European University Hospital Alliance

EUHA Consensus Positions on Artificial Intelligence

Proposals for the Responsible Development, Regulation, and Implementation of AI in European Healthcare

EUHA Position Paper

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Credits
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This paper was subsequently discussed in the EUHA Digital Health and Data Network and the EUHA Policy Working Group with representatives from all EUHA members.

Johan Van Eldere (EUHA) coordinated the writing group and wrote the final version.

The EUHA Members' Assembly discussed and approved the paper at its meeting in Rotterdam on Wednesday, 25 June 2025.

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Introduction

The European University Hospital Alliance (EUHA) recognises the great potential of artificial intelligence (AI) to enhance the quality and efficiency of healthcare. EUHA members will encourage the exploration and implementation of AI within their institutions, sharing experiences and expertise in this field across their networks, and integrating AI into future healthcare provider (HCP) training programmes. Similarly, EUHA acknowledges the importance of the EU regulations in AI in creating a strong framework that prioritises better conditions for the development and use of this innovative technology in the EU.

The following EUHA positions are formulated in response to the different EU regulations related to AI, data handling, and implementation in healthcare settings. These positions aim to ensure optimal and responsible use of AI, given the potential paradigm-changing impact of AI on the healthcare sector.

Data Requirements, Environment, and Data Handling

We Support Federated Data Handling

The use of sensitive medical data for the development of AI medical device software (MDSW) must comply with the General Data Protection Regulation (GDPR). However, the varying interpretations of the GDPR across different Member States (MS), certainly for research purposes, have created significant challenges. Additionally, discrepancies between the definitions and concepts outlined in the GDPR and the AI Act have further complicated the issue.

