CRDS-FY2017-RR-01

Study Report

Medical Research & Development Platforms

– Comparison of Research Systems in Overseas University Hospitals –

Center for Research and Development Strategy,
Japan Science and Technology Agency

Executive Summary

The Center for Research and Development Strategy (CRDS), Japan Science and Technology Agency (JST) (hereinafter referred to as “JST-CRDS”) is one of the public think tanks that exhaustively follows trends (panoramic view survey), performs analyses and makes proposals concerning science and technology (ST). With the aim of improving the quality of national healthcare and providing healthcare more efficiently, CRDS Life Science and the Clinical Research Unit have been conducting surveys on systems (medical R&D platforms) that promote medical R&D in advanced and emerging countries since April 2016. This study report summarizes the results of a case study analysis in the US, Netherlands, Germany, South Korea and Japan; with findings obtained based on a comparison of the cases and policy suggestions for establishment of a medical R&D platform in Japan.

This case study analysis was conducted in advanced university hospitals in the US, Netherlands, Germany, South Korea and Japan. In each institution, systems for medical R&D (medical R&D platforms), including, organization, financing and governance, were examined. As a result, elements that help medical doctors (MDs) and Doctors of Philosophy (PhDs) to perform research were identified and structuralized (Table i). The organizational or financial independence of university hospitals was the common fundamental element observed in all the overseas cases.

Table i Elements and Structure of Medical R&D Platforms Covered in the Survey of Overseas Cases

Research-promoting factor		Policy in each country
Promotion of clinical research by MDs	Reduction in clinical workload	Clinical faculty positions → improvement of medical functions by recruiting outstanding clinicians Branch hospital → functional independence of research/education/medical care Financial/organizational independence of university hospitals → increases in the number of MDs employed
	Increases in research resources	Research laboratories under the hospital organization/JV research laboratories, cross-appointments → strengthening collaboration between MDs and PhDs Industry-government-academia collaboration, financial and organizational independence of university hospitals → increases in research budgets or improvement of research environment
	Improvement of skills and incentives	System to foster MDs with research skills Industry-government-academia collaboration, cross-appointments → patent/ventures etc. Project positions → increased income
Promotion of clinical research by PhDs	Systems/positions for research in the clinical setting	Financial/organizational independence of university hospitals → industry-government-academia collaboration, cross-appointments, research laboratories under the hospital organization/JV research laboratories, project positions
	Increases in the number of research topics	Industry-government-academia collaboration, branch hospitals → creation of research sites, diversity MD-PhD collaboration → more clinical research being undertaken

Reductions in clinical workload, increases in research resources and improvement of skills and incentives are effective ways to promote research by MDs. Various policies have been adopted in institutions in each country to reduce the clinical workload of MDs so that MDs with research skills and motivation can invest their time in research. For example, the US, Germany and South Korea have introduced clinical faculty positions. This policy can improve the clinical functions of a hospital by recruiting MDs with outstanding skills in clinical care, thereby allowing other MDs to invest more time in research and improve hospital management. The title of “clinical faculty” can work as an incentive for MDs with superior medical care skills to seek to obtain positions in universities. This is an important element especially in universities like Harvard University that has many affiliates. The clinical faculty positions in these countries can be operated flexibly according to the management/R&D strategy of the hospital as university hospitals are organizationally/financially independent.

Having branch hospitals and affiliates is also effective in promoting research performed by MDs. Harvard University, Erasmus MC (Netherlands) and Seoul National University have branch hospitals and affiliates, and the research, education and clinical functions can be divided between the faculties of medicine, main hospital, branch hospital(s) or affiliates.

Branch hospitals and affiliates can utilize the brand power of the university to contribute to overall management and increase the resources that MDs and PhDs of the faculty of medicine and main hospital can invest in research. Furthermore, an increasing pool of human resources, (big) data etc., which can be easily utilized strategically, will contribute to the promotion of research.

Research laboratories under hospital organizations or joint research laboratories with other institutions and cross-appointments between hospitals and other university departments or external institutions are policies widely noted in the surveyed cases. Research laboratories employ PhDs, who are not medical doctors, and have established systems in which internal and external PhDs can obtain cross-appointments in hospitals or faculties of medicine and promote research in collaboration with MDs. In addition, systems that utilize human and economic resources outside the hospital through industry-government-academia collaboration have been established to promote research by MDs. While financial and organizational independence of university hospitals is not a necessary condition, it is thought to improve responsiveness and speed of decision-making in hospitals and contribute to promotion of industry-government-academia collaboration.

Financial/organizational independence of university hospitals can bring about the strategic operation of medical fees-based revenues and establishment of staff positions (especially, the clinical faculty position described earlier) in hospitals, thereby facilitating the promotion of R&D in these hospitals. In the Netherlands, a health insurance system based on the concept of “management competition” has been implemented and hospitals negotiate prices with insurers regarding healthcare services that the hospitals provide. In this system, because hospitals are constantly exposed to competition in terms of innovation creation, strategic budget operation of the UMC, which is separately incorporated, becomes an essential condition for prompt entry into R&D that meets the needs of MDs and PhDs of the UMC. In South Korea, Seoul National University Hospital, Severance Hospital Yonsei University and other university hospitals, which are designated under the research-oriented hospital system introduced in 2013, are financially or organizationally separate from the universities. Therefore, a condition whereby a specific percentage of hospital income is invested in research, in other words, a mechanism that channels the income from medical practices back into research funds, could be embedded in the system.

Enhancement of the research skills of MDs or incentives for engaging in research are important for establishing a medical R&D platform. Germany and the Netherlands, in particular, enthusiastically promoted a policy to develop MDs with research skills. The clinician-scientist system introduced in Charité-Universitätsmedizin Berlin is a contract to “buy research hours” for young doctors. These initiatives are based on the awareness that it is of vital importance to secure young talents, who determine the quality of medical care and research in hospitals, under the competitive environment that characterizes top-ranking universities in the US, UK and other countries. If the ranking of a university (faculty of

medicine) is raised by increasing the numbers of papers, citations and highly cited papers (HCPs) through the development of MDs with research skills, young talents will emerge. These young talents will create high-quality research results with the effect that the cycle repeats itself.

Industry-government-academia collaboration and cross-appointments with other institutions can incentivize MDs to engage in research through the acquisition of patents and involvement in venture start-ups. Erasmus MC has over 25 affiliates and faculty members of Erasmus MC participate in clinical research and commercialization of research results through cross-appointments. Revenues and patent revenues generated by these ventures act as incentives to MRs to engage in translational research (TR) and clinical research.

In the US and EU, it is common to pay research salaries from the external research funds. If someone has the capacity to obtain funds for research from an external source, the motivation to win positions from direct incentives, i.e., increases in income, will be developed. Furthermore, if a specific amount from an external research fund can be continuously obtained even if the fund is changed, the project's position can be maintained virtually without a finite term. Project positions operated under such a system can act as effective incentives for MDs with the ability to conduct research.

On the other hand, it is effective in the promotion of research by PhDs to increase systems/positions that allow PhDs, who are not MDs, to conduct research in the clinical setting, and to increase research themes where PhDs can be effectively utilized. As described above, the financial/organizational independence of university hospitals will affect the promotion of industry-government-academia collaboration and cross-appointments, strategic establishment/utilization of research laboratories, and the flexible operation of project positions etc. If PhDs, who are not MDs, are to conduct research in the clinical setting, collaboration between MDs and PhDs or positions that allow PhDs to conduct research independently are necessary. Industry-government-academia collaboration and research laboratories where MDs and PhDs get together may be effective ways to bring about collaboration between MDs and PhDs and positions at hospitals for PhDs through cross-appointments and making project positions available may be effective in the latter case.

Cases in each country suggested that intensive development or diversification of research sites through industry-government-academia collaboration and establishment of branch hospitals/affiliates are effective ways to increase research themes in which PhDs can actively participate. Even if there are restrictions so that development of systems does not proceed and PhDs cannot work independently on research themes closely related to clinical areas, advancement of collaboration with MDs will provide sufficient scope for PhDs to play an active part.

Based on the knowledge obtained from the survey, policy proposals for establishing a medical R&D platform in Japanese national university hospitals were reviewed.

As seen in each country, financial independence of university hospitals can be an important policy when the hospital management develops/implements a strategy that integrates management and research/education as one. In Japan, there has been a movement to bring about the financial/organizational independence of university hospitals. In particular, separate incorporation of university hospitals utilizing the regional medical collaboration promotion corporation system is the most forward-thinking effort. The Okayama University Medical Center Concept for Okayama University, which led the discussion and attracted attention as a pilot case, has not been realized yet due to a lack of evidence that supports benefits for the university and hospital and legal advice on avoiding/addressing risks. Overseas cases that separately incorporated university hospitals through structural reforms of universities considered systems that allow hospitals to operate independently and the legal systems that guarantee that this can be created. The financial/organizational independence of university hospitals is not necessarily the only avenue, and there are other measures such as clarification of separate accounting, establishing university hospitals as a department, etc. that can be implemented before financial/organizational separation. Furthermore, the feasibility and effect of financial/organizational separation is affected by the regional characteristics of the location of the target university hospital and its history. If still considering organizational separation, systems such as those covered in the “National University Hospital Corporation Act” need to be discussed.

Not only the systems concerning university hospitals but also the meta-systems, for example, the health insurance system and university system may become targets for discussion. In Japan, the open-door policy, meaning that researchers who are not MDs can actively participate in medical R&D and that medical expenses (medical fees), which have not previously been a source of the research finds, will be partially linked to the research finds, will be important in the long run. For this to come about, consolidation or organic collaboration of the research departments of national R&D corporations, educational reform of faculties of science/engineering and other meta-systems should be also considered to reduce vertical segmentation within or between universities, ministries and research institutions.

Financial/organizational independence of university hospitals is not easily realized and does not necessarily guarantee a satisfactory level of benefits. Therefore, it is important to consider policies that contribute to the promotion of medical R&D without depending on financial/organizational independence. First, it is necessary to establish an environment in which PhDs, who are not MDs, can play an active part in medical R&D. As widely seen in the surveyed cases, a platform where MDs and PhDs can collaborate and PhDs can independently engage in medical R&D is needed.

It is also important to employ PhDs with well-developed research expertise, and who can obtain an abundance of external research funds, in faculties of medicine and hospitals. To serve this purpose, incentives for PhDs need to be created. Cases seen overseas, such as

flexible operation of project positions, discretionary power over human resources (HR) in faculties of medicine/university hospitals, which are related to a high rate of indirect costs and overhead, are important discussion points when reviewing a strategy to obtain research resources in Japan.

Human resources departments in Japanese universities tend to value impact factors (IFs) in relation to the recruitment of faculty members and the dominant research promotion strategy may be described as that of “big game hunters.” This will impair diversity in research and reduce the possibility of innovation. On the other hand, research promotion strategies that value the numbers of citations and HCPs, which are considered to contribute to the recent assessments of universities, including their ranking, have been adopted in the countries surveyed. In order to acquire young talents to further globalize higher education and research fields, HR management and intelligent allocation of research budgets that place value on research achievements, such as IFs, the number of citations and HCPs, contributing to the international reputation of the university may be effective approaches.

Overseas cases reveal the measures taken to promote MD-PhD collaboration under industry-government-academia collaboration and collaborations with external institutions. Although rigidity of decision-making and accounting due to the vertically segmented structure of universities is an issue that needs be resolved, the policy to establish a site for promotion of industry-government-academia collaboration has been already implemented in many Japanese universities. It is necessary to increase opportunities to employ persons with PhDs and implement research that allows MDs-PhDs to work together to further promote collaboration.

Contents

1. Background and Objectives

1-1. Japan's Research Capability has Stalled

Recently, it has often been mentioned that Japan's capacity to conduct research has been diminishing. For example, Nature Index 2017 Japan (Nature 2017) reported that Japanese scientific research has stalled or stagnated over the last 10 years compared to China and other rapidly growing countries and it has become a hot topic of conversation. The ratio of Japanese papers relative to the scientific papers in the Nature Index decreased from 2012 to 2016, in contrast to China, which continues to rapidly expand its share, and the UK, which shows steady growth (Figure 1). During this period, the number of papers by Japanese researchers registered in the Nature Index fell by 8.3%, while the UK and China showed increases of 17.3% and 47.7%, respectively. The Nature Index includes Scopus by Elsevier in the analysis and stated as follows: "The total number of papers registered in the database increased by about 80% from 2005 to 2015. On the other hand, the number of Japanese papers increased by only 14% and the ratio of Japanese papers relative to the total number of papers reduced from 7.4% to 4.7%"[1] (Figure 2).

[1] http://www.natureasia.com/ja-jp/info/press-releases/detail/8622

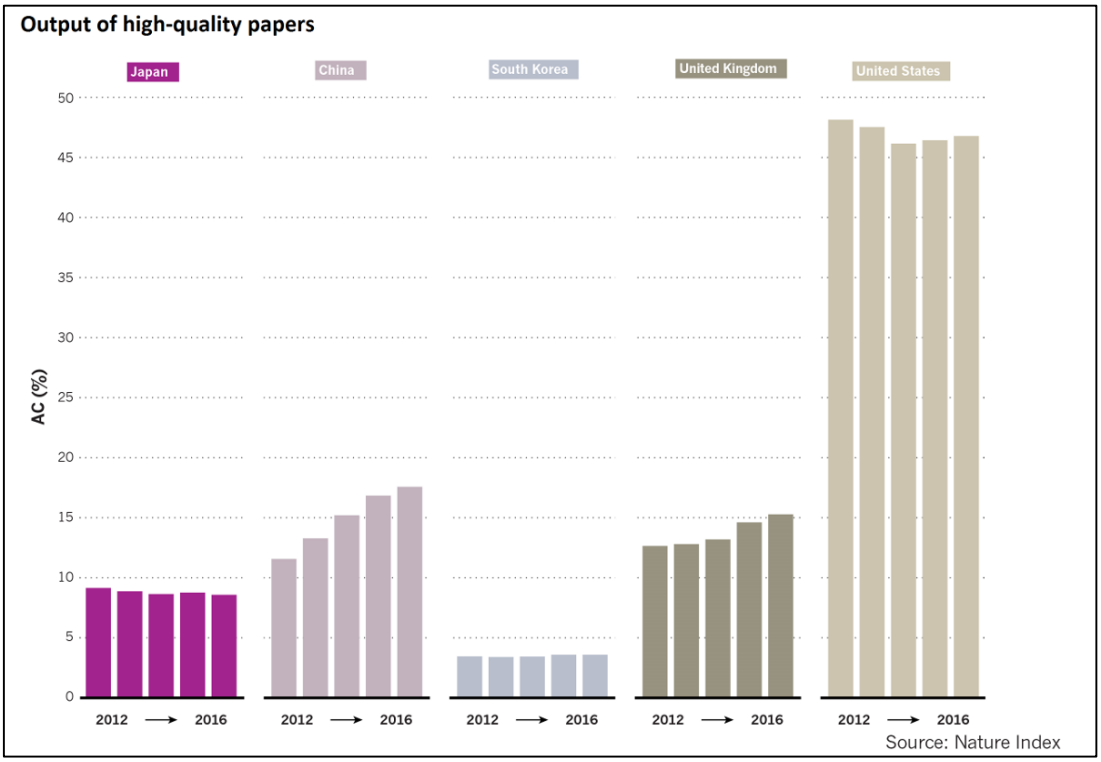


Figure 1 Changes in the Share of High Quality Scientific Papers Registered in Nature Index (2012→2016)[2]

[2] https://www.natureindex.com/news-blog/the-slow-decline-of-japanese-research-in-five-charts

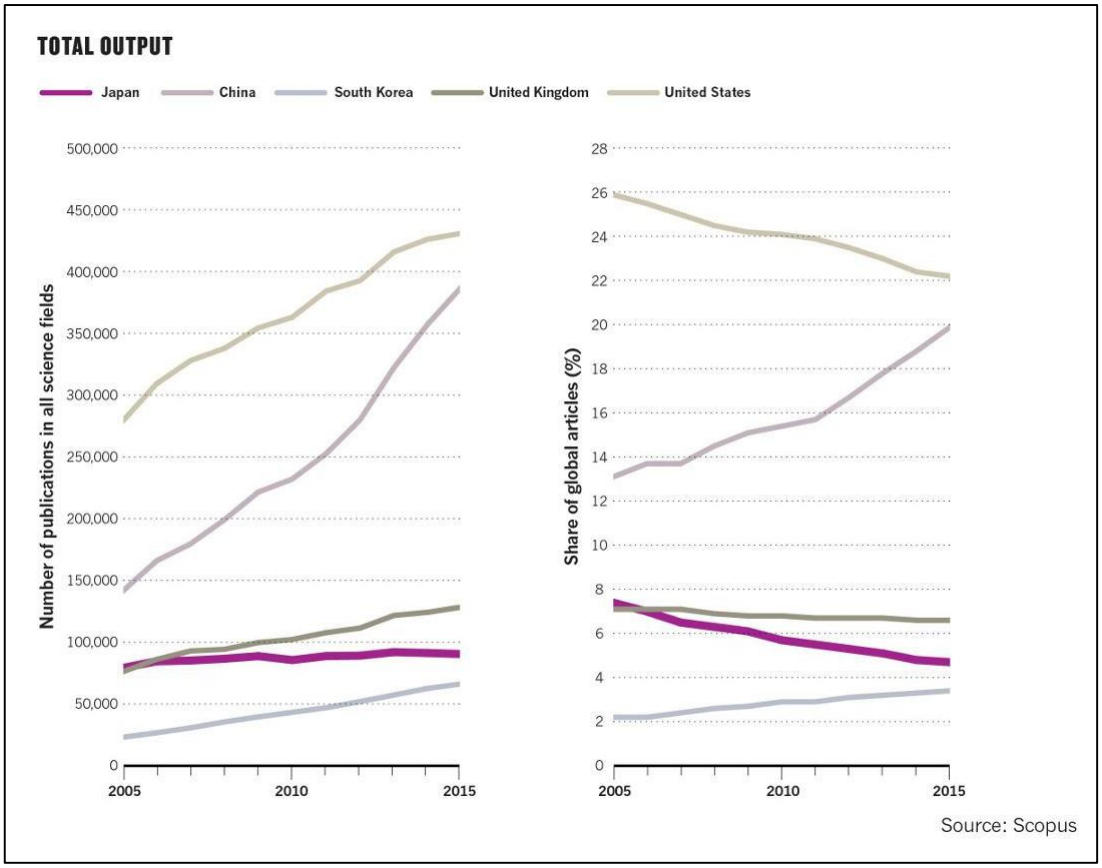


Figure 2 Changes in the Number of Papers in Scopus (2005→2015)[2]

Nature Index 2017 Japan listed stagnation of the R&D budget as one of the factors responsible for stalled Japanese scientific research. In contrast to Germany, China and South Korea, which are significantly increasing their funding of R&D, “the amount of money allocated to R&D by the Japanese government has remained roughly flat since 2001 though the level of research is still top class by international standards.” According to the National Institute of Science and Technology Policy (NISTEP) (2017) data, Japan is ranked third in the world in terms of the ratio of total R&D funds relative to GDP (Figure 3). While Japanese GDP has increased slightly over the last 10 years, the US, China, Germany and South Korea have achieved significant increases in GDP. Furthermore, the ratio of total R&D funds relative to GDP has also increased (Figure 4) in these countries. Therefore, the impact on R&D can be seen in the differences in the allocation of funds.

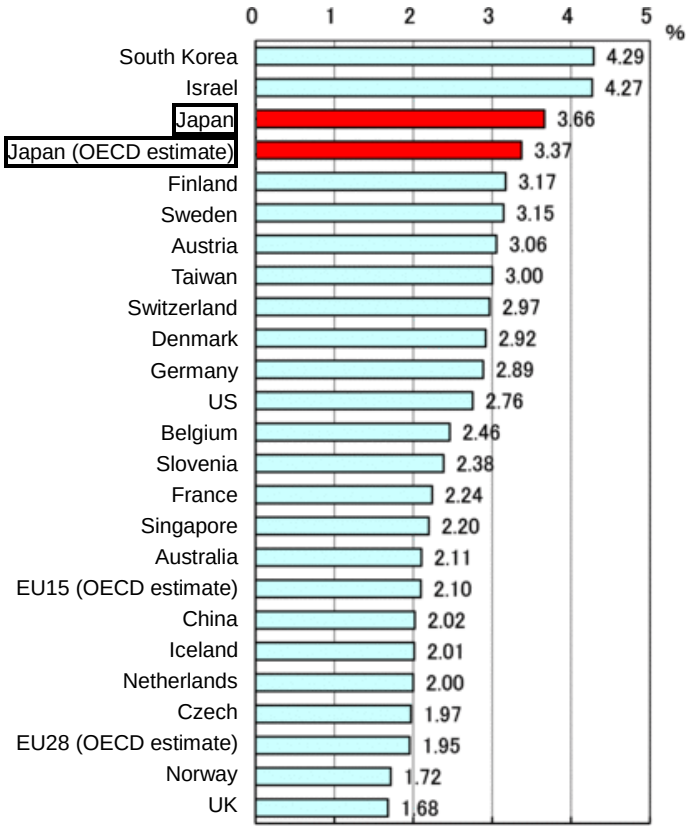


Figure 3 Ratio of Total R&D Funds Relative to GDP in Each Country/Region (2014)[3]

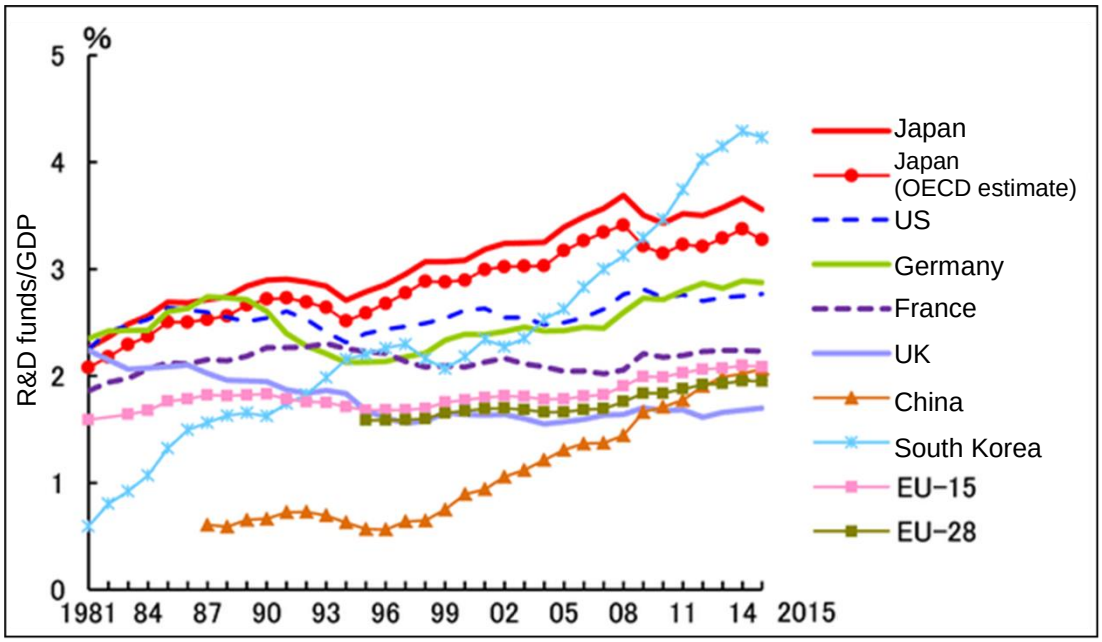


Figure 4 Changes in the Ratio of Total R&D Funds Relative to GDP in Major Countries[3]

[3] http://data.nistep.go.jp/sti_indicator/2017/RM261_11.html

As a result of the management expense grants being reduced by approximately 1% yearly from 2004, ≥ 1/3 of national universities did not fill tenured positions for professors after retirement but instead shifted to employment of researchers on short-term contracts.[4] Although the government implemented a policy[5] to increase postdoc in the 1990s to strengthen national competitiveness by increasing the number of researchers in the private sector, many remained in the academic world, contrary to expectations, and this problem is particularly serious in the life science field in which the government actively invested during the early 2000s.[4] While the number of researchers aged ≤ 40 years fell by 11% from 2004 to 2013, the number of researchers aged ≤ 40 years, who were employed for on short-term contracts, increased by ≥ 2-fold from 2007 to 2013.[4] Since enrollments in doctoral courses are declining, there is a warning over the possibility that Japan's capability in the area of scientific research may face further difficulties in the future.

