

Facilitating inter-organizational collaboration initiated by small- and medium-sized enterprises for promoting a medical device industry in Fukushima prefecture

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ABSTRACT

The purpose of this study is to propose systematic knowledge about how inter-organizational collaboration can be effectively facilitated. Today, inter-organizational collaboration is the key for creating new businesses and industrial promotion in local region. As a trend in Japan, in order to cope with declined transactional opportunities of existing businesses, small and medium-sized enterprises (SMEs) are attempting to create new businesses by collaborating with other institutions. Although thousands of SMEs have attempted to enter the medical device industry, which is regarded as a field with high potential, many of them have failed due to the lack of information and the inaccessibility to collaborators. Under these circumstances, SMEs in Fukushima Prefecture have been increasingly entering the market with the prefectural government's support to facilitate the collaboration. In this study, firstly, "interactions and common understandings" of the parties involved in the process of establishing inter-organizational collaboration is considered. Then, how the process can be facilitated is examined. Here, "Place" and "Intervention," are key facilitation factors. In addition, the impact of the situations that the parties were involved in (referred to as "Initial Conditions") are considered. Based on these key factors, the conceptual Model is presented then; the adequacy of the model is examined through the case study about Fukushima. A certain adequacy of the conceptual model, which presents theoretical framework on how inter-organizational collaboration can be facilitated, is confirmed by the case study. Moreover, some practical implications are also found.

Keywords: collaboration, SMEs, intervention, organization

INTRODUCTION

In recent years, increasing importance is placed on inter-organizational collaboration in various fields for the creation of new businesses and the promotion of local industries. Likewise, small- and medium-sized enterprises (SMEs) are increasingly conducting collaborations with other companies, research institutions, and the public sector, among others, which are outside of the traditional subcontracting networks. In the

local region like Fukushima Prefecture, in order to promote industries, it is essential to utilize capabilities of SMEs through inter-organizational collaboration. Because:

1. Presence of SMEs in terms of their impact on economy and employment is larger than that of big cities.
2. However, it is difficult for SMEs to create new businesses by themselves.
3. Therefore, inter-organizational collaborations between SMEs and other institutions are necessary.

The purpose of this study is to propose systematic knowledge about how inter-organizational collaboration can be effectively facilitated to establish new businesses. The overall process of inter-organizational collaboration between SMEs, the public sector, medical institutions, and research institutions, was examined by focusing on the following factors: "Initial Conditions," "Interaction and common understanding," "Place," and "Intervention." Based on these factors, the conceptual model was presented, then, a case study was conducted to examine the adequacy of the model. In order to conduct the study, the following research questions (R.Q.) were presented:

- R.Q.1: What were the Initial Conditions affecting the establishment process of inter-organizational collaboration, and what was the impact?
- R.Q.2: What types of interactions and common understandings did people from different groups form in the process to establish inter-organizational collaboration?
- R.Q.3: Who was involved, how were they involved in the intervention, and what roles did the intervention play in facilitating the establishment process of the inter-organizational collaboration?
- R.Q.4: By whom and how were the Places prepared for facilitating the establishment process of the inter-organizational collaboration, and which functions were played by the place?

In the case study, Fukushima Prefecture where SME start-ups entering the medical device industry were promoted by the prefectural government was examined. Through the case study, a certain adequacy of the conceptual model, which presents theoretical framework how inter-organizational collaboration can be facilitated, is confirmed. Moreover, some practical implications are also found.

The remainder of this study is structured as follows. First, conducting a literature review and evaluating the establishment process of such inter-organizational collaborations provide the viewpoint of this study. Second, after presenting the research design, it focuses on inter-organizational collaboration for the promotion of medical devices in Fukushima Prefecture. Finally, it presents the interpretations and conclusions of the findings.

LITERATURE REVIEW ON INTER-ORGANIZATIONAL COLLABORATIONS: ESTABLISHMENT PROCESS OF INTER-ORGANIZATIONAL COLLABORATION, ROLE OF INTERVENTION, AND FUNCTION OF PLACE

In this study, inter-organizational collaboration is defined as the "cooperation between members of different organizations when establishing new businesses." Barnard (1938) viewed cooperation "as a social aspect of the total situation and social factors arise from it... the process of interaction must be discovered or intervened" (p. 60), while he defined social processes as "those in which the action is a part of the system of action of two or more men" [of which] its most common form is "verbal communication" (p. 20).

The importance of communication is that it is in the nature of social systems and organizations (Kaz & Kahn, 1966), and communication is in the nature of organizational activities (Bavelas & Barrett, 1951). According to Rogers (1986), communication provides the meaning of certain information, after which the parties involved exchange ideas and reach a common understanding. However, in the preceding studies, the process of inter-organizational collaboration has not been sufficiently explained, especially with regard to the establishment, maintenance, and dissolution of organizations through communication (Monge & Contractor, 2001).

At this point, let us focus on the study by Follett (1927), which described the process of inter-organization cooperation and focused on personal interactions and relationships. It also proposed that there are three fundamental principles of a dynamic process: interaction, unification, and emergence. In addition, the total situation will be created where individuals are interacting with each other in being related with the functionality that relates mutually. Moreover, it is pointed out that the total situation can be developed by the interactions between individuals. Based on the above findings, establishing clear objectives, roles, and processes can be deployed by interactions among individuals, which, in turn, can help establish and develop inter-organizational collaborations.

Regarding the factors that facilitate the establishment of inter-organizational collaboration, Follett (1918) indicated the necessity of leaders who coordinate and establish relationships between people in the process of interaction. Similarly, assuming that network organizations are self-organized through the spontaneous formation of relationships among people, Imai and Kaneko (1988) highlighted the importance of an entity that intentionally connects and establishes such relationship as well as forms a new context in society. Considering the establishment of inter-organizational relationships, Gray (2008) proposed the concept of "intervention," which impacts the interaction between allied partners, reduces limiting factors, and/or enhances the driving factors in the interaction between organizations. Ring, Doz, and Olk (2005) explained that the role of "triggering entities" is "to make clear to potential partners the benefits of collaboration, to support the formation process (of collaboration), to ensure various contributions in a timely and harmonious manner and to double-check each incentive." Sagawa and Segal (2000) introduced the role of the "relationship manager," who constructs and strengthens relationships between organizations. Williams (2002) discussed the role of "boundary spanners," who have the skills to build and maintain relationships among individuals as well as manage the interdependencies between organizations in order to increase the likelihood of collaborations. Henton et al. (1997) introduced "civic entrepreneurs," who facilitate collaborations between governments or companies in different fields, and provide support for the creation of new businesses or contributions to local industries. In addition, they stated that the motivation of being civic entrepreneurs is "to realize broad, enlightening, and long-term benefits." Gray (2008) asserted that normal intervention should be mainly carried out by alliance partners or third parties. Finally, Radin (1996) suggested that the expansion of boundaries may be carried out by several people, and that it does not necessarily have to be achieved by a single person.

In addition to the arguments regarding intervention, Imai and Kaneko (1988) stressed the importance of an environment that provides access to various ideas and reliable information, and allows individuals to quickly respond to market movements by coordinating expectations of members, condense ideas through necessary exchange of

information for these activities over a short time period. According to Kanai (2005), these arguments are discussed as functions of “place,” which is a social system that encourages interactions between people, fills structural holes (as shown in Burt (1992)), and promotes entrepreneurial activities among organizations in order to create new businesses.

