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論文審査の要旨（2000 字程度）

This doctoral thesis entitled ‘The Impact of Innovation and Regulation on the Formation of the Digital Health Industrial System’ examines the evolution of healthcare in the digital era, with a particular focus on digital health as a pivotal component of healthcare’s digital transformation (Dx). Digital health, broadly defined as the utilization of digital technologies to enhance health and well-being, has evolved significantly—from telemedicine in the 1970s to the integration of predictive analytics, personalized medicine, and the Internet of Things (IoT) since 2015. It addresses critical challenges such as reducing healthcare costs, improving accessibility, and fostering transformative innovation in business models.

Chapter 1 provides an introduction to the study. Historically, research on healthcare Dx has largely concentrated on operational dimensions, often neglecting the strategic and industrial aspects essential for a holistic understanding of the field. This study seeks to bridge this gap by exploring the business models, external alliances, and regulatory impacts underpinning digital health. Using diabetes as a case study, the research offers insights into prevention, diagnosis, treatment, and management, focusing on the processes and dynamics underpinning industrial system formation. This doctoral thesis comprises three studies, each addressing a specific aspect: business models, external alliances, and the influence of regulations on innovation.

In Chapter 2, the first study identifies key technology companies within the digital health ecosystem related to diabetes and classifies their business models. By analysing a dataset of 231 entities and 331 contractual agreements, network analysis reveals central players in the alliance network, including Glooko, DarioHealth, Welldoc, Voluntis, OneDrop, IBM Watson Health, Fitbit, and Noom. These entities exhibit three principal value delivery models: (i) Intermediary Model: platforms that connect patients and providers to facilitate data sharing; (ii) Substitute Model: predictive analytics solutions that augment physicians’ roles; and (iii) Direct-to-Consumer Model: health management solutions marketed directly to consumers. The study underscores the role of technology companies in driving innovation through novel business models, offering insights into the dynamics of digital transformation within regulated industries.

In Chapter 3, the second study investigates the development, characteristics, and impact of alliance networks in the digital health sector. An analysis of temporal changes from 2010 to 2020 highlights a structural evolution. In 2010, pharmaceutical and medical device companies were central to the network. However, technology companies began to enter the ecosystem around 2015, and by 2020, these companies had established networks with pharmaceutical firms, medical device manufacturers, healthcare providers, and other industries. Firms with high network centrality shared several traits: (i) they were technology, pharmaceutical, or medical device companies; (ii) they were geographically proximate to the US Food and Drug Administration (FDA); and (iii) they possessed the capability to develop and market Class III medical devices. This study highlights the strategic significance of proximity to regulatory bodies and the ability to market advanced medical devices in driving innovation and fostering alliance networks. It provides a framework for understanding the strategic behaviour of leading firms in digital health.

In Chapter 4, the third study examines the differing strategies for fostering innovation and leveraging regulations, using representative digital platforms within digital health as case studies. A qualitative analysis of Fitbit and Apple Watch investigates their approaches to product development, market development, and

business development through the lenses of strategic trajectory, competition and coexistence mechanisms, and the interplay between regulations and innovation. Fitbit pursued a path-dependent strategy, securing early market entry, while Apple Watch adopted a path-creation approach, leveraging emergent regulations to establish itself as a leader in subsequent market entries. Apple combined an open strategy to engage complementors with a closed strategy for its core product, ensuring regulatory compliance and avoiding excessive diversification. This study identifies three primary drivers of growth strategies for digital platforms in highly regulated industries: open strategies for engaging complementors, closed strategies for maintaining focus on core products, and path-creation strategies that align with regulatory frameworks. The findings extend existing understandings of open and closed strategies by emphasizing their application to regulatory compliance and ecosystem development.

Chapter 5 concludes this study. These studies explore the dynamics of industrial system formation in digital health. They demonstrate how the entry of technology companies into the ecosystem has stimulated the growth of alliance networks and innovation through novel business models. These networks have facilitated the research and development of digital health products while highlighting the importance of proximity to regulatory bodies such as the FDA. Early entrants benefited from path-dependent strategies, whereas later entrants achieved success through path-creation strategies that rapidly adapted to evolving regulations. The trajectory of digital health reflects a paradigm shift from treatment-centred approaches to prevention-focused care, and from physician-led to patient-centred healthcare. This research underscores the pivotal role of monitoring regulatory developments, which drive subsequent transformations in business models and alliance networks. Participants in the digital health landscape must proactively identify and capitalize on emerging opportunities in this dynamic environment.

This thesis contributes to the study of digital transformation in regulated industries by providing insights into novel business models tailored to digital health, offering practical strategies for establishing external alliances, and elucidating growth strategies for digital platforms navigating complex regulatory environments. Based on the aforementioned, the present research merits the award of a Doctor of Management of Technology.