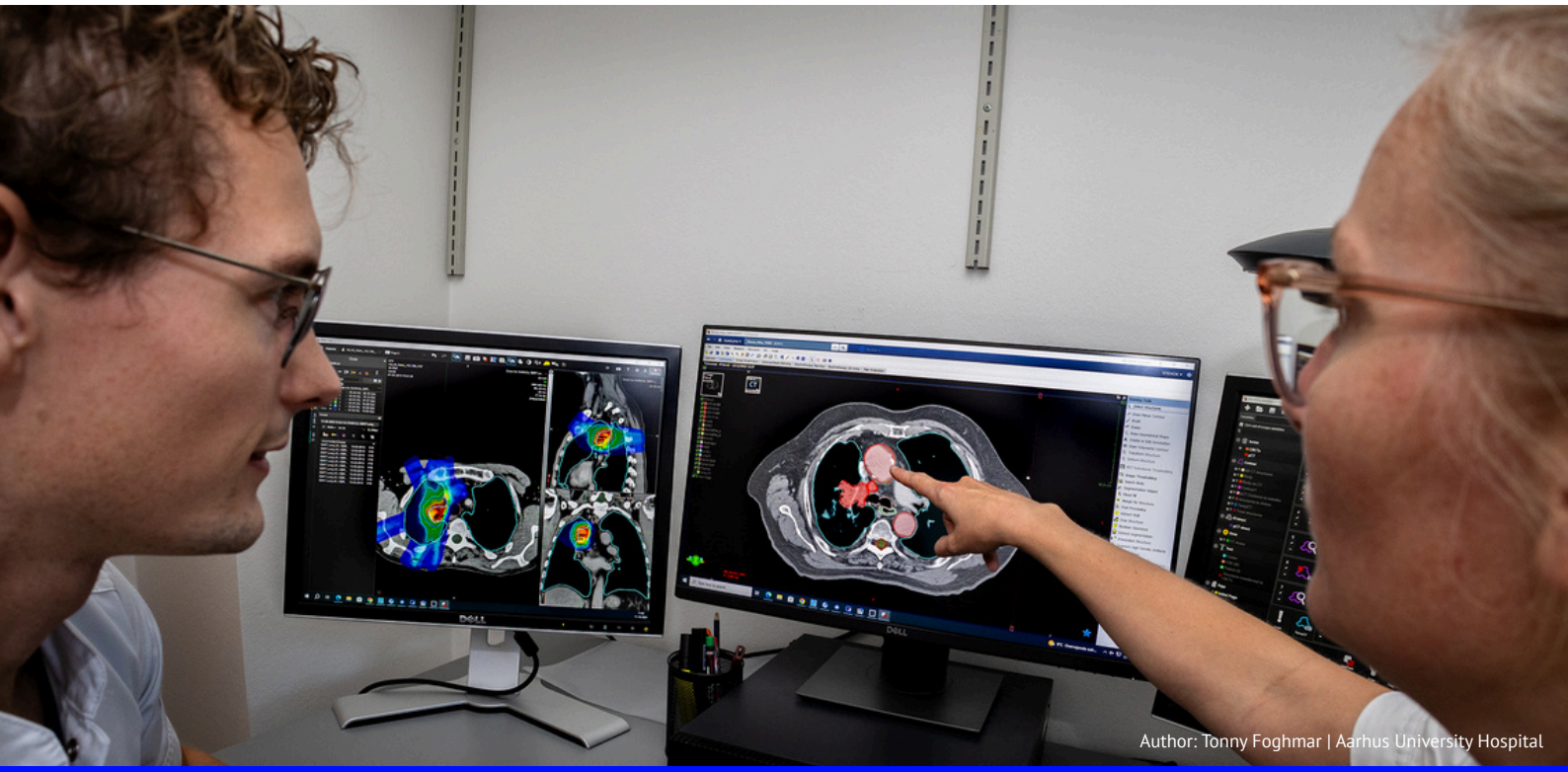
Although pseudonymisation and anonymisation are defined in the GDPR, there is still discussion about the exact interpretation of these definitions. Given the rapid development of de-identification algorithms, particularly in combination with biometric data inherent in medical data, we consider data as pseudonymised by default. However, **we strongly advocate for the development of further practical guidelines for data categorisation.** EUHA acknowledges that the GDPR, the European Health Data Space (EHDS), and the AI Act are important pillars of the regulatory framework for trustworthy development and the use of AI in healthcare. However, there is a need to provide more concrete guidelines that can be used by data protection officers (DPOs) and data protection boards (DPBs). To address this, **EUHA proposes the establishment of an EU-wide network of accredited healthcare institutions-linked DPBs**, which, under the supervision of the EU DPB and starting from real-life cases, will develop a repository of questions and corresponding decisions that can serve as a guide for other DPOs and DPBs across Europe.

Although federated data models may not always provide the necessary support for the development of AI tools, **EUHA supports the idea of federated data models whenever possible, alongside data custodianship and controllership by caregivers.** EUHA does not support data warehousing, custodianship, and controllership at a regional or national level, as this would contradict the EHDS, which asserts that controllership remains with primary data controllers and not at the level of aggregated data collection. Furthermore, such regional or national data management would not comply with the GDPR. We are concerned that it could introduce unnecessary complexity and delay the development of lawful cross-border health data exchanges for research purposes.

We consequently suggest the creation of secure and validated data environments at the level of large healthcare institutions (large hospitals or regional networks of collaborating hospitals, linked with primary care networks). This would enable federated AI tool validation across different geographical settings, allowing data exploitation without the need for transfer.

If the AI application calls for it, Secure Processing Environments (with data warehousing at a supra-caregiver level) with specific data sets can be considered.

To effectively use data from different sources to train and test AI MDSW, the data need to be interoperable. While present ontologies and standards represent a step forward, they only cover a small fraction of the amount of data generated and used in healthcare. Additional semantic and syntactic data standards exist and their evolution will continue in parallel with advancements in data acquisition and analysis technologies. Interoperability alone is not enough to make the data Findable, Accessible, Interoperable, and Reusable (FAIR). The database infrastructure itself also requires standardisation. **Achieving this will require a centralised, directive decision at the EU level (and possibly beyond) to which everyone can (and has to) comply to avoid fragmentation of standards at MS level. A clear roadmap, coupled with assorted funding, is essential to support this process.**



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We Support Data Custodianship by Healthcare Providers

Although many agree that the patient remains the 'owner' of their data, "data ownership" has no legal basis but is commonly interpreted as 'data access right'. For EUHA, it is crucial that healthcare providers or their institutions are acknowledged as data controllers in the GDPR and that this position includes the responsibility for GDPR-compliant use of data.