Gray (1989) described convention, as one style of place, in which all legitimate stakeholders with a strong interest in advancing collaboration gather in one location. Such meetings are led by the conference convener, who must possess the following skills:

- The conference convener must have the power to convene stakeholders.
- He/she must maintain legitimacy, authority, and fairness.
- The purpose of the collaboration must be clarified in order for the stakeholders to understand the potential value of holding such a meeting.
- He/she should have the ability to carry out a cooperative process and to create appropriate context.
- Appropriate stakeholders should be specified.

Gray (1989) also suggested that involvement of key stakeholders with a strong interest in advancing collaboration is important in order to establish social norms and to put them into practice.

PERSPECTIVE REGARDING THE PROCESS TO ESTABLISH INTER-ORGANIZATIONAL COLLABORATIONS

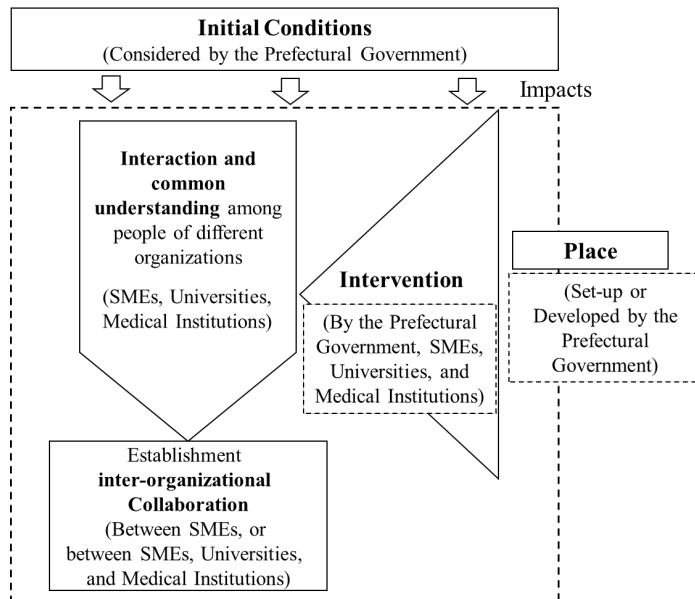


Figure 1. Conceptual Model

This case study examines how inter-organizational collaboration can be effectively facilitated to establish new businesses. Moreover, it focuses on inter-organizational collaborations in which individuals are mutually related in a self-reliant and subjective manner. In this study, the impact of the situations that the parties were involved in

(referred to as “Initial Conditions”) are considered, in addition to three factors: 1) A common understanding reached through the interactions of those from different organizations; 2) A deliberate approach in the establishment of inter-organizational collaboration by promoting interaction and establishment of common understanding (referred to as “Intervention”); and 3) A suitable environment (referred to as “Place”) for creating start-ups through inter-organizational collaboration and the effective exchange of ideas/information among the parties involved. Based on these factors, the conceptual model in this study is as follows (Figure 1).

RESEARCH DESIGN

This case study focuses on the support system led by Fukushima Prefectural Government, which facilitated inter-organizational collaboration for the commercialization of medical devices in Fukushima Prefecture. Since SMEs and other institutions primarily facilitated this commercialization and promotion of medical devices in the prefecture, it is appropriate for this study to examine how to facilitate the process of inter-organizational collaboration where individuals relate mutually in a self-reliant and subjective way.

Since this study explores how the inter-organizational collaboration was established, following Yin (1994), it is appropriate to clarify the process by conducting a case study that evaluates the interactions between individuals as an analysis unit.

Data Gathering and Analysis Method

The data used for this case study was collected from secondary sources as well as from interviews of concerned parties. In this regard, secondary sources include magazine columns, information on the Internet related to this case, and interviews with the following individuals from the Business Creation Division of the Commerce, Industry and Labour Department, Fukushima Prefectural Government, First, “Mr. O” (interview conducted in February 2015), who was engaged in the establishment of the collaboration network for R&D and the application for the national government grant for the R&D for medical devices in 2001. Since 2015, he has served as Director of the Department. Second, “Mr. D” (interview conducted in May 2015), who was the Director and the Director-General of Commercialization Support in the Fukushima Medical Device Industry Promotion Agency, which was established as an extra-departmental body in 2013 to support the commercialization of medical devices in an integrated fashion. He was also involved in R&D and the commercialization of medical devices when he was a staff member of the prefectural government.

Regarding the analysis method, this study performs a qualitative analysis of a single case in order to elucidate the facilitation of inter-organizational collaboration. Thus, the events are chronologically tracked to explore the cause-and-effect relationships, ranging from the situations that the parties were facing at the time of the interactions began to establish the inter-organizational collaboration to the present day.

CASE STUDY – ESTABLISHMENT PROCESS OF INTER-ORGANIZATIONAL COLLABORATION FOR THE COMMERCIALIZATION PROMOTION OF MEDICAL DEVICES IN FUKUSHIMA PREFECTURE

Introduction

Since 2001, the Fukushima Prefecture has been supporting the commercialization of medical devices through industry-academia-government collaboration, led by the Commerce, Industry and Labor Department of the prefectural government. Initially, it began with R&D for medical devices, which was supported by a subsidy from the Ministry of Education, Culture, Sports, Science and Technology. This led to the creation of an independent support project by the prefectural government in 2005, which continues to this day. These movements have been accompanied with setting-up or development of the Place.

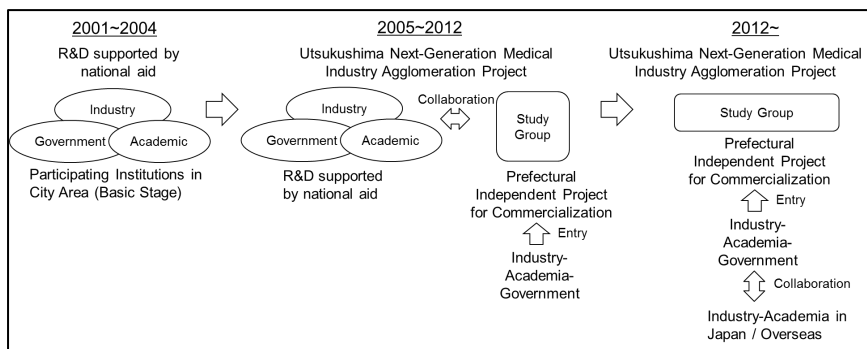


Figure 2. *Development of Places for Facilitating Inter-Organizational Collaboration for the Commercialization of Medical Devices*

Initial conditions before the Prefectural Government was involved in the promotion of medical devices

Firstly, regarding the institutional environment, in 2001, when the Fukushima Prefectural Government became involved in the commercialization and promotion of medical devices, there was an increasing nationwide momentum for the establishment of start-ups through collaboration between industry and academia and communication between different industries. In fact, the Ministry of Education, Culture, Sports, Science and Technology, in response to such a momentum, implemented support measures, such as the “Intelligent Cluster Formation Project” (a subsidy to establish industry-academia-government collaboration for the creation of new industries), in order to facilitate innovation through R&D. In addition, the Ministry of Economy, Trade and Industry (METI) had already implemented support measures to facilitate information exchange between different industries. On the other hand, in Fukushima Prefecture, the “Basic Plan for Fukushima Science and Technology Promotion” was drawn up as a long-term comprehensive plan in 1996, led by the Business Creation Division of the Commerce, Industry and Labor Department and by extra-departmental bodies of the prefectural government. The guidelines included the promotion of joint-research projects by industry-academia-government, support for start-ups, utilization of research capabilities of universities, and the establishment of an R&D hub. Based on these guidelines, in 1999, they conducted the Regional Science Promotion Program, which accelerated the creation of a

research database, industry-academia coordination, and the development of an industry-academia-government network. In 2000, the “Fukushima Facilitation Basic Vision for New Business Creation” was drawn up to provide various measures to support the creation of start-ups. In addition to this project, they began to engage in commercialization support for local SMEs.