Nagayasu Toyoda (2014), President of Suzuka University of Medical Science (former President of Mie University) analyzed the Thomson Reuters InCites data and found that the growth in the total number of Japanese papers and the number of papers per population had slowed down from the late 1990s (Figures 5, 6). Changes in the relative impact of academic papers showed a reduction in differences compared with Asian countries such as South Korea, Taiwan and China (Figure 7). On the other hand, the public R&D funds provided to universities (per GDP) remained roughly flat in Japan but continued increasing in South Korea and Taiwan from 2000 to 2010 (Figure 8).

The rate of increase in the number of papers started slowing down around 2000, and a strategic focus on graduate schools was implemented around this time. Mitsufuji (2005) listed realization of collaborative relationships beyond the areas of specialization and increases in research budgets as the outcome of the strategic focus on graduate schools. On the other hand, reduction in quality due to a mass-production approach to faculty education and increases in the number of research laboratories due to the large lectureship-based credit system, which changed the system to one professor, one assistant professor and one assistant (at that time),[6] imposing a heavier workload on young researchers, were listed as problems. Miyanishi (2017) pointed out that "the target of lecture funding was gradually narrowed down to focus on purely educational purposes and research funding needed to be obtained externally from competitive funds. This made 'long-term execution of basic research' difficult."[7] These comments point to the possibility that the strategic focus on graduate schools might have affected Japan's research capability.

[4] https://www.nature.com/articles/543S10a
[5] "10,000 post-doctors etc. support plan" proposed in the 1st Science and Technology Basic Plan in July 1996
[6] The structure in the old lectureship-based credit system was one professor, one assistant professor and two or three assistants (Maruyama 1996)
[7] http://rigakuyu.sci.osaka-u.ac.jp/talkon/contents_miyanishi.html

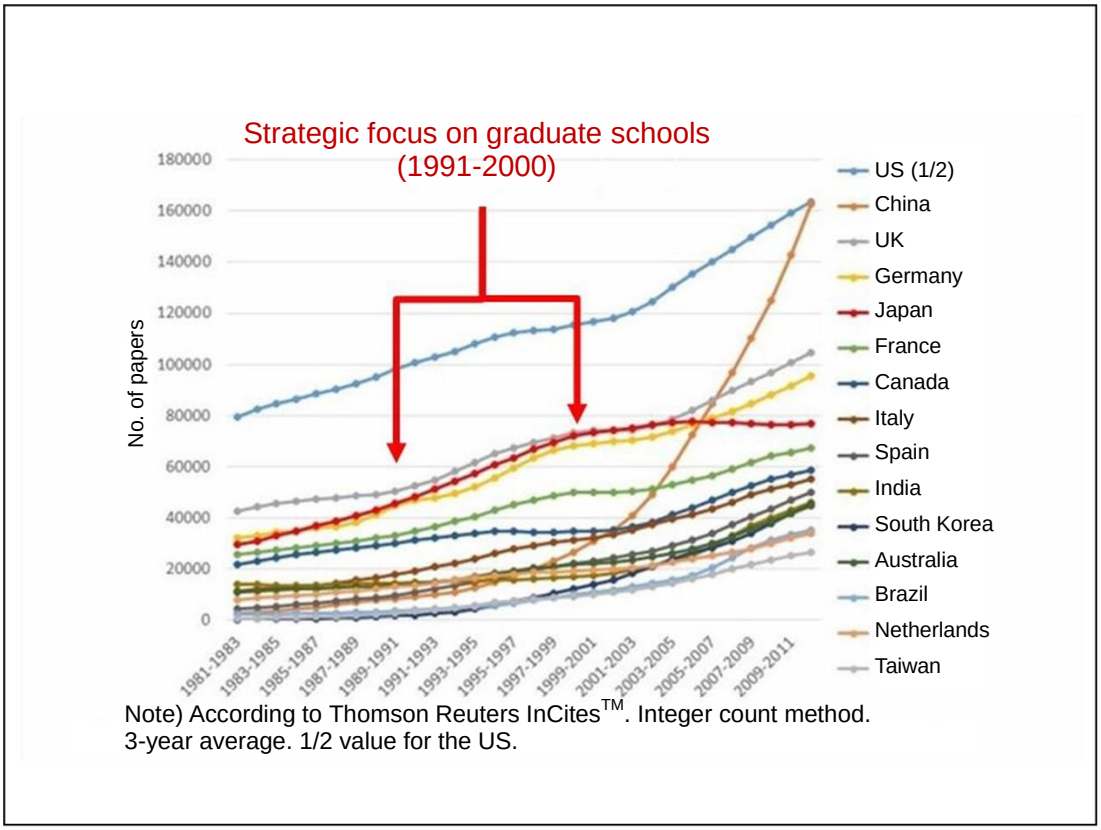


Figure 5 Changes in the Number of Academic Papers in the 15 Major Countries (letters in red inserted by the author)[8]

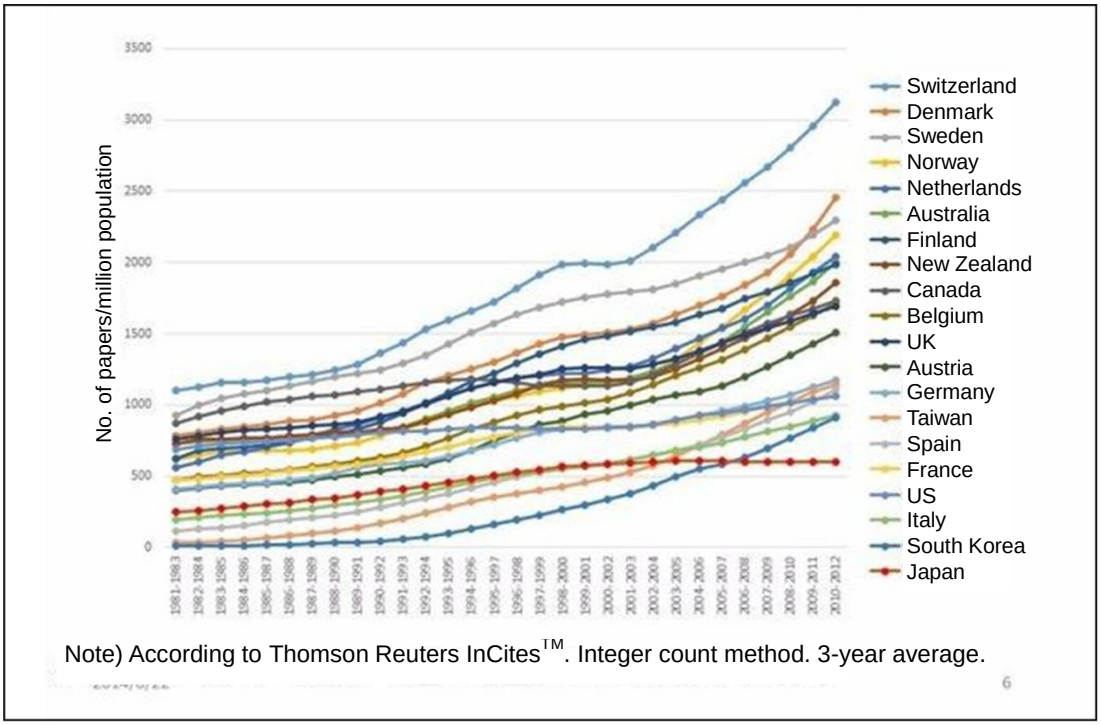


Figure 6 Changes in the Number of Papers per Population in Major Countries[8]

[8] http://blog.goo.ne.jp/toyodang/e/28ce2f95f9d40d860e07adc325bc11e3

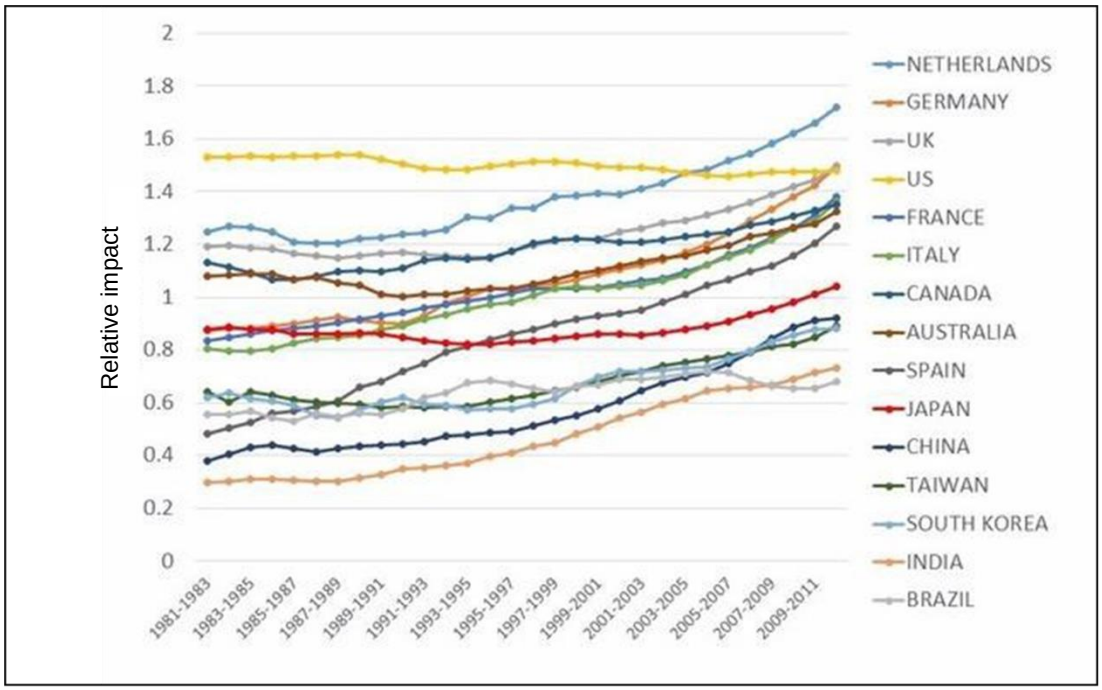


Figure 7 Changes in Relative Impact of Academic Papers in the 15 Major Countries (3-year moving average deviations)[8]

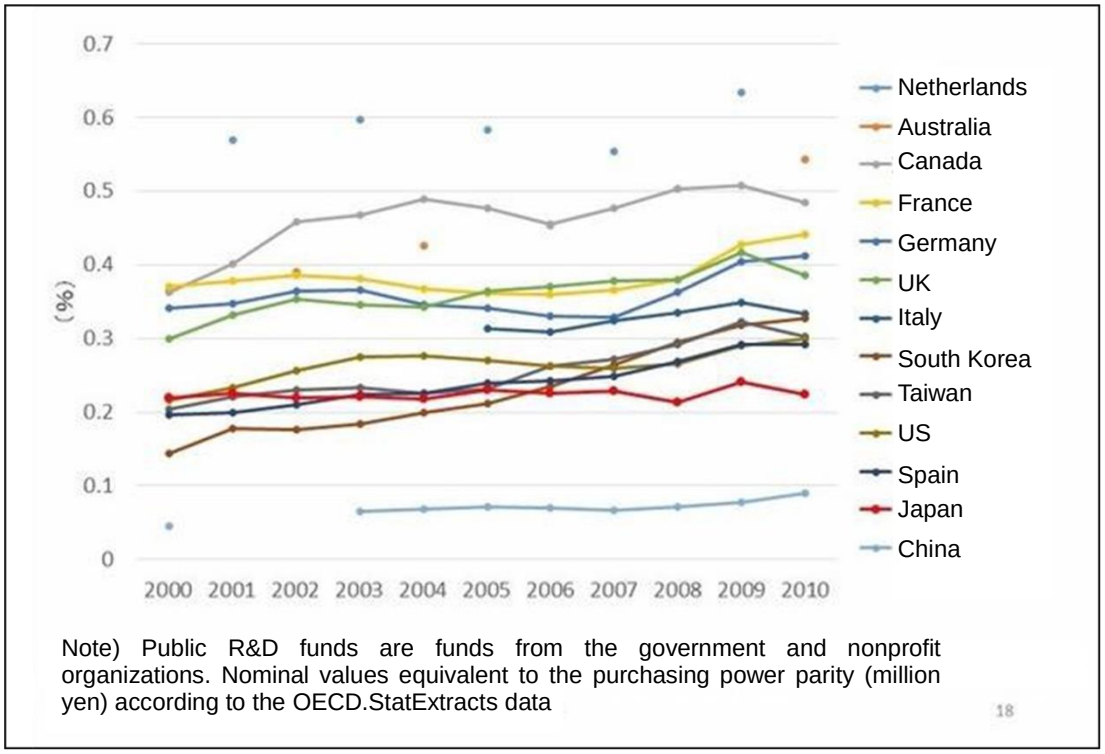
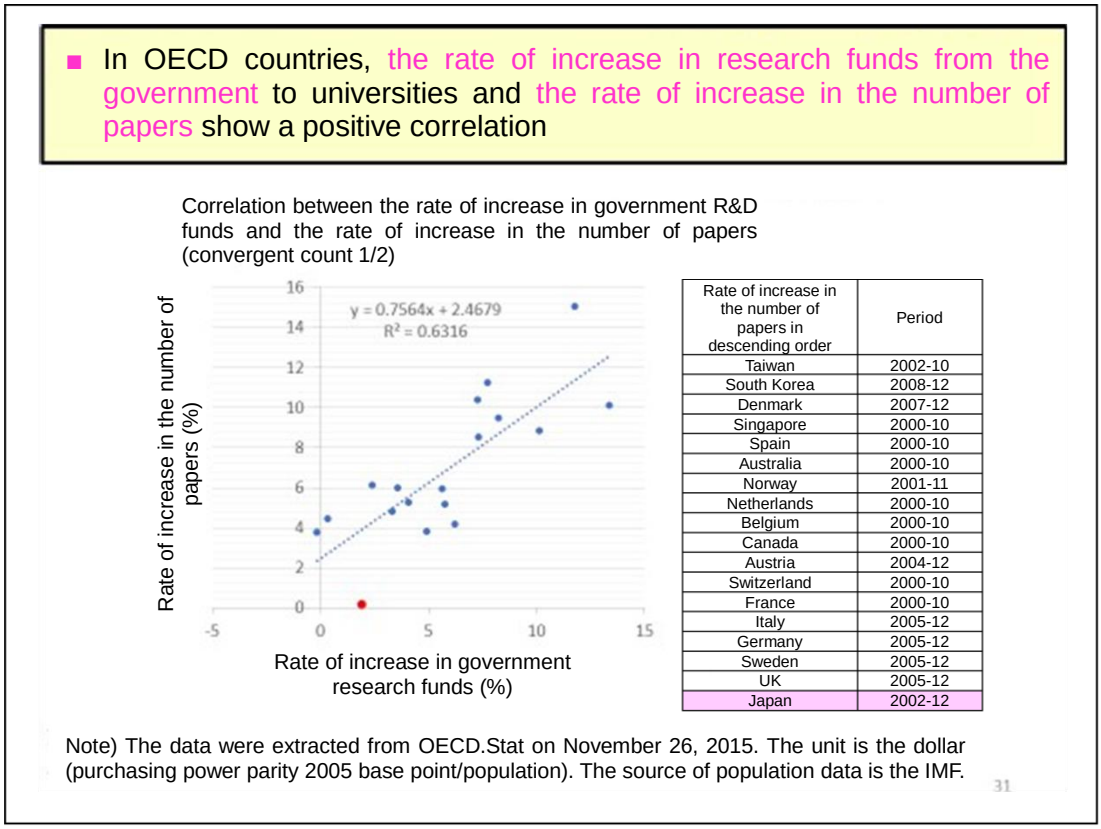


Figure 8 Changes in Public R&D Funds to Universities (per GDP)[8]

Toyoda (2017) listed a reduction in management grants to be used as basic research funding and a reduction in research hours of university faculty members and an associated reduction

in the number of full-time equivalent (FTE)[9] researchers as the background to the sluggish growth of research competitiveness in universities. An analysis using the OECD data showed definite positive correlations between increases in the number of papers and increases in government research funds (Figure 9) and increases in research employees (FTE) (Figure 10). As shown in Figure 8, public R&D funds given to universities remained flat in Japan and this may be a cause for the rate of increase in the number of papers stagnating. The NISTEP survey (Kanda/Tomizawa 2015) showed that research hours of university faculty members fell significantly from 2002 to 2008 and fell slightly up to 2013. On the other hand, hours spent on educational and clinical activities tended to increase (Figure 11). An analysis based on the OECD data performed by Toyoda (2017) showed decreases in the number of Japanese FTE research employees despite an increase in the total number of researchers (Figure 12). In contrast to many OECD countries, where the number of FTE research employees per population tended to increase, the number of FTE research employees per population in Japan reduced and there was also a lowering of standards (Figure 13). This may be a factor in the rate of increase in the number of papers stagnating. Although the relationship between the reduction in management expense grants and reduction in the number of FTE research employees is unknown, there may be a causal relationship considering the potential impact of the strategic focus on graduate schools.



Rate of increase in the number of papers in descending order	Period
Taiwan	2002-10
South Korea	2008-12
Denmark	2007-12
Singapore	2000-10
Spain	2000-10
Australia	2000-10
Norway	2001-11
Netherlands	2000-10
Belgium	2000-10
Canada	2000-10
Austria	2004-12
Switzerland	2000-10
France	2000-10
Italy	2005-12
Germany	2005-12
Sweden	2005-12
UK	2005-12
Japan	2002-12

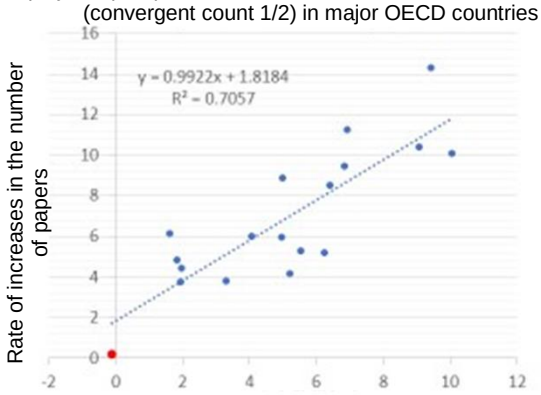
Note) The data were extracted from OECD.Stat on November 26, 2015. The unit is the dollar (purchasing power parity 2005 base point/population). The source of population data is the IMF.

Figure 9 Correlation between the Rate of Increase in Public Research Funds and Rate of Increase in the Number of Papers in Major OECD Countries (Toyoda 2017)

[9] FTE = Research hours relative to the total job hours (Kanda/Tomizawa 2015, p.1). The number of FTE research employees is "for example, if a university faculty member spends 50% of working hours of the year into research, he/she will be counted as 1/2 researcher" (Toyoda 2017).

■ In OECD countries, the rate of increase in the number of research employees and the rate of increase in the number of papers showed an almost one-on-one correlation.

Correlation between the rate of increase in the number of research employees (FTE) and the rate of increase in the number of papers (convergent count 1/2) in major OECD countries



Rate of increase in the number of papers in descending order	Period
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Netherlands	2000-10
Belgium	2000-10
Canada	2000-10
Austria	2004-12
Switzerland	2000-10
France	2000-10
Italy	2005-12
Germany	2005-12
Sweden	2005-12
UK	2005-12
Japan	2002-12

Note) The data were extracted from InCites™ of November 26, 2015 and OECD.Stat. Literature type: original paper. Field classification: ESI. The number of university papers is the number of papers of universities registered in InCites™. "Convergent count 1/2" is a value obtained by subtracting 1/2 of the number of international joint papers from the number of papers.

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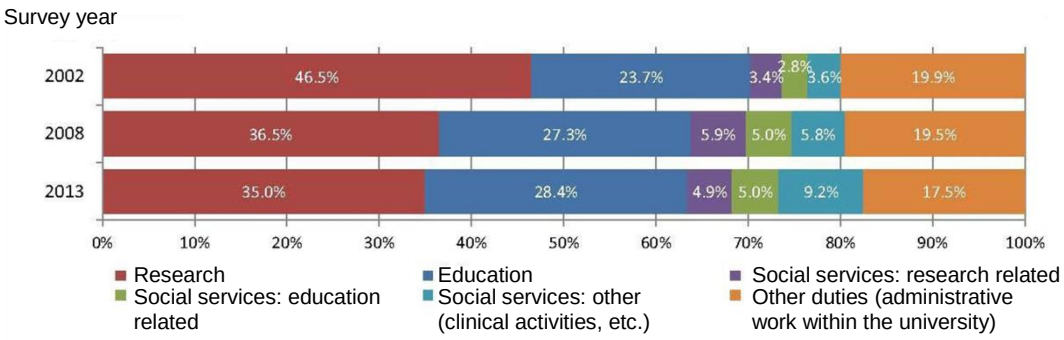
Figure 10 Correlation between Rate of Increase in Research Employees (FTE) and Rate of Increase in the Number of Papers in Major OECD Countries (Toyoda 2017)



Note: In the 2008 and 2013 surveys, the number of faculty members was used as the population and population estimates weighted back by academic field were used.
Material: National Institute of Science and Technology Policy (NISTEP) summarized and analyzed using individual data (through application for secondary use based on the statistical method) of Ministry of Education, Culture, Sports, Science and Technology (MEXT) "Survey of Full-time Equivalent Data at Universities and Colleges"

Figure 11 Ratio of Working Hours of University Faculty Members (Kanda, Tomizawa 2015, p.1)

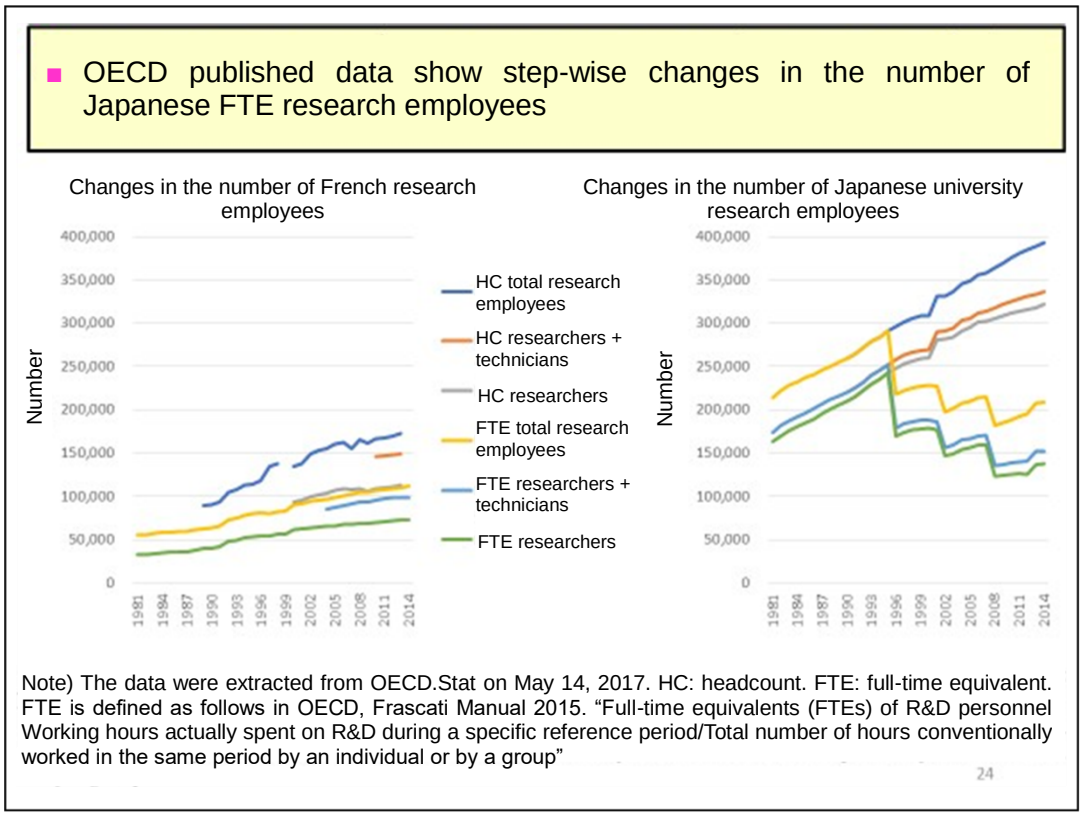


Figure 12 Changes in the Number of Japanese University Research Employees[10]

[10] The step-wise reduction in the number of Japanese FTE research employees is because the FTE calculation was performed in 2002 and 2008. HC = Head Count.

