

論文 / 著書情報
Article / Book Information

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種別(和文)	論文要旨
Type(English)	Summary

論文要旨

THESIS SUMMARY

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Department of, Graduate major in	イノベーション科学 コース	Academic Degree Requested	Doctor of
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Student's Name		Chief Examiner	

要旨 (英文 800 語程度)

Thesis Summary (approx.800 English Words)

This doctoral thesis entitled ‘The Impact of Innovation and Regulation on the Formation of the Digital Health Industrial System’ explores the evolution of healthcare in the digital era, focusing on digital health as a key component of healthcare’s digital transformation (Dx). Digital health, defined as leveraging digital technologies to enhance health and well-being, has progressed from telemedicine in the 1970s to predictive analytics, personalized medicine, and IoT integration since 2015. It addresses critical challenges like reducing healthcare costs and improving accessibility while promoting transformative business model innovation.

Healthcare Dx research has historically concentrated on operational aspects, neglecting the strategic and industrial dimensions necessary for a comprehensive understanding of the field. This study aims to fill this gap by examining the business models, external alliances, and regulatory impacts that form digital health. Using diabetes as a case study, the research provides insights into prevention, diagnosis, treatment, and management, focusing on the processes and dynamics of industrial system formation. This doctoral thesis consists of three studies in the chapter 2,3 and 4, each focusing on one of the following aspects: business models, external alliances, and the impact of regulations on innovation.

Chapter 1 introduces the research background as the above.

Chapter 2 identifies key technology companies within the diabetes-related digital health ecosystem and categorizes their business models. By analyzing a dataset of 231 players and 331 contracts, network analysis revealed companies such as Glooko, DarioHealth, Welldoc, Voluntis, OneDrop, IBM Watson Health, Fitbit, and Noom as central players in the alliance network. These companies exhibited three main value delivery models: (i) Intermediary Model: Platforms connecting patients and providers to share data, (ii) Substitute Model: Predictive analytics that complements physicians’ roles, (iii) Direct-to-Consumer Model: Health management solutions marketed directly to consumers. The study highlights the role of technology companies in driving innovation through new business models, providing insights into the dynamics of digital transformation in regulated industries.

Chapter 3 investigates the formation, characteristics, and effects of alliance networks in the digital health sector. Observing temporal changes in these networks from 2010 to 2020 revealed a structural shift that pharmaceutical and medical device companies were at the center of the network in 2010, technology companies began to enter the ecosystem around 2015, and technology companies formed networks with pharmaceutical companies, medical device companies, healthcare facilities, and other industries in 2020. Companies with high network centrality shared key traits: (i) technology companies, pharmaceutical companies, or medical device companies, (ii) proximity to the FDA, and (iii) the ability to develop and market Class III medical devices. This study emphasizes the significance of proximity to the FDA and the ability to develop and market Class III medical devices in driving innovation and fostering alliance network, offering a framework to understand the strategic behaviors of prominent companies in digital health.

Chapter 4 aimed to understand the differences in strategies for promoting innovation and leveraging regulations, using representative digital platforms in digital health as case studies. To achieve this goal, a qualitative analysis was conducted on the product development, market development, and business development characteristics of Fitbit and Apple Watch. These were examined through the lenses of strategic trajectory, mechanisms of competition and coexistence,

and the relationship between regulations and innovation. Fitbit employed a path-dependent strategy to secure early market entry, while Apple Watch adopted a path-creation approach, leveraging new regulations to establish itself as a pioneer in subsequent entries. Apple also combined an open strategy to engage complementors with a closed strategy for its core product, ensuring regulatory compliance and preventing excessive diversification. The study identifies three key 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 through collaboration with regulatory authorities. This research extends the understanding of open and closed strategies by emphasizing their application to regulatory compliance and ecosystem development.

Chapter 5 summarizes this thesis. This thesis collectively explores the dynamics of industrial system formation in digital health. They reveal how technology companies entering the ecosystem have driven alliance network growth and innovation through new business models. These networks facilitated the research and development of digital health products while emphasizing proximity to regulatory authorities like the FDA. For early entrants, path-dependent strategies were effective, but late entrants benefited from path-creation strategies that swiftly adapted to emerging regulations.

The trajectory of digital health highlights a paradigm shift from treatment-centered approaches to prevention-focused care and from physician-led to patient-centered healthcare. This research underscores the critical role of monitoring regulatory changes, which drive subsequent shifts in business models and alliance networks. Digital health players must proactively identify and leverage new business opportunities within this evolving landscape.

This research contributes to the study of digital transformation in regulated industries by offering insights into new business models tailored for digital health, providing practical strategies for forming external alliances to support these models, and highlighting growth strategies for digital platforms navigating regulatory landscapes.

備考：論文要旨は、和文 2000 字と英文 300 語を 1 部ずつ提出するか、もしくは英文 800 語を 1 部提出してください。

Note: Thesis Summary should be submitted in either a copy of 2000 Japanese Characters and 300 Words (English) or 1 copy of 800 Words (English).

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