Secondly, concerning the economy and industry, the medical device industry has been recognized as a promising industry since the medical and social service-related industries have industry characteristics that are not easily influenced by business conditions. In addition, it has the potential of expanding domestic and foreign markets due to the aging society. Upon envisioning the commercialization and promotion of medical devices in 2001, the Fukushima Prefectural Government was aware of the following aspects in the field. First, shipments of manufactured goods from Fukushima Prefecture increased approximately 1.5 times from 1985 to 1999, and the value of the shipments and the number of manufacturing establishments were the largest in the Tohoku region. In addition, groups of new industries, such as software companies and assistive technology-related companies (which are R&D oriented), had been formed by taking advantage of the technical knowledge held by various universities and institutions in the Koriyama and Aizu regions. Second, large numbers of small- and medium-sized manufacturers were already in place that possessed various technologies, such as metal precision machining, plastic molding, precision welding, plating technology, assembly, electronic technology, and software, all of which were useful for medical device manufacturing. Finally, leading medical device manufacturers, such as Olympus Medical Systems, Johnson & Johnson, and Becton-Dickinson and Company, had established production and importing facilities in Fukushima Prefecture. However, before 2001, this industry was not the subject of focus since there were only a small number of businesses with an equally small volume of production in the industry. Moreover, the number of SMEs entering the medical device industry was limited. However, in 2001, medical device-related parts production has already become the largest in Japan. This finding indicates that they were ready to produce medical devices and even to procure parts and produce such devices since the number of SMEs has increased.

Thirdly, in the commercialization and promotion of medical devices, several universities and research institutions in Fukushima Prefecture initiated collaboration in R&D for medical devices. The first example is the College of Engineering at Nihon University, which has performed clinical research activities in medical devices that utilize haptic technology (under the leadership of “Professor H”) since the 1990s. Other examples include the University of Aizu, which has focused on the transmission of 3D, high-definition images for the creation of medical devices, and Fukushima Medical University, which has been conducting translational research for the commercialization of medical devices. Finally, the Fukushima Technology Center has been supporting the creation of new technologies and start-ups through industry-academia joint research and technology transfer for the purpose of improving the technological foundation of the prefecture.

Lastly, the prefectural government had already established networks for other projects, which, in turn, contributed to the inter-organizational collaboration as well as the commercialization of medical devices. For example, the prefectural government had been communicating with “Professor H” of the College of Engineering at Nihon University, who played a central role in the R&D project in 2002. Contributions by the companies include

facilitating the collaboration based on individual connections with university faculty established in previous joint projects.

The Promotion of Medical Devices by the Fukushima Prefectural Government

The Fukushima Prefectural Government began to stimulate local businesses by taking advantage of the Intellectual Cluster Program, which was initiated by the Ministry of Education, Culture, Sports, Science and Technology in 2001. At the time, "Mr. O" was a staff member in the Business Creation Division of the Commerce, Industry and Labor Department of Fukushima Prefecture, who prepared the business plan for the Intellectual Cluster Program. The preparation of the business plan targeted the industries that could represent the uniqueness of Fukushima Prefecture. As a result of the evaluation, the medical device industry, in which medical device-related parts production marked the top production value in Japan, was the subject of focus, even though the total value was small in comparison to other industries. Overall, medical devices were selected as a target industry for the following reasons. First, achieving the top position in regard to the production value of medical devices was feasible since it had previously reached 7th/8th place in Japan. Second, stable production was expected, regardless of the business conditions. Third, the industry had a high-growth potential since SMEs could easily start new businesses in the industry, since the fundamental technologies used for production were already in place. In Fukushima Prefecture in 2001, this movement triggered the revitalization of the local economy by encouraging innovations in science and technology, and the industrial promotion of start-ups. As a result, the commercialization and promotion of medical devices was fully supported by the entire region.

Regarding the process of the establishment of the collaboration system, in July 2001, "Mr. O" contacted "Professor H" in the College of Engineering at Nihon University, whom Mr. O had been communicating because the Professor was involved in another project subsidized by the prefectural government, in order to apply to the Intellectual Cluster Program and organize the procedures. The subjects of the R&D were narrowed down to five fields that could help develop the haptic technology by "Professor H," which were in line with the needs and commercialization in the future such as development of next-generation virtual systems, and medical and social services information system development, etc. The promotion of R&D in the five fields also required industry-academia collaboration between each university involved and the Fukushima Prefectural Government. Information held by the Fukushima Industrial Promotion Center (which is an extra-departmental body) was subsequently utilized to select the companies for the collaboration. The Fukushima Prefectural Government also approached any companies that had connections with university faculty members or any companies whose technological and business details were aware of through other programs. Moreover, the government approached the medical institutions with which it had been communicating for other joint research projects. As a result, the research members, including those from universities, companies, and medical institutions, took the lead in the R&D of the five aforementioned fields.

After the research group was formed, a review of the detailed studies, establishment of the research system, and the completion of the business plan for the Intellectual Cluster Program were completed. The research members held 2–3 meetings a month to discuss the research details, share what should be done to develop a system, and consider the strategies (i.e., the flow of R&D, production, and sales) for the

commercialization of the medical devices in question. Based on these procedures, the deputy governor was appointed as Chair of the Business Promotion Working Group, which was the consultative body of the entire project. Under this group, a promotion system for the administrative affairs and the research projects was established in order to realize cooperation among local businesses, including SMEs, in the development of new medical devices. In addition, this system helped support the commercialization of the devices through the creation of start-ups and by adding high value to the existing businesses.

The project proposal for the Intellectual Cluster Program was completed in approximately six months after the Ministry of Education, Culture, Sports, Science and Technology had requested the submission. Although the project proposal was rejected for the Intellectual Cluster Program, it was subsequently accepted for the City Area Program (hereafter referred to as "City Area (Basic Stage)") in which the aforementioned Ministry supported only R&D.

Engaging in R&D (2002–2004): City Area (Basic Stage) Project and Consensus after Completion

After being accepted for the City Area (Basic Stage), establishing the promotion system and providing more operators of the project was the first challenge. A similar style used to apply to the Intellectual Cluster Program was adopted for the promotion system. The deputy governor was appointed as the chair of the entire project, while "Mr. K" was selected as the Supervisor of the Commercialization Committee. Under these two individuals were "Mr. F" (the supervisor of the projects) and "Professor H" (the supervisor of the research). "Mr. K" and "Mr. F," who had newly joined the system, were, respectively, the director of a major foreign-based medical device company (which had established a hub in Fukushima) and a business owner of a prestigious pharmaceuticals and medical device company (which was involved in R&D, manufacture, imports, and sales in Fukushima). How Mr. K and Mr. F joined the project was as follows. Mr. K had been communicating with Professor H since long before the project began, and Professor H introduced Mr. K to Mr. O. Then, Mr. O requested Mr. K to participate in the project. On the other hand, Mr. F did not have a connection with any of them, but Mr. O, who knew Mr. F's reputation, approached him to be appointed as the supervisor of the project after the proposal for the City Area (Basic Stage) was accepted.

