

GDPR implementation in healthcare: an analysis of the role of soft law and actor networks

Summary

The introduction of the GDPR in 2018 set rules and principles for organizations processing personal data and needing to comply. It is complemented by national laws and soft laws, which the GDPR promotes due to the complexity of the regulation and the need to adapt it to the specificities of different sectors. This is particularly true for organizations that process sensitive data, such as the healthcare industry, which is one of the organizations most affected by the GDPR (Costina & Corobană, 2021). The aim of the research is twofold. First, we want to analyze the power relations between the stakeholders implementing the GDPR in the health sector through the production of soft laws. We want to know who the most influential actors are and how it is reflected in terms of soft law production and the place occupied by data protection compared to the other health rights. Then, we want to analyze the macro and meso factors that enable or prevent compliance with the GDPR in healthcare organizations. To this end, we will conduct case studies in France, Sweden, and Switzerland, three countries that differ in the regulation of their healthcare systems and in their traditions of soft law regulation. For each country, we analyze the production of soft law in the health sector, the network of actors and the compliance of selected healthcare organizations using document analysis, questionnaires, and interviews. We expect theoretical implications on the role of soft rules in the context of implementing a European regulation, but also practical implications in terms on how to improve compliance. Many unforeseen effects are to be expected.