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Risk Mitigation of Data Causality Analysis Requirements AI Act

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Abstract : Artificial Intelligence has the potential to create and already creates enormous value in healthcare. Prescriptive systems might be able to make the use of healthcare capacity more efficient. Such systems might entail interpretations that exclude the effect of confounders that brings risks with it. Those risks might be mitigated by regulation that prevents systems entailing such risks to come to market. One modality of regulation is that of legislation, and the European AI Act is an example of such a regulatory instrument that might mitigate these risks. To assess the risk mitigation potential of the AI Act for those risks, this research focusses on a case study of a hypothetical application of medical device software that entails the aforementioned risks. The AI Act refers to the harmonised norms for already existing legislation, here being the European medical device regulation. The issue at hand is a causal link between a confounder and the value the algorithm optimises for by proxy. The research identifies where the AI Act already looks at confounders (i.a. feedback loops in systems that continue to learn after being placed on the market). The research identifies where the current proposal by parliament leaves legal uncertainty on the necessity to check for confounders that do not influence the input of the system, when the system does not continue to learn after being placed on the market. The authors propose an amendment to article 15 of the AI Act that would require high-risk systems to be developed in such a way as to mitigate risks from those aforementioned confounders.

Keywords : AI Act, healthcare, confounders, risks
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