There is a wide diversity of public opinion about opt-in, opt-out, consent, public or legitimate interest, and the legal basis for the secondary use of medical data. The EU DPB and Supervisor argue against the widespread use of informed consent, citing the need for repeated re-consent (GDPR only allows informed consent for very specific goals) and the imbalance in the relationship between the patient and HCP. Alternative legal bases for the use of medical data, such as public interest and legitimate interest, are therefore considered better alternatives. However, these options still require strict adherence to other requisites of the GDPR, particularly regarding full transparency to patients about how their data is used.

EUHA shares the opinion of legal experts that research in the public interest constitutes a legal basis for the secondary use of data by public HCPs or universities. We acknowledge that research done in private institutions can also be in the public interest. Additionally, **we also advocate for a broad (static) opt-out model as the only logistically sensible solution, as proposed by the Forschungsdaten Gesundheit Nutzunsggesetz and the EHDS.**

We subscribe to the need for transparency towards patients concerning the use of their data and the AI models used. However, to ensure transparency, AI tools should be accompanied by an EU-wide defined, easy-to-read set of relevant information about the model, the data used, validation processes, etc. This should be presented in a way that the outcome provided by the AI tool can be explained by humans, while also ensuring traceability that includes further real-world development and performance.

Notwithstanding the GDPR, EHDS, AI Act, Data Act and other EU regulations, the governance of data acquired for primary use in healthcare and subsequently solicited for secondary use, i.e. for the development of AI MDSW, has implications for HCPs and their institutions. Depending on the Electronic Health Record (EHR) in use, it can already be difficult to extract the data from the EHR, let alone how to organise the use of such data in a validated, ethical, and responsible way. Healthcare institutions are aware of the intrinsic value of the data and - as custodians of the data - have a responsibility to protect patients by means of a local DPB and by submitting all proposals for use of the data to an Ethical Board (although this is not within their present legal duty). We are also aware of and have to protect against the risk of intentional and unintentional sharing of individual health data. This requires consultation and cooperation with the national and EU levels. **We argue that the additional effort needed on the part of the HCP to extract and validate data for the development of AI MDSW by third parties needs to be compensated.**

The use of individual sensitive health data for the development of AI MDSW also underlines the perceived conflict between individual rights and societal needs and rights. Certainly, when the data have been created using societal funding, a proper balance between these rights, based on appropriate ethical considerations, is absolutely needed. Individual rights are not absolute but are limited by their impact on other's rights and this requires, certainly in the setting of the use of health data, a broad ethical discussion.

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We Support Removing the Distinction Between Health and Wellness Data Because It Is Artificial and Counterproductive

The EU regulations presently exclude patient-generated lifestyle applications. However, some of these applications, especially those related to behavioural changes related to diet, exercise, and mental status, can and often will have major implications on the health of their users. Therefore, it should be obligatory to also provide a benefit-risk balance for these applications (as for the medical applications) to help citizens, patients, and clinicians make informed decisions about their use, including potential advantages and disadvantages. In addition, it is clear that such data will increasingly need to be linked to health data as part of the ongoing evolution towards a more preventive and integrated healthcare system.

EUHA's position is that the distinction between health and lifestyle data is artificial, counterproductive, and should not be used as a means to bypass regulations such as the Medical Device Regulation (MDR). It should also not be left to developers to claim interoperability with the Electronic Health Records. **EUHA advocates for the creation of a category of health-related data that would have to fulfil criteria of quality and interoperability.** Data lakes (or warehouses) of health-related data should comply with GDPR and MDR standards and static opt-out. In addition, there is a need to redefine good clinical practice with regards to the primary use of such data. If the data are generated by the patients, an agreement to enable the lawful primary and secondary use of the data is needed.

