

## EIT Health AI consultation response

- EIT Health welcomes the proposed AI Regulation and its ambition to create horizontal legislation overseeing AI and to maximise the safety and trustworthiness of this technology. We welcome the creation of a risk-classification of AI and prohibition of certain AI in alignment with the OECD, as this type of risk management is vital to ensuring uptake of this important technology.
- With the importance of AI in the healthcare context in mind, the AI Act should support – not suppress – innovation. Additional requirements and conformity assessments imposed by the foreseen legislation should therefore be combined or simplified to the greatest extent possible, and accompanied by clear guidance and support to innovators of all sizes to provide certainty and ensure they are not inhibited by additional regulatory requirements.
- To avoid delays both in terms of innovations coming to market and patient access to new technologies and treatments, notified bodies and other authorities should be supported by the EU to ensure they are able to assess AI coming to market quickly whilst complying with the necessary safety assessments.
- We welcome the European AI Board but stress the need for cohesion with other EU level boards to ensure complete harmonisation of legislation to reduce regulatory burden. The proposed independent expert group is a positive inclusion, and EIT Health would welcome the opportunity to participate to provide insight and real-world evidence generated from its network of health innovators.
- Other stakeholders within the healthcare ecosystem need to be supported in the uptake and use of AI, notably patients and healthcare professionals. Appropriate education and upskilling on all the relevant aspects of AI and its utility in healthcare should be incorporated within existing and future curricula, and continued professional education for healthcare professionals is a vital foundational step. EIT Health's education pillar has trained or educated 43,000 graduates and professionals, through activities including Summer Schools, Fellowships and Master's/PhD programmes. On AI specifically, the EIT Health project HelloAI RES Online (<https://eithealth.eu/project/helloairis/>) was designed to introduce medical professionals to AI and equip them with the skills needed to allow them to benefit from the ongoing evolution of the healthcare field.
- The proposed Regulation must have appropriate flexibility to accommodate sector specific issues, notably in health, where the risks are greater and the level of regulation already high. The proposal finds itself overlapping with many health sector specific and horizontal legislation (DGA, EHDS, MDR, IVDR, EHDS) and appropriate measures must be taken to ensure that health innovation is still allowed to thrive whilst of course ensuring patient safety.
- Further clarity is needed on how healthcare AI outside of the scope of the MDR and IVDR will be regulated, notably when used for research purposes.

- Finally, EIT Health welcomes the assurances created by looking at the whole value chain, and calls upon the Commission to find the right balance between support for innovation and building public trust in clear regulation, enabling safe and secure exchange of data and the development of new innovative AI.