

Can we entrust our health to artificial intelligence?

EASAC and FEAM issue scientific guidance to ensure the responsible use of AI in the European healthcare sector

Brussels, 30 September 2026 – The European Academies Science Advisory Council (EASAC) and the Federation of European Academies of Medicine (FEAM) today published a joint report on ‘AI in European healthcare: policy recommendations for optimising added value and safe, ethical and inclusive adoption.’

The report seeks to inform the implementation of the EU AI Act and the European Health Data Space, relevant pending legislative files and the upcoming EU initiative on AI in Healthcare¹. It has been written by a working group of 22 scientists from across Europe, nominated by EASAC and FEAM member academies.

AI is developing faster than the regulations governing it

The rapid development of AI can overwhelm societies and regulatory bodies. Warnings from leading AI researchers about a potential loss of control highlight just how difficult it is to anticipate and control risks. In the healthcare sector, the stakes are particularly high.

“AI is entering clinical and administrative practice faster than many health systems can independently evaluate, govern and monitor. It’s up to policymakers to ensure the regulatory preconditions for patient-centred, effective, safe, fair and transparent AI approaches,” says Prof. **André Knottnerus**, EASAC Co-Chair of the Working Group.

Benefits – but also risks and side effects

AI systems are already being used in many areas of healthcare, and have the potential of significant added value, mainly in clinical care and public health. However, without clear rules, there is a risk of data breaches, algorithmic bias and a loss of human control.

The EU AI Act and European Health Data Space provide an important foundation, but the scientists identify gaps in their practical application to healthcare. EASAC and FEAM are therefore calling for AI to be treated like any other measure in healthcare: its benefits must be proven, its risks understood and its performance continuously monitored.

“We need clear specifications for demonstrating real clinical benefit across different populations and settings and for ensuring that representative, high-quality data are used,” says Prof. **Luis Martí-Bonmatí**, FEAM Co-Chair of the Working Group. *“Patients also need meaningful explanations and routes for recourse, liability must be clear, and healthcare systems must avoid becoming dependent on individual technology providers.”*

Key messages

1. Proactive regulation is essential: The EU AI Act classifies the health sector as high-risk. The use of AI thus requires regulations that take long-term consequences into account. Provisions of the AI Act need to be integrated with existing regulatory frameworks, such as the Medical Devices Regulation, the GDPR and the European Health Data Space.

2. Prioritising equity and trust: The use of AI can exacerbate existing inequalities, including those related to gender, ethnicity and socio-economic status, as well as disparities between rich and poor countries, and can undermine public trust. The report calls for EU policies that prioritise equitable access, transparency – including

¹ Announced by Commission President Ursula von der Leyen in her State of the Union speech on 16 September

the environmental footprint of AI – and public engagement. Only then can AI meet the goals of universal healthcare and be aligned with democratic values.

3. EU-wide coordination is a must: Fragmented regulation hinders the safety and scalability of AI. The EU must harmonise standards, facilitate cross-border exchange of anonymised data and promote joint oversight to ensure ethical and robust AI applications across all Member States.

A call to policymakers

The authors also recommend testing AI in regulatory sandboxes under controlled conditions before it is deployed more widely. Furthermore, investment should be channelled into research on approaches that deliver reliable results using smaller, carefully selected datasets. *“Now is the time to act, if we want to entrust our health with AI”* emphasises **Knottnerus**. *“With these recommendations, we want to help policymakers drive innovations forward safely.”*

EASAC-FEAM Report: AI in European Healthcare

Link (active from 30 September 2026): <https://easac.eu/projects/details/ai-in-healthcare>

Annex: Ten recommendations for policy action

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About the European Academies Science Advisory Council (EASAC)

EASAC is formed by the national science academies of the EU Member States, Norway, Switzerland and United Kingdom, to collaborate in giving advice to European policymakers. EASAC provides a means for the collective voice of European science to be heard. Through EASAC, the academies work together to provide independent, evidence-based advice to those who make or influence European policies within the European institutions.
www.easac.eu

About the Federation of European Academies of Medicine (FEAM)

FEAM brings together 24 national Academies of Medicine, Pharmacy and Veterinary Science – or the medical divisions of national Academies of Sciences – from across the WHO European region, drawing on the expertise of over 5,000 leading biomedical scientists. Through FEAM, its member academies formulate and express a common position on European matters concerning human and animal medicine, biomedical research, education and health, extending to European authorities the same advisory role they each hold in their own countries. In doing so, FEAM works to underpin European biomedical policy with the best scientific advice the continent has to offer, and to advance the health, safety and wealth of European citizens through a creative, sustainable environment for medical research and training. www.feam.eu

Annex: Ten recommendations for policy action

- 1. Establish robust evaluation of AI's added value in healthcare. Mandate** transparent evaluation of AI's net benefit – clinical outcomes, patient safety, security, equity, quality of life and cost-effectiveness – before and after deployment.
- 2. Develop comprehensive guidelines for responsible AI deployment.** Develop EU-wide guidelines covering methodological quality, bias, external validity, cost-effectiveness, and environmental impacts.
- 3. Broaden ethical principles to encompass societal and long-term dimensions.** Update ethical frameworks to address societal effects, institutional responsibilities, global impacts, and long-term (including intergenerational) consequences.
- 4. Address implementation-related challenges in AI deployment.** Invest in interoperable infrastructure, harmonise rules across Member States, train staff, and support workflow integration with a focus on usability and patient safety.
- 5. Advance AI towards a learning health system.** Support secure data platforms, feedback loops, and adaptive improvement with governance that ensures transparency, accountability, and trust.
- 6. Foster interoperability and data sharing ecosystems.** Incentivise cross-border data ecosystems using common standards, strong privacy safeguards, and clear data stewardship.
- 7. Invest in training, education, and information for AI in healthcare.** Fund interdisciplinary training and continuous professional development for clinicians, developers, and decision-makers to build competence and responsible use.
- 8. Engage stakeholders and protect public trust.** Require participatory design, clear communication, and notification when AI systems are used, and accessible recourse so systems reflect societal values and maintain patient and public trust.
- 9. Define strategic research priorities for AI in healthcare.** Prioritise research on transparency, bias mitigation, clinical validation, integration in practice, equity, and long-term system effects.
- 10. Strengthen governance and oversight structures.** Establish clear accountability, independent monitoring, auditing, and corrective mechanisms to ensure compliance and safe performance over time.