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Case Study 1

STANDARDISATION TRAINING ACADEMY

Topic:

Impact of standards on market creation: Case of medical/healthcare robot HAL by Cyberdyne

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1 Introduction

Innovations based on integration of cyber-physical space, for example artificial intelligence (AI), robotics, and the internet of things (IoT), are taken place and rapidly changing our lives. Rapid diffusion of emerging technologies can entail risks and uncertainties from a safety aspect and the governmental bodies had been managing such risks by means of regulation. Increasingly, it falls short on responding to new technologies, as the rate of change and degree of uncertainty augmented. These can pose challenges to government in dealing with disruptive innovation because such innovations often do not come under the existing product categories nor corresponding regulations.

Certainly, regulation has been influencing the innovation process and even shaped the future competitiveness of the firm (Porter and van der Linde, 1995 among others); however, few literatures refer to the relationship with safety standards and the market expansion. The points can be further discussed that how comprehensive is a scope of standards, and how standards serve as a dynamic platform on the development process. It also makes the analysis deeper to discuss institutional arbitrages from the view point of global market entry/market creation. Thus, this study will answer how standards can impact on market creation of a new product based on emerging technologies, overcoming existing regulatory barriers on safety.

To address the research question, closely examined is the case of Cyberdyne, a medical/healthcare robotics company in Japan, the main product of which is the world's first wearable device based on enhanced human-machine-information hybrid systems. The company produced a product, using the technology contributed to build an international safety standard, ISO 13482. Finally, the case illustrates that standards will be beneficial to all involved parties, facilitating market entry and competition, and serving as a stepping stone to expand an industrial base under an embryonic phase, thereby creating a new market. It concludes with an exploration of policy considerations to set a regulatory mechanism for experimentation and enhance firms' commitment to rulemaking.

The paper consists of following sections: an introduction; theoretical reviews concerning regulations, standards, and relation between them; a description of the methodology and research question; examination of the case of Cyberdyne and ISO1348, followed by discussion, policy implications and conclusion.

2 Theoretical Discussions

2.1 Emerging technology and challenge to regulatory institutions

Recently, emerging technologies are considered to have created an innovation paradigm shift (Kodama, 2018). Some studies emphasize disruption and radical aspect of innovation (Christiansen, 1997), while others emphasize cumulative aspects in the form of transformations effected by business models (Kodama, 2018). Both, albeit working from different perspectives, identify serving "non-consumers (of emerging innovation)" and providing unprecedented products or services as noteworthy outcomes (Christiansen, 1997, Kodama, 2018).

As these innovations are unprecedented, many of them are currently managed under potentially, "misfit", regulations. Many studies agree that the current regulatory institutions are failing to accommodate the speed and degree of change generated by new technologies (Shapiro and Glicksman, 2002). Several studies posit that regulatory institutions need to be more adaptive and flexible (Dietz et al., 2003). Others argue that regulations should keep pace with technological adaptation processes through collaboration among firms, institutions and users from very early stages of product development (Marchant et al., 2011). These; however, identifies clear entity nor time period for this to take place.

2.2 Current understandings of relation between regulation and innovation

Regulatory institutions are said to influence both the "rate" (quantity) and "direction" (quality) of innovation. Several types of regulation, applied both horizontally (across sectors) and vertically (within specific sectors)—governing trade competition and consumer protection—affect both the speed and the direction of commercialization of new products and services.

There are well established theoretical discussions of the relationship between regulation and innovation. Arguments against regulation governing innovation consider that regulation deters firms from investing in R&D due to the added cost of compliance with regulations (Eads, 1980, Milmo, 2000), and heightened perception of risk (Mansfield et al., 1971). In addition, it is argued that as a regulatory control eliminated firms that were not capable of investing to meet regulations, the innovation "rate" would slow as a result of decreased competition (Davis, 1983).

Other studies hold that regulations aim to intervene in the market, addressing market failure, for socially desirable ends, (Nelson, 1959, Arrow 1962) and that well-designed regulations would induce firms to adopt social innovations (Rothwell, 1980, 1992), which could support the opening of new market opportunities in response to public needs (Ashford and Heaton, 1983, Gerstenfeld, 1977; Howes, Skea and Whelan, 1997). In fact, well designed goal- oriented regulation, rather than prescriptive regulation, would leave greater scope for innovation aimed at the achievement of societal goals, and would eventually enhance the competitiveness of firms (Porter and van der Linde, 1995).

These points have been echoed in recently revived discussion of the importance of the demand-side approach in innovation policy. The goal-oriented regulation considers governmental regulatory requirements as an important policy instrument for advancing sustainable and societal agenda (Edler and Georghiou, 2007; Nemet, 2009). Such an approach assumes that the state has a clear image of desirable ends of the potentials of innovation and technology in question (Rothwell and Zegveld, 1981).

The main regulatory areas related to sustainable and societal agenda are health, safety, and the environment (Sharp and Pavitt, 1993). In particular, innovations in health sector is regulated at a national level to ensure the safety of potential users/consumers (Consoli and Mina, 2009) even today; thus innovation in that sector is still greatly influenced by regulation (Nelson and Sampat, 2001). These regulations are also often highly path dependent and idiosyncratic hence coordination poses a big challenge (Tate, 2001).

2.3 Function, role and classification of standards

Standards, one tool of regulatory institutions, are initially used as external points of reference in the assessment of the performance, quality, and physical characteristics of products, standards have supported product operation and thus promote the implementation of mass production systems (Hawkins et al., 1995, Blind and Gauch, 2009, BERR, 2008). Standards have been also useful for reducing information asymmetry between buyers and suppliers, and hence reducing transaction costs (Blind and Gauch, 2009). The presence of reference points have offered clear guidance to companies working to catch up and upgrade their production capability. The frequent entry of firms would reduce product cost, in turn benefiting the consumers (Henson and Jaffee, 2007, Henson and Humphrey 2009, Iizuka, 2009). Standards are further applied to the international coordination and governance of disintegrated segments of interdependent activities along value chains (Hawkins et al., 2017, Henson and Humphrey, 2009). Such changes took place in the 1990s due to globalization, and in that context, the use of standards gradually increased, as can be seen from the increase in adoption of ISO standards since the 1990s, in terms of both areas of coverage and number of entities obtaining certificates (ISO, 2017).

With the emergence of information technology (IT), standards are said to play a new role: serving as a platform for the coordination of firm activities (Blind, 2016, Steinmueller, 2016, Hawkins et al., 2017). That platform can support firms' interactions with customers, buyers and sellers beyond traditional sector boundaries, hierarchies and national borders. In sum, the functions of standards have extended from the original emphasis on 1) interfaces and compatibility; 2) minimum quality/safety; 3) decreased variety; and 4) production description information (Swann 2000:12), to a dynamic platform connecting different segments of industrial activity (Steinmueller, 2016).