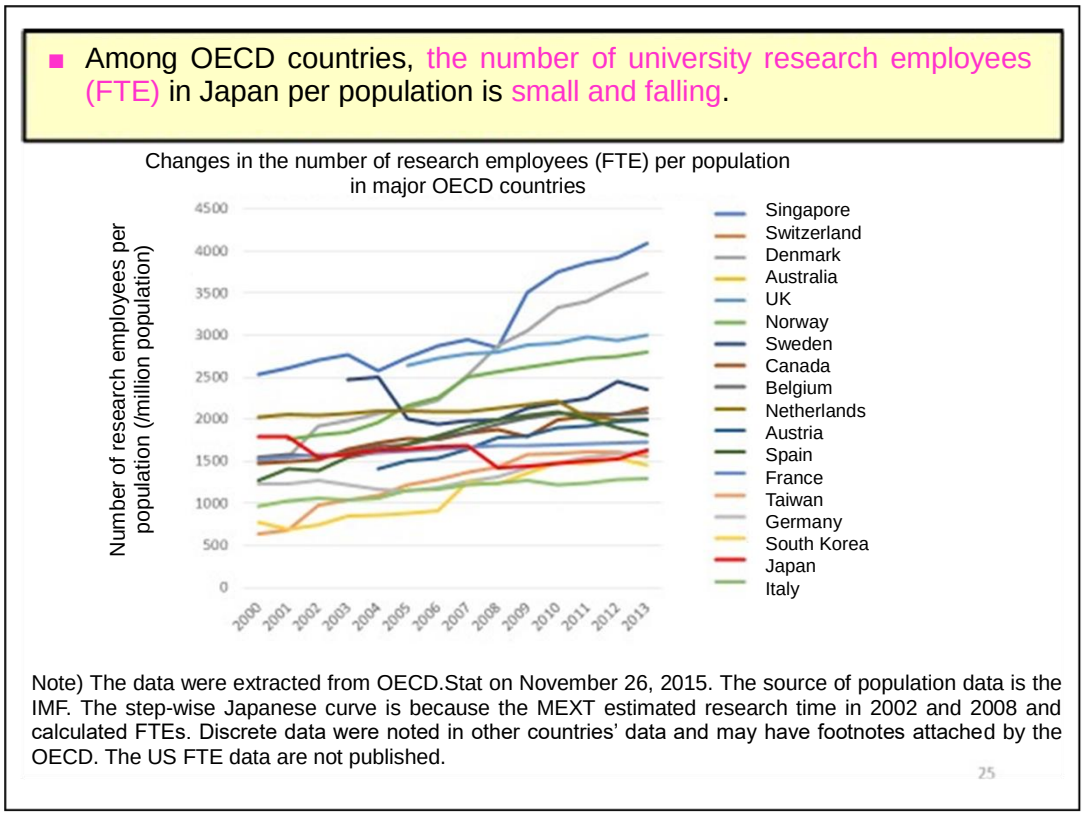


Figure 13 Changes in FTE Research Employees per Population in Major OECD Countries

While Japanese scientific research has been losing momentum, the medical field still continues to fare relatively well. In Nature Index 2017 Japan, changes (2005 vs. 2015) in the number of papers registered in Web of Science were analyzed by Clarivate Analytics. Of the 14 fields analyzed, 11 showed a decrease in the number of papers in 2015 compared with 2005 (Figure 14). Although the medical field is being left behind in terms of growth rate when compared globally, it is one of the few fields with an increase in the number of papers from 2005 to 2015.

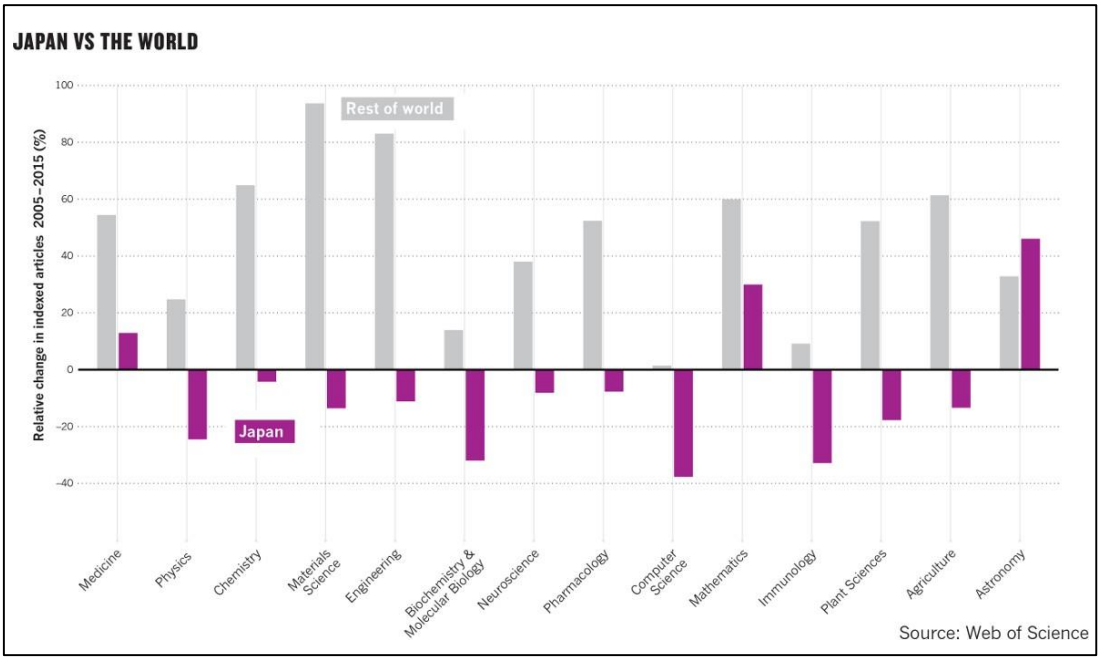


Figure 14 Changes in the Number of Papers Registered in Web of Science (2005→2015), Comparison between Japan and Rest of the World by Field (medical field on the far left)[11]

Toyoda (2017) also pointed out that while the number of Japanese papers had declined in almost all the major fields, the number of papers in the clinical medicine field started increasing around 2010 (Figure 15). After the incorporation of national universities in 2004, university hospital management expense grants were reduced every year and disappeared entirely in 2013. University hospital income increased by 66% over 11 years until 2015 (Figure 16). This suggests that national university hospitals potentially have the capability to improve management.[12] However, it cannot be said that increases in hospital income alone have contributed to the increases seen in the number of papers. Toyoda (2017) performed an analysis using data from Thomson Reuters InCites and the national university hospital database center and showed that the number of clinical medical papers was higher with an increase in the number of doctors (Figure 17), the number of papers per doctor was higher in universities with a higher number of doctors (Figure 18), and the number of papers per doctor increased in universities where the medical care workload per doctor was lower (Figure 19). However, the overall number of papers per doctor has not increased and the medical care workload per doctor actually showed a slight tendency toward an increase (Figure 20), and the increase in the number of doctors (HC) in national universities was thought to have contributed to the increase in the number of papers.

[11] https://www.natureindex.com/news-blog/the-slow-decline-of-japanese-research-in-five-charts
[12] The net (overall) revision rate for medical fees, i.e., the revision rate for medical fees (main) and drug prices/material prices in total was positive for the first time in 10 years in FY2010 and was positive for 3 consecutive revisions up to 2014. This might have contributed to the increases in university hospital income.

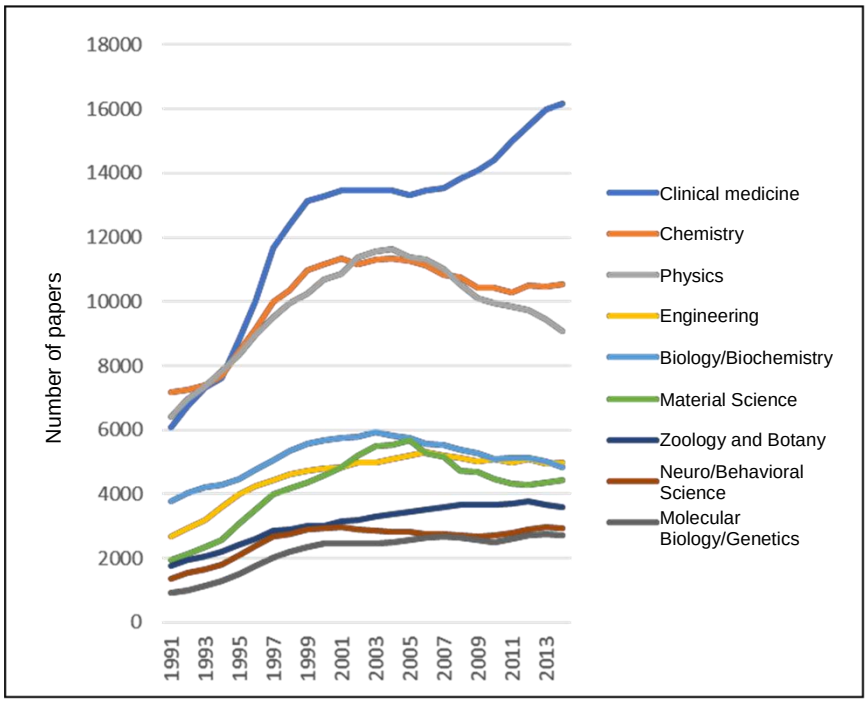


Figure 15 Changes in the Number of Japanese Papers by Field (Toyoda 2017)[13]

[13] From Thomson Reuters InCites; Fild classification, ESI; Literature type, Article; 3-year moving average deviations

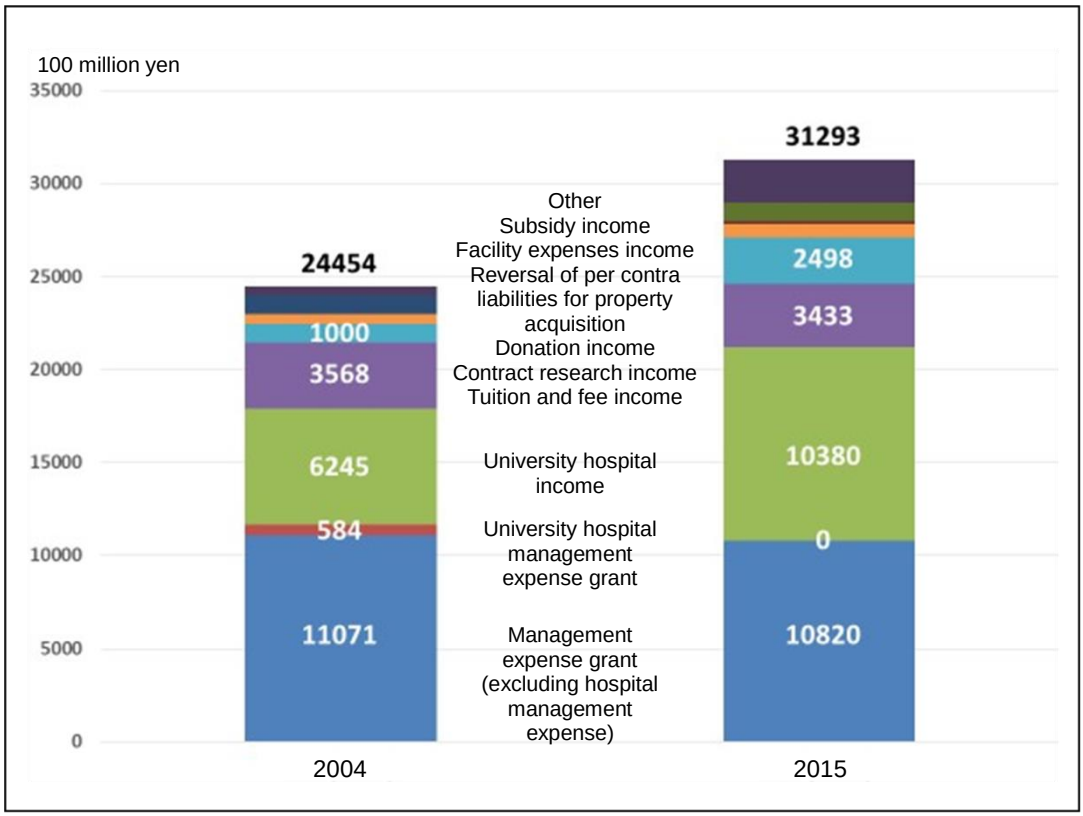
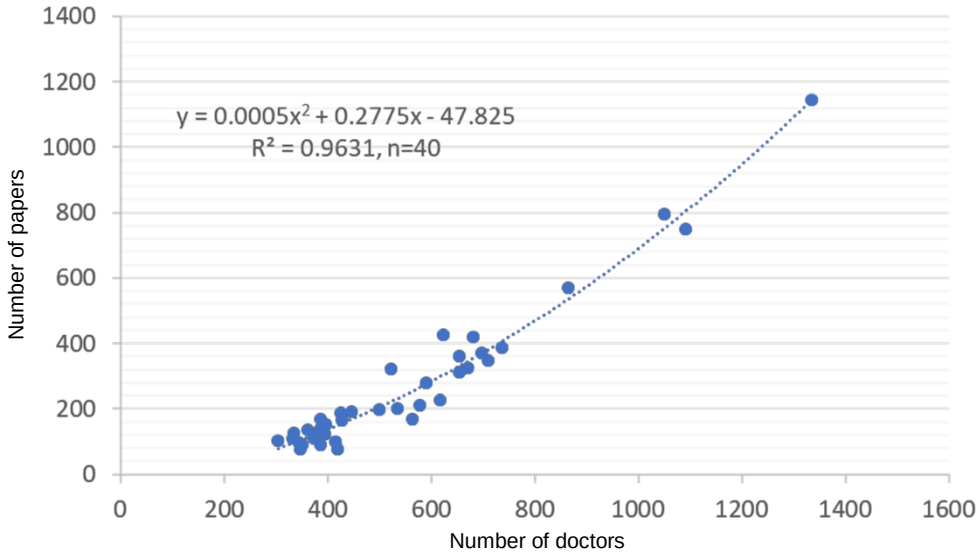


Figure 16 Changes in University Hospital-related Income in the Income Structure of National University Corporations[14]

[14] Developed by the author. The income structure, such as total income and management expenses, is based on the financial statements of national university corporations (MEXT 2005; 2017). However, the university hospital management expense grants are based on information from Oda (2014) and the Japan Association of National Universities (2015). Special management expense grants (for strengthening university hospital functions) and special factor management expense grants are not included in the university hospital management expense grants, but are included in the management expense grants in the figure. The special management expense grants (for strengthening university hospital functions) were approximately 9700 million yen in 2010, increased to approximately 20600 million yen in 2011 and thereafter remain between approximately 20000 to 27000 million yen. The special factor management expense grants were those calculated mainly as retirement allowance expenses for faculty members.

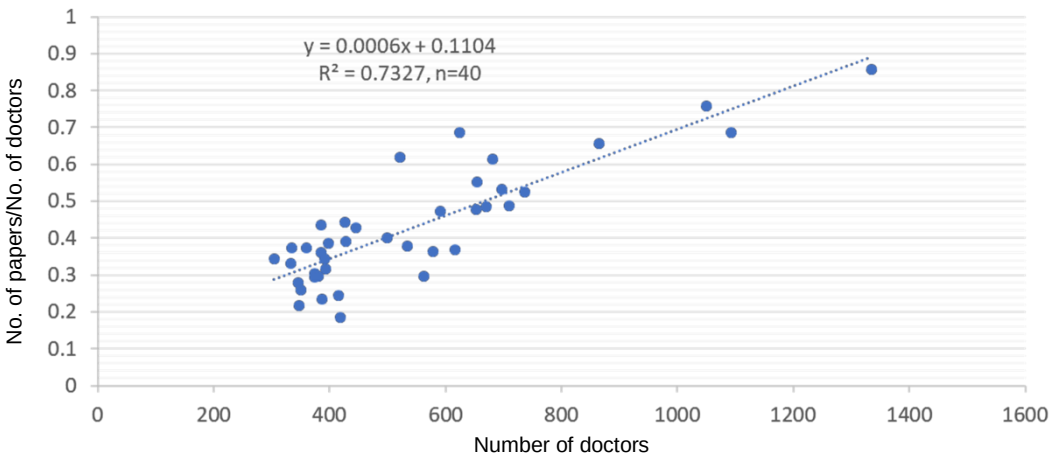
Table 1 Disposition of Management Expense Grant Income Related to National University Hospitals (Board of Audit of Japan 2016; p.20; unit, million yen; %)

Category	2010	2011	2012	2013	2014	Increase from 2010
University hospital management expense grants	18,623	15,057	6,285	-	-	-
Special management expense grants	9,717	20,567	22,022	27,453	25,047	157.7
Special factor management expense grants	12,548	13,627	14,435	12,599	11,856	Δ5.5
Other management expense grants	95,983	84,823	77,513	77,825	91,340	Δ4.8
Total	136,872	134,075	120,256	117,878	128,244	Δ6.3



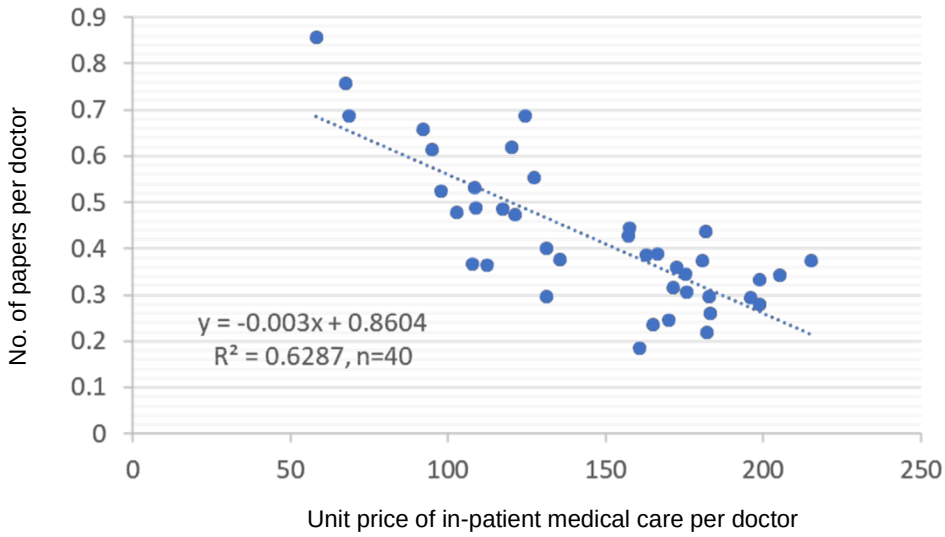
Note) The data on the number of papers were extracted from InCites™ on June 09, 2017. Literature type: original paper. The number of papers obtained by subtracting the number of DENTISTRY, ORAL SURGERY & MEDICINE papers in the field classification method WoS from the number of CLINICAL MEDICINE papers in the field classification method ESI were used for the analysis. The number of doctors was based on information obtained from the national university hospital database center. The analysis was performed in 40 universities; 2 universities were excluded as they were judged to have used different methods for calculating the number of doctors. The 3-year average including the years before and after was used for the number of papers.

Figure 17 Correlation between the Number of National University Doctors (2014) and Number of Clinical Medical Papers (excluding DENTISTRY, ORAL SURGERY & MEDICINE) (2015) (Toyoda 2017)



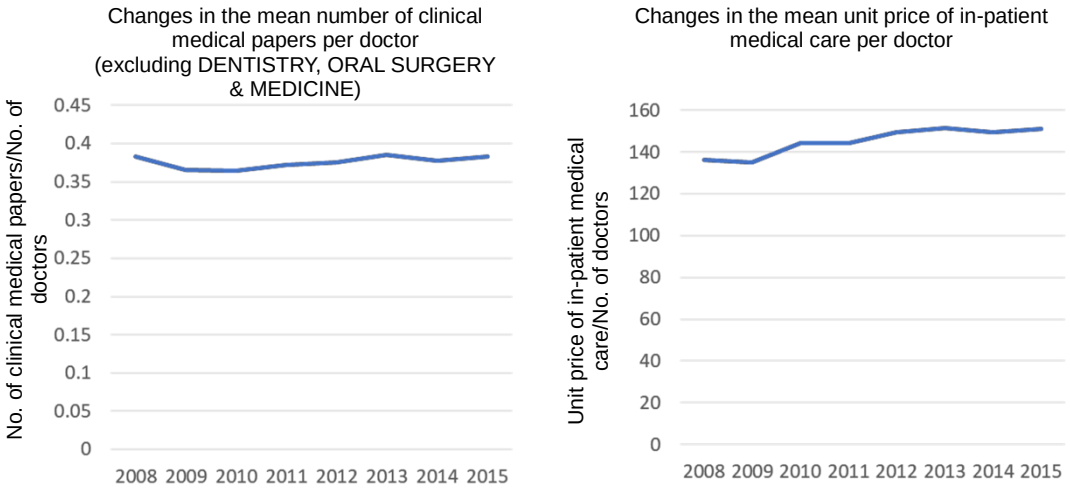
Note) The data on the number of papers were extracted from InCites™ on June 09, 2017. Literature type: original paper. The number of papers obtained by subtracting the number of DENTISTRY, ORAL SURGERY & MEDICINE papers in the field classification method WoS from the number of CLINICAL MEDICINE papers in the field classification method ESI were used for the analysis. The number of doctors was based on information obtained from the national university hospital database center. The analysis was performed in 40 universities; 2 universities were excluded as they were judged to have used different methods for calculating the number of doctors. The 3-year average including the years before and after was used for the numbers of doctors (2014) and papers (2015).

Figure 18 Correlation between the Number of National University Doctors (2014) and Number of Clinical Medical Papers per Doctor (excluding DENTISTRY, ORAL SURGERY & MEDICINE) (2015) (Toyoda 2017)



Note) The data on the number of papers were extracted from InCites™ on June 09, 2017. Literature type: original paper. The number of papers obtained by subtracting the number of DENTISTRY, ORAL SURGERY & MEDICINE papers in the field classification method WoS from the number of CLINICAL MEDICINE papers in the field classification method ESI were used for the analysis. The number of doctors was based on information obtained from the national university hospital database center. The analysis was performed in 40 universities; 2 universities were excluded as they were judged to have used different methods for calculating the number of doctors. The 3-year average including the years before and after was used for the numbers of doctors (2014), unit price of in-patient medical care (2014) and papers (2015).