We Support Continuous Post-Release Validation of AI MDSW in a Network of Secure and Validated Data Environments

The data used for training and testing are always a sample of the general intended populations and therefore carry the risk of bias. Data are also often incomplete and inaccurate when acquired during real-life clinical practice. Data quality assessment and curation is, therefore, an important step in the development of AI MDSW and requires a substantial effort. Testing for bias and retraining of AI is needed but not always easy and will also shift during actual use of the MDSW. This highlights the need for a thorough post-market surveillance aimed at checking for the occurrence of such biases. Accuracy of data and the use of structured versus non-structured data are also significant challenges, which can only be solved by emphasising and facilitating the structured capture of data in the clinical (primary use) environment.

Under the MDR and AI Act, proof that validated data sets are used for developing the AI MDSW will be required. We argue to shift a substantial part of that proof to the post-release phase, with the use of real-world data (RWD) and time-limited conditional marketing authorisation if the benefit-risk ratio is positive. We refer to the already proposed network of secure and validated data environments at the level of large healthcare institutions (large hospitals or regional networks of collaborating hospitals with linked primary care networks including patient representation) to realise both development validation and post-market surveillance. This post-release phase and continuous development of AI tools should be documented and easily accessible to all users who should be able to continuously update their assessment of the tool. We also strongly support further research on frameworks for the responsible implementation of AI in clinical practice. Identifying and optimising implementation strategies for AI is essential to ensure that it can meaningfully benefit patients and other stakeholders.

Guidelines for clinical trial protocols for interventions involving AI are available; the CONSORT-AI (Consolidated Standards of Reporting Trials-Artificial Intelligence) extension and its companion statement for clinical trial protocols, SPIRIT-AI (Standard Protocol Items: Recommendations for Interventional Trials-Artificial Intelligence).

Implementation of AI

Benefit-Risk Assessment of Using AI in Medical Decision-Making

In medicine, no intervention is without risk and every choice is based upon a benefit-risk analysis. This analysis must consider the preferences and expectations of the patient. Therefore, the HCP must be equipped to explain the AI-related elements of treatment to the patient, enabling them to make an informed choice about its use. To do so, the HCP needs to receive the required information (including post-release studies, investigations from the manufacturer, but also other evidence) to adequately explain the AI tool to the patient.

