Cybersecurity, AI, Open Access, and Human Data

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Within the framework of the European data strategy (European Commission. European Data Strategy (2020), (eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_it), the establishment of European data spaces per specific domains (e.g., the European Health Data Space - EHDS) have been proposed with the concomitant strengthening of regulations for governing cybersecurity.

The European Health Data Space aims to create a common space where individuals can easily control their electronic health data by defining directly applicable common rules and principles. It will also enable researchers and policymakers to use such electronic health data reliably and in compliance with privacy regulations.

The sectionalization of data movement spaces has led to increased legislation on cybersecurity, in addition to the GDPR, the EU Institutions have improved the regulation on artificial intelligence, the proposal for data governance regulation, and the proposed regulation on data, Directive (EU) 2016/1148 concerning the security of network and information systems (NIS Directive). The new legal framework is operating within a scenario where the principles of Open Access, Open Science, and FAIR principles are increasingly affirmed. The principles to be introduced within the European legal framework will impact the application of Open Science, Open Access, and FAIR principles. The impact of the ongoing regulatory adoption will also be significant in the context of research projects that concern human data. In particular the Genome Data Infrastructure (GDI) project which will enable access to genomic, phenotypic, and clinical data across Europe. GDI aims to establish a federated, sustainable, and secure infrastructure to access the data. It builds on the outputs of the Beyond 1 Million Genomes (B1MG) project to realize the ambition of the 1+Million Genomes (1+MG) initiative. Additionally, the ELIXIRxNextGenerationIT project for empowering the Italian Node of ELIXIR, the European Research Infrastructure for Life Science Data, has the primary goal of enhancing six platforms: Data, Compute, Tools, Interoperability, Omics, and Training, and integrating the activities of the national infrastructure dedicated to Systems Biology. This contribution aims to outline the legal framework currently being defined and verify the impact of regulations on research activities in the field of Biological Data.