

Publishable summary

The present deliverable, entitled *Guidelines on the Implementation of Requirements*, aims to provide an operational and systematic framework for identifying, coordinating and implementing the main ethical, legal and regulatory requirements applicable to the development and use of AI medical devices within the DARE Project.

The general objective of the document is not to offer a merely descriptive overview of the applicable legislation, nor to provide ready-made compliance solutions. Rather, the deliverable seeks to translate a complex and multi-layered regulatory landscape into practical guidance, capable of supporting researchers, healthcare actors, developers and project partners in understanding which requirements must be considered, how they interact with one another, and which safeguards should be taken into account when artificial intelligence systems are developed, tested, validated or used in medical and healthcare contexts.

This objective is pursued through a progressive analysis of the main legal and ethical dimensions involved in AI medical devices. The starting point is the recognition that such technologies cannot be assessed through a single regulatory lens. Their development and use require the coordination of different frameworks, including medical device regulation, data protection law, rules on data sharing and secondary use of health data, artificial intelligence regulation, ethics in medical research, and civil liability. Each of these frameworks addresses a specific dimension of the same phenomenon: the safety and performance of the device, the protection and circulation of health data, the governance of AI systems, the preservation of patient autonomy and trust, the prevention of discriminatory outcomes, and the allocation of responsibility where harm occurs.

Accordingly, the deliverable first addresses the development phase of AI medical devices, with specific attention to the applicable medical device framework and to the ethical and legal issues arising in medical research and healthcare innovation. This includes the prospective use of synthetic data, telemedicine, remote monitoring and digital health tools; the impact of AI medical devices on the doctor-patient relationship; and the risks of algorithmic bias, discrimination and exclusion, as well as the possible role of AI systems in promoting accessibility and inclusion.

The analysis then focuses on the processing, reuse and circulation of health data, which constitute an essential precondition for the development of AI medical devices. In this regard, the deliverable examines the interaction between the GDPR, EDPB guidance, national legislation, the European Health Data Space and the Data Governance Act. Particular attention is devoted to pseudonymisation, anonymisation, synthetic data generation, scientific research, secondary use of data, data altruism, the qualification of the roles of the actors involved, and the principle of accountability as the criterion for structuring and documenting the compliance pathway.

A further part of the deliverable is dedicated to *Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (“AI Act”)* and, in particular, to the mechanisms that may support the controlled development and testing of AI systems, such as regulatory sandboxes and real-world testing of high-risk AI systems.

This analysis is intended to clarify how innovation-oriented tools may operate together with the safeguards required for the protection of health, safety, fundamental rights and personal data.

Finally, the deliverable considers the use of AI medical devices from the perspective of liability. The analysis distinguishes between medical liability and product liability, and examines the difficulties that may arise where harm results from the interaction between clinical decision-making, organisational choices, product defects, software malfunction, algorithmic opacity or erroneous outputs generated by AI systems. This part of the document also considers possible future-oriented solutions, including compensatory mechanisms aimed at avoiding the risks connected with highly complex and not fully controllable technologies falling entirely on injured patients.

The deliverable is complemented by Annex I, entitled Requirements for the Submission to the Ethics Committee for Study Protocols with Emerging Technologies. The Annex addresses a specific and transversal issue that emerged from the project experience, namely the submission of study protocols involving emerging technologies to Ethics Committees. Its objective is to show how several of the requirements analysed in the main body of the deliverable arise in practice at the stage of ethics review, where regulatory compliance, methodological robustness, data governance, informed consent, participant protection and ethical assessment converge. For this reason, the Annex reconstructs the national regulatory framework governing Ethics Committees, identifies the ethical issues associated with digital health and prevention technologies, maps the main difficulties encountered in project studies, and describes the operational strategies developed to support researchers in preparing more complete, coherent and ethically sound submissions.

In this sense, Annex I should be read as a practical complement to the main body of the deliverable. While the main text reconstructs the substantive regulatory, ethical and liability framework applicable to AI medical devices, the Annex focuses on the procedural and operational stage in which those requirements are translated into Ethics Committee submissions. Overall, the deliverable is intended to support a responsible, legally sound and ethically robust implementation of AI medical devices. Its guiding assumption is that innovation in healthcare cannot be separated from accountability, transparency, risk assessment and the protection of fundamental rights. The implementation of requirements is therefore understood not as a formal exercise, but as a structured and documented process through which technological development, scientific research and patient protection may be made compatible.