During the business promotions for the City Area (Basic Stage), the progress related to R&D was reported at the monthly meetings, and the commercialization was examined at the Commercialization Committee every 2–3 months. From 2002 to 2004, R&D remained the primary focus until it had obtained the basic technological knowledge required for the production of the devices in question.

Although certain outcomes were achieved regarding the basic technology in the City Area (Basic Stage), the commercialization was unsuccessful. The parties involved in the Fukushima Prefectural Government (who performed administrative functions, submitted the application for the project, and provided promotional support) identified the problems as they were preparing their evaluation for the Ministry of Education, Culture, Sports, Science and Technology. The identified problems were shared with the Manager of the Business Creation Division of the Commerce, Industry and Labour Department in the Fukushima Prefectural Government, which was the main constituent of the project. The problems included the following: 1) Communication in the industry-academia-government collaboration was insufficient and it failed to draw upon industry initiatives; 2) A lack of

necessary knowledge and maturity regarding the commercialization of medical devices among businesses in Fukushima; and 3) Commercialization of the R&D, based on the haptic technology engaged in the City Area (Basic Stage), did not have a significant impact. As a result, support measures that reflected the needs of businesses in other fields in the prefecture were provided to expand the market. In addition, a budget was ensured to launch the project and the slogan “pushing for thorough communication in industry-academia-government” was presented in order to initiate support for commercialization. Furthermore, the course of action was shared within the Fukushima Prefectural Government to develop businesses in Fukushima (as an independent project by the Fukushima Prefectural Government) and encourage the commercialization of medical devices by promoting the market entry of SMEs, which include non-medical sectors.

Support by the Fukushima Prefectural Government and the National Government (2005–2012)

Based on the aforementioned problems, the prefectural independent support project for commercialization was launched in 2005. In addition, the R&D project was accepted for the City Area Program (Development Stage) (hereafter referred to as “City Area (Development Stage)”) for three consecutive years starting from 2006. From that point in time, the prefectural independent support project for commercialization and the R&D funded by the national government were introduced as the “Utsukushima Next-Generation Medical Industry Agglomeration Project.”

The first step of the project was to create an opportunity for the medical device industry to be integrated through industry-academia-government collaboration. The second step was to advance the support for SMEs and the development of such enterprises (support for the Pharmaceutical Affairs Act, the acquisition of medical device manufacturing permits, etc.). The third step was to further growth by facilitating the exchange of information between companies in different industries.

Establishment of the Fukushima Medical and Healthcare Device Study Group

The establishment of the Fukushima Medical and Healthcare Device Study Group (hereafter referred to as the “Study Group”) was based on the demands from local businesses that wanted to learn more about the medical devices as well as the projects initiated by the Fukushima Prefectural Government. In addition, “Professor H” suggested holding workshops to share such information with those interested. Furthermore, the project was accepted for the “Wide-Ranging Project to Solidify the Core Support Network for New Business” conducted by METI around the same time period. Following the instructions from METI, which included facilitating cross-industry exchange and network establishment, the Study Group was founded in 2005.

The overall purpose of the Study Group was to develop a wide range of exchanges with the nationwide medical cluster as well as unify the industry in the prefecture. At the same time, the group encouraged local businesses to become involved in the industry through presentations that described the development and manufacture of medical devices, technical seminars on medical device development, seminars related to the Pharmaceutical Affairs Act/ Product Liability Act, presentations of medical needs, and exchange meetings with companies from non-medical sectors. The number of original participants was approximately 50 companies and organizations from the industry, academia, and the government. “Mr. F,” who was the business supervisor of the City Area

(Basic Stage) program, was appointed as the chairman. The members included companies, universities, and government agencies from Fukushima Prefecture, the Tohoku area, and other provinces. The majority of the members were SMEs from a wide range of industries that each had the goal of entering the medical device business. As of June 2014, the number of members exceeded 250.

In February 2015, the Study Group changed its name to “Medical Device Related Industries Council,” which performed activities that were more directly involved in commercialization and business matching. The main focus of the activities was business matching and providing network establishment opportunities such as business information exchange meetings, R&D support, the provision and dispatch of information through various websites. The management of the council was transferred from the Fukushima Prefectural Government to the private sector, with eight organizers and a chairman selected from various private companies.

Promotion of R&D: Utilization of the National Government Grant

The City Area (Development Stage) program was conducted for three consecutive years, starting from 2006. It followed the City Area (Basic Stage) program, which was conducted from 2002 to 2004. The system was run by “Mr. F,” who was appointed as a research supervisor, and under him were “Mr. K,” who served as the business supporter, and “Professor S” from the College of Engineering at Nihon University, who was the newly appointed research supervisor. “Professor H” also participated in the research project. This project focused on commercialization in order to strengthen the development systems led by the private sector. “Mr. K,” who also served as Chairman of the Business Promotion Committee, was responsible for the management and evaluation of entire project, especially in terms of commercialization and business development.

In the promotion of the City Area (Development Stage) program, the project leader evaluated overall progress, while the Business Promotion Committee met every 2–3 months to evaluate the progress from the perspective of production and sales potential of the research outcomes. Furthermore, coordinators were appointed to promote the collaboration between universities and companies as well as between companies that were positioned for the practical application of the research outcomes.

Following the City Area (Development Stage) program, in 2010, the project was accepted for the Regional Innovation Strategy Support Program by the Ministry of Education, Culture, Sports, Science and Technology. Such acceptance encouraged the R&D of optical technology and haptic technology over the course of the three-year project.

As a result of R&D by the two programs, 16 items were developed, including quantification devices that primarily utilized haptic technology to monitor heart palpitations in clinical practice, and other next-generation medical devices. Although some technological knowledge obtained in the projects was not commercialized by the project’s conclusion, they were eventually employed in newly created medical devices in later.