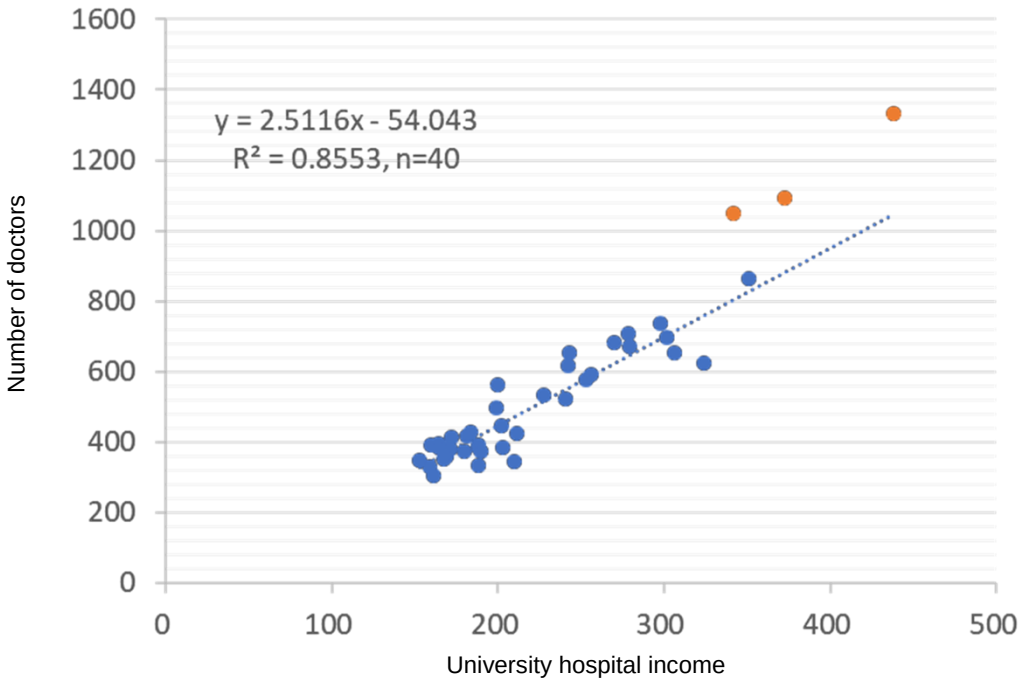
Figure 19 Correlation between Unit Price of In-patient Medical Care/Number of Doctors (2014) and Number of Clinical Medicine Papers (excluding DENTISTRY, ORAL SURGERY & MEDICINE) (2015)/Number of Doctors (2014) (Toyoda 2017)



Note) The data on the number of papers were extracted from InCites™ on June 09, 2017. Literature type: original paper. The number of papers obtained by subtracting the number of DENTISTRY, ORAL SURGERY & MEDICINE papers in the field classification method WoS from the number of CLINICAL MEDICINE papers in the field classification method ESI were used for the analysis. The number of doctors was based on the national university hospital database center. The analysis was performed in 35 universities; 7 universities were excluded, 2 because they were judged to have used different methods for calculating the number of doctors, and 5 because they were judged to have discrete data.

Figure 20 Changes in the Number of Clinical Medicine Papers per Doctor (excluding DENTISTRY, ORAL SURGERY & MEDICINE) and Mean Unit Price of In-patient Medical Care (Toyoda 2017)

A positive correlation was noted between the national university hospital income and the number of doctors (Figure 21). This finding suggests that efforts to improve management of university hospitals contributed to the increase in the number of doctors. The return of doctors to many university hospitals after lifting of the confusion caused by the introduction of the clinical training system in 2004, the sharp reduction in university hospital management expense grants was completed after the end of Phase 1 of incorporation (FY 2009), an increase in the net revision rate for medical fees in FY 2010 (the first increase in 10 years), and the increase in university hospital income, etc. were seen as background factors.



Note) The number of doctors was based on information obtained from the national university hospital database center. The analysis was performed in 40 universities; 2 universities were excluded as they were judged to have used different methods for calculating the number of doctors. The university hospital income was based on the published data of each national university. The 3-year average of 2013 to 2015 was used. The number of doctors was an outlier in the box-and-whisker plot for 3 universities; the values are shown in red and these 3 universities were excluded from the calculation.

Figure 21 Correlation between National University Hospital Income and Number of Doctors (2013-2015 average) (Toyoda 2017)

However, the most prominent problem is the increase in the workload imposed on young researchers in the medical field. The NISTEP survey (Kanda/Tomizawa 2015) showed a constant reduction in research hours of faculty members in the health field in national universities from FY 2002 to 2013 and a constant increase in hours spent for clinical activities etc. (Figure 22). Kanda/Tomizawa (2015, p.24) made the following observation: “Since the medium-term plan of national universities mandates that these institutions are to run on a stand-alone basis, national university hospitals shifted to a policy designed to supplement the reduction in university hospital management expense grants with university

hospital income. Due to this shift, university hospitals increased clinical hours and secured university hospital income by increasing the number of medical services provided." This is consistent with the continuous increase in the medical care workload being imposed on clinical faculty members and an ongoing decrease in the amount of time for research (Figure 23).

Furthermore, the ratio of time spent on clinical activities etc. is higher for young staff members such as lecturers and assistant professors/assistants, and the medical care workload increased significantly for assistant professors/assistants from 2008 to 2013 (Figure 24). The same trend is observed in private universities. The increase in the medical care-related workload being borne by young staff members may result in the rate of increase in the number of papers being published stagnating and a reduction in the number of high-quality and innovative papers. It is very important to resolve these challenges to improve research competitiveness in the medical field in the future

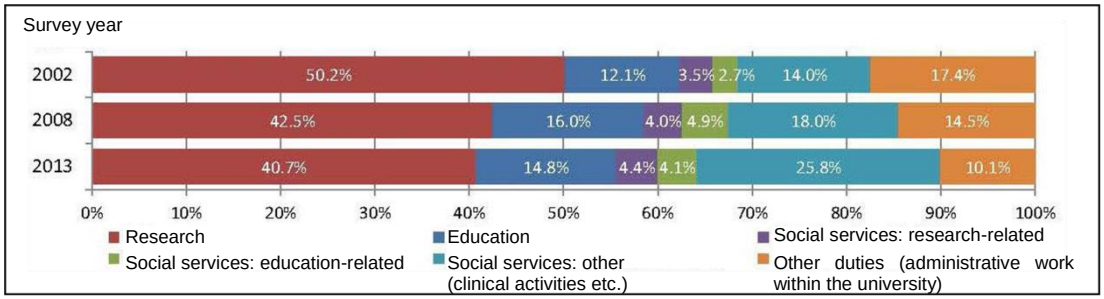
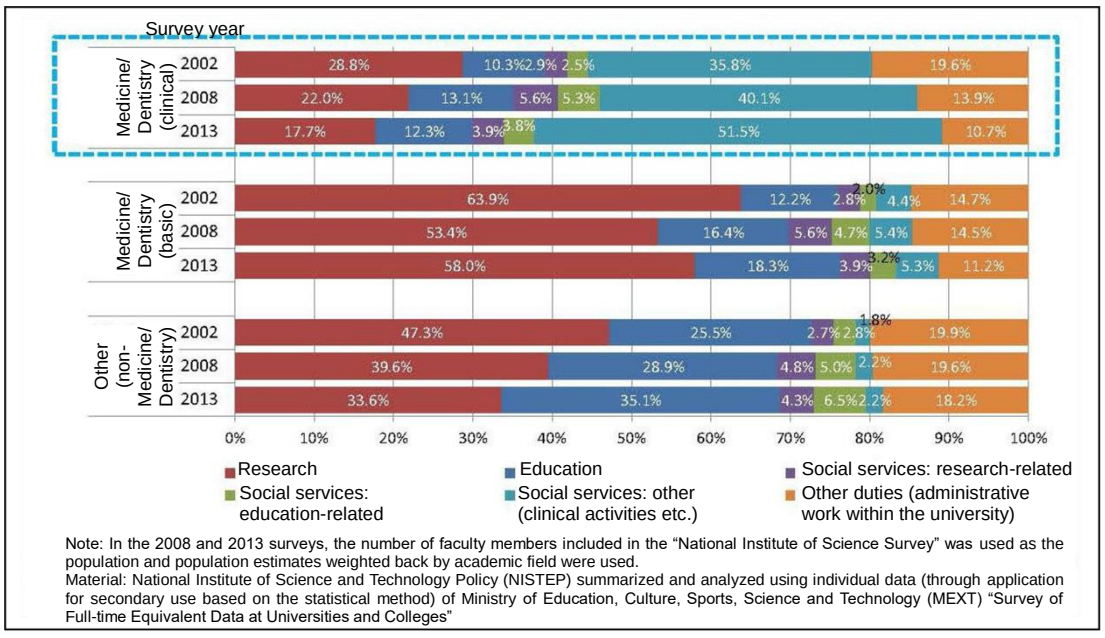
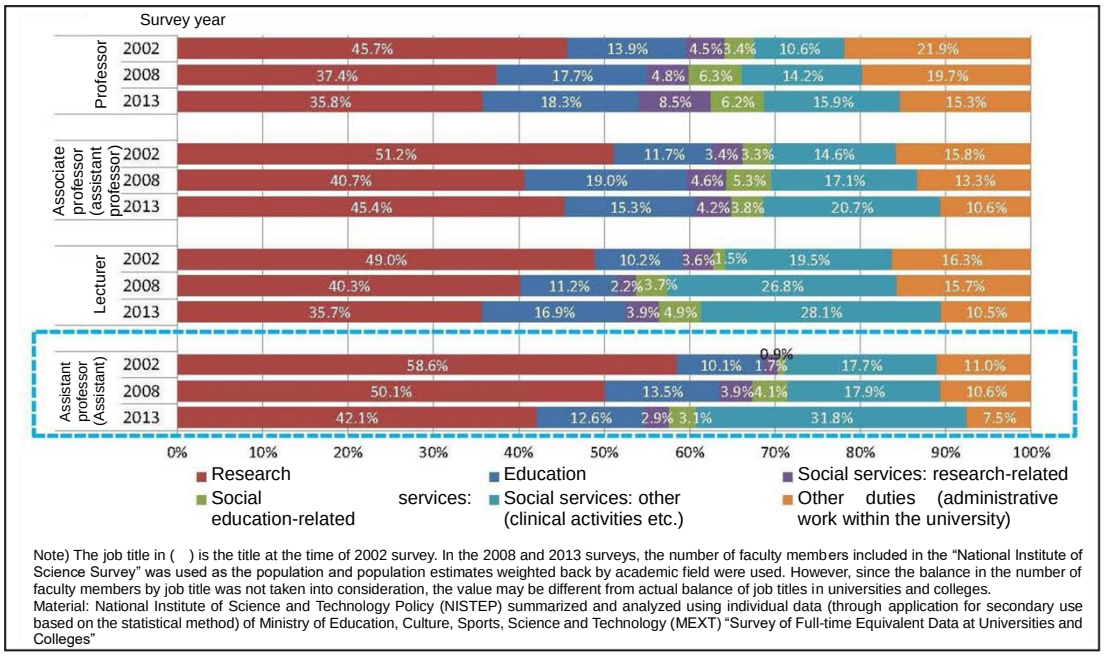


Figure 22 Time Spent by Healthcare Faculty Members in National Universities by Job Activity (Kanda/Tomizawa 2015, p.24)



Note: In the 2008 and 2013 surveys, the number of faculty members included in the "National Institute of Science Survey" was used as the population and population estimates weighted back by academic field were used.
Material: National Institute of Science and Technology Policy (NISTEP) summarized and analyzed using individual data (through application for secondary use based on the statistical method) of Ministry of Education, Culture, Sports, Science and Technology (MEXT) "Survey of Full-time Equivalent Data at Universities and Colleges"

Figure 23 Time Spent by Faculty Members by Job Activity and Specialized Health Care Field (Kanda/Tomizawa 2015, p.21)



Note) The job title in ( ) is the title at the time of 2002 survey. In the 2008 and 2013 surveys, the number of faculty members included in the "National Institute of Science Survey" was used as the population and population estimates weighted back by academic field were used. However, since the balance in the number of faculty members by job title was not taken into consideration, the value may be different from actual balance of job titles in universities and colleges.
Material: National Institute of Science and Technology Policy (NISTEP) summarized and analyzed using individual data (through application for secondary use based on the statistical method) of Ministry of Education, Culture, Sports, Science and Technology (MEXT) "Survey of Full-time Equivalent Data at Universities and Colleges"

Figure 24 Time Spent by National University Faculty Members by Job Activity and Job Title (Kanda/Tomizawa 2015, p.24)

1-2. National Medical Care Expenditures and Medical Research Funds

According to the Ministry of Health, Labour and Welfare (MHLW) (2017), the national medical care expenditure in FY 2015 was 42.3644 trillion yen, an increase of 3.8%, 1.5573 trillion yen, compared with 40.8071 trillion yen in the previous year. By financial resource, public funds accounted for 16.4715 trillion yen (composition ratio: 38.9%), of which that from the national treasury was 10.8699 trillion yen (25.7%), and that from local governments was 5.6016 trillion yen (13.2%). The state liability has been increasing year by year from 7.8113 trillion yen in FY2002 to approximately 1.4-fold that figure in FY2015. The ratio relative to the general account budget increased from approximately 9.3% in FY2002 to approximately 11%[15] in FY2015. The ratio relative to GDP was 7.96% (FY2015) showing an increase from 6.01% in FY2002.

The main factor contributing to increased medical expenses is the medical expenses of citizens aged ≥ 65 years accounting for ≥ 50% of medical expenses (59.3% of the overall figure in FY2015). The national medical care expenditure per capita was 184,900 yen for persons aged < 65 years and 741,900 yen for persons aged ≥ 65 years. The medical expenses at medical departments were 125,100 yen for persons aged < 65 years and 542,700 yen for persons aged ≥ 65 years. The aging of society will continue for the next few decades, so it is not easy to suppress increases in medical expenses.

On the other hand, further development of medical research and optimization of medical care

[15] According to 2015 Settlement of General Account (http://www.mof.go.jp/budget/budger_workflow/account/fy2015/ippan.pdf)

through utilization of genome information, big data etc. are required to improve the efficient use of medical/care expenditures and to strengthen the international competitiveness of medical/social security services. To achieve this, cyclic R&D, in which the processes cycle through from basic research into translational research (TR), verification in the clinical setting, and verification in a large patient population, is important, along with identification of new challenges to basic research and utilization of big data in each process. With an awareness of these issues, the Japan Agency for Medical Research and Development (AMED) was established in 2015 to integrate each area of medical research, which had previously been carried out in a vertically segmented manner by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) (basic research), MHLW (clinical research) and the Ministry of Economy, Trade and Industry (METI) (practical application). Approximately 140 billion yen of research funds were consolidated in AMED (> 150 billion yen in FY2016) and the Headquarters of Healthcare Policy, Cabinet Secretariat is responsible for overall coordination.

While these systems were being developed, medical R&D funds showed negligible increases compared with increases in the expenditure on national medical care and its central government's burden. Young, et al. (2015) calculated increases/decreases in medical R&D funding taking the consumer price index (CPI) and exchange rates into consideration and showed significant increases in China and South Korea, small increases in Japan, Australia and India, and decreases in the US and Canada. According to AMED (2015), Japanese R&D funding in the medical field is approximately 280 billion yen: 65 billion yen for scientific research funds, approximately 140 billion yen for AMED and approximately 75 billion yen for national in-house research institutions.[16] This was 0.66% of the national medical care expenditure (FY2015) and 1.7% of its publicly funded expenditure. In the UK, where research competitiveness is steadily improving, approximately 1 billion pounds (at the time of establishment in 2007) were allocated as a budget to the National Institute for Health Research (NIHR), which is described below, and approximately 600 million pounds (budget in 2007/08) to the Medical Research Council (MRC).[17] This is 1.35% of the 2007 national medical care expenditure (118.3 billion pounds[18]) and 1.66% of its publicly funded expenditure (96.2 billion pounds). The level of medical research funding relative to national medical care expenditure in Japan is only half that in the UK though a direct comparison is not easy due to differences as to how funding is allocated in national medical care expenditure.

In the UK, ≥ 80% of the budget for the National Health Service (NHS) is provided through taxes and medical care funding relative to the GDP has (politically) been increased from 7.6%

[16] Additional increase of approximately 360.0 billion yen if supplementary budgets (In FY2016 second supplementary budget, 61.8 billion yen as AMED expenses and 1.1 billion yen as in-house research institution expenses) and 17.5 billion yen allotted as R&D-related adjustment expenses for the medical field from Cabinet Office "Science, Technology and Innovation Promotion Funds" are added.
[17] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/248447/0904.pdf
[18] https://www.ons.gov.uk/ons/rel/psa/public-service-productivity/1997-2009/expenditure-on-health-care.pdf

in 2002 to 9.3% in 2013. The UK also faces an aging society, and the number of persons ≥ 65 years increased from approximately 9.40 million (approx. 16.0% of the population) in 2002 to 10.99 million (approx. 17.5% of the population) in 2013. Under these circumstances, the 2006 Cooksey review pointed out that diseases etc., which are the main factors contributing to medical expenses, did not always coincide with how research funds were allocated, and funding for research-clinical TR was not sufficient. This was considered due to the aspiration to (1) promote research and application of research results to diseases that incur substantial medical expenses in the clinical setting and (2) be seen at the forefront of research and promote market expansion by the healthcare-related industries and as a result promote economic development in the UK. Prior to the Cooksey review, similar problems were pointed out in the "Best Research for Best Health" (January 2006), a strategic recommendation issued by the Department of Health (DH) under the leadership of the cabinet, and the National Institute for Health Research (NIHR) was established in the NHS system (April 2006). Furthermore, the Office for Strategic Coordination of Health Research (OSCHR) was established in 2007 to further prioritize TR through coordination between DH (NHS, NIHR responsibilities) and innovation/universities/Department for Business, Innovation and Skills (another public healthcare-related research funding agency, MRC responsibility) (consolidate health/research-related budgets and request funding from the Exchequer). As a result, approximately 1 billion pounds (approx. 200 billion yen at that time) were allocated as a budget for the NIHR. This accounted for approximately 1% of the NHS budget.

In 2005, the Exchequer indicated that it intended to consolidate MRC budgets under the responsibility of the Office of Science and Technology (OST) of the Department of Trade and Industry (DTI) and NIHR budgets under the responsibility of the DH to establish an organization, which was to be governed by and allocated a single health/research budget (Yamada 2008). Sir David Cooksey, a former venture-capitalist and who acted as the chairman of the Joint Healthcare Research Delivery Group (organization that coordinates research functions of DH an MRC) published the Cooksey review in December 2006, having been entrusted to produce a survey report by the Exchequer. However, the plan to establish a single health/research funding agency was shelved due to a concern that the MRC, which is a bigger organization and focuses on basic research, might dominate the integrated organization. Consequently, the above OSCHR alone, which is equivalent to the Headquarters of Healthcare Policy in Japan, was established.

The factor that governs medical R&D system and research funding system in the UK is that the healthcare system is a publicly provided system and its resources are almost entirely covered by the general account. In other words, the DH and NHS are the sole bodies that provide and purchase medical services, and therefore they have incentives to optimize/develop their services as well as incentives to request budget increases to bring about optimization/development. In Japan on the other hand, although the MHLW is responsible for approximately 11 trillion yen of the government's contribution to medical

funds, the allocation of medical funds is determined by medical fees according to the report from the Central Social Insurance Medical Council (CSIMC) (i.e., optimization of the healthcare system is based on medical fees) and therefore it is not clear what incentives the MHLW has to disburse R&D budgets.

1-3. Objectives of the Study

To a certain degree, the AMED addressed challenges such as consolidation of resources and general coordination of research strategies. However, these two wheels will not be aligned in the promotion of cyclic R&D until a platform to realize the cycle (basic to clinical, or medical-engineering collaboration) in university hospitals, which are the actual R&D setting, is established. Such development of R&D is expected to improve the quality of national medical care and contribute to the realization of more efficient healthcare delivery. This study aimed to clarify how medical R&D in university hospitals is promoted (medical R&D platform) mainly in countries where recommendations for system development can be obtained through case study analysis.

The US, which is the global leader in medical R&D, the Netherlands and Germany, which are the roots of Western medicine in Japan and competitive through implementation of unique medical R&D, and South Korea, as a representative of emerging Asian countries which have recently shown a rapid increase in international competitiveness through promotion of investment in medical R&D as a national policy, were selected as the survey countries. Although it may be very difficult for Japan to catch up with the US in terms of research scale and achievements, the Netherlands, Germany and South Korea were selected with an expectation that there would be policies and practical lessons that Japan could learn from these countries.

2. Summary of the Study

In this study, a literature survey using the statements of account and financial statements of university hospitals, university regulations in each survey country in addition to papers, journals and online articles was performed to elucidate the status of medical R&D in each country and systems, budgets and allocation of human resources for R&D in university hospitals. R&D in university hospitals is significantly affected by budget allocation, income structure, governance structure, HR allocation, etc. In the US, Netherlands, Germany and South Korea, information disclosure occurs to an advanced degree and the information can be confirmed by referring to documents published on the Web.

Six preliminary interview surveys were conducted in Japan to obtain advice on the survey countries and survey plan and information on the existing surveys (Table 2). The interviewee of AMED, provided information on the situations in the UK and Germany. The interviewee of Suzuka University of Medical Science provided information on fundamental problems in Japanese medical R&D, specifically information on the basis of quantitative research and information on the situation in Taiwan. A close discussion was held with a professor of Seoul National University concerning the situation of medical R&D in Seoul National University and policies promoting medical R&D in Korean university hospitals. A Counsellor at the Embassy of the Federal Republic of Germany in Tokyo provided information on the overall picture of medical R&D and federal policies in Germany. The interviewee of Elsevier Japan K.K., provided information on medical R&D in the Netherlands and its policy-making stakeholders. A researcher of Japan Science and Technology Agency (JST) provided information on past medical R&D in Germany, specifically the outcome of the investigation into the Berlin medical research center.

Table 2 Preliminary Interview Surveys in Japan

Date of survey	Affiliate
June 22, 2016	AMED
June 28, 2016	Suzuka University of Medical Science
July 23, 2016	Seoul National University, South Korea (Interviewed in Tokyo)
August 02, 2016	Federal Republic of Germany in Tokyo
August 03, 2016	Elsevier Japan K.K. (hearing by telephone)
Sep 16, 2016	Department of Information Planning, JST

Overseas on-site surveys were conducted to gain an understanding of the overall picture of R&D in university hospitals, problems and discussion points for comparison in each country. The surveys are listed in Table 3 for South Korea, Table 4 for the Netherlands, Table 5 for Germany and Table 6 for the US. In the interview surveys, 20 persons from a total of 17 institutions were interviewed.

