●	●
Poland	●●	●●●	●●●	●●	●●●	●●	●●	●●	●●	●●●	●●	●●
Portugal	●●●	●●●●	●●●	●●●●	●●●●	●●●	●●●	●●●	●●●●	●●●	●●●	●●●
Romania	●●●●	●●●	●●●●	●●	●●●	●●	●●●●	●●	●●●●	●	●	●
Slovakia	●●●	●●●●	●●	●●●	●●●	●●	●●	●●●	●●	●●●	●●●	●●
Slovenia	●●●	●●●	●●●	●●●	●●	●●	●●	●●●	●●	●●●	●	●
Spain	●●●	●●●●	●●●	●●●	●●●●	●●●●	●●●	●●●●	●●●	●●●●	●●●	●●●
Sweden	●●●●	●●●●	●●●●	●●●●	●●●●	●●●●	●●●●	●●●	●●●●	●●●	●●	●●●

●●●● Major importance ●●● Moderate importance ●● Minor importance ● No importance

Financial affordability was the highest ranked barrier, with 41% of EU Member States (11 of 27) ranking it of major importance. In the broader WHO European Region this was the second highest ranked option, with 46% of Member States (23 of 50) rating it as being of major importance, which was slightly below legal uncertainty, the highest rated in the WHO European Region with 48% (24 of 50). Interestingly legal uncertainty was selected as being of major importance by only 33% of EU Member States (nine of 27), possibly reflecting the greater legal clarity and stability provided by new EU AI legislation.

Other major important barriers in the EU include data quality and standards (33%; nine of 27), capacity (26%; seven of 27), AI strategy (26%; seven of 27), AI product approval processes (26%; seven of 27) and evidence (26%; seven of 27).

Trust and cultural impact were less consistently selected as being of major importance; however, both were selected by 93% of Member State (25 of 27) as having some level of importance, indicating that they may considered these less urgent in the current policy landscape but still importance factors to consider.

Job displacement was rated by 74% (20 of 27) as having some level of importance. While the majority of Member States rated it as being of minor importance, Cyprus, Greece and Italy rated it as being of major importance.

Environmental impact was rated the least important barrier, with none of the Member States rating it as being of major importance; 41% of EU Member States (11 of 27) rated it as having no importance, indicating that while environmental impact is increasingly part of the broader AI discourse, sustainability considerations have yet to gain traction as a regulatory priority in the health sector.

In addition to the 12 barriers shown in Table 7, several Member States elaborated on additional barriers to the widespread implementation of AI in the health sector. One Member State emphasized the difficulty in recruiting highly skilled technical personnel, noting that the health sector often lacks appeal for professionals with expertise in emerging technologies such as data science. Another Member State pointed to challenges within government administrations in maintaining up-to-date knowledge on rapidly evolving technologies, which hampers informed decision-making and policy development. Ethical concerns were also raised, particularly regarding the collection and use of data in AI systems, which continue to generate public and institutional apprehension. Additionally, the fragmentation of AI initiatives across different regions and institutions limits the potential for coordinated progress. Finally, a lack of cooperation between key stakeholders – highlighted by yet another Member State – was identified as a critical barrier to scaling and integrating AI solutions effectively across health systems.

Policy enablers of AI adoption in the health sector

Seven enabling policy options were assessed offering valuable insights into how the adoption of AI in health care can be accelerated. Each enabler was rated on a scale from "no positive impact" to "major positive impact", providing a clear picture of the perceived effectiveness of these measures in the EU (Table 8).