Table 1: General effects of standards on the innovation process

Type of	Positive effects	Negative effects

standard		
Compatibility/ interface	Provides network externalities Avoids lock-in of old technologies Increases variety of systems products Makes global value chains more efficient	Allows monopolistic power Locks in old technologies if network externalities are too strong
Minimum quality/safety	Corrects adverse selection Reduces transaction costs by creating trust Prevents negative externalities	Generates regulatory capture by raising rivals' costs
Harmonization/ variety reduction	Allows economies of scale and reduces unit cost Builds critical mass in emerging technologies, products and services	Reduces choices Generates market concentration Makes premature selections
Information	Provides codified knowledge Reduces transaction costs, information asymmetry	Enables regulatory capture
Interoperability /Platform	Enables collaboration Supports consumer participation Creates dynamic ecosystems for new business	Leads to platform dominance Lacks regulatory control of consumer participation

Source: Based on Blind (2010), Hawkins et al. (2017), Steinmueller (2016)

Along distinct stages of industrial life cycles, namely, fluid (embryonic), transitional and specific stages, standards play different roles (Freeman and Soete, 1997, Utterback and Abernathy, 1975, Klepper, 1997, Anderson and Tushman, 1990): first, they create open and transparent regulatory platforms to reduce risks related to the use of emerging technologies while at the same time ensuring minimum standards; second, they create products and improve their quality in open access form so that diverse participants can be included and compete; and third, they ensure positive externalities by means of good governance (Edler and Georghiou, 2007).

Standards can be classified into three types: first, de-facto standards whose specifications are determined by market competition (e.g. Schilling, 2002, Suarez, 2004); second, de jure standards whose specifications are agreed by formal committee based institutions with stakeholder participants (e.g. ISO) (Jain 2012; Narayanan and Chen, 2012); and third, government-based standards (e.g. Buthe and Mattli, 2011), which are de jure standards devised and monitored by government within the nation's borders (Wiegmann et al.,2017). The third type is closer to regulation in the traditional sense, while the first and second are increasingly being employed in response to globalization of firm activities (Dan, forthcoming). Much studies were done on market competition based de-facto standards to understand firm strategy, associating with obtaining the "dominant design" and platforms (Gallagher, 2012; den Hartigh et al., 2016) with examples of competing innovations (blue-ray vs HD-DVD vs DVD, IBM vs Apple). Similarly, studies on committee based standards are also being conducted to understand its impacts on innovation, firms' strategic decision and knowledge diffusion (Manders et al., 2016), however, less attentions have been given to regulatory aspects of standards that ensure levels of safety in use of emerging technologies.

2.4 Increasing roles of standards in a new era

As mentioned, standardization process is considered to mediate and catalyse emerging innovations, connecting actors beyond national and sectoral boundaries (Featherston et al., 2016). It has been observed that, with the growing global interdependence of knowledge in the form of networks, the value of innovation has shifted from knowledge creation to knowledge diffusion (Blind, 2016). In this new context, standards, rather than some national regulatory forms, can provide more space for coordinating and facilitating participation by multiple stakeholders in voluntary consensus creation (Steinmeuller, 2016) , and international standards institutions such as the International Organization for Standardization (ISO) will serve as a dynamic interface (Blind, 2010, 2012, Steinmueller, 2016, Tassey, 2017). Under the institutions such as ISO, standards' setting processes can be open and transparent, offering a flexible form of technological governance (Borras and Edler, 2014, Wiegmann et al., 2017).

Additionally, systems level standardization has been widely prevailed. According to ISO Survey (2017), the use of ISO management system standards (in terms of number of valid certifications) continues to rise; in 2016 it increased by 8% across all industry sectors. The scope of management system standards is not a product nor something sector-specific; the concept is broader, covering inter-related areas of businesses to facilitate integrated solutions. For example, standards for "Sustainable cities and communities" (ISO/TC 268) was set up through the participation of more than 50 countries around the world. Similarly, ISO/IEC 27001 and ISO/IEC 27002, information security management system standards to help organizations address security and privacy issues, are now being set up. In sum, standards are increasingly covering issues at the systems level in society (e.g. safety, sustainability, IT security) rather at product and technology levels. The systems approach is considered to be important for following reasons: (1) more value is created by systems

than by individual devices (c.f. “think systems not technologies”) (Aikman, 2017, WEF, 2018); (2) strategic importance is attached to achieve a dominant platform (“Winner-takes-all”) (METI, 2016). [1]

2.5 Firm behaviour under misaligned institutions

In the 1990s in the context of increased internationalization of firm activities, in “Varieties of Capitalism", firms engage in distinctive behaviours due to differences between the institutions where the firms are embedded, since firm actions are motivated not only by economic efficiency, but also by institutional advantage (Hall and Soskice, 2001). In other words, some elements of institutional conditions help particular industries to grow because those elements reinforce certain actions. Conversely, certain institutional conditions prevent firms from growing because they constitute barriers. Following that logic, it is considered that firms operating under global competition tend to engage in institutional arbitrage, i.e. they “...may shift particular activities to other nations in order to secure the advantages that the institutional framework of their political economies offer for pursuing those activities” (Hall and Soskice, 2001:57). Hall and Soskis claim that such cases of institutional arbitrage are more prevalent in countries where societal coordination is a prerequisite for institutional change (Witt and Lewin, 2007). Nowadays, firms are operating in an increasingly competitive global market characterized by rapid technological change. Variances in speed of change at different technological and institutional levels could be grounds for institutional arbitration by firms looking overseas for more favourable institutional settings to develop their activities employing new technologies. Firms must adapt to that rapidly changing global environment if they are to gain market access.

[1] Based on above thinking, the Japanese Industrial Standardization Act, which was revised in 2018, covers management, service and social systems. Those regulatory institutions are expected to adapt to technological change via private-public collaboration in the context of international standardization (METI, 2018). This case study predates that reform.

3 Research Questions, Methodology, and Case Background

3.1 Research Questions

The literature review in the previous section reveals the following understandings and gaps. While policy space for regulations at a national level had diminished in last decades of liberalization, selected areas where "market failure" occurs—namely health, safety and environmental areas—are still well regulated by the states (Mina and Consli, 2009). Certainly, safety standards, which are one type of regulatory institutions, can influence the innovation process of emerging technologies; however, few literatures refer to its relationship and balance between regulatory safety and the market expansion. The points can be further examined that how expansive is a scope of standards, and how standards serve as a platform for the coordination on the development process. It also makes the analysis deepen to discuss institutional arbitrages at different dimensions from the view point of global market entry/market creation. Based on above, this paper addresses a following question: How will standards impact on market creation of a product based on emerging technology, overcoming existing regulatory barriers on safety?

This paper examines the case of Cyberdyne, a medical/healthcare robotics company in Japan, the main product of which is the world's first wearable device based on enhanced human- machine-information hybrid systems. It is safe to state that the product represents an emerging innovation based on integration of cyber-physical space, and is under the embryonic stage (Utterback and Abernathy, 1975, Anderson and Tushman, 1990). The company contributed to build an international safety standard, ISO 13482 to overcome regulatory barriers after institutional arbitrages on different levels. Among others, it can be stated that Japan's regulatory institutions governing the medical area more rigid and inflexible (Tate, 2001, Ikeda, 2016); however, when it comes to the healthcare (non-medical) area, that seems to be another story. Against all odds, the firm managed to not only entered into the markets inside and outside Japan, but also contributed to the market creation, in other words, broadened the industrial base on the embryonic phase by building an international safety de-jure standard, ISO13482 ("Robots and robotic devices -- Safety requirements for personal care robots"). The following sections will identify that how expansive is the scope of the overarching standard like what is called systems level standards, and how effective was the making process as a dynamic platform connecting different segments. We can also observe that, before standardization at ISO, the company initially took a survey on domestic and international regulatory institutions and then adopted a strategy of institutional arbitrage to overcome above regulatory obstacles.

