A Role Model of Large-Scale University–industry Collaboration in Japan: The Case of Chugai Pharmaceutical and Osaka University

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Abstract: Large-scale university–industry collaborations that are worth some 10 billion yen and run for 10 years have begun to appear in Japan since the mid-2010s. This paper focuses on the drug development project being conducted by Chugai Pharmaceutical Co, Ltd. and Osaka University, which is a pioneering case of this kind of collaboration, and explores the background of how this project came to be. For the companies involved in university–industry collaborations, the most important point for consideration is generally whether or not they will achieve results (from the university's contributions) that are sufficient to justify their investment. For Chugai Pharmaceutical, the deciding factor in making its 10-billion-yen investment was that Osaka University had been selected for the World Premier International Research Center Initiative (WPI) of the Ministry of Education,

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Culture, Sports, Science and Technology (MEXT) and had built up research capabilities to make a sufficient contribution to Chugai. In that sense, we could say that this collaboration came into being because of the government's support in building the innovation base and because of switching over from government sponsorship to corporate sponsorship after the operation of the base was on track. This so-called government-support-based, large-scale university–industry collaboration is a potential role model for university–industry collaborations in the future.

Keywords: university–industry collaboration, research and development, pharmaceutical industry, open innovation

Introduction

Since open innovation (Chesbrough, 2003, 2006) became popular in Japan in the 2010s, university–industry collaboration has been focused on as a way for firms to obtain external resources (Kuwashima, 2018, 2019; Manabe & Yasumoto, 2010; Nagahira, 2010).¹ According to the Ministry of Economy, Trade and Industry questionnaire survey on research and development at large Japanese corporations, universities were currently cited as the most frequent collaboration partners, as well as the most likely partners for collaboration in the future (Japan Open Innovation Council (JOIC) & New Energy and Industrial Technology Development Organization (NEDO), 2016).

By its nature, research and development takes a long time to yield results. Therefore, when firms and universities conduct joint research, it is best to do it over the long term. However, because firms and universities have different goals and motivations in collaborating,

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¹ See Sawada (1990), Tamai & Miyata (2007), and Yoda & Kuwashima (2019) for the history of university–industry collaboration in Japan.

there is concern that opportunistic behavior and problems between the organizations will occur (Azoulay, Ding, & Stuart, 2009; Baba & Goto, 2007). So, entering into large-scale contracts is very risky for companies funding universities. Therefore, the conventional university–industry collaborations in Japan were often short-term and small-scale contracts. On the other hand, in recent years, a large-scale university–industry collaboration contract with a total cost of 10 billion yen for 10 years has appeared. This paper focuses on the drug development project undertaken by Chugai Pharmaceutical Co., Ltd. and Osaka University, which is a pioneering case of this kind of collaboration. In 2019, this project, which was lauded for its social impact and sustainability,² received the Minister of Education, Culture, Sports, Science and Technology Award at the 1st Japan Open Innovation Prize (JOIP) sponsored by the Cabinet Office with the theme, “University–industry co-creation from the basic research stage: Collaboration between organizations.”³ Let’s use this case study to look into why large-scale university–industry collaboration, which had formerly not taken place, has become possible.

Overview of the Collaboration of Chugai Pharmaceutical and Osaka University⁴

On May 19, 2016, Chugai Pharmaceutical and Osaka University’s Immunology Frontier Research Center (IFReC) unveiled a comprehensive collaboration agreement (Osaka University & Chugai

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² The 1st Japan Open Innovation Prize (JOIP):

<https://www8.cao.go.jp/cstp/openinnovation/prize/index.html>

³ Osaka University, Chugai Pharmaceutical, Otsuka Pharmaceutical, and Daikin Industries jointly won this award.

⁴ The descriptions in this section are based on three interviews conducted with Chugai pharmaceutical, additional questions by e-mail, and published materials.

Pharmaceutical, 2016). The IFReC, which was selected for the World Premier International Research Center Initiative (WPI) of the Ministry of Education, Culture, Sports, Science and Technology (MEXT), was founded by Osaka University in October 2007 as a research hub in immunology.⁵ The WPI was launched by MEXT in 2007 to build within Japan “globally visible” research centers that boast a very high research standard. It is Japan’s largest competitive research funding program, and the centers that are selected receive research funding amounting to 1.3 billion yen to 1.4 billion yen per annum.⁶ In 2007, the first time it granted funding, it selected five centers, including the IFReC.⁷

The IFReC has achieved impressive research results since its inception. In 2011, Thomson Reuters ranked Osaka University at number one in its rankings of global research institutions in the field of immunology, which are based on the citation impact of academic papers.⁸ In 2015, Thomson Reuters included six researchers from the IFReC on its list of “The World’s Most Influential Scientific Minds

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⁵ As of 2020, the IFReC is under the direct control of Osaka University’s International Advanced Research Institute (IARI), which was founded in April 2017. The IARI was founded to set up new world-class research hubs by supporting the acquisition of large-scale external funding (International Advanced Research Institute (IARI): <https://www.osaka-u.ac.jp/en/academics/wpi>).

