“Health Data: quality and governance”

Secondary use of health data in research: The complexities of EU data governance

Maria Christofidou
i~HD Early Stage Researcher

The European Commission has, since the introduction of the General Data Protection Regulation (GDPR), made efforts towards the implementation of policies and regulations which are fit for the digital age while also ensuring trustworthy and safe use and reuse of data. Some examples that can act as testaments to this include the recent adoption of the Data Governance Act (‘DGA’) by the responsible European Parliament committee and its upcoming vote by the European Parliament, the new Medical Devices Regulation, the Proposal on AI as well as the Data Act Proposal, all of which can be interconnected when it comes to data use and secondary use in the field of innovation in healthcare.

The DGA is the first of a set of measures announced in the 2020 European strategy for data and offers a new form of data governance through the establishment of an alternative model to the data-handling practices of the big technology platforms. An aspect of this model is the provision of a framework for sharing data on “altruistic grounds” stating that individuals and organizations can engage in data altruism. The DGA is aimed at overall better exploiting the potential of ever-growing data in a trustworthy European framework while keeping the GDPR as one of its integral parts. However, in spite of the promising steps taken towards regulating and furthering innovation, the criticisms over the difficulties that the GDPR poses towards secondary uses of health data for research are by no means novel and still remain unresolved. The guidelines issued by the European Data Protection Board as well as the creation of the European Health Data Space and the introduction of the DGA framework hold great promise yet also come with skepticism as to their actual effectiveness and grammatic use.

Considering the upcoming vote on the DGA by the European Parliament, the interconnection of the DGA with the GDPR play a vital role considering the data protection and privacy implications play in this field. This paper aims to provide an updated and detailed review of data protection legislation that would be applicable in the space of European health data reuse alongside with views that stem from research. The findings and recommendations in this paper are a result of a review of the literature as well as learning taken from participations in European funded projects.