3.2 Methodology

This study applies a qualitative case study methodology (Yin, 2009), which is suitable for identifying with rich insights from the case of Cyberdyne, standardization process of ISO13482 and the impact on market creation. Several in-depth interviews were conducted with related stakeholders representing distinct areas: government, standardization body, review administration, certification body, insurance company, hospital/user, related firm, academics, think tank, and consulting company (see Appendix 1) during the period June 2015 to July 2016. The interviews were conducted using a semi-structured interview approach in order to allow for open-ended responses. Government policy documents and company reports were used to triangulate information obtained from interviews. And the nations stated through the qualitative approach are Japan and Germany, the foremost runners suffering from aging societies where medical/healthcare services can be highly demanded.

4 Case Study

4.1 About Hybrid Assistive Limb (HAL) and Cyberdyne

This case study depicts the initiative taken by a leading character, Cyberdyne on creating new standards on medical /healthcare Robotics to expand market. The company aimed to introduce Hybrid Assistive Limb (HAL), the world's first cyborg-type medical/healthcare robot, into the market. HAL is a robot that can supplement, expand or improve on the user's physical capabilities, particularly people who have physical mobility difficulties as a result of car accidents, illness or aging. HAL supports and improves the user's physical mobility, monitoring the user's center of gravity to infer intended body movement and direction of movement. Sensors attached to the skin pick up bio-potential signals generated in the brain immediately after the user attempts muscle movement, and operates motors incorporated in the user's joints. The technology is based on cybernics, a frontier research area whose products have no antecedent (Cyberdyne, 2017a). Cybernics is the area where fused are Information Technology (IT), cranial nerve science, behavioral science, robotics, system integration technology, physiology, psychology, MEMS-Technology, neuroscience, bio- system theory and so on, focusing on Cybernetics, Mechatronics, and Informatics. Cyberdyne Inc. was established in Japan as a university start-up company to introduce HAL to the market. The firm grew rapidly [2] after its establishment in 2004. [3] The current sales destination is Japan, extending to overseas markets such

[2] This is a spinoff company of the University of Tsukuba, under the direction of Prof. Sankai. The company was established in 2004 and was listed on the High-Growth and Emerging Stock Market in 2014. The scale of consolidated net sales is about 1.7 billion dollars (exchange rate: 1 US dollar was equivalent to 109 Japanese yen as of 10 June 2018)), increasing by 30% within a few years and still growing. By March 2019, 17% of total sales are from overseas.

[3] It received the Japan Venture Grand Prize and the Prime Minister's Prize in 2017.

as the EU, the US, Saudi Arabia and South-east Asia (Cyberdyne, 2019b). The expansion of their market was not smooth due to under provision of safety standards in medical /health care Robotics.

Leading to a detailed discussion of the overview of ISO13482, the following section summarizes characteristics of emerging medical/healthcare robots in Japan. Here, medical device is defined as "a product, such as an instrument, machine, implant or in vitro reagent that is intended for use in the diagnosis, prevention and treatment of diseases or other medical conditions." [4] Assistive device is defined as instrument for personal care for disable or otherwise unable to care for themselves in managing bodily functions. [5]

4.2 Emergence of medical/healthcare robot sector in Japan

4.2.1 Ambiguous boundaries of emerging products

Medical/healthcare robotics is an emerging sector with high growth potential. Due to the sector's embryonic status, its product boundary is not clearly defined and new products can be classified under multiple categories such as medical devices and assistive devices (amongst many possible categorizations). Such ambiguous product definitions lead to ambiguity in legal status when the products are heading for commercialization. However, once a product is assigned to a specific category, the regulatory institutions influence the trajectory and the rate of innovation (MHRA, 2016). Safety standards, in particular, strongly influence the framing of a technology in the early stages of development (Delemarle, 2017). In other words, the choice of regulatory institution can influence the developmental pathway of embryonic products and technology because regulations can ultimately shape the product.

4.2.2 Product diversity

The application of robotics in the field of healthcare is diverse. These robotic technologies include home automation, ambient intelligence, ubiquitous network societies, and assistive technology (Lau et al., 2009). Figure1 presents the diversity of medical/healthcare robots, classified according to two characteristics: mechanical features (low to high tech) and intelligence (low to high). Conventional assistive technologies are located low on the intelligence scale; such devices can also be AI controlled humanoid-type, seen in the top right-hand corner of the figure. The diversity of product type again confirms the view that health robotics is

[4] Medical robot application of ISO are published in 2019. These are: IEC 80601-2- 77:2019, Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment; and IEC 80601-2- 78:2019, Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation.

[5] ISO defines personal care robot to include: "mobile servant robot, physical assistant robot and person carrier robot. These robots typically perform tasks to improve the quality of life of intended users, irrespective of age or capability." (ISO 13482, 2014)

still at an early, fluid stage of the industrial life cycle, where dominant design is not yet clearly defined and expanding product diversity makes existing regulations increasingly irrelevant.

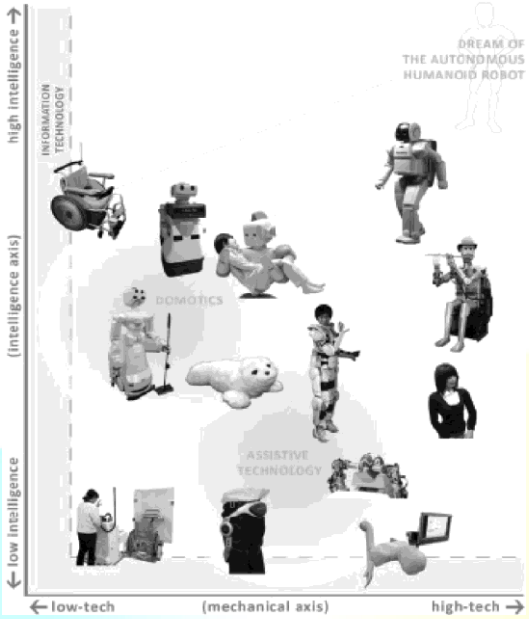

Fig. 1: Diversity of the emerging medical/healthcare/personal care robotics sector Source: Lau et al. (2009)

4.3 Overview of ISO13482

4.3.1 Development process

To create a ISO standard of safety requirements for personal care robots, technical committee (TC) 184/SC2/WG7, a team consisting of more than 50 nominated experts and observers from 12 countries, was created under the ISO in 2011. In the process of negotiating the standard, Japan took the initiative and proposed measures for risk assessment at a systemic level, ranging from the product conceptualization stage to design management and development. Japan's proposal had an advantage: Cyberdyne was already developing personal care robotics and was experimenting with prototype safety measures at the Robot Safety Center, leading to evidences for proof of safety. Japan's proposal to the ISO was supported by METI, NEDO, and Cyberdyne among others. Furthermore, certification of safety standards by Japan Quality Assurance Organization (JQA) helped to spearhead negotiation process (Nabeshima, 2016). Then, Cyberdyne commercialized HAL with the certification by JQA in as early as 2013 when safety standards certified by JQA became equivalent to Draft International Standards (DIS) of ISO 13482. [6] This is because that they were

[6] In reality, Cyberdyne did not wait until the publication of ISO13482 to commercialize. The steps for establishing International Standards (IS) are as follows: 1) A proposal or the standards is approved by relevant

confident that DIS is going to be approved (Government, personal communication, May 11st, 2016). In fact, after the series of discussions among stakeholders, ISO adopted Japan's proposal and issued ISO 13482, standardization titled, "Robots and robotic devices -- Safety requirements for personal care robots," officially published in February 2014.