Promotion of Commercialization Support: Prefectural Independent Project

The prefectural independent support project for commercialization, established from the lessons learned in the City Area (Basic Stage) program, was introduced to engage companies to design and manufacture medical devices in Fukushima Prefecture. The objectives of the project were to establish industrial clusters through the promotion of material supply/OEM/prototype research, various entities through industry-academia-

government collaboration, and start-ups in the field of medical devices. Thus, the project was established to create a seamless process from R&D to commercialization. The support measures also helped local businesses become involved in the medical device industry, while further developing an environment that supported the development and production of medical devices. In addition to the lessons learned from the previous failure, the support measures reflected the opinions expressed by the members of the Study Group, especially concerning the lack of knowledge regarding the pharmaceutical regulatory application procedures. In response to the opinions, in 2007, pharmaceutical-related licensing support had been initiated. As a result, the following support measures were implemented for the commercialization:

- Establishment of the Fukushima Medical and Healthcare Device Study Group
 - See above for the details.
- Business-matching services
 - The prefectural government staff introduced the development project proposals of medical device manufacturers to local companies as well as the prototype projects from university researchers. They also conducted business-matching services between local manufacturing companies, medical device manufacturers, and universities.
- Consultations in relation to the Pharmaceutical Affairs Act
 - The prefectural government staff, with knowledge of the Pharmaceutical Affairs Act, facilitated start-ups by helping local businesses in non-medical sectors obtain production and sales permits in the medical device field. In addition, they provided consultations regarding specific medical devices and sent consultants to provide pharmaceutical consultations.
- Medical-Manufacturer Human Resources Development Program
 - In collaboration with the universities in Fukushima Prefecture, practical training opportunities were offered, such as tours of operating rooms and the manufacturing sites of leading medical device manufacturers, in order to provide companies in different fields with the necessary knowledge to effectively support their start-ups in the medical device industry. Additionally, lectures on transaction methods, medical device needs, and related laws were provided.
- Market expansion support
 - “Medical Creation Fukushima,” an exhibition specializing in medical devices, has been held every year since 2005. In 2014, more than 200 companies and organizations in and outside of the prefecture participated in the exhibition. These exhibitions have contributed to market development, business expansion, improving the reputation as a cluster region, and advertising the products of parts manufacturers to medical device manufacturers. Other activities include the participation of local companies and organizations in similar exhibitions held in other countries such as the United States and Germany. Initially, organizers of the exhibition were mainly from the Fukushima Prefectural Government. However, in 2010, an executive committee, formed by the participating

companies and the organizations, was established to carry out such exhibitions.

- Subsidy system by the Fukushima Prefectural Government
 - The prefectural government established subsidies to help cover the necessary costs of prototype productions, performance evaluations, and clinical trials. As part of the “Commercialization Support System,” it supported seven cases in 2009 and 11 in 2010. In addition, the Fukushima Industrial Promotion Center has been conducting the “Fukushima Industries Support Fund,” which has accumulated more than five billion yen since its introduction in 2008. The fund provides subsidies for research and market development, including medical device businesses.
 - In 2011, a fund of approximately 50 billion yen was established to help recover from the Great East Japan Earthquake. In addition, more than 50 enterprises, including medical device businesses, were supported from the “Fukushima Medical and Assistive Device Development Subsidy,” which totaled 7.7 billion yen. These subsidies were designed to partially cover the costs of commercialization, R&D, and the acquisition of manufacturing permits and sales permits of medical devices. Although the subsidies also helped companies outside of Fukushima, the qualifications for the subsidies included commercialization in Fukushima Prefecture itself.

Background and Changes of the Operating Structure

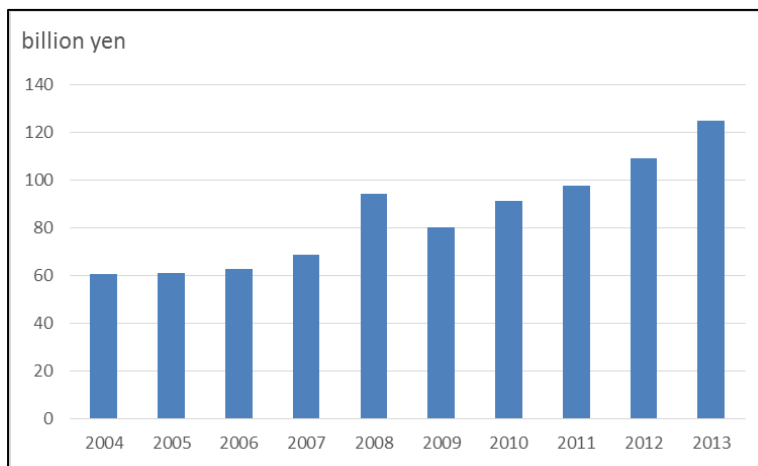
Since the Regional Innovation Cluster Program, which is a R&D program subsidized by the national government in 2010, a research center was established at the Fukushima Medical University. In addition, the Fukushima Medical-Industry Liaison Office was established at the university in April of the same year to improve collaborations in independent prefectural support projects for commercialization as well as R&D projects. This office, introduced in response to the requests by members of the Study Group, included several staff members from the prefectural government who were responsible for “building a bridge” between medicine (and/or universities) and industries as well as providing information about clinical sites to various industries. Although the office operated for roughly three years, it was closed since the overall goal was not achieved. Such failure was due to the lack of doctors who aimed to develop medical devices in collaboration with industries, and the differences in opinions among the parties who focused on research (Fukushima Medical University) and the parties who focused on businesses (Fukushima government).

Based on this line of events, the Fukushima Prefectural Government established the “Fukushima Medical Device Industry Promotion Agency” (hereafter referred to as the “Agency”) in May 2013, as an agency with aggregating functions that include a point of contact for supporting commercialization and business-academia collaboration. In FY2016, the Agency plans to introduce the “Fukushima Medical Device Development Support Center,” which offers various services such as safety evaluations of medical devices, business-matching services between companies or companies and medical institutions, consultations regarding necessary improvements, pharmaceutical-related matters, and training of medical personnel. In addition, a system will be established to integrally support

additional procedures ranging from development and approval of medical devices to their commercialization.

Outcomes (to date) - R&D Supported by National Aid vs. the Prefectural Independent Support Project

To date, the outcomes of such promotional efforts in Fukushima Prefecture include the following. First, the medical device production value was 124.5 billion yen in 2013, which was almost double the amount in 2004 (60.4 billion yen). In addition, such production value reached 3rd place in the national rankings in 2013, which was up from 9th place in 2004. Other outcomes in 2013 were that the entrusted production value of medical devices reached 35.2 billion yen (“Annual Report on Statistics of Production by Pharmaceutical Industry in 2013” by the Ministry of Health, Labour and Welfare), while the production value of medical device parts reached 13.3 billion yen (“Industrial Statistics Survey in 2012” by the Ministry of Ministry of Economy, Trade and Industry), which marked the largest in Japan.



Source: Annual Report on Statistics of Production by Pharmaceutical Industry

Figure 3: Medical Device Production Values in Fukushima Prefecture

In regard to the outcomes of R&D funded by the national government, a total of 16 items, including the world’s first non-contact tonometer, were developed, after which the technology obtained more than 50 patents in 20 countries. However, the sales of the commercialized medical devices did not increase. As a result, the Fukushima Prefectural Government and the parties involved in the Agency have been focusing on the causes of this failure, one of them being that the R&D was mainly led by universities, which focused on the novelty and originality of the medical devices instead of market needs. Moreover, the R&D conducted by the Regional Innovation Cluster Program (which started in 2010) could not generate products for commercialization, and the national grant program was terminated at the project’s conclusion in 2012.

Contrary to the poor performance, in terms of commercialization of the R&D outcome funded by the national government, the prefectural independent support project

had successful results. For example, as of 2014, the member of the Study Group reached 250. Among them, the number in the prefecture exceeded 150, of which many were engaged in product development and parts manufacturing for medical manufacturers. As a result of the Pharmaceutical Affairs Act-related consultations, 65 companies obtained manufacturing permits for medical devices, which increased by approximately 1.5 times over the course of the last decade. Their business activities also expanded to include original equipment manufacturer (OEM) and prototype productions entrusted by the medical device manufacturers as well as medical device productions not limited to parts production. In addition, the number of exhibitors at Medical Creation Fukushima has increased from 50 organizations in 2005 to 218 in 2014. Another notable fact is that the number of business-matching activities has been increasing through the domestic and international exhibitions.