Table 8. Perceived impact of policy enablers for AI adoption across the EU

Country	AI transparency for trust	Accountability and liability for AI	Legal guidance on health data use	AI certification in health care	Postmarket AI surveillance	Privacy and data for AI	Ethical AI development in health care
Austria	●●●●	●●●●	●●●	●●●	●●●	●●●	●●●
Belgium	●●●	●●●	●●●●	●●●	●●●	●●●	●●●●
Bulgaria	●●●	●●●	●●●●	●●	●●●	●●●	●●●
Croatia	●●●	●●●●	●●●●	●●●	●●●	●●●	●●●
Cyprus	●●●●	●●●●	●●●●	●●●	●●●	●●●	●●●
Czechia	●●●	●●●●	●●●●	●●●●	●●●●	●●●●	●●●●
Denmark	●●●●	●●●●	●●●●	●●●●	●●●●	●●●●	●●●●
Estonia	●●●●	●●●	●●●	●●●●	●●●	●●	●●
Finland	●●●●	●●●●	●●●	●●●●	●●●●	●●●●	●●●●
France	●●●●	●●●	●●	●●	●●●	●●●	●●●
Germany	●●	●●●	●●●	●●	●●	●●	●●
Greece	●●●●	●●●	●●●●	●●●●	●●●●	●●●●	●●●
Hungary	●●●●	●●●●	●●●●	●●●●	●●●	●●●●	●●●
Ireland	●●●●	●●●	●●●●	●●●	●●●●	●●●●	●●●●
Italy	●●●●	●●●●	●●●●	●●●	●●●●	●●●●	●●●
Latvia	●●●●	●●●●	●●	●●●●	●●●●	●●●●	●●●●
Lithuania	●●	●●●	●●●●	●●	●●	●●●	●●●
Luxembourg	●●●●	●●●	●●●	●●●●	●●●●	●●●	●●●●
Malta	●●●●	●●●●	●●●	●●●●	●●●●	●●●●	●●●●
Netherlands (Kingdom of the)	●●●	●●●●	●●●●	●●	●●●●	●●●	●●●
Poland	●●●●	●●●	●●●	●●●●	●●●●	●●●	●●●
Portugal	●●●	●●●●	●●●	●●●●	●●●	●●●●	●●●●
Romania	●●●	●●	●●●●	●●●	●●●●	●●●●	●●
Slovakia	●●●●	●●●●	●●●●	●●●●	●●●	●●●	●●●
Slovenia	●●●	●●●●	●●●	●●●●	●●●	●●●	●●●
Spain	●●●●	●●●	●●●	●●●●	●●●●	●●●	●●●●
Sweden	●●●●	●●●●	●●●●	●●●●	●●●●	●●●●	●●●●

●●●● Major positive impact ●●● Moderate positive impact ●● Minor positive impact

Notably, none of the proposed policy actions were rated as having "no positive impact", underscoring the strong and consistent recognition of the critical role that policy plays and will continue to play in enabling the safe, ethical and effective adoption of AI in health care. Denmark and Sweden both rated all seven policy enablers as having a major positive impact.

The policy enabler cited as having the highest major positive impact was guidance on transparency, verifiability and explainability of AI solutions to ensure trust in outcomes: 63% of Member States (17 of 27) selecting it. Similarly, accountability and liability rules for manufacturers, deployers and users applicable to AI systems in health care were rated as having major positive impact by 56% of Member States (15 of 27). This strong emphasis on transparency reflects a growing recognition that trust and accountability is foundational to the successful integration of AI in health care.

Legal clarification and guidance on secondary use of health data and certification of AI systems to be developed and used in health care and therapeutic development were both rated as having a major positive impact by 56% of Member States (15 of 27). Similarly, certification processes help to ensure that AI systems meet rigorous safety, efficacy and ethical standards before being deployed in clinical settings.

Clarification on how privacy and data protection rules apply to AI was selected as having a major positive impact by 44% of Member States (12 of 27). This underscores the ongoing need for clear, actionable guidance on how existing legal framework such as the GDPR intersect with emerging AI technologies. Policies and guidance around the ethical development and use of AI in health care was selected as having a major positive impact by 41% of Member States (11 of 27).

When comparing the results for the EU with the wider WHO European Region, there are many similarities. When looking at which policy enablers were rated to have the highest impact or a major positive impact, the percentage across the seven proposed actions was almost identical.

3.6.2 Summary

Across the EU, the adoption of AI in health care faces significant challenges, with financial affordability emerging as the most frequently reported barrier, followed by legal uncertainty and data quality and standards. Markedly the environmental impact of AI was not considered a major barrier by any EU Member State. Despite the challenges, there was broad consensus on the policy measures that could facilitate AI uptake. Over half of EU Member States viewed guidance that ensures transparency, verifiability and explainability of AI solutions as essential for building trust in AI-driven outcomes. Similarly, liability rules for manufacturers, deployers and users of AI in health care was considered a key policy enabler.

The high upfront costs associated with developing, procuring and maintaining AI technologies can be prohibitive, particularly for resource-constrained health systems. These costs include not only the technology itself but also the necessary investments in infrastructure and workforce training. Without sustainable financing models or targeted public investment, there is a risk that AI adoption will be uneven, exacerbating existing disparities between health systems that are well or poorly resourced. While legal uncertainty was the highest rated barrier in the wider WHO European Region, it was notably lower in the EU, suggesting that the EU's regulatory trajectory anchored by the AI Act and GDPR may be providing a stabilizing influence.