Table 3 On-Site Surveys in Korea

Date of survey	Affiliate
July 27, 2016	Seoul National University Hospital
July 27, 2016	Severance Hospital, Yonsei University
July 28, 2016	Korea Health Industry Development Institute (KHIDI)[19]
July 28, 2016	Seoul Medical Center
July 29, 2016	College of Medicine, Inha University Global Stem Cell & Regenerative Medicine Acceleration Center (GSRAC)

Table 4 On-Site Surveys in the Netherlands

Date of survey	Affiliate
September 26, 2016	Health Council of the Netherlands
September 26, 2016	Ministry of Education (OCW)
September 27, 2016	Ministry of Health (VWS)
September 27, 2016	Erasmus MC
September 29, 2016	LUMC (Leiden University Medical Center)
September 29, 2016	Elsevier

[19] Quasi-governmental think tank of Ministry for Health & Welfare, South Korea (responsible for the welfare area in the Japanese MHLW)

Table 5 On-Site Surveys in Germany

Date of survey	Affiliate
September 30, 2016	Berlin Institute of Health (BIH)
October 04, 2016	University Medical Center Göttingen
October 05, 2016	Charité (Universitätsmedizin Berlin)
October 05, 2016	Charité
October 06, 2016	German Aerospace Center (DLR)[20]
October 06, 2016	German Research Foundation (DFG)[21]

Table 6 On-Site Survey in the US

Date of survey	Affiliate
October 10, 2016	Stanford Medicine

After summarizing the information to a specific level, additional interview surveys (Table 7) and a closed workshop (Table 8) were conducted in Japan to clarify the information collected and lessons to be learned from the overseas cases taking the Japanese situation into consideration.

Table 7 Additional Interview Surveys in Japan

Date of survey	Affiliate
February 27, 2017	The University of Tokyo Hospital
June 21, 2017	AMED
July 12, 2017	MEXT
July 27, 2017	Okayama University
July 28, 2017	Shionogi & Co., Ltd.
July 28, 2017	Suzuka University of Medical Science
August 01, 2017	Medical Education Division, Higher Education Bureau, MEXT
August 03, 2017	Office of Healthcare Policy, Cabinet Secretariat
August 08, 2017	University of Tokyo/KAWASAKI INSTITUTE OF INDUSTRIAL PROMOTION Innovation Center of NanoMedicine (iCONM)
August 08, 2017	University of Tokyo
August 29, 2017	Health Policy Bureau, MHLW

[20] Deutsches Zentrum für Luft- und Raumfahrt: An institution, which is responsible not only for R&D of aerospace technologies, it also plays similar roles to those of JST in Japan under Bundesministerium für Bildung und Forschung (BMBF)

[21] Deutsche Forschungsgemeinschaft: An independent research funding institution operated with federal and state government's fund. While it plays similar roles to those of JST and JSPS in Japan, it is a member of the International Council for Science (Science Council of Japan in Japan)

Table 8 Outline of Workshop by CRDS

(Information on the program, attendees, etc. is omitted due to the closed nature of the workshop)

JST-CRDS Life Science and Clinical Research Field
Workshop on medical R&D platforms

1. Event Outline

Title:	JST-CRDS Life Science and Clinical Research Field Workshop on medical R&D platforms
Date & Time:	Saturday, September 23, 2017; 13:00 – 16:00
Venue:	Japan Science and Technology Agency, Residential Building 1F, Meeting Room 5-3, Yonbancho, Chiyoda-ku, Tokyo 102-8666 Japan TEL: 03-5214-7481 FAX: 03-5214-7385
Sponsor:	Japan Science and Technology Agency (JST) Life Science and Clinical Research Unit, Center for Research and Development Strategy (CRDS)

2. Objectives

The JST-CRDS Life Science and Clinical Research Unit (supervisor: Ryozo Nagai, Senior Fellow) investigates R&D trends occurring in the life science and clinical research fields in Japan and overseas, evaluates R&D strategies that Japan should promote and provides information and policy recommendations to relevant ministries, organizations, etc.

Recently, there is a growing sense of crisis over the R&D capability and environment of Japanese universities. In medical R&D in particular, the need to promote data-driven R&D and cyclic R&D (basic research-TR-clinical studies-basic) is recognized and establishment of a platform is an important challenge for Japanese university hospitals.

This Unit has been conducting investigations on cases in countries since 2016 and extracted lessons and challenges that will contribute to the establishment of a platform for the promotion of research in university hospitals. Based on the obtained information, we will hold a closed workshop to deepen discussion with experts and specialists about the ideal form of R&D in Japanese national university hospitals.

In the workshop, we will share information on R&D environments in Japanese and overseas university hospitals and exchange opinions on detailed R&D strategies that Japan should promote.

3. Medical R&D Platforms of University Hospitals in Each Country

3-1. US

In the US, medical R&D platforms were investigated. First in Stanford University, in which a medical school and hospital are incorporated into the university organization similarly to Japanese university hospitals, and Harvard University, where the hospital is independent from the university (Figures 25, 26). Information on Stanford University was obtained through literature investigations and interview surveys. Information on Harvard University was obtained through literature investigations only.

Stanford University is a private university (trust) established in 1885 by a former California governor (later federal senator) Leland Stanford and his wife, Jane. Stanford's School of Medicine originated from the School of Medicine, University of the Pacific established in San Francisco in 1858. This university's School of Medicine discontinued operations in 1862 and was reestablished as the Cooper Medical College in 1870, then devolved to Stanford University in 1908. In the 1950s, there was a discussion to move the School of Medicine, Stanford University from San Francisco to Palo Alto, and at that time Palo Alto-Stanford Hospital Center was established as a university hospital. The relocation and establishment of the hospital were completed in 1959. At first, Palo Alto-Stanford Hospital Center was co-funded with Palo Alto city, and Stanford University bought it from the city in 1968 and renamed it Stanford Health Care. Subsequently, in parallel with multiple research laboratories, another university hospital, Lucile Packard Children's Hospital, was established in 1991. These two university hospitals and the School of Medicine are what constitute the so-called Stanford University Medical Center.

The Stanford School of Medicine was ranked No. 2 in the US[22] in the 2018 U.S. News & World Report after Harvard Medical School, and 4th equal[23] in the world according to the 2018 Times Higher Education by field and is recognized as a globally competitive School of Medicine.

At Stanford University, a California trust, the Board of Trustees (Board of Directors/Board of Trustees/Trustee Council) is the institution's highest decision-making body. The university's President is appointed by the Board of Trustees and the university President appoints the Provost upon approval of the Board of Trustees. At Stanford University, the Provost is responsible for administering the academic program, including both instruction and research, and budget management etc., and all HR-related matters in each faculty have to be approved by the Provost.

The School of Medicine, Stanford University also has a similar university governance system

[22] https://www.usnews.com/best-graduate-schools/top-medical-schools/research-rankings
[23] https://www.timeshighereducation.com/student/best-universities/best-universities-medicine

but with some exceptions. For HR, some positions are not controlled by the Provost. For instance, the School of Medicine, Stanford University has Academic Council Professoriate positions (a little fewer than 500 members), which are part of the university faculty council, Medical Center Line positions (500 members), which are not part of the university faculty council but belong to the medical faculty council, and Clinician Educator positions (clinical faculty positions) (1200 members), which are not part of the university or medical faculty council. Of these positions, candidates for the Academic Council Professoriate and Medical Center Line positions need to be escalated to the Provost from the Dean of the School of Medicine for approval. On the other hand, candidates for the position of Clinician Educator can be determined at the discretion of the Vice Dean of the School of Medicine. All of these three types of positions double as positions at Stanford Health Care or Lucile Packard Children's Hospital. The Academic Council Professoriate retains the balance of research, education and medical care (research is important), the Medical Center Line conducts some research while focusing on education and medical care, and the Clinician Educator focuses on education and medical care. The first two types of faculty members, who conduct research, can establish a laboratory or participate in laboratory activities.

Financially, Stanford University Medical Center is independent from Stanford University. The two university hospitals have a combined budget of 3,570 million dollars (approx. 430,000 million yen),[24] and of this budget, 983 million dollars (approx. 105,000 million yen) are allocated to the School of Medicine.[25] This accounts for 43% of the annual budget (2,286.10 million dollars; approx. 245,000 million yen) of the School of Medicine. Furthermore, 1% (approx. 23 million dollars; approx. 2,500 million yen) of the budget for the School of Medicine is obtained from patent income.

While fiscal statements are also separated, they are related to university governance in four areas. First, the indirect costs (Facilities and Administrative [F&A] Cost) relative to the external research funds (663 million dollars overall for the School of Medicine, 29% of the School of Medicine's budget) will be paid to the university. This rate is between 28.5% and 57% depending on the location (on/off campus) of research sites. Second, all assets, including the School of Medicine and university hospital, are the property of the university. Therefore, a budgetary provision needs to be obtained via a university-level deliberation for renovation or new construction. However, expenses related to asset holdings such as property tax etc. are paid by the university. Third, although the accounts for Stanford University Medical Center are separate from those of the university, it pays 110 to 120 million dollars (approx. 12,000 to 13,000 million yen) to the university.[26] Fourth, university funds are managed on a "whole university" basis, and offer funding to the university (approx. 1,100 million dollars; 23% of

[24] The budget for the university hospitals is based on information from the budgets for FY2014 to 2015 (year ended on August 31). The telegraphic transfer middle (TTM) rate on the day of year end was used for the conversion. TTM = 121.18
[25] The budget for the School of Medicine, funding for the School of Medicine, and hospital income are based on the budget plan of June 2016 (as of June 08). TTM = 107.12
[26] The university budget and fund income are according to the budgets for FY2015 to 2016 (year ended on August 31). TTM = 103.18

the total budget) and School of Medicine (approx. 182.90 million dollars; 8% of the budget for School of Medicine).

Harvard University is a private university established in 1636, during the British colonial period. Harvard Medical School was established in Cambridge in 1782. After the relocation to Boston in 1810, Harvard Medical School was moved to the current Longwood Medical and Academic Area in Boston in 1906. During this period, Harvard Medical School relocated several times. From 1847 to 1883, Harvard Medical School was located next to Massachusetts General Hospital (MGH), which was established in 1811. Such an approach led to the Harvard's unique system, which has no university hospital and performs research, education and medical care in close collaboration with affiliates.

Harvard University has two organizations at the top of the governance structure. First, there is an organization called the Harvard Corporation (officially, the President and Fellows of Harvard College), which consists of the university President, Treasurer and Fellows (n=11). This organization is responsible for academic/financial affairs, engages in long-term strategies etc., and provides advice to the university President. Second, there is an organization called the Board of Overseers, which consists of the university President, Treasurer, and persons elected from Harvard degree holders (n=30). This organization has a major influence on the university's strategic decision-making etc. and has the authority to approve decisions of the Harvard Corporation while also complementing it. These two organizations perform functions similar to those performed by the Board of Trustees at Stanford University while complementing one another (they have joint committees for HR and other matters depending on the content). In addition to the university President, the Provost is established as the superintendent of academic affairs in the same manner as Stanford University.

Harvard University does not have a university hospital though Harvard Medical School is included in the university organization. Harvard Medical School, which is owned by Harvard University, has ten Basic and Social Science Departments[27] to which 176 tenured or tenure-track faculty members belong. The budget for this "main body" of Harvard Medical School is approximately 656 million dollars (approx. 68,000 million yen);[28] 9% comes from donations, 41% is from external research funding and 27% are from the university funds. Although the size of the institution is far smaller than that of Stanford University when looking at the "main body" only, there are 18 clinical departments and 38 hospital-based departments in the 16 affiliates, which collaborate in research, education and clinical care. There are full-time faculty members, including faculty members with voting rights in the university faculty council, in the affiliates and the total number of faculty members is 11366: 5813 faculty members with voting rights and 9332 full-time faculty members. The School of

[27] Due to the characteristics of the location, it is called "The Quad."
[28] The university budget, fund-related and budget for School of Medicine are according to the budgets for FY2015 to 2016 (year ended on June 30). TTM = 102.91

Medicine, Harvard University has concluded individual affiliation agreements with these affiliates. The affiliates are Beth Israel Deaconess Medical Center, Boston Children's Hospital, Brigham and Women's Hospital, Cambridge Health Alliance, Dana-Farber Cancer Institute, Harvard Pilgrim Health Care Institute, Hebrew SeniorLife, Joslin Diabetes Center, Judge Baker's Children's Center, Massachusetts Eye and Ear, Massachusetts General Hospital, McLean Hospital, Mount Auburn Hospital, Spaulding Rehabilitation Hospital, VA Boston Healthcare System and The Forsyth Institute.

For example, Beth Israel Deaconess Medical Center (BIDMC) is operated by Beth Israel Deaconess Care Organization (BIDCO), an Accountable Care Organization (ACO), and separate from the university in terms of management. BIDCO has a President and CEO and BIDMC also has a President. Furthermore, while "Faculty members of Harvard Medical School" (1250 full-time faculty members) working at BIDMC belong to a separate organization, namely, the Harvard Medical Faculty Physicians (HMFP), they are in a collaborative relationship both with BIDMC and Harvard Medical School. The annual budget of BIDMC is approximately 1,873 million dollars (approx. 183,000 million yen) and approximately 11% of that amount comes from the BIDMC funds (funds separate from the university) and an amount of approximately 227.3 million dollars, approximately 12%, comes from external research funds.[29]

Dana-Farber Cancer Institute, an affiliate, has a President & CEO (concurrent post) and Board of Trustees as decision-making body, and they are independent from the university. It has an annual budget of approximately 1,221 million dollars (approx. 146,000 million yen) and 479 full-time faculty members (264 MDs, 93 PhDs who are not MDs, and 122 MD-PhD double degree researchers), 539 research fellows and 61 clinical fellows.[30] Of the budget, approximately 29%, an amount of approximately 357.6 million dollars, comes from external research funds. The FY2016 budget for large affiliates, Massachusetts General Hospital (MGH) and Brigham and Women's Hospital alone came close to 1 trillion yen, and the total budget of all 16 affiliates is estimated to exceed 1 trillion yen.[31]

In Harvard University, the rate of indirect costs relative to the external research funding is set significantly high, between 26% and 69.5% depending on the type. The rate of indirect costs for Harvard Medical School is determined after negotiation by the Office of Sponsored Programs Administration (SPA) of Harvard Medical School separately from the university. In the same manner as the rate of indirect costs, the rate of fringe benefits relative to the external research funding is also stipulated. For example, faculty members can add 24.2% of the external research funding to income.

[29] According to the statements of account for FY2012 to 2013 (year ended on September 30). TTM = 97.75
[30] According to the annual reports for FY 2014 to 2015 (year ended on September 30). TTM = 119.96
[31] Rough estimation as the budget data in the same fiscal year could not be obtained.

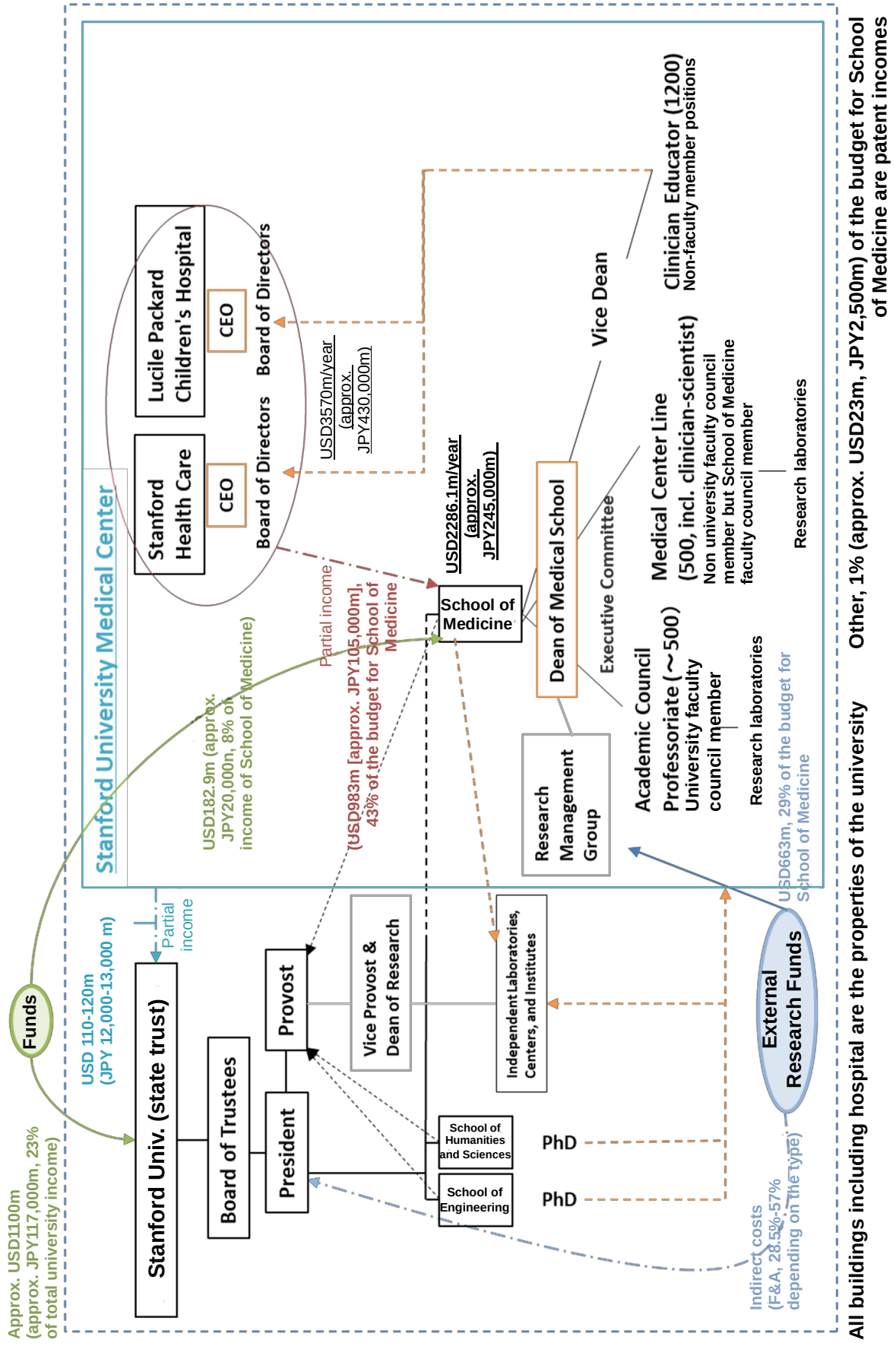


Figure 25 Medical R&D Platform of Stanford University

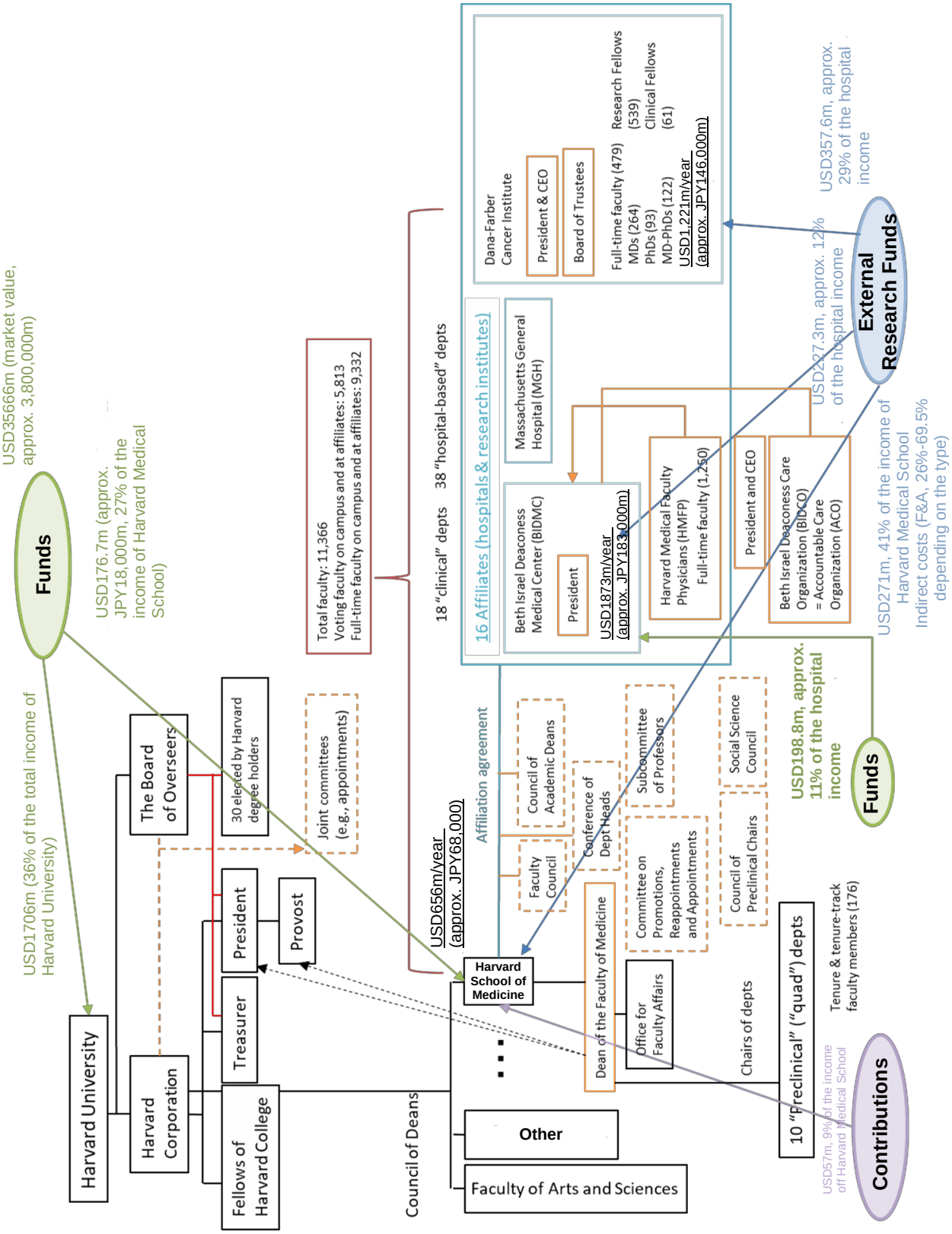


Figure 26 Medical R&D Platform of Harvard University

3-2. The Netherlands

In the Netherlands, integration (University Medical Centre = UMC, separate corporation from the university) of the faculty of medicine and university hospital (educational hospital) began in the 1990s, and all faculties of medicine, i.e., eight faculties of medicine, in the Netherlands had become UMCs by 2008. A UMC is a private nonprofit corporation.

The Academic Medical Center (AMC) of the University of Amsterdam was integrated as the first UMC in 1994. The AMC was established in 1983 as an educational hospital that collaborates with the School of Medicine, University of Amsterdam. Niek Urbanus served as the chairman of the AMC and as university president. From the late 1980s, when he gained control of the Board of Directors, he pushed through establishment of the Faculty of Clinical Epidemiology/Biostatistics (first in the Netherlands), integration of the School of Medicine and university hospital, and independence (establishment of the UMC) from the university. Although it cannot be verified if these reforms were effective, the AMC was ranked in the world Top 50 (46th in Medical Universities/Faculty of Medicine) only 30 years after its establishment.

As part of the on-site survey, two UMCs, Erasmus MC and LUMC (Leiden) were investigated. The structure of the medical R&D platform (Figure 27) was clarified specifically as a result of the survey of Erasmus MC, for which an understanding of the overall picture of the medical R&D platform was gained through an interview with the CEO and the rich collection of published materials were obtained. In ranking by subject according to the 2018 Times Higher Education World University Rankings' table, Erasmus MC was ranked in the global Top 40,[32] the highest ranking in the Netherlands.[33]

After the shift to the UMC in 2002, Erasmus MC became organizationally and financially separate from the "parent university" Erasmus University Rotterdam. However, Erasmus University itself came into being as a result of a merger of the Netherlands School of Economics (Nederlands Economische Hogeschool [NEH]) and Medische Faculteit Rotterdam in 1973. Furthermore, Medische Faculteit Rotterdam originated from Coolsingel Hospital, the first hospital in Rotterdam, founded in 1840, and was established as the 7th medical university in the Netherlands in 1965 as part of Dijkzigt Hospital founded in 1961 after the end of World War II. Erasmus MC and Erasmus University Rotterdam historically had a basis for separation.