⁶ World Premier International Research Center Initiative (WPI): <https://www.jsps.go.jp/english/e-toplevel/index.html>

⁷ The other four centers were: Tohoku University (Advanced Institute for Materials Research (AIMR)), University of Tokyo (Kavli Institute for the Physics and Mathematics of the Universe (Kavli IPMU)), Kyoto University (Institute for Integrated Cell-Material Sciences (iCeMS)), and the International Center for Materials Nanoarchitectonics (MANA). Subsequently, one additional institution was selected in 2010, three in 2012, two in 2017, and two in 2018, so that as of 2020, a total of 13 centers have been selected (World Premier International Research Center Initiative (WPI): <https://www.jsps.go.jp/english/e-toplevel/index.html>).

⁸ Based on data published by Clarivate Analytics in “TOP 30 INSTITUTIONS IN IMMUNOLOGY, 2000–2010” http://archive.sciencewatch.com/dr/sci/11/apr10-11_1D/

2015,” which was compiled from article citation data (Thomson Reuters, 2015).

The comprehensive collaboration agreement runs for the 10-year period from April 2017 through March 2027. During this time, Chugai Pharmaceutical will pay research funding to Osaka University of 1 billion yen per year, for a total of 10 billion yen (Osaka University & Chugai Pharmaceutical, 2016). According to MEXT data, in fiscal 2016, there were 18 university–industry joint projects in Japan receiving research funding of over 100 million yen per year. This comprised a mere 0.06% of the total (Ministry of Education, Culture, Sports, Science and Technology, 2018). Accordingly, we can see that annual funding of 1 billion yen is a very large-scale project. The goal of this collaboration project is to create new cutting-edge drugs in immunology-related epidemiology by combining the IFReC’s store of immunology research with Chugai Pharmaceutical’s knowhow in drug research (Osaka University & Chugai Pharmaceutical, 2016). At the collaboration’s inception, researchers from the IFReC consisted of 27 chief researchers (of which 5 were non-Japanese and 1 was female), 100 other researchers (of which 35 were non-Japanese and 15 were female), and 66 research assistants (Immunology Frontier Research Center, 2018).⁹

Below is the basic scheme of the comprehensive collaboration agreement between the IFReC and Chugai Pharmaceutical (Osaka

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⁹ The IFReC’s budget (total expenditures) consists of two major types: funding from firms in the form of comprehensive collaboration agreement grants and funding from other sources (such as management expense grants from the university, Grants-in-Aid for Scientific Research, and donations), under the “matching fund” system. In fiscal 2017, the initial year of this collaboration, the Center’s total expenditures of about 3.1 billion yen consisted of about 1 billion yen from the comprehensive collaboration agreement and about 2.1 billion yen from other sources. Expenditures under the comprehensive collaboration agreement were 49.0% for personnel, 31.7% for project activities, and 18.8% for equipment (Immunology Frontier Research Center, 2018).

University & Chugai Pharmaceutical, 2016).

1. IFReC researchers will continue academic basic research without restriction.
2. Research outcomes of independent research projects that IFReC is engaged in will be regularly disclosed (reported) to Chugai twice per year.
3. Chugai will select research projects for joint research on the basis of the reports.
4. IFReC researchers will engage in joint research with Chugai.
5. In and after the final stages of non-clinical research, Chugai may engage in research development independently.

A distinctive feature of this scheme is that this comprehensive collaboration includes the basic research stage. In the past, the collaborative research contract between companies and universities were often concluded for each theme (that is, for each project or product) from the applied research stage and based on universities' basic research outcomes. In contrast, this collaboration starts at the basic research stage. While the IFReC freely selects basic research themes without restrictions from Chugai Pharmaceutical, it discloses the research results to Chugai Pharmaceutical before publishing them externally.¹⁰ Chugai Pharmaceutical will then determine whether to conduct joint research on these research outcomes (each research theme) with a view to their commercialization.¹¹

When conducting joint research, the joint research contract (separate from the comprehensive collaboration agreement) is signed

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¹⁰ In other words, Chugai Pharmaceutical has the right of first access to these research outcomes.