4.3.2 ISO13482 and impact on market creation

The development of the new standard can guarantee Cyberdyne an early-mover advantage and enhance the global recognition of its product brand (Robotics company, personal communication, April 18th, 2016). But perhaps the most important advantage of ISO 13482 is that it will open up the market for a new generation of robots. The standard is an overarching safety standard, the scope of which is not limited to a single device and comprehensively covers various types of products, acting like a systems level standard. It also sets clear general/minimum safety requirements for health robotics, while leaving ample space for exploration towards innovation and avoiding a lock-in effect at the early stage of product development (Standardization expert/professor, personal communication, March 23rd, 2016). The positive impact is well described by the interview conducted by ISO to the CEO of Cyberdyne. According to him, standards for emerging technology are imperative, especially "...because the world has not seen anything like these robots before, there is no legislation in place to protect users. International standards are therefore crucial for creating and showing confidence to users in these products" (ISO, 2014). Before ISO13482 is created, healthcare robotic devices have been required to comply with high safety regulations similar to those of the medical field, which leads to the entrance barriers to a market. Furthermore,"ISO 13482 is not difficult to apply and should be a good standard for many companies to receive certification and get started in the domain of personal care robots," and thus "the standard levels the playing field for new companies wishing to enter the emerging industry" (ISO, 2014). In sum, ISO13482 is one example where standards can pave the way for innovation. Standardization is considered beneficial to all involved parties, facilitating market entry and competition, and serving as a stepping stone to expansion of the market to global scale (Hawkins et al., 2017).

Also, as stated above, ISO 13482 was established through collaborative efforts involving more than 50 nominated experts and observers from 12 countries. That is, the process of standardization can bring diverse stakeholders together to work towards one purpose. This will be important because frontier technologies (e.g. medical/health robotics) require the collaboration of persons with diverse technological backgrounds, so as to make optimum use of their potential. For instance, in Japan, medical/healthcare robotics

subcommittee(SC) or technical committee (TC); 2)Working group (WG) of experts is set up by SC/TC for the preparation of draft; 3) WG creates working draft (WD) for internal revision; 4) WD becomes committee draft (CD); 5) with positive votes of approval by WG, CD becomes final committee draft (FCD); 6) FCD becomes draft International Standards (DIS) after revision on technical contents; 7) DIS is submitted to national bodies for voting and comments within the period of 5 months for approval to be the final draft International Standards (FDIS); 8) FDIS becomes IS if a two-thirds majority of the members of the TC/SC are in favor and not more than one-quarter of the total number of votes negative (ISO, 2007). It is possible that with a strong technical leadership, it is a matter of time for DIS to become ISO.

development brought together diverse actors: automotive companies (e.g. Toyota, Honda); hospital management electronics corporations (e.g. Panasonic), university start-ups (e.g. Cyberdyne), telecommunication companies (e.g. NTT Docomo), home construction companies (e.g. Daiwa House). In this context, the process of standardization, can provide an open common space where a diverse set of stakeholders beyond national and sectoral boundaries can negotiate and shape an effective regulatory regime. It may also have a signalling power to the regulatory authorities which are slow to change in the time when institutional arbitrages can be accelerated.

4.4 Institutional arbitrages in different dimensions

Cyberdyne wanted to commercialize HAL with public medical insurance coverage. In order to be covered by the public insurance in Japan, it had to comply with a rigorous medical safety regulation with clinical trials. These posed to Cyberdyne some challenges, a procedural burden of collecting clinical trial data and a long time lag before getting government approval. In order to overcome above regulatory obstacles, Cyberdyne adopted the strategy of institutional arbitrage in various forms (Hall and Soskice, 2001).

4.4.1 Product level institutional arbitrage

Cyberdyne initially took advantage of the ambiguous nature of Japanese product classification. In Japan, HAL could be categorized as a medical device or as an assistive device. Each comes under different regulatory institutions.

In Japan, if a new device is categorized as a medical device, it falls under the jurisdiction of the state managed Ministry of Health, Labour and Welfare (MHLW) under the Pharmaceutical and Medical Device Act, and thus requires state-managed approval from the MHLW, based on a long scientific review at the Pharmaceuticals and Medical Devices Agency (PMDA). PMDA basically assesses the safety of products based on previously existing similar medical products, so it is almost impossible for a product like HAL, with no precedent product, to obtain a quick approval. On the other hand, if a device is categorized as an assistive device, it is not subject to review by any sector-specific regulatory authority. For assistive devices, firms usually make use of voluntary standards, such as the Japan Industrial Standard (JIS) T 9201 (safety of manually-propelled wheelchairs) and acquire certification by a private certification body to guarantee reliable business transactions, public procurement and personal purchases (Government, personal communication, May 11st, 2016). And Japan's standardization system is governed under the Japan Industrial Standardization Act (JIS-Act) by the Ministry of Economy, Trade and Industry (METI). Due to the relative ease of obtaining third-party certification under such voluntary standards, this category can be used like a loophole for commercialization of new healthcare devices, which makes companies establish a track record in the market (Asahi Research Center, 2016).

Given the above institutional environment, Cyberdyne first opted to commercialize HAL as an assistive device. [7] Categorization as an assistive device in Japan usually requires proof of safety, certified by a third party on voluntary terms. A typical product must comply with generic standards for devices; however, for a product like HAL, there was no precedent product that could serve as a reference. Hence, Cyberdyne had to create its own proof of safety, to be certified by a third party. This means that Cyberdyne had to collect and analyse data, formulate safety standards, and establish testing methods (Weng, Sugahara and Hashimoto, 2015). This would be an unprecedented undertaking for a start-up company like Cyberdyne.

In order to accumulate evidences for a proof of safety, Cyberdyne sought the support of the Robot Safety Center, a public institution located in the Tsukuba International Strategic Zone (Tokku). The center was jointly established by METI and the New Energy and Industrial Technology Development Organization (NEDO), Japan's largest publicly managed organization promoting research and development and deployment of new technologies. This center facilitated the necessary testing and collected proof of safety data. Eventually, in response to a number of such demands, METI and NEDO jointly launched the Project for Practical Application of Service Robots and in 2009 established the Robot Safety Center, an experimentation laboratory for the verification of safety of new technology, and an international robot certification organization. This project was in place until 2013; in February 2013 HAL was certified by the Japan Quality Assurance Organization (JQA), and could then be commercialized as an assistive device. A set of evidence created during this period became basis for the evidence presented to establish ISO standards on robotics safety. In fact, the certification published by JQA is equivalent to the Draft ISO 13482 (Draft International Standard: DIS) that was published in February 2014.