4. The way forward for AI in health care

Across the EU, AI is beginning to transform health systems, promising more efficient services, improved patient outcomes and reduced pressure on overburdened health workforces. The 2024–2025 survey on AI for health in the WHO European Region has highlighted significant progress across Member States, yet it also underscores persistent challenges, gaps and uncertainties that require careful attention.

A few EU Member States have developed, or are in the process of developing, health-specific AI strategies, while many others rely on cross-sectoral approaches. Although most Member States have adopted national cross-sectoral AI strategies, many remain in the early stages of revision or lack a clear definition of AI. Cross-sectoral strategies provide broad oversight and promote consistency across domains, but they may not fully address health system priorities. Therefore, it is important to ensure that cross-sectoral strategies are aligned with national health objectives and priorities.

Engaging stakeholders is essential to ensure relevance, trust and ethical grounding. Across the EU, consultations have primarily involved government actors, health care providers and academic institutions, with patient associations and the broader public less frequently engaged. Training opportunities for health care professionals remain limited and fewer than half of Member States have created new professional roles for AI and data science expertise within health systems. Limited stakeholder engagement and workforce capacity risk producing AI tools that fail to meet real-world needs or that reduce adoption or exacerbate inequities.

Legal, ethical and regulatory frameworks continue to evolve, although progress is uneven. While many Member States are assessing legal gaps, AI laws specific to the health sector remain uncommon. Only a few Member States have issued health-specific ethical guidelines and the postmarket monitoring of AI products is limited. Current legal efforts primarily focus on ethical integration, data accountability and practical guidance, with less attention to liability standards, environmental impact or monitoring adoption. Strengthening harmonized and adaptive legal frameworks will be vital to safeguard patients, clarify responsibilities and support innovation.

Despite these challenges, AI adoption in the EU is advancing in alignment with immediate health priorities. AI-assisted diagnostics is the most widely reported use, while conversational chatbots are increasingly supporting patient engagement and autonomy. These tools demonstrate potential to ease clinician workloads, improve patient outcomes and strengthen health system responsiveness.

Across the EU, the main barriers to adoption include financial affordability, legal uncertainty and data quality and standards, while environmental impact was not considered a major constraint. Funding for AI in health care remains uneven. While the majority of Member States have identified key areas where AI can deliver value, fewer than two thirds have allocated specific funding for development, testing and deployment. High upfront costs – including technology, infrastructure and workforce training – pose a particular barrier for resource-constrained health systems. Without sustainable financing models and

targeted investment, adoption risks being uneven, reinforcing disparities between health systems that are well or poorly resourced.

Together, these findings point to a way forward that balances strategy with practical implementation, robust governance, stakeholder engagement, workforce development and sustainable financing. The following highlights key areas of action and considerations drawn from the findings presented in this report.

- **National AI strategies**
  - Update and adapt AI strategies by regularly revising health-specific or cross-sectoral strategies to reflect evolving health system priorities and technological advances, while integrating inclusive stakeholder engagement and sustainability measures.
  - Clarify oversight responsibilities by designating responsible entities for implementing AI strategies to ensure accountability, coordination and continuity across sectors.

- **Stakeholder engagement and health workforce development**
  - Embed inclusive and early engagement to involve health professionals, patients, developers and researchers from the start to integrate ethical considerations, ensure context-specific solutions and adopt coregulation models that balance innovation with independent oversight and accountability.
  - Create centres of excellence by establishing hubs for piloting technologies, sharing best practices and developing guidelines. These centres can enhance digital literacy, support knowledge exchange, standardize AI deployment and accelerate regulatory alignment across the EU.
  - Enhance public engagement and literacy through public education initiatives to improve understanding of AI, including workshops, courses and partnerships with health agencies and advocacy groups, ensuring culturally sensitive and patient-centred AI adoption.
  - Enhance workforce AI competencies by integrating AI training into education and professional development, offering tiered programmes on AI fundamentals, ethics, data governance and clinical integration.

- **Legal and regulatory landscape for AI in health**
  - Establish clear liability mechanisms and define clear responsibilities for developers, clinicians, data providers and institutions, supported by mechanisms for timely redress and accountability when AI systems cause harm.
  - Implement structured risk assessment and monitoring processes, mandate rigorous pre- and postdeployment testing, promote indemnification clauses to clarify responsibilities between developers and deployers and establish clear guidelines to ensure informed patient consent when AI is used in diagnoses or treatments.
  - Ensure transparency and rigorous testing and require developers to provide accessible information on AI design, decision-making, risks and limitations while safeguarding intellectual property. Conduct rigorous real-world testing to evaluate accuracy, reliability, explainability and safety across diverse clinical contexts, with standardized reporting of validated use cases and performance benchmarks.
  - Promote ethical AI by design through the development and dissemination of practical and sector-specific guidance on integrating ethics by design into AI systems for health to ensure

responsible development, deployment and alignment with patient safety and rights. Support adoption through incentives such as grants for ethically designed AI solutions and/or labelling or certification programmes that recognize tools meeting high ethical and safety standards, complemented by precertification programmes and continuous performance monitoring.

