Chapter 11
Blockchain and Clinical Data Economics:
The Tokenization of Clinical Research in the EU

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ABSTRACT

Clinical research evolved side-by-side with technology, leading to exponential data generation contributing to social and economic development. Nevertheless, data storage, integrity, and privacy concerns have emerged, raising trust issues regarding data sharing. This chapter will demonstrate how blockchain technology (BT) can address these problems and help optimizing processes, minimize costs, and monetize data. It will explain why these models are not fully explored and how cryptocurrencies are advantageous compared to traditional currency. Worldwide examples of companies developing network infrastructures that rely on private players will be provided, and European cases, where consortium models that count with different partners to build health blockchain infrastructures are being developed, will be discussed. Considering the business models to be addressed under the European Union (EU) jurisdiction, a hypothetical BT-based healthcare model with potential application in the EU scenario will also be highlighted.

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INTRODUCTION

In 1956, IBM launched IBM 305 RAMAC, the first computer with a hard drive weighing over 900 kg, but this supercomputer could only hold around five megabytes of data (Bhushan, 2018; Lesser & Haanstra, 2000). In 2007, 51 years after the first computer, a hard disk drive (HDD) reached one terabyte size, while only two years later, that capacity doubled. Ten years later, the largest commercially available HDD can store at least 15 terabytes. Electronics have increasingly become much smaller, powerful, and cheaper. The American businessman, engineer, and co-founder and chairman *emeritus* of Intel Corporation, Gordon Moore, had predicted this exponential growth in 1965, saying that a computer processor speed would double every two years (Moore, 1998). It can be perceived how accurate Moore's Law was, as technology exponentially evolved as predicted.

Nowadays, data and technology are a crucial part of our daily life. Simple actions, such as calling someone on the phone, or even paying for lunch using a bank card, rely on digital technology. It is safe to say that humans would not be able to grow on a scientific, industrial, and economic basis as effectively as we did if it was not for the advancements in technology. As human civilization demanded, technology got more intricate and subtle, becoming almost imperceptible.

Digital technology has evolved in every sector, and the healthcare field is not an exception. Clinical research has grown side-by-side with technology development, leading to an exponential increase in data generation and analytics worldwide. Clinical trials are a significant part of the clinical research world. Nevertheless, it is essential to note that clinical research comprises a continuum of studies involving healthy people, patients, diagnostic clinical data (such as biopsies), or specific populations (with a particular pathology, per example). It includes biomedical research, observational studies, translational research, genetic diagnosis, health promotion, real-world evidence (RWE) studies, and even health services research (outcomes and economic analysis) (Coorevits et al., 2013; Salber, 2002). All these steps are under the umbrella of the "clinical research" concept, having the common goal of contributing to disease prevention, diagnosis, and treatment. Therefore, massive amounts of data are generated, analyzed, stored, and accessed daily to achieve this objective.

Along with the clinical research data exponential, several social and economic opportunities have emerged. The use of the most up-to-date and trustworthy clinical data in the healthcare sector provides an advantage to all involved parties, including patients, researchers, pharmaceutical companies, and even the government (PwC Portugal, 2019). Regarding patients, early access to innovative therapies is one of the most significant benefits of a better quality of life. On the scientific community side, clinical research leads to knowledge acquisition, scientific publications, higher recognition by other entities, and collaborations. From a governmental perspective, clinical research can boost economic development.

Moreover, access to better therapies can significantly reduce healthcare expenses while creating an attractive environment for international investment entry that boosts the national economy. Unfortunately, all this potential is not fully explored, partially due to the lack of data reproducibility (Eisner, 2018; Resnik & Shamoo, 2017). Additionally, data sharing, personal data privacy concerns, and patient enrolment also present significant challenges for contemporary clinical research and its development (Benchoufi & Ravaud, 2017). All these factors lead to trust issues between the parties involved in this data-sharing system, and blockchain technology (BT) has emerged as a viable solution.