4.4.2 Country level institutional arbitrage

When Cyberdyne was beginning its effort to get an approval for HAL, there was a little chance of obtaining a quick approval from MHLW, because there are no precedent products similar to HAL. Practically, Cyberdyne would have to wait until another company (outside or large) began commercialization of a similar product in Japan. To overcome that barrier, Cyberdyne commercialized HAL as a medical device in Germany, certified to ISO13485 (Medical devices -- Quality management systems -- Requirements for regulatory purposes), which is one of harmonized standards, necessary for declaration of conformity to essential principles of EU's Medical Device Directive (MDD) [8] (93/42/EEC), Directive for In Vitro Diagnostic Medical devices (98/79/EC) and Directive for Active Implantable Medical Devices (90/385/EEC) by TÜV Rheinland, a private certification body. The clinical trial is also required for Germany; however, unlike in Japan, this comes after the approval (Ikeda and Iizuka, 2019). It may be safe to demonstrate that Cyberdyne took advantage of differences in regulatory systems to commercialize the product quickly.

[7] Here selection of category is by self-declaration (Asahi Research Center, 2016).
[8] The MDD published by the EC shows manufacturers the "essential requirements" and/or "performance levels" and "Harmonized Standards" to which the products must conform. The MDD is transposed into the German Medical Devices Act, called the Medizinproduktegesetz (MPG-"Medical Devices Act")(Ikeda, 2016)

Although Japan and Germany have mandatory regulatory frameworks for medical devices, set by their governmental bodies, they differ in terms of the culture of management of the regulatory environment. It can be said that Japanese regulatory institutions are more paternalistic and dependent on state authority, whereas German institutions value the concept of self-responsibility of each actor (Hospital/doctor, personal communication, March 22nd, 2016). Moreover, the system in Germany is more decentralized, and includes numerous private certification bodies, which enables a quicker certification process. The number of private certification bodies in Germany was about five times that in Japan (German-based certification body, personal communication, April 28th, 2016). Such institutional differences in certification bodies would certainly restrict the speed with which standardization spread among firms. Hence providing support in an innovation-friendly ecosystem would become an increasingly important task for the government.

At the same time, German firms are ready to take on a proactive role in the rulemaking process, preparing proof of safety for new medical/healthcare devices. In fact, some large global firms have their own regulatory affairs division to formulate global business strategies and at times to actively lobby over regulatory issues. On the other hand, in Japan, it is believed that there has been a clear separation of roles: the government establishes regulations based on prior experience, and firms follow those rules (German-based certification organization, personal communication, April 28th, 2016). In Germany, governed by the Medical Device Directive (MDD), a new health device like HAL is categorized solely as a medical device strictly by its function regardless of its risk levels on safety. The review of medical devices is always certified by a notified body (NB), a private institution, hence the procedure is codified, open and transparent. As a result, the time required for approval of new medical devices in Germany became substantially less than in Japan (PMDA, 2018). [9] In August 2013, HAL was certified as a medical device by TÜV Rheinland (a private German certification body), and was subsequently commercialized in Germany and Europe.

4.4.3 Regulatory institutional arbitrage: Creating ISO 13482

As already stated before in section 4.3, parallel to getting HAL certified as a medical device in Germany, Cyberdyne engaged in the creation of ISO standards for safety of personal care robots, including healthcare robots and established ISO13482.

4.4.4 Getting national approval from PMDM

In November 2015, HAL was approved as a medical device by MHLW in line with Japanese safety regulations. Soon after getting approval from PMDM, Cyberdyne filed application to be covered by National Health

[9] Approval of medical device in the US requires 1.9 year less than that of Japan. There is no statistic directly comparing EU and Japan but generally the time required for obtaining certification in EU is even less than in the US. (https://www.pmda.go.jp/files000222042.pdf.)

Insurance. This was granted in September, 2016 (Cyberdyne, 2016). [10] Cyberdyne then began commercialize HAL with public insurance coverage in Japan (Cyberdyne, 2016).

Table 2: Process of institutional arbitrage: The case of Cyberdyne's HAL [11]

Date of approval	Arbitrage between Chosen / Avoided		Place/ certified body	Approve d as/for Market in	Type of regulatory institutions used
February 2013*	Assistive device	Medical device	Japan Quality Assurance Organizati on (JQA), Japan	Assistive device, in Japan	Committee-based standard agreed at national level
Same as above	Draft ISO(13482)** * (ISO 13482 was published in February, 2014)	Gov't based regulation	Same as above	Same as above	Committee-based standard agreed at international level

[10] Different from medical devices, the coverage of National Long-term Care Insurance was not extended to cover HAL as assistive devices. The discussion of extending National Long-term Care Insurance to Robotics for assistive purposes only recently started in order to lessen the burden of care takers and scarcity in numbers (Cyberdyne, 2019).

[11] Note:
*The version certified by JQA became equivalent to Draft International Standards (DIS) 13482.
** ISO 13482 was published in February, 2014. However, as Cyberdyne did not wait and commercialized with DIS.
*** In addition to MDD, the Directive for in Vitro Diagnostic Medical devices (98/79/EC) and Directive for Active Implantable Medical Devices (90/385/EEC). (TUV website https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/medical-devices-and-ivd/quality- management-and-quality-control-for-medical-devices/iso-13485-quality-management-system-for-medical- devices) accessed Sept. 21, 2019.

August2013	Germany ISO13485 harmonized to EU's Medical Device Directive (MDD) (93/42/EEC) etc.***.	Japan Pharmaceutical and Medical Device Act	TÜV, Germany	Medical device, in Germany and EU	Gov't based regulation/standard agreed at Germany and EU
November 2015			MHLW, Japan	Medical device, in Japan	Gov't based regulation agreed at national level

Source: Authors, based on Ikeda (2016)

5 Policy implications

The previous section reveals that standards can be considered beneficial to all involved parties, facilitating market entry and competition, and serving as a stepping stone to expansion of the emerging market up to a global scale. It can be maintained that a regulatory mechanism like Special Zone (Tokku in Japanese) plays a key role in making rules on emerging innovations because it allows actors involved to conduct experimental trials under a deregulated environment and then analyse safety requirements useful for the standardization process subsequently. Also, considering the role of standards as a dynamic platform and the importance of strategically arbitrating various institutional environments to overcome existing regulatory barriers, it will be significant to encourage firms' commitment to rulemaking so that they can take initiatives in that process.

5.1 Set a regulatory mechanism for experimentation

For emerging technologies, the experimentation phase can be more crucial because the products and services using those technologies are unprecedented, and potentially "misfit" regulations may be applied. Hence, firms will require institutional facilities that enable them to conduct experimentations in the early stages of the industrial cycle and the evidence and date gathered there will be useful to think about what kind of regulations and standards well fit. Now, we can find state initiatives both domestically and

internationally to implement such a regulatory mechanism so that they can benefit from creating markets of new innovations.