The subsidies by the Fukushima Prefectural Government are intended for companies to engage in the commercialization of medical devices, instead of universities to conduct research. In order to qualify for the subsidies, the R&D themes should have high commercialization potential or marketability, rather than novelty and originality. Thus, many development projects are not developed from scratch. Instead, they are generally improved versions of existing products by adding value such as better usability and quality, or by cutting price. The aforementioned subsidy projects that were carried out before the 2011 earthquake contributed to the local companies as supply parts and OEM to the manufacturers in Japan and overseas. After the earthquake, the recovery of medical-related industries was set as one of the pillars of industrial recovery in Fukushima Prefecture. As of 2015, more than 50 projects were related to pharmaceutical regulatory applications or commercialization, after which a virtuous cycle in which the mass production and commercialization of medical devices has emerged. Since then, the prefectural government and the Agency have recognized that the independent prefectural support project had been successfully handling the entire process from R&D to commercialization.

With respect to R&D and inter-organizational collaboration, universities and medical institutions began approaching the Agency and proposing joint R&D projects in Fukushima Prefecture. As a result of the Agency's acknowledgement, there has been an increase in sales promotions and autonomous trading with leading manufacturers as well as a rise in the number of local SMEs obtaining OEM deals, participating joint developments and supplying materials. Moreover, the numbers of SMEs that have entered into the medical device industry and the companies that have acquired manufacturing permits have increased.

Perceptions regarding the Commercialization of Medical Devices, the Course of Actions, and Future Challenges

Activities related to the commercialization of medical devices in Fukushima Prefecture have been understood, at least among the parties involved in the prefectural government and the Agency, as striving for the third step in the development stage mentioned above. Subsequently, it is expected to reach the fourth step, which aims to further expand into overseas markets.

To achieve the development steps described above, Fukushima Prefecture, based on its relatively low wages and vast available land, should become a hub in regard to the design, manufacture, and commercialization of medical devices. The prefectural

government and the Agency as the course of actions in the future share this vision. The government is also aware that more support is necessary to broaden the base of the medical device industry, especially regarding the acquisition of manufacturing permits, making technological improvements, and supporting start-ups by local SMEs.

Their goal is to reach 175 billion yen in the production of medical devices by 2020. However, the immediate challenge is to provide successful outcomes for all ongoing projects, including those with substantial subsidies provided by the recovery fund. The parties involved recognize the necessity of support by the prefectural government and the Agency in order to overcome the challenge. In addition, the establishment of business funds and low-interest loans by local banks are underway, which should be adequate for supporting medical device companies and related projects. The prefectural government and the Agency are also aware of the challenges of reducing the obstacles caused by the Pharmaceutical Affairs Act. Such obstacles include reducing the waiting period of assessments and supporting the R&D and manufacture of high-quality, safe medical devices that meet international safety criteria. All of these measures should be implemented (in addition to the ongoing support program) by the Fukushima Medical Device Development Support Center, which is scheduled to open in 2016.

ANALYSIS AND INTERPRETATION

In this case, the prefectural government decided on the commercialization and promotion of medical devices as the overall purpose, based on the situation that the prefecture was facing at the time (Initial Conditions). The establishment of inter-organizational collaboration was facilitated by setting the Places that could form cooperative relationships among the members. In this process, the first Intervention facilitated the interactions and established a common understanding for the setting and the development of the Places, while the second Intervention helped establish inter-organizational collaborations for the commercialization of medical devices.

Initial Conditions

In 2001, Fukushima Prefecture was preparing to facilitate inter-organizational collaboration for the commercialization of medical devices in the prefecture. However, the staff members from the prefectural government faced Initial Conditions, which are categorized as follows.

Facilitation Factors

Various factors that facilitate inter-organizational collaboration are found in the institutional environment, economy and industry, local research institutions, and networks. In the institutional environment, there was support from the national government and Fukushima Prefectural Government for engaging in the promotion of start-ups and long-term projects such as joint research projects targeting SMEs. More specifically, it helped facilitate information exchange between industry-academia-government as well as across industry sectors in each region.

In terms of economy and industry, since medical device businesses have high-growth potential, many small to medium-sized manufacturing companies with advanced technologies have converged in Fukushima Prefecture, in addition to several leading medical device companies, which have established their production and sales hubs. As a result, medical device-related parts production is the largest in Japan.

Regarding universities and research institutions for the R&D of medical devices, there have been several prefectural research institutions, including Nihon University and Fukushima Medical University.

In regard to networks, the prefectural government had a good understanding of the research institutions and companies that would be necessary for the commercialization of medical devices. The reason being that it had obtained sufficient knowledge about faculty members and their research as well as business owners and their operations through the various subsidy programs provided by the prefecture. In some previous projects, the universities and companies had built a network through joint development.

Based on the prefectural government's understanding of the factors mentioned above, especially at the time of the project's introduction in 2001, medical devices were selected for the promotion. In addition, the Places were set up through the Intervention by utilizing the networks among the companies and research institutions.

Obstacles in the Promotion of Inter-Organizational Collaboration

There were several major obstacles in the promotion of inter-organizational collaboration for the commercialization of medical devices. First, there were not enough companies available to engage in such commercialization, due to the difficulty of acquiring knowledge about the characteristics and sales of medical devices. Second, there were difficulties in acquiring manufacturing permits, which were mandatory for entering the medical device field full scale. Third, the SMEs had difficulty coping with the system related to the Pharmaceutical Affairs Act, including application procedures to obtain production permits. Although these obstacles were not identified at the time of the project's introduction in 2001, the prefectural government did comprehend them several years into the project. As a result, some projects included countermeasures to overcome these issues.

Establishment of Interactions and Common Understandings

Interactions and Common Understandings for the Set-up and Development of the Places

During the promotions of start-ups in the medical device industry, the parties involved shared the details of the support by the national government, the industrial promotion guidelines by the prefectural government, the economic and industry conditions, the presence of research institutions in the prefecture, and the potential for medical device businesses to succeed. Thus, industry-academia-government collaboration was recognized as the next important step.

When setting up the Places to promote inter-organizational collaboration, the interactions and common understandings between the parties involved became the subject of focus. After the prefectural government offered its support in 2001, the common understanding regarding the R&D of medical devices in the five fields (based on haptic technology) was reached between "Mr. O" from the prefectural government and "Professor H" from Nihon University. Furthermore, the research members discussed the details of the initial goals, the roles played in the five fields, and final target. As a result, they effectively established the Places where members could further discuss the options as well as communicate with others outside of the group in order to foster inter-organizational collaboration and improve R&D projects funded by the national government.

In the development of the Places, a common understanding was reached, based on the lessons learned from the City Area (Basic Stage) program. In this regard, the members suggested that consistent support be provided for the commercialization of medical devices by targeting a wider range of fields. Then, the prefectural independent support project for commercialization and the R&D funded by the national government were combined into the “Utsukushima Next-Generation Medical Industry Agglomeration Project.” Furthermore, many more constituents, including SMEs in the prefecture, began participating in medical device businesses through information sharing with the prefectural government and the local companies. Finally, the Place called the “Study Group” was established as the foundation of the project. As a result, they had reached a common understanding that there was a need to establish an inter-organizational collaboration and the Place called “Study Group” was established as the foundation of the project.