The highest executive body of Erasmus MC is the Board of Directors, which consists of the CEO (board chair), Dean of the School of Medicine (vice chair) and CFO. The Supervisory Board is the highest decision-making body and approves budgets and the appointment of the CEO. The CEO is primarily responsible for medical care/management-related activities at the hospital, and the Dean of the School of Medicine is in charge of research/education-related

[32] https://www.timeshighereducation.com/student/best-universities/best-universities-medicine
[33] AMC, in the top 2 in the Netherlands, and is ranked in the World Top 48; LUMC, in the top 3 in the Netherlands, and is ranked in the World Top 51.

activities and the CFO is in charge of finance and pharmacy/radiology-related activities at the hospital. Candidates for faculty positions are proposed by the Dean of the School of Medicine and deliberated by the Board of Directors. The Dean of the School of Medicine also acts as the Rector (Provost in the US) of Erasmus University Rotterdam. The highest executive body, the Executive Board of Erasmus University Rotterdam, consists of the Rector, President and a third member. Erasmus MC is positioned as a subsidiary of a holding company, Erasmus MC Holding BV, and includes over 25 affiliated companies/organizations (mainly start-ups by faculty members etc.)

The total number of staff of Erasmus MC (School of Medicine + research laboratory + hospital) is approximately 13,000 and 730 of these are members of the medical faculty (disposition of professors etc. is unknown). According to 2013 data, the number of PhDs awarded in that year was 220. The annual budget is approximately 1,394 million euros (approx. 183,700 million yen).[34] All funds obtained from medical fees (insurance), Ministry of Health, Welfare and Sport (VWS), Ministry of Education, Culture and Science (OCW) and external research funds are provided to the UMC and the UMC has sole discretion regarding their use. Therefore, for example, how much of the funding from the OCW was used for what purpose cannot be tracked. It came to light during the interview surveys that there were some complaints from the government concerning this situation.

Funds flowing to the UMC come from the following four sources: “1st Source” from the OCW and VWS, “2nd Source,” to which competitive external funds are added to the competitive funds that come from the OCW via the Netherlands Organisation for Scientific Research (NWO) and the VWS via the Netherlands Organisation for Health Research and Development (ZonMw), “3rd Source,” which is mainly donations from foundations etc. and “4th Source,” which is made up of external contract research funds from companies etc. Erasmus MC (2015) had an income of approximately 296 million euros (approx. 39,000 million yen) when the funds from these sources are combined. According to the annual research report (2014) of Erasmus MC, 75% of “1st Source”, which is equivalent to the management expense grants in Japan, was lump-sum fixed payments and 25% was performance-linked funding, for which the number of PhDs awarded, acquired external funds, the number of high-quality papers etc. are used as the assessment criteria.

Based on the 2012 data, the medical fee income of Erasmus MC was approximately 1,161 million euros (approx. 153,000 million yen): approximately 191.3 million euros (approx. 21,900 million yen) from “1st Source,” approximately 85 million euros (approx. 9,800 million yen)[35] from “2nd Source,” approximately 7.5 million euros (approx. 860 million yen)

[34] Erasmus MC budgets are according to the 2015 account documents (in Dutch). The disposition of budgets is according to the 2012 data from the following document (in Dutch). All values were converted to Japanese yen using the last TTM exchange rate of the year (as the information on the exchange rate on December 31 cannot be obtained though the closing date is December 31.) On December 30, 2015, TTM =131.77. On December 28, 2012, TTM = 114.71. https://www.rathenau.nl/nl/file/162/download?token=C0cGKSXk

[35] Of this, competitive external funds from the EU contributed approximately 40.9 million euros (approx. 4,700 million yen). The competitive external funds were obtained from the National Institutes of Health (NIH), the Royal Netherlands Academy of Arts and Sciences (KNAW) etc.

from “3rd Source” and approximately 11.90 million euros (approx. 1,400 million yen) from “4th Source.” The patent income was 2.2 million euros in 2011, 2.8 million euros in 2012, 2.5 million euros in 2013 and 0.44 million euros in 2014 though there are significant variations depending on the year.

Active double appointments of faculty members is a characteristic of the Netherlands. In research schools, affiliated companies under Erasmus MC Holding BV, needless to say, double appointments with organizations/universities that comprise local research consortiums called “Medical Delta” are also made. For example, “Medical Delta” includes not only local healthcare-related companies but also Delft University of Technology, Erasmus University Rotterdam, Erasmus MC, LUMC and Leiden University. One example is Richard Goossens, who serves as a professor of Industrial Design at Delft University of Technology and is also a professor of Physical Ergonomics at Erasmus MC.

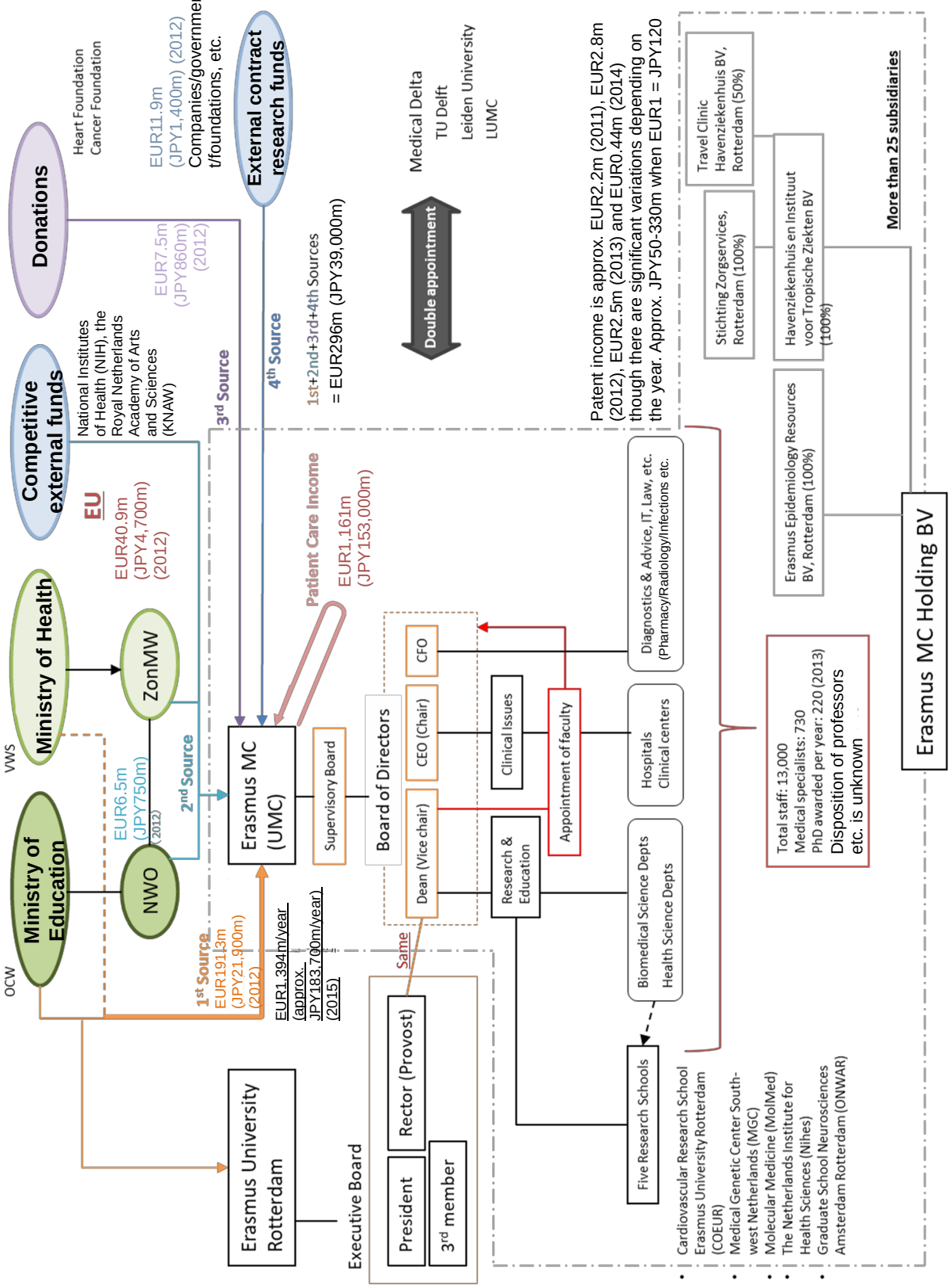


Figure 27 Medical R&D Platform of Erasmus MC in the Netherlands

3-3. Germany

In Germany, there is no organization like the National Institutes of Health (NIH). The federal R&D budgets are the responsibility of the German Federal Ministry of Education and Research (BMBF) and allocation is supported by the German Research Foundation (DFG) etc. While medical R&D is mainly conducted in research institutions (specifically research associations), collaboration, primarily with university hospitals, is essential as research associations do not provide accommodation in the clinical setting. Therefore, policies such as cross-appointments with universities (or university hospitals) and research laboratories affiliated with the research associations have been introduced.

Among the four major research associations (Max Planck, Helmholtz, Leibniz, Fraunhofer), the Fraunhofer Association is increasing its presence as an industry-academia "bridge."[36] Approximately 70% of budget of the Fraunhofer Association is made up of external funds (40% from companies, 30% from public research business) and they focus on acquiring funds from companies. The Association actively accepts doctoral students and postdocs through cross-appointments and 6400 of the 22000 faculty members are students. This is an attractive career path for those wanting to move into blue-chip companies.

As seen with the Fraunhofer Association, it is common in Germany to obtain PhDs from a university while conducting research and generating income in research laboratories affiliated with the research associations. There are some pioneering initiatives to further advance this. For example, the Max Planck Association and the German Rectors' Conference established the International Max Planck Research School (IMPRS) in 2001. In IMPRS, the two associations jointly provide programs for PhD candidates and researchers belonging to the research associations can be involved in the teaching and evaluation of students. However, the right to award degrees belongs to the university and diplomas state only that the Max Planck Association was involved. The Helmholtz Association instituted a law to merge the university (Universität Karlsruhe) in Karlsruhe and a research center affiliated with the Helmholtz Association into a single research education facility in 2009 and founded Karlsruher Institut für Technologi (KIH). This was based on an agreement between the Federal Government and Land Baden-Württemberg, and KIH is a research facility of the Helmholtz Association as well as a state university. A significant difference from IMPRS, which provides joint programs only, is that KIH has the right to award degrees. However, it is said that a complete merger like KIT will not take place again.[37]

In Berlin on the other hand, Berliner Institut für Gesundheitsforschung (Berlin Institute of Health [BIH]) was established in 2013 as a result of the federal strategy to promote innovative themes and TR. This is a joint foundation [38] formed by Charité-Universitätsmedizin Berlin and the Max Delbrück Center for Molecular Medicine

[36] http://www.meti.go.jp/committee/sankoushin/sangyougijutsu/kenkyu_hyoka/pdf/002_02_00.pdf
[37] According to a discussion at the time of the interview survey conducted by Overseas Research Unit of the center.
[38] Called "joint research laboratory"

(MDC) affiliated with the Helmholtz Association. Of a total budget of a little over 300 million euros for the period from 2013 to 2018, 90% is provided by the federal government and the remaining 10% is provided by the state government. There is a joint appointment called the BIH professorship and cross-appointments with Charité or MDC and BIH professorship occur.

Charité-Universitätsmedizin Berlin started as a facility founded in 1710 by Friedrich Wilhelm I, King of Prussia, to care for victims of the plague. After the foundation of the University of Berlin (current Humboldt University of Berlin) in 1810, Charité became the university hospital attached to the university in 1828. Now, after the unification of East and West Germany, it is a university hospital which collaborates both Humboldt University of Berlin and the Free University of Berlin. Due this historical background, Charité operates independently from the university but it still holds true that Charité is jointly operated by the Humboldt University of Berlin and the Free University of Berlin. As of February 2018, the Executive Board includes the CEO and Dean of the Faculty of Medicine. The CEO is a researcher with a close relationship with Humboldt University of Berlin, and the Dean is a researcher having a close relationship with the Free University of Berlin.

Although Charité is a special case affected by the unification of East and West Germany, it is financially independent from the universities (Humboldt University of Berlin, Free University of Berlin). There are two financial systems in Germany: an “integration model” in which a faculty of medicine and a university hospital are merged and financially separated and an “cooperative model” in which a faculty of medicine and a university hospital exist under the university like Japanese university hospitals. Examples of the former are Charité and Georg-August-University Göttingen and an example of the latter is Heidelberg University. This study elucidated the structure of the medical R&D platform (Figure 28) in Georg-August-University Göttingen, for which detailed information was obtained through on-site interview surveys. At the same time, interview surveys were conducted at Charité and BIH and information on the medical R&D system in Germany was obtained.

The Faculty of Medicine, Georg-August-University Göttingen has, as described above, been merged with the university hospital and is financially separate from Georg-August-University Göttingen. University Medical Center Göttingen (UMG), which was established in 2003 by merging the Faculty of Medicine and the university hospital, belongs to the Göttingen University Foundation as with Georg-August-University Göttingen, but is operationally and financially independent. The university hospital (Göttinger Universitätsklinikum [UKG]) is a representative hospital in the southern area of Lower Saxony State. It has 1500 beds, a total of 7700 staff and receives approximately 60000 inpatients and 173000 outpatients per year.[39]

After the establishment of the preceding hospital (St. Crusis Hospital) in 1390 and the establishment of Georg-August-University Göttingen (including the Faculty of Medicine) in 1732, the hospital (clinic) was merged with the university in 1752. Furthermore, a

[39] http://www.med.uni-goettingen.de/de/content/ueberuns/139.html

university-owned hospital (Wundärztlichen Hospitals) was newly established in 1781 and positioned as the university hospital (Akademischen Hospital) in 1793. Although there were no changes to the organization of the University of Göttingen, the faculty of medicine and university hospital, even following some subsequent revisions of the facility/organization, UMG was founded in 2003 and is operationally/financially separate from the university. However, it is not completely separate in terms of organization. For instance, the Senate, which is the operational decision-making body at Georg-August-University Göttingen, includes seven professors from each faculty as voting members and the deans of each faculty play an advisory role. These seven voting professors may be UMG faculty members (as of February 2018, 2nd position of the three alternative members)[40] and deans of faculties playing an advisory role include the Dean of the Faculty of Medicine.

The total annual income of UMG was approximately 651 million euros (2014, approx. 96,000 million yen)[41] showing a significant increase from approximately 441 million euros (approx. 48,000 million yen)[42] in 2010. Of these, competitive external funds (DFG, BMBF, EU, foundations, contract research etc.) were approximately 65.80 million euros (2014, approx. 9,700 million yen). Materials that show the comprehensive financial situation of UMG could not be obtained and details of funds from Lower Saxony and the federal government could not be ascertained. Moreover, budget data from the same year could not be obtained. For reference, the income from medical fees was approximately 315 million euros (approx. 34,000 million yen) in 2010 accounting for approximately 70% of total income. According to one document[43] issued in 2008, the percentages of competitive external funds obtained were respectively 35% from DFG, 17% from the federal government (BMBF, Ministry of Health [BMG] etc.), 14% from the EU, 6% from foundations etc., 12% from Lower Saxony, 3% from contract research etc. and 1% from donations.

In UMG, operational decision-making is undertaken by the Board of Directors that has three directors: Director of Management & Administration, Director of Patient Care and Director of Research & Teaching. The Director of Research & Teaching is the Dean of the Faculty of Medicine.[44] The Faculty of Medicine has 105 professors and there are also approximately 100 lecturers.[45]

As often seen in Germany, Georg-August-University Göttingen has various types of research laboratories including those managed by faculty members of the Faculty of Medicine,

40 https://www.uni-goettingen.de/en/senate/22448.html
41 Accordingto the Lower Saxony meeting material (https://www.bayern.landtag.de/www/ElanTextAblage_WP17/Drucksachen/Basisdrucksachen/0000013000/0000013187.pdf). Since the information is as of December 31, 2014, the values were converted to Japanese yen using the last TTM exchange rate of the year. On December 31, 2014, TTM = 148.04.
42 http://www.management-krankenhaus.de/news/universitaetsmedizin-goettingen-positive- bilanz-fuer-das-jahr-2010 Converted using the last TTM of the year (December 30, 2010) = 109.4.
43 https://www.med.uni-goettingen.de/de/media/forschung/forschungsbericht/forschungsbericht_2008.pdf
44 http://www.med.uni-goettingen.de/de/media/organisation/organigramm_gesamtvorstand_de.pdf
45 Slightly different from the clinical faculty members in other examples. They are somewhat similar to external lecturers teaching at partner medical institutions. http://www.med.uni-goettingen.de/de/content/ueberuns/138.html

research laboratories jointly operated by UMG and Georg-August-University Göttingen and research laboratories jointly operated by external institutions (e.g., research institutions affiliated with the Max Planck Association and companies). For example, the European Neuroscience Institute was jointly founded by UMG and multiple research institutions affiliated with the Max Planck Association and funded by Schering AG (private company).

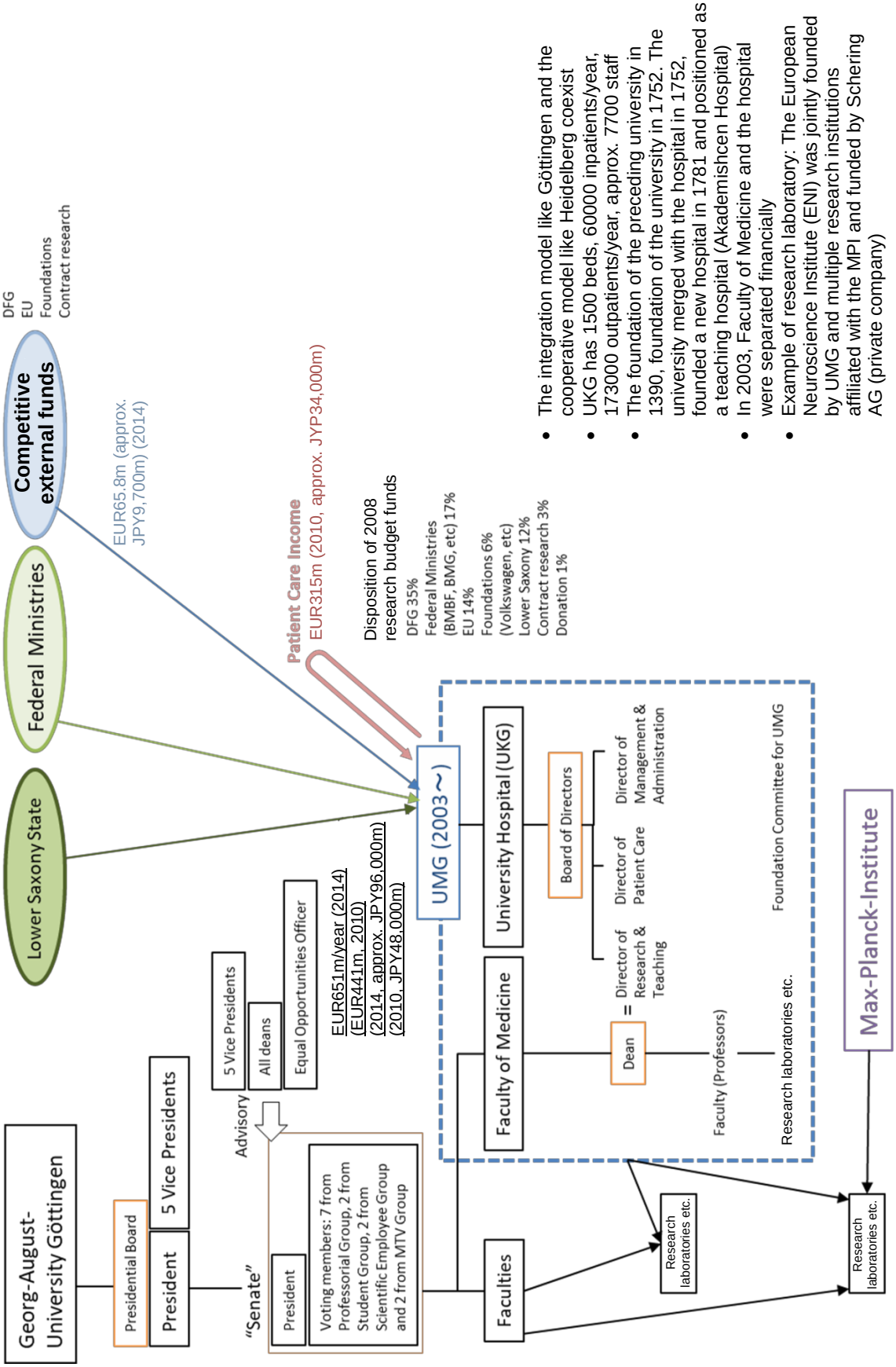


Figure 28 Medical R&D Platform of Georg-August-University Göttingen

3-4. South Korea

In South Korea in 2004, medical care funds were 43,339,300 million won and government liabilities were 3,438,000 million won, accounting for only about 8% of the funds. For the purposes of social insurance in South Korea, wage earners and non-wage earners are divided into "workplace subscribers" and "local subscribers." "Governmental funding," which is a governmental subsidized fund, and "cigarette contributions," which is support from national health promotion funds, are injected as "government liabilities" only to "local subscribers" (National Federation of Health Insurance Societies 2007).

In South Korea, a national health insurance scheme was set up in 1989 and medical fees are centrally controlled by a point system. However, the healthcare system was reformed in 2000 and the insurance societies were integrated into the National Health Insurance Corporation (NHIC), and the Health Insurance Review and Assessment Service (HIRA) came into being as an independent body, which reviews receipts and evaluates the appropriateness of benefits. At the same time, medical IT and the penetration of electronic invoicing (electronic data interchange, EDI) rapidly advanced and the HIRA became a mega data warehouse. The HIRA "has accumulated information on the medical care status of 50 million citizens over 5 years and can ascertain, for example, differences in the administration rate of antibiotics for the same disease among medical institutions and the survival rate following myocardial infarction in in-patient treatment almost in real time" (Okamoto, 2008, p.113). The foundation of a single insurer, the National Health Insurance Corporation (NHIC), and introduction of IT, including penetration of the national identification number system and EDI, significantly contributed to realization of the healthcare policy system using these data, and this is a significant difference compared with Japan.

Major healthcare service providers (medical institutions) in South Korea are Christian missionary hospitals, which have a history extending back to before WW2, clinics (and hospitals developed from clinics) founded after the establishment of the certified doctor system in 1958, private hospitals founded with support from the government (due to the delay in the reform of public hospitals because of political restrictions) and specifically university hospitals, which marked a rush of new establishments from 1970s. A recent characteristic in South Korea is that conglomerates/companies first establish a hospital and then establish a medical university. Furthermore, the reform of public hospitals is also advancing (belatedly) as seen when Seoul National University Hospital[46] became a special corporation in 1978 and was managed/operated based on the corporate model.

The Ministry of Health and Welfare in South Korea, which is equivalent to the MHLW in Japan, "formulated a strategy to promote business-oriented R&D activities by subject for each fiscal year to control the progress of the R&D business, and the specialized agency, Korea Health Industry Development Institute (KHIDI) is in charge of the business processes

[46] It was called "Hospital Affiliated with the College of Medicine of Seoul National University" until 1978.

including management of the R&D business. The fundamental principle of the KHIDI for management of the R&D business is to promote voluntary participation from the private sector in the entire process of deregulating control over research such as improvement of various procedures/systems according to the stage of R&D, establishment/operation of a systematic evaluation management system and government R&D" (Ministry of Health and Welfare 2013).[47] However, there is no system like AMED in Japan or OSCHR in the UK. In addition to the Ministry of Health and Welfare, the Ministry of Science, ICT and Future Planning (similar to the Science and Technology Agency in Japan) and the Ministry of Trade, Industry and Energy (similar to the METI in Japan) also have large healthcare-related R&D budgets and are positioned within a highly vertically segmented administrative system.

