

**PRESS RELEASE***SEPTEMBER 2025*

## AI for Better Care: EUHA's Policy Perspective on Innovation and Regulation

The European University Hospital Alliance (EUHA) is pleased to announce the release of its new Position Paper, “EUHA Consensus Positions on Artificial Intelligence: Proposals for the Responsible Development, Regulation, and Implementation of AI in European Healthcare”. Developed through a series of EUHA member AI expert consultations held throughout 2024 and into mid-2025, the paper acknowledges the great potential of Artificial Intelligence and positions university hospitals as powerful innovation hubs, uniquely equipped to responsibly exploit AI for the benefit of patients and the healthcare sector.

EUHA recognises the great potential of Artificial Intelligence (AI) to enhance the quality and efficiency of healthcare. Additionally, EUHA acknowledges the importance of EU regulations, such as the General Data Protection Regulation (GDPR), the European Health Data Space (EHDS), and the AI Act, in laying a strong foundation for the trustworthy development and use of AI in the EU. However, given the rapid evolution of the technology, this paper outlines a series of EUHA consensus positions to address critical challenges on AI in healthcare. These positions aim to ensure the optimal and responsible use of AI, given the potential paradigm-changing impact of AI on the healthcare sector.

EUHA supports federated, hospital-level data governance, strong custodianship by providers, integration of lifestyle and health data, continuous post-market validation of AI tools, and EU-wide training and liability frameworks – all aimed at ensuring responsible, ethical, and effective use of AI in healthcare.

EUHA calls for:

- **Federated Data Handling:** EUHA supports federated, hospital-level data environments rather than centralised national warehouses. This model ensures GDPR compliance, avoids complexity, and enables cross-border research. To address inconsistent GDPR interpretations, EUHA proposes an EU-wide network of accredited healthcare Data Protection Boards, alongside EU-level directives and funding to secure interoperable and FAIR data standards (Findable, Accessible, Interoperable, and Reusable).
- **Data Custodianship by Healthcare Providers:** Healthcare providers must remain the primary custodians of patient data. EUHA's position is that research in the public interest constitutes a legal basis for the secondary use of data by public healthcare providers or universities. We acknowledge that research done in private institutions can also be in the public interest. This should be combined with a broad opt-out model. Patients deserve clear, standardised information on how their data and AI tools are used. Providers, who bear the burden of data preparation and validation, should be recognised and compensated for this responsibility.

- **Health and Wellness Data:** The separation of health and lifestyle data is artificial. Behavioural and wellness data, such as those from diet or exercise apps, can directly impact health and must be regulated to the same standards as clinical data. EUHA calls for a new category of health-related data that meets GDPR, Medical Device Regulation (MDR), quality, and interoperability requirements to support preventive and integrated care.
- **Continuous Validation of AI:** AI tools must be validated not only before release but throughout their use in clinical practice. EUHA proposes conditional approvals tied to robust post-market surveillance using real-world data in secure hospital-based environments. Continuous monitoring will help detect bias, ensure safety, and maintain trust. Validation outcomes should be publicly accessible, enabling informed decisions by clinicians and patients.
- **Implementation in Clinical Practice:** AI in healthcare must follow established benefit–risk principles, with patients involved in shared decision-making. For black-box systems, individual caregivers cannot bear full liability; EUHA supports a no-fault liability model at the EU level. To prepare the workforce, AI training should be embedded across medical education and professional development, coordinated at the European level to build a digitally prepared healthcare sector.

### Expressions of Support

The paper is now open to individuals or entities who wish to express their support. Quotes or statements of support are welcome to be received at [secretariat@euhalliance.eu](mailto:secretariat@euhalliance.eu). Please note that expressions of support may be used for promotional purposes.

### Contact Information

For inquiries, kindly contact the EUHA Office

- Johan Van Eldere, EUHA Secretary-General: +32 496 20 50 17 or [johan.vaneldere@euhalliance.eu](mailto:johan.vaneldere@euhalliance.eu) & [secretariat@euhalliance.eu](mailto:secretariat@euhalliance.eu).
- Martina Garriga, Communications Officer: + 34 647 27 62 23 or [m.garriga@euhalliance.eu](mailto:m.garriga@euhalliance.eu) & [secretariat@euhalliance.eu](mailto:secretariat@euhalliance.eu).

### About EUHA

The European University Hospital Alliance, founded in 2017, is formed of 11 leading European university hospitals. University hospitals play an essential role in healthcare systems and society, taking care of the most complex patients, performing research, pioneering healthcare and innovation, and training the next generation of healthcare professionals.

The members of EUHA are:

- Aarhus University Hospital

- Vall d'Hebron Barcelona Hospital Campus
- Charité – Universitätsmedizin Berlin
- HUS Helsinki University Hospital
- UZ Leuven
- King's Health Partners
- Ospedale San Raffaele
- Assistance Publique – Hôpitaux de Paris
- Erasmus MC University Medical Centre
- University Hospital Vienna & Medical University Vienna
- Karolinska University Hospital & Karolinska Institutet

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