The development of the Places in the “Utsukushima Next-Generation Medical Industry Agglomeration Project” after 2010 included the following steps. First, the “Fukushima Medical-Industry Liaison Office” was established to oversee the collaborations between the industries and Fukushima Medical University. The transfer of the R&D hub to Fukushima Medical University, which was initiated by the Regional Innovation Cluster Program, triggered this. However, in light of the purpose of the commercialization of medical devices, the unsatisfactory results were shared among the parties involved in the prefectural government. Then, a common understanding regarding the necessity of establishing a system to integrally support the commercialization process was reached, leading to the establishment of the “Fukushima Medical Device Industry Promotion Agency” in 2013. Finally, the Study Group members had reached common understanding regarding the need to focus more business-oriented activities for the commercialization of medical devices. As a result, they changed their name to the “Medical Device Related Industries Council,” which was managed by interested private companies.

Interactions and Common Understandings in the Inter-Organizational Collaboration for Commercialization

For the commercialization and promotion of medical devices, cooperation between the parties across sectors was found in the R&D, material supply, OEM, and joint development of the products. In the R&D projects funded by the national government, the Places had been configured and set up by the members from the industry-academia-government in order to apply for the Intellectual Cluster Program in 2001. In addition, the Places contributed to the establishment of inter-organizational collaboration and the promotion of R&D projects through interactions among the parties involved. The inter-organizational collaboration was established by realizing some product developments in the City Area (Development Stage) program. In order to improve marketability, this required modifications of the promotion systems and the roles of the project managers and the coordinators.

The establishment of inter-organizational collaboration in materials supply, OEM, and joint product development were facilitated by the prefectural independent support project for commercialization. Companies from different industries to enter the medical device industry, especially after acquiring such information from the Study Group and the “Utsukushima Next-Generation Medical Industry Agglomeration Project.” Subsequently, the continuous acquisition of knowledge and interactions between companies and research institutions inside and outside of the prefecture increased opportunities to

contact potential partners, share and adjust business goals and roles to play, etc. As a result, inter-organizational collaboration was increasingly established between companies, or between research institutes, medical institutions, and the companies (particularly SMEs) in Fukushima Prefecture for the purpose of commercialization.

The Role of Interventions and the Functions of Places

The Role of Intervention for the Set-up and Development of Places

This case study shows that the Places effectively contribute to industry-academia-government collaboration for the R&D of medical devices funded by the national government. As stated earlier, Intervention to set up the Place was initiated when “Mr. O” from the prefectural government (who was in charge of the project) approached “Professor H,” who later played a central role in the R&D project. Moreover, Mr. O, parties involved in the prefectural government, university faculty in order to expand the members of the Place, initiated additional Interventions.

Then, based on the lessons learned from the results of the City Area (Basic Stage) program, the parties involved recognized the necessity for stronger promotion of the commercialization process. This led to the development of Places for the R&D funded by the national government as well as the prefectural independent support project, under the name of “Utsukushima Next-Generation Medical Industry Agglomeration Project” in 2005, through the following Interventions by the parties involved in the prefectural government. First, in the “City Area (Development Stage)” program, which was a R&D project funded by the national government, the members of the industry-academia-government were well informed that R&D should directly target commercialization. Second, the Study Group was set up under “Utsukushima Next-Generation Medical Industry Agglomeration Project” was established as the Place to facilitate inter-organizational collaboration and to realize the commercialization of medical devices in broader fields. The group was formed with requests for the chairman and organizers as well as public invitations to the members. Third, based on the requests from the members of the Study Group, the functions of the Places had been improved by approaching the parties involved inside and outside of the prefectural government and obtaining cooperation from them.

After 2010, based on the requests from the members of the Study Group, the “Fukushima Medical-Industry Liaison Office” was established with the Intervention by the parties involved in the prefectural government to the parties involved in Fukushima Medical University. Although there were no sufficient outcomes from this establishment, certain guidelines were created in order to improve the system and support the commercialization process in an integrated manner. In 2012, led by the parties involved in the prefectural government, the “Fukushima Medical Device Industry Promotion Agency” was established. Since then, it has served as an integrated point of contact for industry-academia collaboration as well as for commercialization support. As stated earlier, the Study Group changed its name to the “Medical Device Related Industries Council,” which focuses on commercialization efforts as well as business-matching services. Although this change did not address Interventions by a single party, it did develop a Place in which the members could be more self-reliant.

Roles of Interventions and Places in the Establishment of Inter-Organizational Collaboration for Business Promotion

The functions of Places in facilitating the establishment of inter-organizational collaboration include: direct outcomes that build relationships by providing Interventions to potential collaborative partners; and indirect outcomes that lead to prompt Interventions among potential collaborative partners.

In regard to direct outcomes, after the discussion about the commercialization of medical devices, “Mr. K” and “Mr. F” were approached during the City Area (Basic Stage) program, and an Intervention was conducted to project leaders and coordinators via public invitations in the City Area (Development Stage) program. In this case, the direct outcome was that such an Intervention facilitated the establishment of inter-organizational collaboration, which, in turn, established cooperation among the parties involved in the R&D projects.

Regarding the indirect outcomes, induced by the independent prefectural support projects, there were numerous aspects, including: Study Group activities, Pharmaceutical Affairs Act-related consultations, human resources development programs, sales expansion support, and subsidies. These measures provided as the functions of the Place and they contributed to providing information and learning opportunities for local companies to effectively enter into the medical device industry and to provide opportunities for information exchange with potential collaboration partners. In addition, this case study found that the functions of Place activated autonomous Intervention to facilitate interactions between various parties (i.e., companies, universities, and medical institutions) in and outside of the prefecture for the collaboration.

Based on the analysis of the case study, Figure 4 presents the establishment process of the inter-organizational collaboration:

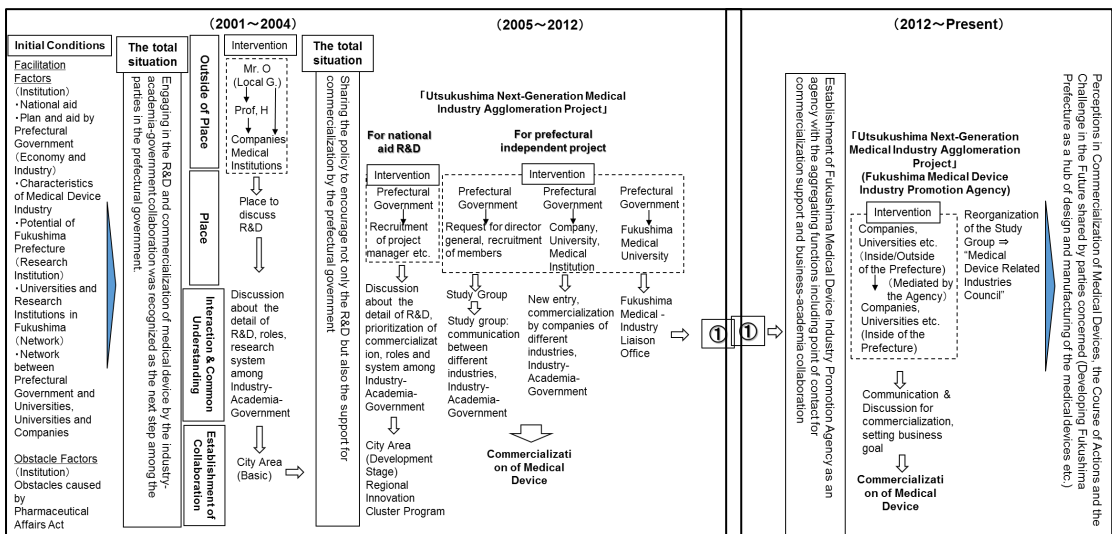


Figure 4. The Establishment of Inter-Organizational Collaboration

Evaluation of the Conceptual Model

Regarding the conceptual model described earlier, this study verified the adequacy of the conceptual model, thus suggesting that the setting of the Place and the Intervention can facilitate interactions and common understandings to establish inter-

