Abstract

Clinical trials aim at finding new treatments to improve patients lives. These trials rely on patients clinical data which is particularly sensitive and raises privacy concerns, especially in the context of rare disease such as Motor Neuron Disease (MND) which motivates this research project. An approach to empower patients gaining control over their data consists in requiring their consent with particular clauses regarding data (e.g. what data is shared, with who, for what purpose). This dissertation investigates the usage of blockchain to manage patients consent in clinical trials.

An iterative and multidisciplinary literature review is conducted to determine methods, models and regulations in place for consent management in clinical trials with a focus on the European Union (EU). State-of-the-art usage of blockchain in clinical trials is also reviewed and results in the identification of a knowledge gap that exists. While intrinsic properties of blockchain makes it interesting to address patients consent management (e.g. decentralised, privacy- and integrity-preserving, tamper-proof), this approach currently lacks of evaluation regarding its compliance with regulations such as the GDPR. Furthermore, it is unclear from previous work what exactly should be the scope of the blockchain for managing patients consent in clinical trials. The design-science framework and the underlying notion of *wicked problems* are followed to design an artifact which addresses the sole problem of patients consent management while maximising its interoperability with other artifacts.

In this dissertation, a prototype of a Blockchain as a Service (BaaS) for consent management is designed and implemented, and its compliance with regulation is evaluated with the example of the GDPR. It results in a functional BaaS which demonstrates feasibility as well as fulfilment of the requirements (i.e. implementation of consent clauses and compliance with the GDPR). The prototype provides with encouraging results, although it raises limitations that are discussed. This dissertation paves the way for future work and investigation to solve related (sub)problems by designing further artifacts.