Dominik Geller

Master Thesis
Evolving Applications of Artificial Intelligence in Pharma: Key Regulatory and Legal Challenges

Abstract

In this paper we explain the basic principles of narrowly defined artificial intelligence (AI) and typical applications of this technology in pharma companies. We describe and evaluate key challenges of manufacturers who develop, produce and market such AI applications in the healthcare sector from a legal and regulatory perspective. AI as a technology, its use and the related regulatory environment are evolving fast. We consider selected key current and emerging international and national laws and regulations with regard to AI and their intrinsic challenges, to which we also put forward recommendations to prepare for anticipated developments. We show the important role of a current, state of the art Quality Management Systems and point at how the re-identification risk of patient data with ever growing combination of datasets can be addressed. Further, we elaborate on the potentially growing importance of copyright protection of data collections, notably when used for AI training.