

# La *cybersecurity* nel quadro dello European Health Data Space

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## *Cybersecurity in the Context of the European Health Data Space*

**Abstract:** The recent COVID pandemic clearly showed the difficulties that may arise when trying to achieve a wide and effective sharing of health data, aimed at facilitating biomedical research in Europe. This situation triggered the European Commission to move forward with the project of creating a common European health data space. The European Health Data Space (EHDS) Regulation adopted in January 2025 addresses two challenges: on the one hand, the need to expand the use of health data to provide healthcare to the individual from whom such data were collected and, on the other hand, the need to improve research, innovation, policy-making, patient safety, personalized medicine, official statistics and/or regulatory activities. Although the number of contributions addressing the risks and issues associated with the secondary use of health data has steadily increased, less attention has been paid to the analysis of the rules applicable to the primary use of data, and in particular to cybersecurity requirements. This contribution aims to fill this gap, focusing on the rules applicable to electronic health record systems and those applicable to devices and so-called wellness applications which, according to the definition of the EHDS, guarantee interoperability with electronic health records. The security requirements envisaged, though relevant, are still insufficient to safeguard the cybersecurity of the data collected and stored in electronic health records. This negative assessment can still be mitigated, but coordination with the Regulation on horizontal cybersecurity requirements for products with digital elements (Cyber Resilience Act) is crucial to at least partially address the critical issues.

**Keywords:** Cybersecurity, Electronic health records, Health data, Wellness device.

*notizie di POLITEIA*, XLI, 158, 2025. ISSN 1128-2401 pp. 45-59