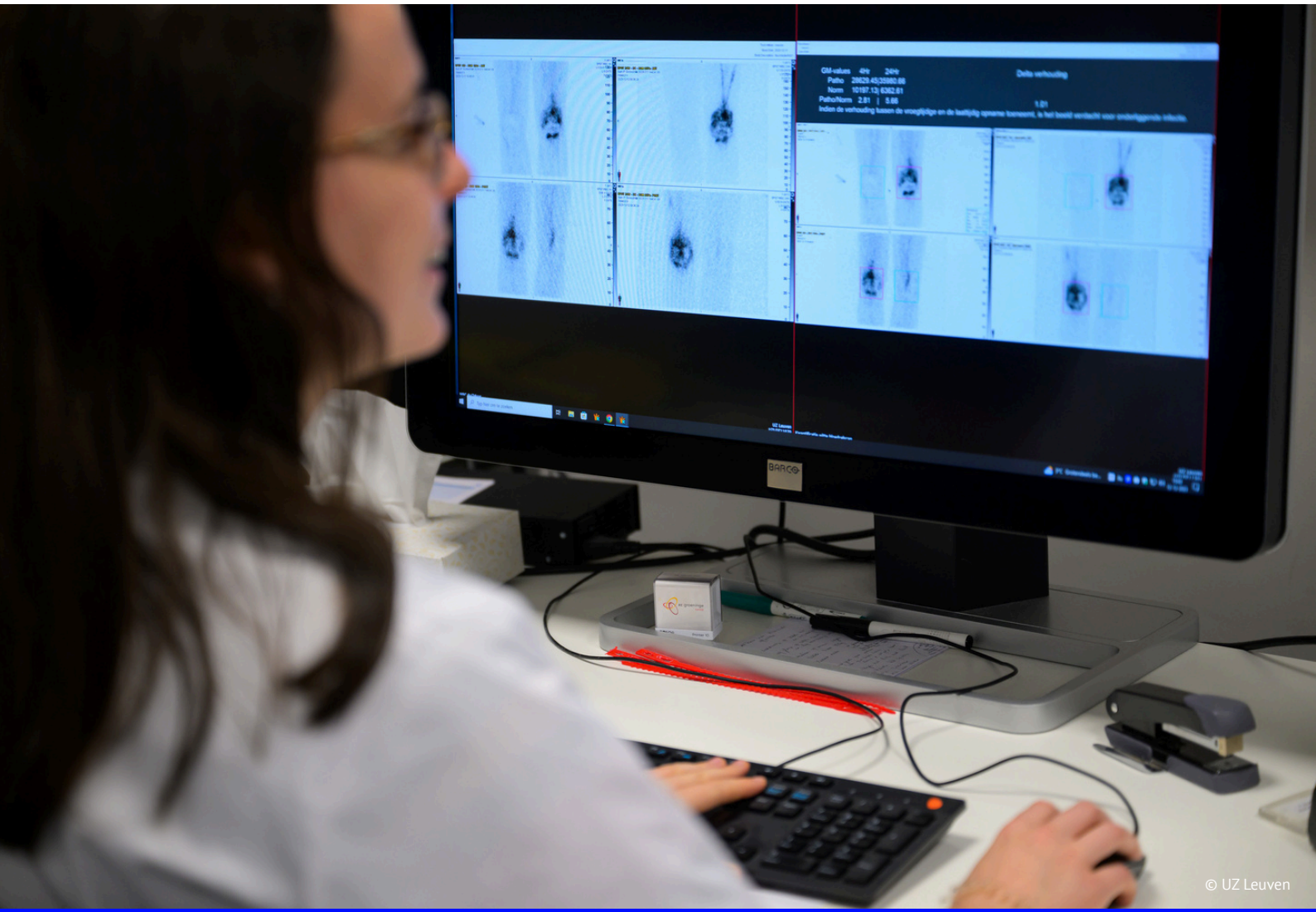
Many regulations, including MDR and the AI Act, stress the need for a human-in-the-loop, i.e. a human who makes the final decision about the use and outcome of an AI algorithm. This is possible if the AI algorithm is not a black-box type or if it is verifiable. The relevance of the human-in-the-loop principle can be questioned in circumstances where the human is not capable of such interpretation or verification. In such cases, the human-in-the-loop is then reduced to a mere blind validator and cannot take full legal responsibility and accountability for that act. This raises the question of whether AI should be treated differently from any other expert system that HCPs have used so far in reaching a diagnostic or therapeutic decision, including their own expertise, guidelines, etc. Since AI, contrary to guidelines or own expertise, operates independently, we believe that the clinician cannot and should not take legal responsibility in those circumstances.

EUHA's position is that legal responsibility when using a black-box type AI should not rest with the individual caregiver, who is in most cases unable to judge the value of the AI. A no-fault liability as put forward in the proposal for an AI liability directive would provide a solution. It remains with the HCP to decide whether to accept the advice or conclusions of the AI system and use them in co-decision-making with the patient. In this regard, the AI system is not different from any other medical decision support mechanism.

Training of Healthcare Professionals

When we want to implement responsible AI in healthcare and make full use of all its possibilities, we need to address how to build as fast as possible a new mindset in patients and HCPs.

Therefore, **we strongly advocate an enhanced package of digital education in the pre and postgraduate training of all HCPs.** We also advocate training initiatives for current staff to get updated on the current opportunities and challenges of AI. This package should contain a clear understanding of the workings of AI and would be based on EU-wide coordination on the content and endpoints of this education. This proposal would involve both the medical faculties and the university hospitals, as it implies education and training at both the pre and postgraduate levels. We are aware that this proposal would have a significant impact on the current curricula but deem it necessary, given the impact of AI.