In Japan, the government provides restricted zones for experimentation with new initiatives by firms employing new technologies. For instance, the National Strategic Special Zone in the Kansai region promotes deregulation of the medical field, in instances such as the effective use of iPS cells (induced pluripotent stem cells). Other examples are agricultural reforms in Niigata City and Yabu City, deregulation of employment to support business formation in Fukuoka City, and deregulation supporting the promotion of international tourism in Okinawa. These Special Zones (Tokku) are areas deregulated to support experimentation towards new innovation and verification of effects and issues for the establishment of appropriate regulatory regimes prior to scaling up. Furthermore, to allow progress beyond special zone work, a regulatory sandbox is implemented in Japan to promote and experiment with new technology such as fintech (financial technology) and the sharing economy. This approach balances innovation and regulations by providing firms with limited-time use of "free space" for testing products, services and business models based on emerging technology, without conventional regulatory requirements, to enable commercialization while government collects the data and experience needed to frame appropriate regulations (FCA, 2017). Regulatory sandboxes are seen as more flexible than special zones, since they take into account the uncertainty of technological transformation.

Some countries have strategically responded to such needs by providing venues for experimentation. For instance, Singapore and the United Arab Emirates are providing demonstration test sites for development of flying cars, autonomous vehicles that can take off and land vertically. Moreover, Singapore is working to become a prime testing location for identifying means by which developed nations can best manage disruptive technologies such as advanced robotics and AI. Furthermore, to attract multinational firms working on autonomous vehicles, Singapore created one of the most permissive regulatory regimes for the testing of driverless cars, even opening up public roads for experimentation.

Similarly, developing countries are strategically inviting high tech start-up firms and offering them a lightly regulated environment to exploit the potential for social impacts generated by emerging technologies. Those firms are attracted by the opportunity to experiment around the use of their products, and to accumulate experiences while responding to societal challenges. For example, a Silicon Valley start-up, Zipline, [12] has been using its drones to deliver life- saving blood in Rwanda within 30 minutes of receiving emergency calls, using advanced logistic services connected to satellite systems. Also, the Japanese start-up drone company CLUE, Inc. has collaborated with the Ghana Highways Authority (GHPA) to provide inspection services for major infrastructural works in Ghana.

Looking from a broader standpoint, the above examples confirm that faster, more agile regulatory governances are needed to keep pace with rapid technological change by enabling experimentation (WEF,

[12] Zipline is also operating in Ghana from May, 2018. The company was participating the U.S. Department of Transportation's Unmanned Aircraft Systems Integration Pilot Program, out of 149 applicants. (Bright, 2019) https://techcrunch.com/2019/04/24/drone-delivery-startup-zipline-launches-uav-medical-program-in-ghana/ Accessed June 15, 2019.

2018, Marchant et al., 2011). The examples also indicate that the important factors of competitiveness are shifting from competitive products to competitive regulatory systems that enable effective governance of emerging technologies, speeding up a market creation of emerging innovations while ensuring public well-being. With rapid changes in technology, to implement a regulatory environment that allows experimentations in the early stages of the industrial cycle is getting more critical for both firms and governments.

5.2 Enhance firms' commitment to rulemaking

Understanding an impact of standards on market entry/market creation, more firms will need to participate in rule-setting processes to ensure their future competitiveness. In addition, as seen in the case of Cyberdyne, in order to overcome existing legislative barriers and conduct an institutional arbitrage from a global perspective, they should be familiar with regulatory institutions including standards. Participation in negotiations for international rulemaking like ISO requires a wide range of skills: technical knowledge, negotiation capability, communication ability in English and familiarity with regulatory frameworks. Thus, it would be useful to support educational programs for firms to help them acquire such skills more swiftly. Delivering lectures on standardization targeting university and college students will be also effective in the long run.

It generally takes two to three years to establish a standard and the ISO/IEC meetings are held over the globe. Totally committing to the development process would be a burden on firms, especially SMEs and start-ups, due to shortages of human resources and finances. Hence, financial support for travelling expenses etc. can be useful. It is also effective to attract ISO/IEC international conferences to a home country, so that a number of local people concerned will more easily attend and take the advantage of the opportunity to lead a discussion.

6 Conclusion

The case study demonstrates that standards for emerging technology are beneficial to all involved parties. The reason is not only they can ensure safety of emerging products to users, but level the playing field to following companies, thus creating market of emerging industry. In case of ISO 13482, it sets an overarching scope and clear general/minimum safety requirements for healthcare robotics, which are not difficult to apply for many companies. The safety standard facilitates market entry and competition, while leaving an ample space for exploration towards further innovation. Hence, standards can serve as a stepping stone and pave the way to expand emerging markets. Regarding a policy governance, a regulatory mechanism that allow experimentation of emerging technologies can be said to play a key function, and many governmental bodies have engaged in implementing more flexible or agile institutional measures.

Focusing on the development process of standards, they offer a dynamic platform for interaction, negotiation and collaboration among a diverse set of stakeholders. With rapid integration of cyber-physical space beyond conventional sectoral boundaries, the new role of standards is expected to be more crucial in expanding an industrial base on the embryonic phase.

The case also describes that in order to overcome regulatory obstacles, Cyberdyne adopted an institutional strategy of arbitraging in various dimensions; definition of product, market country and regulatory form. Focusing on the role of standards as a dynamic platform described above and the importance of institutional arbitrages, it will be significant to encourage firms' commitment to rulemaking so that they can take initiatives in that process.

Last but not least, the authors are aware that there are limitations inherent in drawing a generic understanding from a single case of Cyberdyne. Further exploration of similar studies (of cases such as self-driving vehicle, flying car and artificial intelligence) are needed to confirm the observations presented here. [13]

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7 Summary

Emerging innovations, based on integration of cyber-physical space (artificial intelligence, robotics, the internet of things etc.), are expected to improve business productivity and quality of life. In the meantime,, the diffusion of such innovations involve risks and uncertainties regarding safety aspects. Generally, these risks are managed by governments by means of regulations. Yet, it increasingly falls short on responding to those new technologies due to the rapid and dynamic progress. Those circumstances pose challenges on creating a market because emerging innovations are disruptive, often do not come under the existing product categories nor corresponding regulations. Thus, this study will answer how standards, one type of regulatory institutions, can impact on market creation of a new product based on emerging technologies, overcoming existing regulatory safety. To address the research question, examined is the case of Cyberdyne, a medical/healthcare robotics company in Japan, the main product of which is the world's first wearable device based on enhanced human-machine-information hybrid systems. The company contributed to build an international safety standard, ISO 13482 after institutional arbitrages on different levels. The case illustrates that standards will be beneficial to all involved parties, facilitating market entry and competition, and serving as a stepping stone to expand an industrial base under an embryonic phase. It concludes with an exploration of policy considerations to set a regulatory mechanism for experimentation and enhance firms' commitment to rulemaking.

Appendix I. List of interviews/personal communications

Questioned items:

- Current status on healthcare/medical robotics and medical device
- Specific definition of healthcare/medical robotics and medical device
- Certification schemes and main stakeholders
- Philosophy and Concept behind the Certification
- Balancing commercialization of frontier technology and regulatory mechanism
- Potential policy supports as well as direction of future private and public collaborations

Stakeholders	Data when interview was conducted
Government	Person1: February 16, 2016 Person2: May 11, 2016
Standardization body	March 9, 10, 2016 (lecture)
Review administration	March 15, 2016
Certification Body	April 28, 2016
Insurance company	June 30, 2016
Robotics company	April 18, 2016
Hospital/User	March 22, 2016
Academia	March 23, 2016
Think tank Consulting company	May 12, 2016

Bibliography

Aikman, David., 2017. The Fourth Industrial Revolution. Available at http://www.meti.go.jp/press/2017/12/20171201005/20171201005a.pdf

Anderson, P, Tushman, M.L., 1990. Technological Discontinuities and Dominant Designs: a Cyclical Model of Technological Change, Administrative Science Quarterly, 35(4), 604-633.