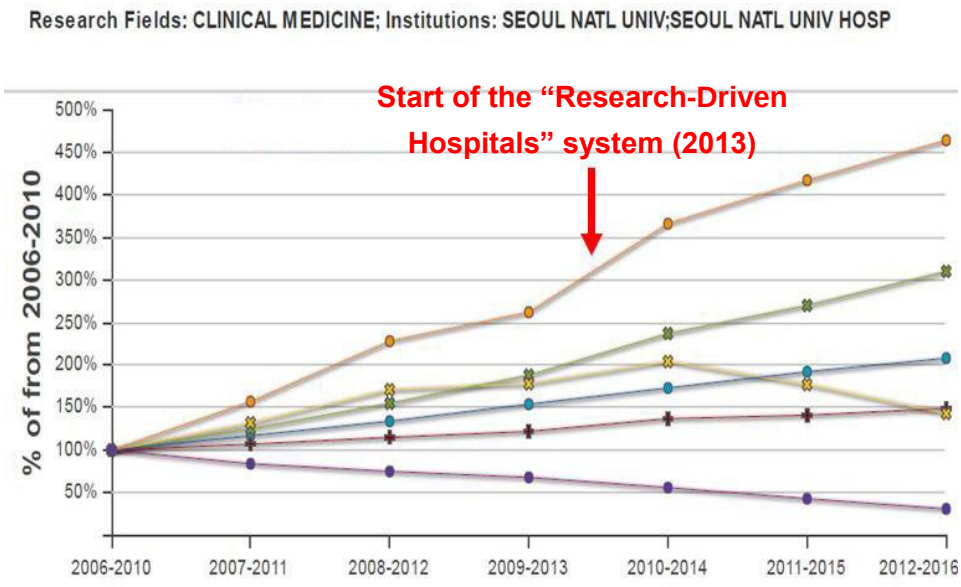
In South Korea, although 146,000 million won (approx. 145 million dollars) were invested in research in 64 hospitals/medical universities in 2004, it cannot be said that doctors etc. are sufficiently engaged in research and the lack of resources to promote research has been pointed out (Lee 2008). Therefore, the "Research Hospital Program" was established in the autumn of 2006 with the aim of securing research resources in Medical Care, promotion of TR, university-hospital-industry collaboration etc., and two hospitals (Asan Medical Center[48] [IICR[49]] and Seoul National University Hospital [IRICT][50]) were designated as research hospitals (12 hospitals applied).[51] "Research hospitals" receive a subsidy of 20,000 million won (approx. 20 million dollars) for five years from the central government and support/advice from the Operating Committee of the Ministry of Health and Welfare. In 2008, a policy discussion toward system revision started and a policy to separate "leading research hospitals" from "special research hospitals" was established.

In the first two hospitals selected under the "research hospitals" system, a succeeding system, "Research-Driven Hospitals," was formulated in 2011, five years after the start of the subsidy program in 2007, and multiple systems were subsequently developed until ten hospitals were designated in 2013.[52] A research budget of 840,000 million won (approx. 73,000 million yen[53]) will be provided over 12 years to "Research-Driven Hospitals" by the Ministry of Health and Welfare. This is an annual budget of approximately 600 million yen per hospital on average. This system is characterized by the fact that the designated hospitals are requested to not only invest in research but also reinvest a specific proportion of hospital income back into research.[54] The proportion is said to be 8% and the designated hospitals are requested to increase the proportion every year. Although it was explained that preferential treatment for medical fees was being reviewed, the direct return of a portion of hospital income to research alone is an important policy aimed at expanding the financial resources

47 Translation by Meiji Institute for Global Affairs (MIGA)/Do Research Institute (2015)
48 A company hospital of Hyundai Group that collaborates with the University of Ulsan College of Medicine and Asan Institute for Life Sciences, etc. of Hyundai Group
49 Institute for Innovative Cancer Research
50 Innovative Research Institute for Cell Therapy
51 Subsequently, Severance Hospital Yonsei University, Korea University Anam Hospital, etc.
52 http://www.londonhealthforum.org/wp-content/uploads/2013/09/Introduction_Research-driven-Hospitals-in-Korea.pdf
53 TTM on August 01, 2013 is 100KRW = 8.74JPY
54 According to the interview at Yonsei University

available for medical R&D. Since the income of doctors used to be on a fee-for-service basis until recently, discussions held during the interview survey uncovered the fact that “before 2000, the idea that doctors conduct research did not exist.” The Ministry of Science, ICT and Future Planning and the Ministry of Health and Welfare value TR and clinical research and the roles of doctors in research are increasing. The “Research-Driven Hospitals” system and multiple policies made it easier for clinical faculty members to obtain research funds, thereby facilitating their involvement in research. Furthermore, the employment of researchers who are not doctors is also being promoted.

In healthcare-related R&D, which is the responsibility of the Ministry of Health and Welfare, allocation of funds to university hospitals is being increased through political means. Of the R&D budget of the Ministry of Health and Welfare, the percentage allocation to university hospitals was increased from 45% in 2005 to 67% in 2009 and approximately 80% are concentrated in the Seoul metropolitan area (Kim 2012). Although policies such as the “Research-Driven Hospitals” system and focused allocation of medical R&D budgets to advance medical research have been implemented to promote medical research in university hospitals, satisfactory outcomes have not been achieved (Kim 2012). The budgetary provision for the “Research-Driven Hospitals” system is smaller than that for advanced hospitals in the US etc. and deregulation and a provision to reduce the clinical activities of doctors engaged in research are not sufficient. However, improvements in research outcomes at Seoul National University and Seoul National University Hospital in clinical medicine as measured by Thomson Reuters InCites (Figure 29) show the effect of the policies. After the start of the “Research-Driven Hospitals” system in 2013, the number of citations has been increasing rapidly



Normalized	2006-2010	2007-2011	2008-2012	2009-2013	2010-2014	2011-2015	2012-2016
Total Papers	100%	117%	134%	154%	173%	192%	208%
Total Citations	100%	125%	155%	188%	237%	270%	310%
Total Citations per Paper	100%	107%	115%	122%	137%	141%	149%
Highly Cited Papers	100%	157%	228%	262%	366%	417%	464%
Citations to Highly Cited	100%	132%	171%	178%	204%	177%	143%
Citations per Highly Cited	100%	84%	75%	68%	56%	43%	31%

Figure 29 Improvements in Research Outcomes in Clinical Medicine at Seoul National University and Seoul National University Hospital (2006-2010 to 2012-2016, Changes in data over 5 consecutive years)

In South Korea, the on-site surveys were conducted at Seoul National University, a representative national university, and Yonsei University, a private university. In South Korea, Seoul National University, as a national university, became the first independent administrative corporation in 2012. However, as described above, in 1978, more than 30 years earlier, the university hospital changed its status and became a special corporate body, Seoul National University Hospital, a corporation independent from Seoul National University. In the case of Yonsei University and Severance Hospital, Yonsei University, Yonsei University Health System, which is composed of the College of Medicine, College of Dentistry, College of Nursing and university hospitals, are virtually financially separate from the university. This is due to the historical background that Yonhi University and the Severance Medical School merged to become Yonsei University in 1957. Of these two

representative university hospitals in South Korea, the structure of the medical R&D platform (Figure 30) of Seoul National University Hospital (SNUH), for which detailed information was obtained through the interview survey and information including financial statements could be confirmed, was elucidated.

For historical reasons, Seoul National University, which opened in 1946 by incorporating with nine colleges including a college of medicine, adopted a president system similar to the University of Tokyo. While each College (e.g., College of Medicine) of Seoul National University has a Dean, the university President is responsible for overseeing Seoul National University in its entirety. The university President and Dean used to be elected directly by faculty members after democratization in the late 1980s. It seems that changes have been made to the HR systems due to the recent incorporation of national universities led by the national government.

The College of Medicine, Seoul National University, has a total of 1585 staff members under the Dean: 525 faculty members and other staff. Of the 525 faculty members, 106 are basic faculty members and 419 are clinical faculty members. Of the 525 faculty members, approximately 200 are endowed chair professors and approximately 300 are tenured or tenure-track faculty members. The annual amount of research funds allocated to the College of Medicine is 202,200 million won (2015, approx. 20,900 million yen).[55] A reasonable portion of this is allocated as external contract research funds though details are unknown.

Seoul National University Hospital (SNUH), which became an independent corporation in 1978, has five affiliated hospitals with the President and CEO as the top management. The largest hospital is the main hospital with an annual clinical income of approximately 910,800 million won (2015, approx. 94,000 million yen), and 1372 doctors (almost all of them are FTE).[56] It obtained approximately 87,900 million won (2015, approx. 9,100 million yen) a year. Of the 1372 doctors in the main hospital, 248 are faculty members with a concurrent position at the College of Medicine, 201 are clinical professors, which is a clinical faculty position in the hospital, 181 are clinical lecturers and 529 are medical specialists. According to the interviews conducted at Seoul National University Hospital, the College of Medicine has a significant effect on HR management of clinical faculty members, as well as the faculty members with a concurrent position at the College of Medicine. Bundang Hospital, which is the biggest among the affiliated hospitals, has an annual clinical income of approximately 557,600 million won (2015, approximately 57,600 million yen), 732 doctors and has annual external research funding of approximately 23,470 million won (approx. 2,400 million yen).[57] Many of the doctors in these affiliated hospitals have a concurrent position at the main hospital or College of Medicine.

[55] The budget of College of Medicine is estimated based on the following: The TTM exchange rate (100KRW = 10.33JPY) as of December 30, 2015, which was the closest to the closing date of December 31, 2015, was used.
http://medicine.snu.ac.kr/sub4/present/index.htm
http://en.medicine.snu.ac.kr/sub1/Overview/snucmpr/en_brochure/preview_en_170206/index.htm
[56] http://alio.go.kr/managementOrganView.do?seq=C0083&sname=서울대학교병원
[57] http://alio.go.kr/popReportAll.do?apbaId=C0444&nowYear=2016&nowQuarter=1#toc-122

Compared with the University of Tokyo Hospital, which is described in a subsequent section, the scale of SNUH is significantly larger. The University of Tokyo Hospital has 1163 beds, approximately 1600 (FTE 732) doctors, 1324 nurses, slightly more than 700,000 outpatients/year, slightly more than 380,000 inpatients/year and performs 10962 surgical procedures/year. SNUH has 1786 beds, 1372 (almost all of them are FTE) doctors, 1982 nurses, slightly more than 2,300,000 outpatients/year, slightly more than 620,000 inpatients/year and performs 41940 surgical procedures/year. A comparison of the numbers of beds and FTE doctors may help to explain differences in other parameters to a certain degree, and it is obvious that resources and patients are concentrated in SNUH. The ratios of outpatients and surgical procedures are significantly high relative to the number of doctors. The discussions held during the interview survey suggested that sharing functions among doctors is advanced (some doctors are allowed to allocate time for research at the hospital and have a reduced clinical workload.)

The main hospital of Seoul National University Hospital and some affiliated hospitals have research laboratories. In the main hospital, for example, there are many research centers etc. under the SNUH Biomedical Research Institute. There are 62 principal investigators in the SNUH Biomedical Research Institute and three[58] of them are researchers with PhDs who are not doctors. This shows that clinical research etc. with collaboration between PhDs and doctors is promoted at Seoul National University Hospital, although few in number.

[58] http://en.bri.snuh.org/investigators/_/labguide/list.do

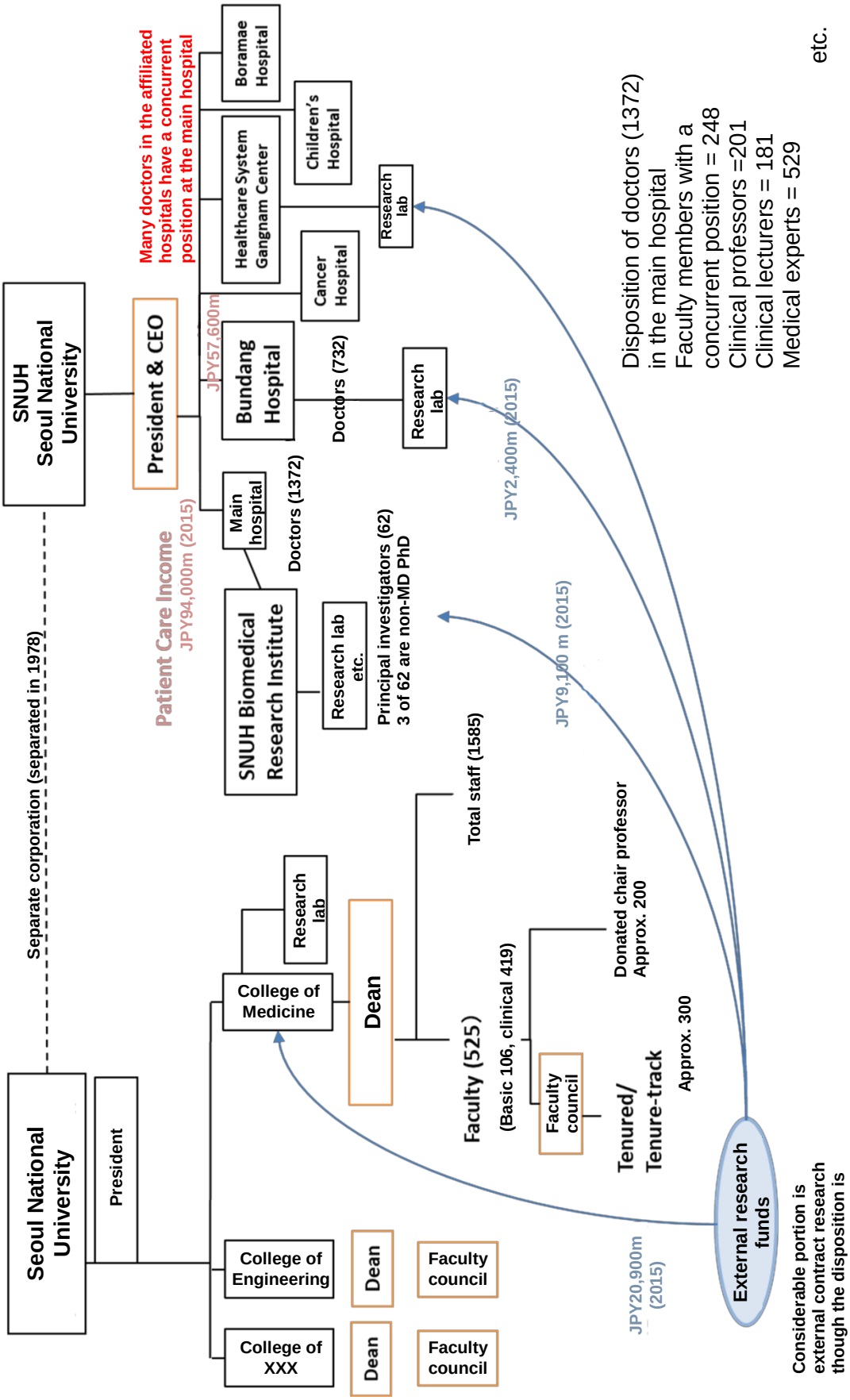


Figure 30 Medical R&D Platform of Seoul National University

3-5. Japan

The current situation of medical R&D and related policies in Japan have been discussed in Chapter 1 and the latest developments including financial/organizational independence of university hospitals as seen in other countries are discussed in Chapter 5. This Chapter clarifies the medical R&D platform (Figure 31) of the University of Tokyo Hospital by comparing it with the other cases surveyed. The University of Tokyo Hospital was selected as it is a university hospital affiliated to a faculty of medicine of a national university ranked at the top in Japan on global rankings and for which the collection of information is relatively easy.

The management of the national university corporation, University of Tokyo, is carried out by the Board of Directors comprising the President, Executive Vice Presidents, and Comptrollers. The President is the representative of the university corporation and has jurisdiction over the university's functioning as the head of the University of Tokyo established by the corporation. For management, education and research, the Administrative Council and the Education and Research Council serve as a kind of audit body. The University of Tokyo, with the President at the apex, has a university-wide organization directly under the President, and graduate schools, faculties and institutes make up the Department of Education and Research. Each institution has a faculty council (or steering committee) and the council provides advice to the head of the institution (deans of graduate schools in graduate schools).

Due to the strategic focus on graduate schools, these schools, which used to be integrated into faculties, were turned into departments as basic units of education and research. Furthermore, the graduate schools became the main affiliation of faculty members, and the faculties were managed concurrently by the faculty members of graduate schools. Although the faculties and graduate schools have their respective deans and faculty councils by legal mandate, in practice, there is a lord-vassal relationship between the graduate schools and faculties.Therefore, for example, there is the Dean of the Graduate School of Medicine, who concurrently serves as the Dean of the Faculty of Medicine in the Graduate School of Medicine, and there is the Faculty Council of the Graduate School of Medicine as the major decision-making body. The Faculty Council is composed of 178 tenured faculty members (lecturer or higher positions) who belong to the Graduate School of Medicine. In the Graduate School of Medicine, there are 84 lecturers/assistants, who are not tenured or members of the Faculty Council, and many specially appointed faculty members (project position), who are also not members of the Faculty Council.

The University of Tokyo Hospital is placed under the jurisdiction of the Faculty of Medicine. The top of hospital management is the hospital Director. The Hospital Management Council is established as an advisory body. The chair and two members of the Hospital Management Council are appointed by the University President and the members of the Council include the Dean/Vice Dean of the Graduate School of Medicine. The operation of the University of Tokyo Hospital is influenced not only by Graduate School of Medicine but also by the

administrative office of the university.

The University of Tokyo Hospital has clinical divisions, departments, centers etc. and the heads of divisions, departments, centers etc. are FTE faculty members. The University of Tokyo Hospital has approximately 1400 doctors including residents and some of the faculty members of the Graduate School of Medicine are included in this number.

The medical fee income generated by the University of Tokyo Hospital was 43,161 million yen in FY2015,[59] and the accounts are maintained by the university instead of by the hospital (the medical fee income is handled as income of the university). As described earlier, the public funds provided to the university hospital in the form of special management expense grants (for strengthening university hospital functions) are included in the university-wide management expense grants even though the hospital university management expense grants have already been abolished (a total of 25,000 million yen to all national university hospitals in FY2014[60]). It is considered that the management expense grants allocated to the Graduate School of Medicine within the university include funds to cover the cost of strengthening functions. The external research funds, which the Graduate School of Medicine and the University of Tokyo Hospital receive, totaled 6,258 million yen in FY2015. Indirect costs related to the funds are paid to the administrative office of the university. The annual budget for the Graduate School of Medicine, Faculty of Medicine and university hospital combined is approximately 50,000 million yen.

In addition to the organizations related to the Graduate School of Medicine, the University of Tokyo includes the Institute of Medical Science, the University of Tokyo (IMSUT) and IMSUT Hospital. The IMSUT is headed by a Dean and under the Dean there are faculty members (43 tenured members, who are lecturers or in higher positions), the Faculty Meeting and IMSUT Hospital. The hospital Director is appointed as a supervisor who oversees the management of IMSUT Hospital.

[59] All data are according to the explanatory documents from the member(s) of the University of Tokyo Hospital.
[60] Board of Audit (2016, p.20)

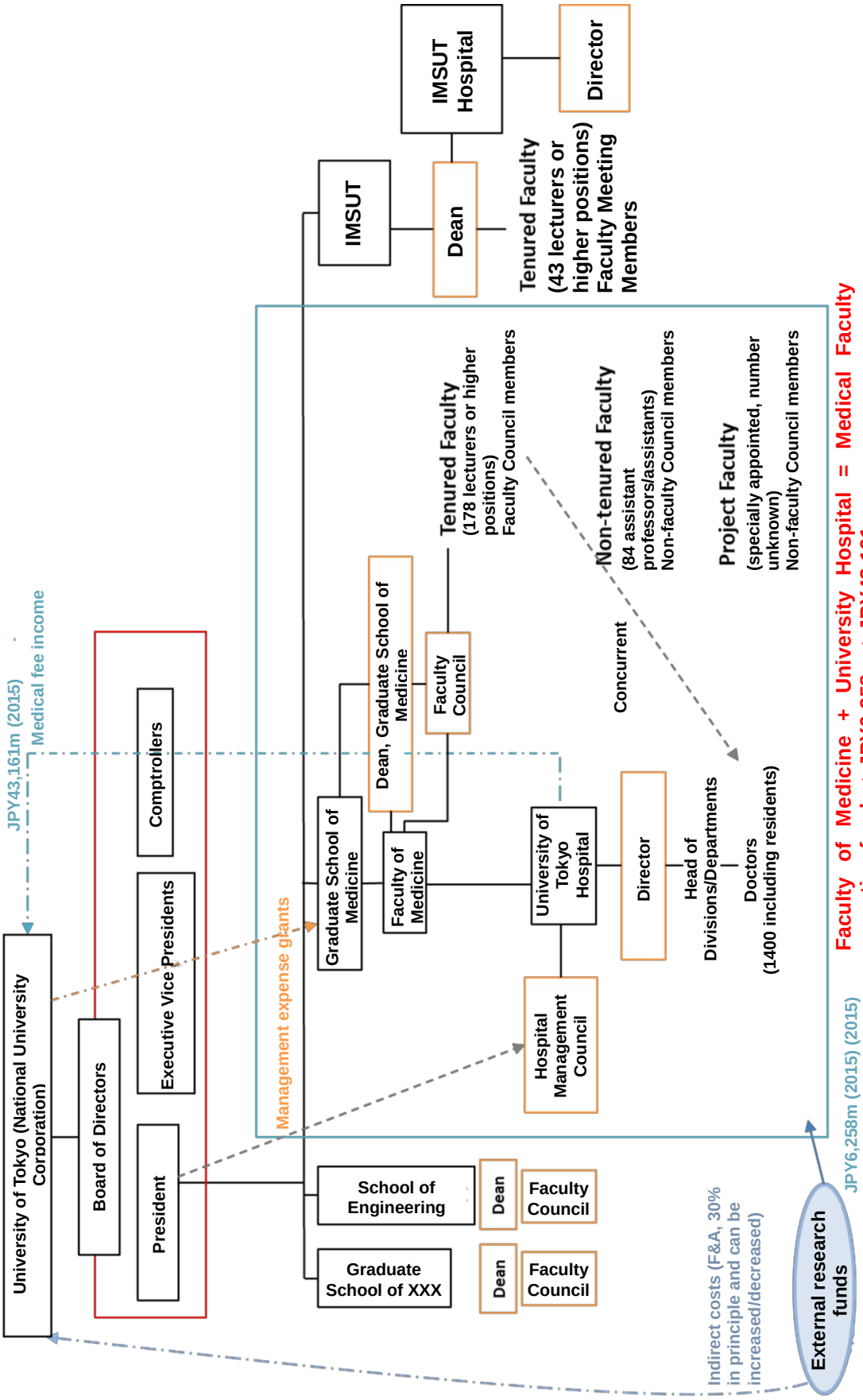


Figure 31 Medical R&D Platform of the University of Tokyo

4. Findings Based on Comparing the Countries Surveyed

4-1. Comparison of Research Budgets, Human Resources and Achievements

Table 9 shows a comparison of the budget size of the faculties of medicine and university hospitals (or the combined budget) for the university hospitals in the countries surveyed. As described earlier, the budget of the School of Medicine, Stanford University was approximately 245,000 million yen and the budget of the two university hospitals combined was approximately 430,000 million yen. Since approximately 105,000 million yen are "returned" to the School of Medicine from the two university hospitals, the total budget of the School of Medicine and university hospitals combined is approximately 570,000 million yen. For Harvard University, the budget is approximately 68,000 million yen for Harvard Medical School alone. However, the 16 affiliated hospitals/research laboratories (affiliates) alone have a budget significantly larger than that of Harvard Medical School. The total budget of Harvard University including these affiliates comes to a maximum of 1,000,000 million yen. Erasmus MC in the Netherlands has a budget of approximately 180,000 million yen as UMC. For Seoul National University in South Korea, the budget is approximately 20,900 million yen (only external research funds) for the College of Medicine alone. However, the budget comes to approximately 103,000 million yen for Seoul National University Hospital (main hospital) alone and approximately 220,000 million yen when the five affiliated hospitals are included.