¹¹ Instead of engaging in joint research, Chugai Pharmaceutical can also apply to IFReC for the right to use the patent resulting from the basic research. See Kishi and Takahashi (2010), Nakano and Takahashi (2012), and Takahashi and Nakano (2003) regarding technology transfers from universities to firms in Japan.

after the director of the research theme of IFRc and Chugai Pharmaceutical have reached an agreement.¹² Once the agreement is signed, the joint research will be implemented at the Joint Research Chair of Innovative Drug Discovery in Immunology (known as the Collaboration Promotion Laboratory), which was established in Osaka University. When the Collaboration Promotion Laboratory was set up in 2017, its staff included 12 researchers from Chugai Pharmaceutical (Nikkei Biotechnology & Business, 2017). If necessary, some of the joint research may take place at Chugai Pharmaceutical's Fuji Gotemba Research Laboratories and Kamakura Research Laboratories.

The expectation is that using this scheme for the collaboration will enable a smooth link between the basic research stage and the applied research/development stage of the drug development process, thereby increasing the potential for creating new drugs.

Since it typically takes at least 10 years to develop a new drug, this collaboration has yet to produce any new products. However, as of March 2020, it had generated several research papers and patents as basic research outcomes.¹³ Also, between 5 and 10 joint research agreements have been signed based on the basic research findings.¹⁴

Furthermore, patent applications that result from this collaboration are filed in line with the following process. Patents from outcomes at the basic research stage of the collaboration process (research performed by Osaka University alone) are sole applications by Osaka University. Even though Chugai Pharmaceutical is providing funds under the comprehensive collaboration agreement, it is not a joint application because the firm does not directly take part

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¹² Cases of joint research implementation are capped so as to match the amount of funding contributed by Chugai Pharmaceutical.

¹³ The actual number of papers, patents, and joint research agreements resulting from this collaboration have not been disclosed.

¹⁴ According to interviews and email questions sent to Chugai Pharmaceutical.

in the basic research process. For patents based on joint research findings in the applied research/development stage of the collaboration process, the patent application can be either sole or joint depending on the relative contributions of Osaka University and Chugai Pharmaceutical to the research.

Factors for Forming Large-Scale University–industry Collaboration

In this section, we consider the factors that have made it possible to engage in large-scale university–industry collaboration in Japan, when it had formerly not taken place. Research and development projects, including those for pharmaceutical products discussed in this paper, generally take a long time to achieve results.¹⁵ Thus, it is a given that joint research conducted by firms and universities should ideally take place over a long period of time. However, the motivations and goals of the stakeholders (firms and universities) participating in university–industry collaborations are not necessarily aligned (Azoulay et al., 2009; Baba & Goto, 2007; Lee, 2000; Rosenberg & Nelson, 1994). For example, firms are most interested in launching new products onto the market as a result of the collaboration, while universities tend to be more interested in such matters as securing research independence and writing academic papers than in launching new commercial ventures. There is also the issue that it is difficult for firms to get an accurate picture of universities’ research capabilities ahead of time. This makes it difficult for firms providing research funding to universities to make large investments before they can be sure that they will get a return that is in line with the investment they are making. This is why most university–industry collaborations in Japan have consisted of small-scale agreements in the past. So, how have Chugai

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¹⁵ See Kuwashima (2015, 2016) for more on the features of pharmaceutical research and development.

Pharmaceutical and Osaka University been able to carry out such a large-scale collaboration? Below, we examine the viewpoints of both Chugai Pharmaceutical and Osaka University (IFReC).

Let us first examine how Chugai Pharmaceutical came to the decision that it would be able to obtain a return that is in line with its investment. The major factor is the IFReC's impressive research capabilities built up prior to its collaboration with Chugai Pharmaceutical. As mentioned above, it has been 10 years since the IFReC was selected for the WPI by MEXT in 2007, and during this time, it has built up excellent capabilities as a research hub. In the past, universities' research capabilities have usually been built up independently, at the individual researcher level or the research lab level. In contrast, the IFReC built up its research capabilities as an organization at its IFReC research hub, and this was important for Chugai Pharmaceutical. Regarding this point, a senior vice president at Chugai Pharmaceutical stated, "The IFReC was building up its research capabilities as an organization. This made us confident that it would be able to continuously provide Chugai with the high-quality ideas and seeds needed to carry out multiple drug discovery projects in the field of epidemiology."¹⁶ In other words, Chugai Pharmaceutical was confident that the IFReC could contribute enough to create multiple new drugs because IFReC accumulated sufficient research capability not at researcher level or laboratory level but at research hub or organization level. This led them to make the decision of a large investment of 10 billion yen.