organizational collaboration. Based on the analysis of this case study, Figure 5 presents a modified conceptual model:

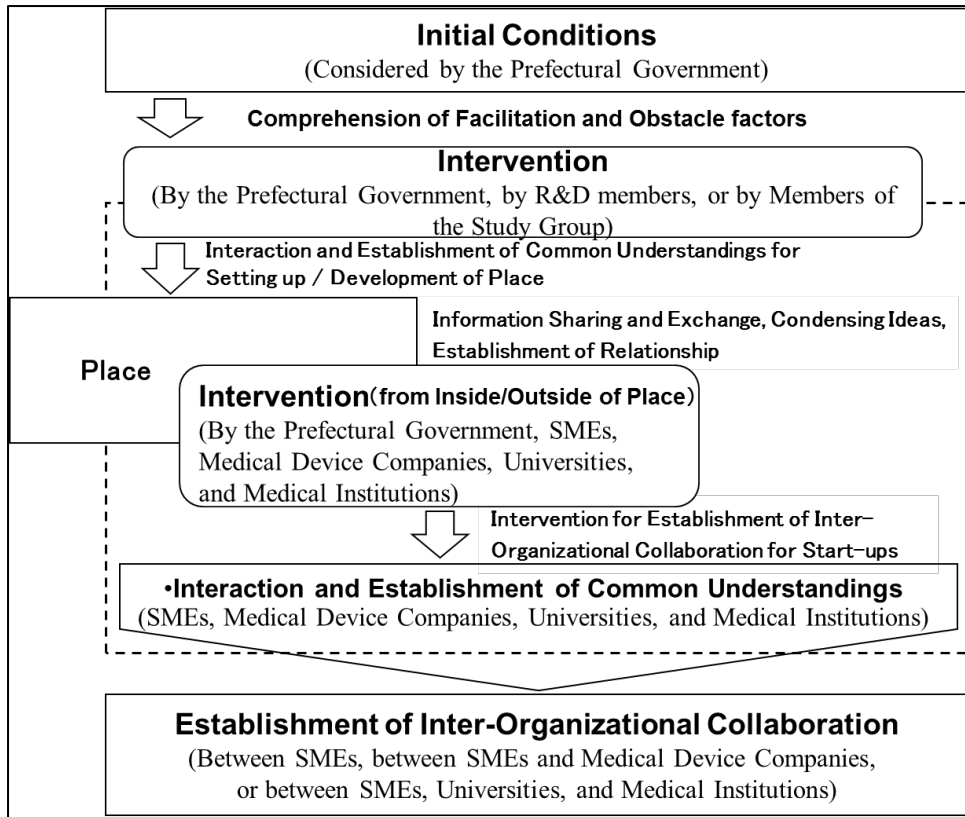


Figure 5. Modified Conceptual Model

According to the modified conceptual model, several findings are apparent. First, the Initial Conditions had an impact on the establishment of inter-organizational collaboration. More specifically, it had an effect on the selection of start-ups (collaboration domain), the setting of Places, and the implementation of Interventions.

Second, the interactions and the establishment of common understandings existed in both the set-up/development of Places and the establishment of inter-organizational collaboration. The details of the interactions and the establishment of common understanding reach for each occasion are also found in this case study.

Third, Interventions occur when setting/developing the Places. Moreover, interventions are also provided as direct and indirect outcomes of the Place. The roles of these Interventions were to facilitate the interactions and the establishment of common understandings necessary for the relationship building. In this study, people who mainly intervened were the parties involved in the prefectural government, but so were the university faculty members and the companies that participated in the inter-organizational collaboration. This fact suggests that the parties intervene can vary, and potential collaboration partners might become autonomous and turn into the parties who intervene.

Finally, this study found that Place (which provides opportunities for information sharing and exchange) can lead to direct Interventions or autonomous Interventions for facilitating the interactions and the establishment of common understanding to achieve the goal of inter-organizational collaboration. This is because the potential collaboration partners inside and outside of the Places build the relationship. It was also found that the set-up/development of the Places was realized through the Intervention or interactions and common understanding between the members of their own accord.

CONCLUSION

This case study examined how inter-organizational collaboration can be effectively facilitated to establish new businesses by focusing the Initial Conditions, interactions and establishment of common understanding, the Place, and the Intervention. More specifically, this was an inter-organizational collaboration study that focused on the process in which SME start-ups entering into the medical device industry are promoted in Fukushima Prefecture.

The findings from the case study confirmed that the leading constituents for the facilitation of inter-organizational collaboration include the selection of domains, the setting of the Place, and the Intervention, based on the Initial Conditions. In addition, the interactions and establishment of common understandings was facilitated through the Intervention and led to the establishment of inter-organizational collaboration. This case study also confirmed that, based on the requests of the parties inside or outside of the Place, the Place developed through Intervention, or autonomous interactions and common understanding of them. The potential collaboration participants inside and outside of the Place found the process of successful inter-organizational collaboration in carrying out autonomous Intervention. From the above findings, it is confirmed that the conceptual model presented at the beginning shows a certain adequacy; furthermore, the modified conceptual model can be presented.

The academic value of this study, since previous studies addressed only a few, is to contribute to the paradigm focused on the interactions and the establishment of common understanding by key individuals and the factors to facilitate establishment of inter-organizational collaboration for business promotion. Besides, the medical device field was rarely chosen in the previous business studies. The practical value is that this study contributes to finding the implications how to promote inter-organizational collaboration in order to overcome the promotional challenges of SMEs for start-ups in the medical device industry. Because it is essential to take advantage of the capabilities built in the SMEs to promote the industry, which has a high potential for growth and significant impact on the local economy.

However, evaluation of the single case study has limitations to obtain sufficient views on theory building and on management. In order to increase the significance of the study, the following are necessary. First, since this evaluation simply focused on a single prefecture, it is important to conduct comparative studies by examining cases of inter-organizational collaboration in other regions of Japan or overseas which have their own industrial structure and the companies. Second, since the target of the survey in this study was mainly from the perspective of operating side, it is necessary to continue the research in order to derive more profound implications for the mechanism and the management of the establishment of inter-organizational collaboration by broadening the survey to the parties involved, particularly companies that were involved in collaborative projects.

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