- Strengthen oversight and monitoring, expand postmarket surveillance and implement continuous monitoring mechanisms to ensure AI products in health care remain safe, effective and compliant with established standards.
- Enhance regulatory capacity and collaboration by investing in regulatory agencies to improve approval and monitoring processes while fostering cross-country collaboration and knowledge-sharing to harmonize governance practices and accelerate safe AI adoption.

- **Health data governance**
  - Ensure that Member States implement the governance and technical aspects needed for the successful introduction of the EHDS framework in March 2029.
  - Ensure that all stakeholders involved are timely informed and adequately engaged so that they are ready to comply with obligations deriving from the introduction of EHDS and prepared to explore the opportunities it will enable, in particular with regards to the development and validation of AI solutions in health.
  - Expand the establishment of best-practice networks to ensure equitable AI integration across the EU.
  - Clarify legal and regulatory alignment within the EHDS, GDPR and national data protection laws.
  - Provide targeted financial incentives by offering grants, subsidies and tax benefits to support health care providers and AI developers in adopting standardized, interoperable systems, addressing adoption barriers and fostering sustainable and equitable AI-driven health care innovation.

- **AI opportunities and applications**
  - Ensure context-specific AI design by developing AI systems tailored to clearly define reliable and context-appropriate tasks that strengthen health system capacity, protect patient interests and align with national health goals. Capabilities, limitations and operational conditions should be transparently communicated to all stakeholders.
  - Mandate independent impact assessments, which require comprehensive and independently audited impact assessment before and after deployment, aligned with international standards; make the findings publicly available to strengthen accountability and trust.
  - Create a centralized catalogue of verified AI solutions by establishing an EU-wide, regularly updated platform categorizing validated AI tools by functionality, specialty, performance and operational context, supported by health care institutions, AI developers and Member States to guide safe and equitable adoption.
  - Introduce structured accreditation and certification processes to ensure developers integrate evolving ethical, legal and regulatory considerations into AI design, deployment and monitoring.

- Promote transparency in public–private partnerships and require full public disclosure of terms and conditions in AI-related public–private partnerships to ensure accountability, safeguard public interest and maintain trust.
- Foster continuing developer education and encourage AI developers to engage in ongoing training on evolving ethical, legal and regulatory requirements, embedding responsible innovation practices throughout the AI life-cycle.

- **Barriers and policy enablers for AI adoption in health systems**
  - Implement regulatory sandboxes and assurance laboratories by establishing flexible controlled environments to test AI technologies, enabling real-time learning and adaptive legal frameworks.
  - Encourage assurance laboratories in leading health facilities to conduct local performance testing, assess real-world impact and monitor postdeployment use with anonymized, ethically sourced data.
  - Assess cost–effectiveness, support high-priority AI and evaluate AI technologies against traditional methods to ensure alignment with clinical, regulatory, infrastructural and human rights standards.
  - Provide consolidated funding, grants and subsidies to accelerate development, piloting and deployment, particularly for smaller or resource-limited settings.
  - Link reimbursement to clinical performance through clear reimbursement guidelines tied to clinical efficacy, safety and patient outcomes, which would provide incentives for developers to create high-quality, clinically validated AI applications.
  - Strengthen liability and accountability frameworks by assigning responsibility for adverse outcomes through updated liability frameworks covering product, personal, input and data donor liability; frameworks should address causal responsibility, objective liability, retrospective harm and mechanisms for vicarious liability to safeguard patients and support accountable AI use.
  - Balance AI benefits with environmental impact and evaluate the carbon footprint of AI models. Consider the indirect health impacts of AI-related emissions and weigh the trade-offs between AI-driven health gains and potential climate-related health risks to ensure responsible deployment that minimizes harm.

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World Health Organization
Regional Office for Europe
UN City, Marmorvej 51
DK-2100, Copenhagen Ø, Denmark
Tel: +45 45 33 70 00
Fax: +45 45 33 70 01
Email: euhiudata@who.int
Website: https://www.who.int/europe

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