

## Publishable summary

In the previous deliverable, SP1.D2.1 Inventory of the Ethical and Legal Framework, the WP2 group conducted an in-depth analysis of European regulations and legislative proposals relevant to the DARE project. Key normative references were identified in critical areas such as personal data protection, artificial intelligence regulation, civil liability, and cybersecurity. This document, delivered in December 2023, highlighted the importance of a comprehensive and harmonized regulatory framework to support and govern technological development.

A central focus was on personal data protection, with an emphasis on the GDPR (Regulation (EU) 2016/679) and updated national legislation, particularly regarding the processing of data for scientific research, including special categories of data. The importance of the data minimization principle and security mechanisms, such as Privacy by Design and Privacy by Default, was underscored as essential to ensuring compliance with European regulatory requirements. Additional insights were provided on the Data Governance Act (Regulation (EU) 2022/868), which promotes secure data sharing, and the proposed Data Act, aimed at facilitating data access and use by consumers and businesses, fostering a data-driven economy.

Another key aspect was the analysis of regulations on artificial intelligence, including the Artificial Intelligence Act and the Ethics Guidelines for Trustworthy AI. These legal instruments represent fundamental pillars for developing reliable AI systems, with provisions that promote transparency, security, and accountability while safeguarding human rights. Complementary initiatives, such as the White Paper on Artificial Intelligence and policy recommendations for a human-centered approach, were also examined, emphasizing the importance of integrating ethical principles into innovative technologies. With this deliverable, an analysis of recent regulatory developments has become essential, such as the NIS 2 Directive, the Product Liability Directive, and the Artificial Intelligence Liability Act, to identify operational tools useful for addressing the practical challenges of the DARE project. In particular, the NIS 2 Directive introduces stricter obligations to ensure the security of networks and information systems, a critical aspect for digital technologies operating in the healthcare sector. These regulations provide practical guidelines for developing innovative technologies, ensuring a balance between technological progress and the protection of fundamental rights.



An additional focus is on the recent amendment to Article 110 of Legislative Decree 196/2003, which governs the processing of data for research purposes. This amendment has prompted the Italian Data Protection Authority to initiate a consultation process to update ethical rules in this area. This update is particularly significant for the DARE project, which involves the use of sensitive data in innovative contexts, requiring a careful balance between research needs and citizens' rights. For this reason, Annex A presents a proposal for ethical guidelines developed by the WP2 team to support the DARE Foundation during the consultation process.

This deliverable aims to identify the regulations relevant to the DARE project's research and prevention goals by updating the regulatory context, highlighting potential application challenges, and providing, through ethical guidelines, effective solutions to facilitate the use of data – including health data – in compliance with the project's objectives. Specifically, the first chapter focuses on regulatory updates and their implications for the DARE project, the second chapter examines the application of the AI Act in healthcare, with particular attention to medical devices, and the third chapter, along with Annex A, addresses updates in privacy legislation.