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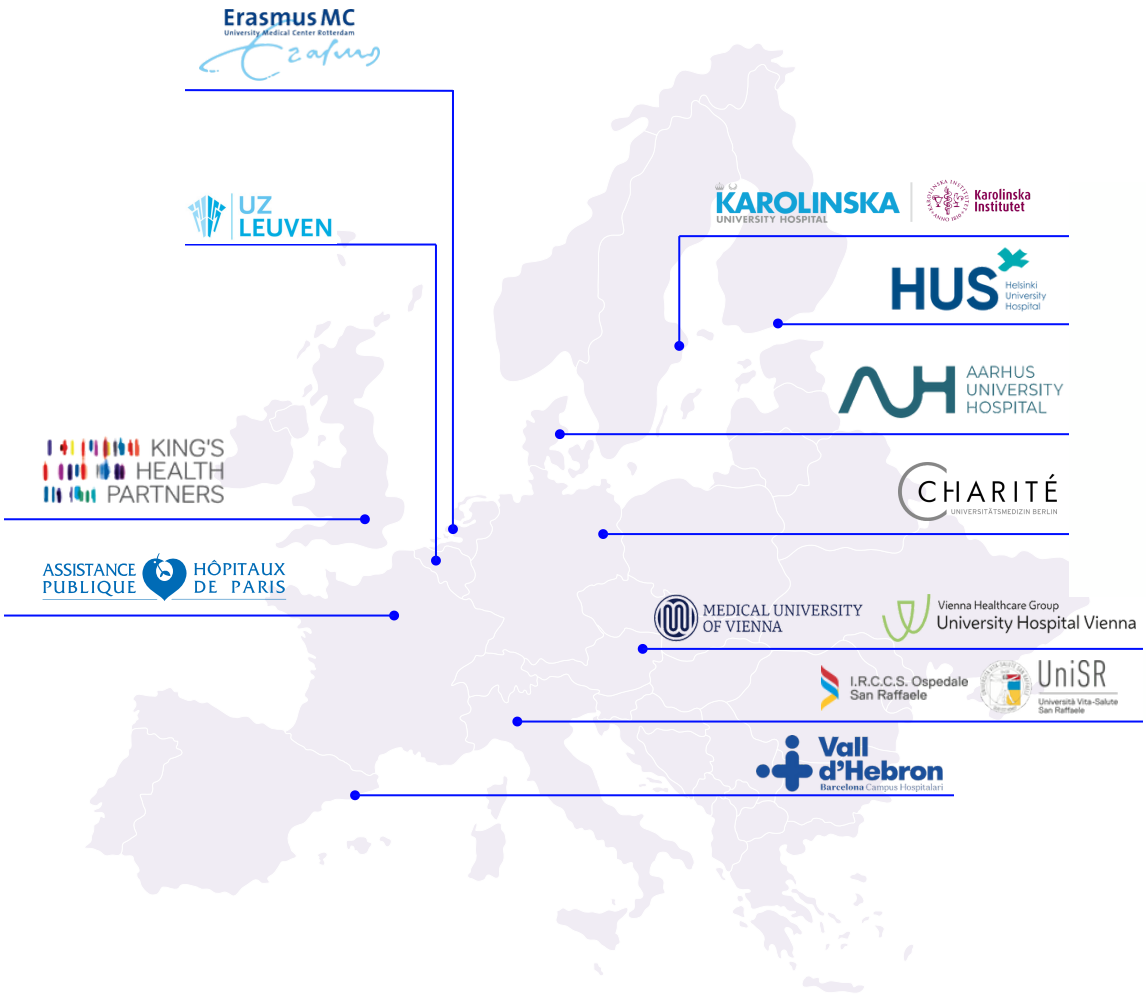
About EUHA

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.



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