At the same time, from the university's point of view, one of the biggest issues in collaborating with a firm from the basic research stage over a long time period was the potential loss of its basic research independence or academic freedom (Azoulay et al., 2009; Krinsky, 2003; Washburn, 2005). Even in this collaboration, the

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¹⁶ From an interview conducted in March 2018.

maintenance of its research independence was a key issue for Osaka University.¹⁷ This issue was resolved in the first item in the collaboration's basic scheme: "IFReC researchers will continue academic basic research without restriction." In typical university–industry collaborations, the use of the funds provided by the firm are usually restricted, but in this collaboration project, Chugai Pharmaceutical has not only given the IFReC 1 billion yen per year but has not designated how the funds are to be used. Thus, we see that from a funding perspective, the independence of the IFReC's research activities is being preserved.

Besides the store of organizational research capabilities and the maintenance of research independence, another key issue in realizing this collaboration is the close communication between the IFReC and Chugai Pharmaceutical at an organizational level. As noted above, Chugai Pharmaceutical has assigned more than 10 researchers to the IFReC's Collaboration Promotion Laboratory, cultivating a climate where researchers from Chugai Pharmaceutical and the IFReC can hold both formal and informal meetings on a daily basis. Also, a large-scale research symposium is held every six

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¹⁷ In a news release on the collaboration between Osaka University and Chugai Pharmaceutical, IFReC Director Shizuo Akira stated, "Going forward, we plan to continue advancing our research based on the concept of researcher independence..." (Osaka University & Chugai Pharmaceutical, 2016). Also, in the Osaka University newsletter, Osaka University President Shojiro Nishio commented, "These funds being received by Osaka University will be earmarked mainly for operating expenses at our Immunology Frontier Research Center (IFReC). In doing so, we will be able to maintain an academic environment where researchers can concentrate on conducting independent basic research in advanced epidemiology" (Osaka University, 2017). Likewise, at the award ceremony for the 1st Japan Open Innovation Prize, Osaka University Executive Vice President Yasushi Yagi stated, "The use of this research funding has not been pre-allocated, so we will freely engage in research by using the funds to pay our researchers." (Osaka University, 2019). These comments show that maintaining research independence is a key issue for the IFReC in this collaboration.

months. In other words, various measures have been taken to promote communication between researchers from Chugai Pharmaceutical and the IFReC. Of course, firms were posting researchers to universities in previous university–industry collaboration projects as well, but in these cases, the communication was mainly between individual (such as university faculty members) and individual (such as the researchers sent by the firm). In contrast, this case is distinguished by the characteristic that Chugai pharmaceutical had established a research base at Osaka University and assigned a certain number of researchers to it, so that IFReC and Chugai Pharmaceutical could closely communicate at an organizational level. Frequent communication has enabled both sides to keep abreast of the progress of the research and check up on the contributions made by the other party. For Chugai Pharmaceutical, which is providing the funding, such close communication between the organizations has led to less unease about potential opportunistic behavior by the other party. This had a significant impact on the decisions that Chugai Pharmaceutical made before the collaboration began and also helped to generate results that met the criteria determined before the collaboration began.

Conclusion

As we have seen, Chugai Pharmaceutical and the IFReC have been able to implement a large-scale university–industry collaboration project, which previously would have been difficult, due to such factors as the accumulation of organizational research capabilities, the maintenance of research independence, and close communication on an organizational level. Of these three factors, the second and the third are key when designing a collaboration scheme. Therefore, those conducting similar large-scale

university–industry collaboration projects in the future should bear the second and third factors in mind. On the other hand, we need to point out that the first factor was not the issue of the collaboration scheme but was important in the IFReC’s having been selected for MEXT’s World Premier International Research Center Initiative (WPI) in 2007. In other words, the IFReC built up its research capabilities as a research hub because it was receiving governmental support of 1.3 billion yen to 1.4 billion yen per year over a period of 10 years due to its selection by the WPI. Then, just as the governmental support was running out, the organization started receiving support of 1 billion yen per year from Chugai Pharmaceutical due to its established research capabilities.

In other words, the large-scale university–industry collaboration between Chugai Pharmaceutical and the IFReC came about not merely as a result of designing a scheme for collaboration, but because of the result of the Japanese government’s policies on innovation. In this sense, we could say that this collaboration came into being because of the government’s support in building an innovation base and because of switching over from government sponsorship to corporate sponsorship after the operation of the base was on track.¹⁸ Although this type of government-support-based, large-scale university–industry collaboration has only just begun in Japan, it could become a role model for university–industry collaboration in the future.

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¹⁸ Regarding the universities selected by the WPI, Osaka University, as well as the University of Tokyo, the Tokyo Institute of Technology, and others have succeeded in obtaining large-scale research funding from firms and other private-sector foundations due to their support from the WPI (Ministry of Education, Culture, Sports, Science and Technology, 2017).

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