Abstract

Transparency can lack an adequate conceptualization for the context in which it is being applied. According to this thesis, positive outcomes may nevertheless be expected from its application. Through a critical analysis, the thesis reveals that transparency is context dependent, even within sectors such as the biomedical research literature or legal frameworks such as the General Data Protection Regulation (GDPR). When the GDPR was adopted, transparency was introduced as an independent principle with detailed provisions on which information should be provided to data subjects, cf. Art. 5(1)(a), cf. Art. 12-14 GDPR. The term 'transparency', is however not defined in the GDPR and is indeed referred to in various other provisions of the Regulation. Through a critical analysis of the GDPR, this research provides a working definition of transparency when applied to the relationship between a data controller who uses clinical data for the purposes of biomedical research and a data subject. Transparency in this context means (1) disclosure, access, or communication of (2) procedural-like conditions that are further stipulated in the Regulation and which may entail (a) effective and (b) timely revealing of content. Against this background, the thesis examines the regulatory purposes and legal scope of the GDPR's transparency conditions when clinical data is processed for biomedical research. It examines whether the conditions are appropriate and sufficient to effectively achieve the regulatory purposes and identifies the factors that could influence the outcome of the conditions.

The research demonstrates that transparency is established and introduced in the GDPR to strengthen individuals' rights. This was considered essential to establish the trust necessary for the digital economy. Furthermore, the thesis examines the legal scope of the transparency conditions when clinical data is processed for biomedical research purposes. The analysis shows that sufficient disclosure of clearly formulated information is beneficial for data subjects in biomedical research to exercise their rights. Such disclosure should be framed and perceived as procedural requirements, applied relationally to their context and considering the identified factors that can have an impact on whether the conditions can effectively achieve their regulatory purposes.

Based on the analysis, the thesis lays out minimum content standards that should be disclosed to data subjects whose clinical data is being processed for biomedical research purposes. The thesis highlights the importance of differentiating between the purpose of strengthening individuals' rights, and moral values such as trust. It demonstrates the challenges in associating transparency with perceptions, values and beliefs, and argues that such (naturalized) discourses should be avoided as a rationale for lawmaking.