Asahi research Center, 2016. Japan, advantageous in developing heath care robots. available at https://www.asahi-kasei.co.jp/arc/service/pdf/1002.pdf (in Japanese)

Ashford, N. A. and G. R. Heaton., 1983. Regulation and technological innovation in the chemical industry, Law and Contemporary Problem, 46, (3), 109-157.

Arrow, K., 1962. Economic welfare and the allocation of resources for invention. In The rate and direction of inventive activity: Economic and Social Factors., Ed Universities-National Bureau Committee for Economic Research, Committee on Economic Growth of the Social Science Research Council, Princeton University Press, pp. 609-626.

BERR, 2008. Regulation and Innovation: evidence and policy implications, BERR Economics Paper
No.4 Department of Business, Enterprise and Regulatory Reform (BERR), London, UK.

Blind, K., Gauch, S., 2009. Research and standardization in nanotechnology: evidence from Germany,
Journal of Technological Transfer, 34: 320-342.

Blind, K., 2010. The Use of the Regulatory Framework for Innovation Policy, in Smits, R.E, Kuhlmann, S., Shapira, P.(eds) The Theory and Practice of Innovation Policy: an International Research Handbook, Edward Elgar, Cheltemham, UK.

Blind, K., 2016. Standardization and Standards as Research and Innovation Indicators: current opportunities and future challenges, paper presented at Bluesky forum OECD, September, Ghent, Belgium.

Borras, S., Edler, J., (eds) 2014. The governance of socio-technical systems: explaining change, Edward Elgar, Cheltenham, UK.

Bright, J., 2019. Drone delivery startup Zipline launches UAV medical program in Ghana. Accessed June, 2019.
https://techcrunch.com/2019/04/24/drone-delivery-startup-zipline-launches-uav-medical-program-in-ghana/ accessed June 15, 2019

Buthe, T., Mattli, W., 2011. The New Global Rulers. Princeton University Press, Princeton, NJ.

Cabinet Office of Japan., 2016. Society 5.0. available at http://www8.cao.go.jp/cstp/english/society5_0/index.html

Christensen, Clayton M., 1997. The innovator's dilemma: when new technologies cause great firms to fail, Boston, Massachusetts, USA: Harvard Business School Press

Consoli, D., Mina, A., 2009. An evolutionary perspective on health innovation systems, Journal of Evolutional Economics, 19: 297-319.

CYBERDYNE Inc., 2015. nNewsn Application for national health insurance coverage for HAL for Medical Use (Lower Limb Type) submitted to the Ministry of Health, Labour and Welfare, Press release. Available at at http://www.cyberdyne.jp/ Dec. 3, 2015 [accessed: June,3, 2019.]

CYBERDYNE Inc., 2016. nNewsn Ministry of Health, Labour and Welfare to announce an explanation of the insurance points for the technical fee regarding the treatment of rare neuromuscular disease patients using HAL—World's first determination of an insurance reimbursement price for treatment with Robots, Press release. Available at at http://www.cyberdyne.jp/ April, 25th, 2016 [accessed: September,11th , 2019.]

CYBERDYNE Inc., 2017a. General information. Available at http://www.cyberdyne.jp/ (in Japanese)

CYBERDYNE Inc., 2017b. Financial Results for Year Ended March 31, 2017. available at https://www.cyberdyne.jp/company/download/20170515_financialresultssummary_en.pdf

Dan, J.M., forthcoming, How interface formats gain market acceptance: The role of developers and format characteristics in the development of de facto standards, Technovation.

Davies, J.C., 1983. The effects of federal regulation on chemical industry innovation, Law and Contemporary Problems, 46. (3), 41-58.

Delemarle, A., 2017. Standardization and market framing: the case of nanotechnology, in R.Hawkins, K. Blind and R. Page (eds). Handbook of Innovation and Standards, Edward Elgar, Chaltenham, pp. 353-373.

Den Hartigh, E., Ortt, J.R., van de Kaa, Stolwijk, C.C.M., 2016. Platform control during battles for market dominance: The case of Apple versus IBM in the early personal computer industry, Technovation, 48-49, 4-12.

Dietz, T., Ostrom, E., & Stern, P. C., 2003. The struggle to govern the commons. Science, 302(5652), 1907-1912.

Dunning, J., 1979. Toward an Eclectic Theory of International Production: Some Empirical Tests. Journal of International Business Studies. 11 (1): 9–31

Eads, G. C., 1980. Regulation and technical change: Some largely unexplored influences, American Economic Review, 70, (2), 50-54.

Edler, J., Georghiou, L., 2007. Public procurement and innovation—Resurrecting the demand side, Research Policy, 36, 949-963.

European Commission (EC). Notified bodies. available at https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en European Commission (EC)., 2017. Germany: Industrie 4.0. available at https://ec.europa.eu/growth/.tools-databases/dem/monitor/sites/default/files/DTM_Industrie%204.0.pdf

Featherston, C.R., Ho, J-Y., Brevignon-Dodin, L., O'Sullivan, E., 2016. Mediating and catalysing innovation: A framework for anticipating the standardisation needs of emerging technologies, Technovation, 48-49, 25-40.

Financial Central Authority (FCA), 2017. Regulatory Sandbox. available at https://www.fca.org.uk/firms/project-innovate-innovation-hub/regulatory-sandbox

Freeman, C., 1987. Technology Policy and Economic Performance: Lessons from Japan, Pinter Pub Ltd,

Freeman, C., & Soete, L., 1997. The economics of industrial revolution. Pinter, London.

Government of Japan., 2014. JIS-Act. available at http://law.e-gov.go.jp/htmldata/S24/S24HO185.html (in Japanese)

Gallagher, S.R., 2012. The battle of the blue laser DVDs: The significance of corporate strategy in standards battles, Technovation, 32, 90-98

Gerstenfeld, A., 1977. Government Regulation Effects on the Direction of Innovation: A Focus on Performance Standards, IEEE Transaction on Engineering Management, 24. (3), 82 - 86

Hall, P. A. and Soskice, D., (eds) 2001. Varieties of Capitalism: The institutional Foundations of Comparative Advantage, Oxford, Oxford University Press.

Hawkins, R., Mansell, R., & Skea, J., 1995. Standards, innovation and competitiveness. Edward Elgar Publishing.

Hawkins, R, Blind, K., Page, R., (eds) 2017. Handbook of Innovation and Standards, Cheltenham, Edward Elgar.

Henson S., Jaffee S., 2007. Developing Country Responses to the Enhancement of Food Safety Standards. In: Grote U., Basu A.K., Chau N.H. (eds) New Frontiers in Environmental and Social Labelling. Sustainability and Innovation. Physica-Verlag HD.

Henson, S., Humphrey, J., 2009. The impacts of Private Food Safety Standards on the Food Chain and on Public Standards-setting Processes, Paper prepared for FAO/WHO for Joint FAO, WHO Food standards Programme, Codex Alimentarius Commission.

Howes, R, J. Skea and B. Whelan., 1997. Clean and Competitive?: Motivating Environmental Performance in Industry, London: Earthscan.

Ikeda, Y., 2016. Ensuring safety while stimulating innovation for emerging industry: The case of medical robots in Japan and Germany. Master thesis submitted to UNU-MERIT.

Iizuka, M., 2009. Standards as a new platform of innovation and learning in the global economy: a case study of a natural resource in a catching-up country, International Journal of Technology Learning, Innovation and Development, 2,(4), 274-293.

Ikeda, Y and Iizuka, M., forthcoming, Public policy and global strategy for commercializing innovation: the case of medical medical robot, HAL, RIETI Discussion Paper (in Japanese).

Jain, S., 2012. Pragmatic agency in technology standards setting: the case of Ethernet, Research Policy, 41, 1643-1654.

Japanese Industrial Standards Committee (JISC)., 2017. General information. available at http://www.jisc.go.jp/

Japan External Trade Organization (JETRO)., 2012. How to Well Make Use of Certification Bodies. available at https://www.jetro.go.jp/ext_images/jfile/report/07001046/europe_certification.pdf

Josanoff, S., 2004. States of Knowledge: The Co-Production of Science and the Social Order, Routledge.

Klepper, S., 1997. Industry life cycles. Industrial and corporate change, 6(1), 145-182.

Kodama, F., 2018. Learning Mode and Strategic Concept for the 4th Industrial Revolution, Journal of Open Innovation: Technology, Market and Complexity 4 (32), 1-17.

Lau, Y. Y. C., van't Hof, C., & van Est, Q. C., 2009. Beyond the surface: an exploration in healthcare robotics in Japan.

Mansfield, E. J. Rapaport, J. Schnee, S. Wagner and M. Hamburger., 1971. Research and Innovation in the Modern Corporation. London: Macmillan.

Marchant, G. E., Allenby, B. R., & Herkert, J. R. (Eds.). , 2011. The growing gap between emerging technologies and legal-ethical oversight: The pacing problem, Springer Science & Business Media.

Medicines and Healthcare Products Regulatory Agency (MHRA) of UK government. (2016, May).
Guidance on legislation - Borderlines with medical devices. available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284505/Borderlines_ with_medical_devices.pdf

Milmo, S., 2000. Europe face an innovation lag, Chemical Market Reporter, Mar. 26, Vol 259 No. 13, FR-9.

Ministry of Economy, Trade and Industry (METI)., 2016. Industrial Structure Vision, Industrial Structure Council. available at http://www.meti.go.jp/committee/sankoushin/shin_sangyoukouzou/pdf/008_05_01.pdf (in Japanese)

Ministry of Health, Labour and Welfare (MHLW), 2016, Reference material for medical device cost. https://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-
Sanjikanshitsu_Shakaihoshoutantou/0000189388.pdf [accessed July, 27, 2019].

Nabeshima, C (2016) The Reality of International Standardization, Journal of Robotics Society in Japan, 34(6): 386-389 (in Japanese)

Narayanan, V.K. Chen, T., 2012. Research on technology standards: accomplishment and challenges
Research Policy 41: 1375-1406.

Nelson, R. R., 1959. The simple economics of basic scientific research. Journal of political economy, 67(3), 297-306.

Nelson, R. & B. Sampat., 2001. Making Sense of Institutions as a Factor Shaping Economic Performance. Journal of Economic Behaviour and Organization, 44, pp. 31–54.

Nemet, G.F., 2009. Demand-pull, technology-push, and government-led incentives for non- incremental technical change. Research policy, 38, 700-709.

Pharmaceuticals and Medical Devices Agency (PMDA). (n.d.). Estimation of Device Lag. available at http://www.pmda.go.jp/files/000206037.pdf

Porter, M. E., & Van der Linde, C., 1995. Toward a new conception of the environment- competitiveness relationship. Journal of economic perspectives, 9(4), 97-118.

Rothwell, 1980. The Impact of Regulation on Innovation: Some U.S. Data. Technological Forecasting and Social Change, 17. (1),7-34.
Rothwell, R., Zegveld, W., 1981. Industrial Innovation and Public Policy: Preparing for the 1980s and the 1990s. Pinter, London.
Rothwell, R., 1992. Industrial Innovation and government environmental regulation: some lessons from the past, Technovation, 12, (7), 447-58.
Schilling, M. A., 2002. Technology success and failure in winner-take all markets: the impact on learning organization Timing and network externalities. Academy of Management Journal, 45: 387- 398.
Sharp, M., & Pavitt, K., 1993. Technology policy in the 1990s: old trends and new realities. Journal of Common Market Studies, 31 (2) 129-151.
Shapiro, S., & Glicksman, R., 2002. Risk regulation at risk: restoring a pragmatic approach. Stanford University Press.
Steinmueller, E., 2016. Platforms and Standards: An Historical Perspective, a paper presented at SPRU 50th Anniversary Conference 7-9 September, 2016, Brighton, UK.
Suarez, F.F., 2004. Battles for technological dominance: an integrative framework. Research Policy, 33, 271-286.
Swann, GMP., 2000. The Economics of Standardization, London: Department of Trade and Industry. Szalavertz, A., 2018. Industry 4.0 and capability development in manufacturing subsidiaries,
Technological Forecasting and Social Change, in press.
Tassey, G., 2017. Standards and expansion paths in high-tech industries. in R.Hawkins, K. Blind and
R. Page (eds). Handbook of Innovation and Standards, Edward Elgar, Chaltenham, pp.135-161. Tate, J., 2001. National varieties of Standardization, in Hall, P and Soskice, D (eds.) Varieties of
Capitalism: The institutional Foundations of Comparative advantage, Oxford University Press: Oxford, pp. 442-473.
Utterback, James M. and Abernathy, William J., 1975. A Dynamic Model of Product and Process Innovation, Omega 3(6), 639-656.
Vogel, Ezra F., 1981. Japan as number one: Lessons for America. Harvard University Press.
Weng, Y. H., Sugahara, Y., Hashimoto, K., & Takanishi, A., 2015. Intersection of "Tokku" special zone, robots, and the law: a case study on legal impacts to humanoid robots. International Journal of Social Robotics, 7(5), 841-857.
Witt, M. A., Lewin A.Y., 2007. Outward Foreign Direct Investment as Escape Response to Home Country Institutional Constraints, Journal of International Business Studies, 38 (4),579-594.
Wiegmann, P.M., de Vries, H. J., K. Blind., 2017. Multi-mode standardisation: A critical review and a research agenda, Research Policy 46, 1370-1386.
World Economic Forum (WEF), 2018. Agile Governance Reimagining Policy-making in the Fourth Industrial Revolution. available at http://www3.weforum.org/docs/WEF_Agile_Governance_Reimagining_Policy-making_4IR_report.pdf
Yin, R.K., 2009. Case study research: design and methods, 4th edition, Los Angeles: SAGE.