The budget of the Faculty of Medicine, the University of Tokyo and the University of Tokyo Hospital combined is approximately 50,000 million yen. If the budget of the University of Tokyo is taken as 1, that of Seoul National University is 4.4-fold larger (2.5-fold larger for the main body alone), Erasmus MC is 3.6-fold larger and for advanced universities in the US it is 10 to 20-fold larger. The budgets of the faculties of medicine/university hospitals in Japan are significantly smaller compared with the budgets of advanced universities in the US and EU. There are significant differences even compared with Seoul National University in South Korea, which is an emerging country in Asia.

Even if limited to the external research funds, the budget was approximately 4,230 million yen for the Faculty of Medicine/Graduate School of Medicine, the University of Tokyo,[61] 6,260 million yen for the university hospital and approximately 10,500 million yen in total. On the other hand, the budget was approximately 30,000 million yen for College of Medicine, Seoul National University and the main hospital alone, approximately 39,000 million yen for Erasmus MC and approximately 71,000 million yen for Stanford University. However, as described earlier, there are positive correlations between the income of the national university hospital and the number of doctors and between the number of doctors and research

[61] http://www.u-tokyo.ac.jp/content/400064271.pdf (p.2-18)

achievements (Toyoda 2017). Considering these points, it is appropriate to compare the total budget instead of focusing on the external research funds when making comparisons in terms of research capability.

Table 9 Comparison of Budget Size of University Hospitals

Million yen

	Faculty of Medicine	University hospital	Total	Ratio
Stanford	245,000	430,000	570,000	11.4
Harvard	68,000	Total of 16 Affiliates 600,000-900,000	700,000-1,000,000	14-20
Erasmus MC	(calculated for merged UMC only)		180,000	3.6
Seoul National University	20,900	≥ 200,000 (Main hospital: 103,000)	≥ 220,900 (123,900 for the main body only)	2.5-4.4
University of Tokyo	(disposition unknown)		Approx. 50,000	1

Since Harvard University has 16 independent affiliated hospitals and each of them are managed differently, there are reasonable differences in the budget and HR allocation. These should be individual targets of the analysis of the medical R&D platform. Therefore, the following comparison was made focusing on four universities (Stanford, Erasmus MC, Seoul National University, University of Tokyo), for which the hospital and university are closely related even though they are financially/organizationally separate.

Table 10 shows a comparison of the four universities in relation to the number of personnel (hereinafter referred to as “HR size”) estimated to be involved in medical R&D and the budget per each research person using the budget data shown in Table 9. Compared with Stanford University and Erasmus MC, the University of Tokyo has many researchers relative to the size of the budget. The amount of funds allocated per researcher in the Faculty of Medicine, the University of Tokyo and the University of Tokyo Hospital combined is approximately 1/3 to 1/7 of that in other advanced countries.

Table 10 Comparison of HR Size and Budget Size per Person in University Hospitals

	Tenured	Non-tenured	Total	Total budget/ No. of researchers
Stanford	A little less than 500	500 (School of Medicine) + 1200 (clinical faculty)	≥ 2200	2.59 (5.7 excluding clinical faculty)
Erasmus MC	730	Unknown	≥ 730	2.47
Seoul National University	525	≥ 600 (clinical faculty etc.)	≥ 2500	0.88 (4.2 for tenured only)
University of Tokyo	178	84 (assistant professors) + 1400 (university hospital doctors)	1626	0.36 (2.81 for lecturer or higher positions only)

Compared with the differences in the budget and HR sizes, there was no significant difference in the research achievements between the four universities. Table 11 shows the results of an analysis performed using the data on the numbers of citations and HCPs[62] between 2012 and 2016 (5 years) as recorded in Clinical Medicine from Thomson Reuters InCites. For the University of Tokyo, the number of HCPs was 79 and the number of citations was 51900. When these numbers are taken as 1, the numbers of HCPs and citations were 2.76-fold and 1.75-fold greater, respectively, for Seoul National University (College of Medicine + Seoul National University Hospital), 4.0-fold and 2.20-fold greater, respectively, for Erasmus MC and 5.5-fold and 2.57-fold greater, respectively, for Stanford University.

These differences in the research achievements were compared with the differences in the budget and HR sizes as presented in Tables 9 and 10. In terms of the budget, the University of Tokyo shows “efficient” research achievements compared with the other three universities. Compared with Stanford University and Seoul National University, the numbers of HCPs and citations showed achievements that compensated for the differences in the budget. Compared with Erasmus MC, the difference in the number of citations was not as large as the difference in the budget. When the size of HR is taken into account, the University of Tokyo is “inefficient” in terms of the number of HCPs, compared with the other three universities. Since the number of citations compares well with the other three universities, possible explanations are as follows: (1) the other three universities have many highly skilled researchers and produce HCPs and on the other hand, other researchers do not conduct very much research and (2) in the University of Tokyo, researchers produce papers of average quality (which are not counted as HCPs) or there are researchers who produces HCPs that are frequently cited.

[62] A “Highly Cited Paper” (HCP) is defined as a paper with more than a specified number of citations. In Clinical Medicine, the criteria are 89 for papers in 2012, 67 in 2013, 44 in 2014, 23 in 2015 and 7 in 2016. New papers are highly likely to be HCPs and only a limited number of old papers will be HCPs.

Table 11 Comparison of Research Achievements, Budget Size and HR Size in University Hospitals

(Ratio)	Highly Cited Paper (HCP)	Citation	Budget	No. of researchers (tenure/tenure-track or higher positions)
Stanford	5.5	2.57	11.4	3.82
Erasmus MC	4.0	2.20	3.6	2.79
Seoul National University	2.76	1.75	4.4	2.00
University of Tokyo	1	1	1	1

The total number of papers and the number of citations were compared between the four Japanese universities (Top 3 Japanese universities [University of Tokyo, Kyoto University, Osaka University, and Okayama University, which is described later] in QS World University Rankings by Subject 2017) using the data[63] between 2006 and 2010 and between 2012 and 2016 for a more detailed analysis of research achievements by the University of Tokyo (Figure 32). The University of Tokyo showed a significant increase in the number of citations compared with the increase in the total number of papers. This shows that the University of Tokyo has researchers who produce papers that are frequently cited rather than researchers who produce papers of average quality.

Therefore, the number of citations per HCP was also compared. New papers with a shorter elapsed time after publication generally have a lower number of citations per HCP. However, according to the 2012-2016 data, the number was 242.09 for the University of Tokyo, 112.30 for Stanford University, 132.46 for Erasmus MC and 125.32 for Seoul National University, and the University of Tokyo showed a markedly higher number (81.98 for Kyoto University, 91.70 for Osaka University, 125.95 for Okayama University; the same trend as that of the University of Tokyo was observed for Okayama University.) According to the 2006-2010 data, the number was 406.51 for the University of Tokyo, 375.92 for Stanford University, 389.72 for Erasmus MC and 407.47 for Seoul National University, showing no appreciable difference between the four universities. These results strongly suggest that the University of Tokyo has researchers who produce “true top papers” that are frequently cited relative to the budget. On the other hand, the results also suggest that the number of papers, which are counted as HCPs but not frequently cited (though affecting the ranking), for the other three universities is higher than that for the University of Tokyo. It is estimated that Stanford University and Erasmus MC have researchers who produce “average” HCPs on a more or less equal basis.

[63] Thomson Reuters InCites data

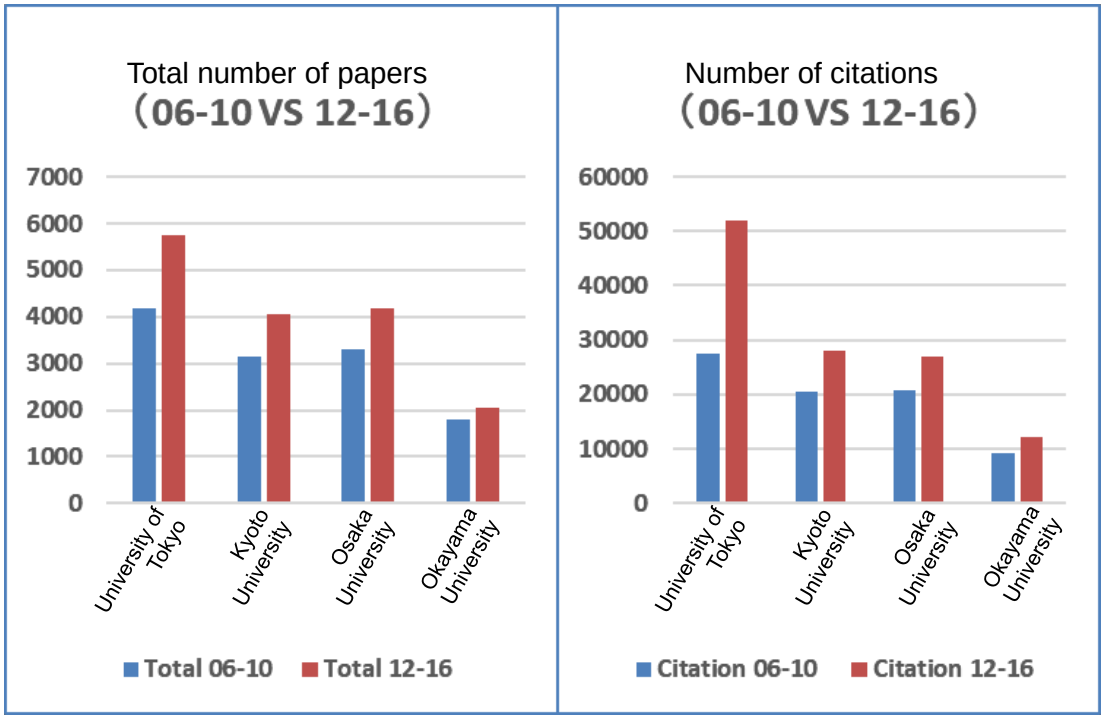


Figure 32 Comparison of Changes in Research Achievements in 4 Japanese Universities (2006-2010→2012-2016)

4-2. Financial/Organizational Independence of University Hospitals

The cases examined in each country had a feature in common, namely, that the university hospital or faculty of medicine and the university hospital are financially independent from the university. For example, Stanford University is said to have relatively strong university governance in the US. The Stanford University Medical Center, which is composed of a School of Medicine and university hospitals, maintains a certain financial independence from the university. Even in the same country, at Harvard University, hospitals are much more independent from the university. Harvard Medical School has signed partner agreements with 16 hospitals and research laboratories which are managed by different corporations. In the Netherlands, the integration (University Medical Centre = UMC, a separate corporation from the university) of the faculties of medicine and university hospitals (teaching hospitals) proceeded from the 1990s, and all faculties of medicine in the Netherlands had become UMCs by 2008. In Germany, in the “integration model” including the University of Göttingen, the faculty of medicine and the university hospital are merged and financially separate from the university. In South Korea, Seoul National University separated the university hospital to become a separate corporation very early on (1978), and the College of Medicine and the university hospital are financially/organizationally separate. Yonsei University is one of the representative private universities, and the College of Medicine and the university hospital are merged and financially separate from the university like UMC in the Netherlands and the integration model in Germany.

If the university and university hospital (or faculty of medicine + university hospital) are financially separate like those in the overseas cases investigated, medical fees can be utilized directly/indirectly for education and research. First, profits obtained from medical fees can be invested directly in education/research. For example, in the interview at Yonsei University in South Korea, the interviewee commented that "if a hospital is designated as a research-driven hospital, a specific proportion of hospital income, e.g., 8%, needs to be reinvested in research. The proportion is increased every year." The hospital income is directly returned to research.

Second, the income obtained from medical fees can be actively invested in hospital human resources, facilities etc. indirectly leading to an increase in research achievements. In Japanese national universities, in which the university and faculty of medicine + university hospital are not financially separated, a positive correlation was noted between hospital income and the number of doctors (Toyoda 2017, described above). Financial independence is expected to facilitate faster decision-making.[64] For example, in the interview at Stanford University, the interviewee commented as follows: "According to the funds flow agreement, which is generally renewed every 5 years, a specific portion of hospital income will be returned to the Dean's Office and each clinical department. This money is used to fund the salaries of clinical faculty. Part of it may also be used as research funds for clinical research."

Third, if the promotion of research contributes to hospital profits, such as improved efficiency of medical care and introduction of new therapies based on research results, the incentive for management initiatives to directly/indirectly invest in such research will be increased. In other words, it will lead to the circulation of medical fees (hospital income) and research funds. In the interview at Erasmus MC, the interviewee commented as follows: "In the Netherlands, hospitals need to negotiate with insurers every year (concerning the price and quality of healthcare services to be provided) under the management competition system. Therefore, innovation through research is necessary, and profits obtained from innovation – this will be also negotiated between the insurer and me (CEO) – will be plowed back into research.[65] (snip) Therefore, it is important for Erasmus MC that medical care is linked to research/education that leads to innovation. Professors who do no research and who are not involved in innovation have no place at the hospital no matter how talented they may be."

Furthermore, organizational independence of the faculty of medicine + university hospital from the university as in the Netherland generates research benefits. Because basic faculty members work under the same systems of budget, organization, recruitment and salary as those of clinical faculty members, this has the effect of promoting research activities (interview at Erasmus MC). Since recruitment is determined by deliberations of the Board of Directors (Dean of School of Medicine, CEO, CFO at Erasmus MC), HR policies aligned

[64] As described earlier, the authority of the hospital director is being strengthened in Japanese national universities and some of them are actively recruiting doctors and nurses. For example, in the University of Tokyo Hospital, the number of doctors was increased from 700-800 in 2004-2005 to over 1100 in the next 10 years or so. During the same period (with slightly delayed timing), medical fee claims increased from 30,000 million yen to 43,000 million yen, an increase of 43%.

[65] In the original comment, the order before and after the omitted part is the other way around. The author changed the order based on the meaning.

with the management strategy of the hospital can be rapidly implemented.[66] At Stanford University, which has no such organizational separation, it takes nine months or more to hire faculty members for the Academic Council Professoriate and Medical Center Line (interview at Stanford University). However, at Stanford University, there are benefits arising from Stanford University Medical Center continuously being a part of the university in terms of synergies generated between and among the faculties of biology, chemistry and biomedical engineering, fields in which the Stanford University is globally competitive (interview at Stanford University).

At Seoul National University in South Korea, employees of the clinical faculty of Seoul National University Hospital, which is organizationally independent, are virtually controlled by the College of Medicine. If the university has the authority to confer degrees and only a particular university educates/produces talented doctors, it is difficult to be independent in terms of HR even though the university hospital is organizationally separate.[67] In order to secure flexible HR, integrating the School of Medicine and university hospital and then separating them from the university in the same manner as UMC in the Netherlands may be an effective first step.

4-3. Policies Regarding Hospital Organization and Financial Systems

Policies regarding hospital organization and finances include a policy to invest in the research/educational functions of hospitals. In Japan, various projects to establish research bases including the 21st Century Center of Excellence (COE) Program have been implemented. Germany has a similar policy called the "Excellence Initiative" and has selectively invested in universities and research clusters (universities are invariably included as liaisons) including many medical research bases. While the initiatives in Japan[68] and Germany are aimed at forming a research base that invariably includes a university, the research-driven hospital system in South Korea is an investment/support system designed to support the research functions of "hospitals." The objective is to strengthen the research functions of hospitals and establish an autonomous research system through evaluation (+ granting benefits). The majority of research funds are from private sources in South Korea, therefore, such a system may have been established from the perspective of R&D in hospitals, which is a clinical setting. These investments in research functions may induce functional

[66] Even if the university and university hospital are separate, it will be complicated when both have the executive body. However, if they are integrated like UMC, decision-making will be simple (interview at LUMC).

[67] It is said that "traditions" like academic cliques and medical offices exist in the US. However, since there are many universities that train talented doctors and there are a number of foreign students, it is estimated that the university does not have undue influence on HR of affiliated hospitals etc. even if the cooperative system like Harvard University is employed.

[68] In the MEXT Guidelines for subsidies for creating research bases funds etc. (http://www.mext.go.jp/a_menu/koutou/coe/05040101.htm), the scope of subsidies is stipulated as follows: "Major (doctoral course level only), research organizations of university research laboratories or equivalent (the standard of research must be shown to be equivalent to the doctoral course level of graduate schools) or a combination of these (combination within the same university only)." Therefore, university hospitals are not considered to be outside the scope institutionally.

differentiation: medical institutions that perform R&D (i.e., medical institutions providing highly advanced medical treatment in some way) are differentiated from other medical institutions. Furthermore, funds may flow in medical institutions, which function as research bases, and such institutions may be evaluated based on their research function, resulting in the concentration of human/financial resources and political support.

As a policy regarding the organizational system, initiatives to collaborate between non-MD-PhD and on-site MD or promote industry-government-academia collaboration through joint ventures (JVs) and joint businesses was noted in Germany. In Germany, the Clusters of Excellence under the Excellence Initiative aim to promote collaboration between research associations/company-based researchers and universities/graduate schools. Moreover, the BIH, described above, is an organization established by a research association, which has no clinical setting (the MDC affiliated with the Helmholtz Association) and Charité-Universitätsmedizin Berlin, which has a university hospital. According to an expert who wished to remain anonymous, the true purposes of the establishment of the BIH were to rescue Charité, which had been facing hardship due to debt, formation of a research cluster in the capital city Berlin, and development of the BIH (90% of federal funds) to become a "federal university," and these purposes did not always have direct links to the promotion of medical R&D. A comment was made that due to the scandal involving Annette Schavan, the Federal Minister of Education and Research, who promoted the establishment of the BIH and her resignation as a result, the BIH is not fulfilling its functions (interview with another expert who wished to remain anonymous).

In the Netherlands, there were cross-appointments with university ventures and university-related companies. For example, Erasmus MC has over 25 affiliated companies and Erasmus MC Holding BV, which includes these affiliated companies. Faculty members of Erasmus MC participated in these affiliated companies through cross-appointments and have contributed to clinical research utilizing university hospitals and financial feedback such as practical application of research results and patent income in the affiliated companies. The patent income through these affiliated companies is approximately 50 to 330 million yen with large variances (Figure 27).

Factors that significantly affect the financial systems of hospitals and universities are indirect costs or overheads paid to universities. Specifically in the US, the indirect costs associated with the external research funds account for a significant percentage. In Stanford University, 28.5% to 57% (rate to the modified total direct cost base [MTDC], where necessary costs are subtracted from the total funds) are paid to the university. The obtained external research funds were approximately 1,000 million dollars (660 million dollars for the School of Medicine) for the entire university, of which, the indirect costs were approximately 250 million dollars (2015). For Harvard University, the rate of indirect costs reaches 26% to 69.5%. While the School of Medicine and university hospital are financially separate at Stanford University, overheads totaling approximately 12,000 to 13,000 million yen are paid

by the Stanford University Medical Center to the university. Such a high rate of indirect costs or high overheads show the expectation for R&D and management efforts in the School of Medicine and university hospital from the university management viewpoint, and lead the university to offer benefits or delegate the discretion to School of Medicine for facilitation of the R&D and management efforts.

4-4. Policies Regarding HR Systems for Doctors and Researchers

In all cases in the US, Netherlands, Germany and South Korea, a clinical faculty system has been introduced. This is a very important policy to facilitate aggregation of doctors/researchers and functional differentiation from the perspective of the three functions, research, education and medical care, which doctors should carry out. The clinical faculty members, who are involved in education and medical care, can contribute to reducing the educational/medical workloads on doctors having a high level of research expertise and to recruiting researchers who cannot be engaged directly in medical care (non-MD-PhD) in hospitals.

As described above, in Stanford University, there are slightly fewer than 500 doctors in the Academic Professoriate Line, which is mainly involved in research and education but is also involved in medical care, 500 doctors in the Medical Center Line, which is involved in research, education and medical care in a well-balanced manner, and 1200 doctors in the Clinician Educator Line, which focuses on medical care and education. The 1200 doctors in the Clinician Educator Line bear most of the overall educational/medical workload so that the 500 doctors in the Medical Center Line can engage in clinical research/TR utilizing the clinical setting. Functional differentiation is advanced.

In Germany, some university hospitals have introduced systems like the clinician-scientist system in Charité. This corresponds to the Medical Center Line at Stanford University, and there is a strong need for doctors who have research skills and can engage in clinical research etc. even if they are not researchers (interview at Charité). Slightly different from functional differentiation, the objective of this policy is to train more doctors who can play multiple roles and specifically perform the research function (the educational effect is described in subsequent sections.)

All cases surveyed have adopted the project position system. Significantly different from Japan, the appointment is maintained provided the research funding (the contributor can be changed so long as it is consecutive), which is the source of salaries, can be maintained. Many project faculty members (researchers) have no medical/educational obligations, and therefore non-MD-PhD can assume these positions. At Harvard University etc., many of the positions at affiliated hospitals are operated under the project position system. This can also be considered to be a policy for differentiating the research/education/medical care functions in the university (hospital). Moreover, project positions are closely related to indirect costs,

and in prestigious universities, research achievements may increase in concert with an increase in income by covering indirect costs through the project position system.

4-5. Policies Regarding Doctor/Researcher Development Systems

The universities surveyed in Germany and the Netherlands were particularly enthusiastic about developing doctors with research skills. These universities are heavily influenced by the competition to attain a favorable an international ranking. It is assumed that the reason for this enthusiasm is that an increase in ranking through an increased number of papers and citations directly results in an increase in talented young human resources. For example, Charité-Universitätsmedizin Berlin promotes the clinician-scientist program in collaboration with BIH. This is a contract targeting Charité MDs where the BHI will provide a budget of 4 million euros (approx. 500 million yen) a year to cover half of the salaries for three to four years and Charité MDs are requested to spend half of their working hours on scientific research in exchange. Erasmus MC in the Netherlands has a similar system called the Research MD system: UMC will pay the salaries and in exchange MDs will engage in research for a specified number of hours/periods. The LUMC in the Netherlands has a system[69] that grants the top student (among 400 students) in the first year the right to move on to an MD-PhD dual course. Although the systems are different, they have the same aspiration, namely, to develop doctors capable of conducting research. It was explained that these programs to develop doctors with research skills are very popular in both countries. Charité has started a junior clinician-scientist program targeting younger medical students.

In Germany, aggregation of hospitals is advanced, and a fixed number quota system is employed for practitioners. As a result, 45% of practitioners, who account for approximately half of all working doctors, are family doctors (general medicine specialists). In Germany, where there is tough competition in the certified doctor system, the stratification of doctors is developing and it is assumed that stratification in education will develop in the future. The interview at Charité revealed the following estimated stratification in the education of doctors: 5% to 10% of all doctors are MD-PhD, 20% are clinician-scientists, 30% to 35% are MDs and the remining 40% are non-MD doctors.[70]

[69] No expenses etc. to salaries. Generally, after obtaining an MD, it will take 4 to 6 years to obtain a PhD and 5 to 7 years to obtain certification as a specialist doctor. The system in LUMC was established based on the thinking that such a system is not attractive to young talents.

[70] In Germany, students take the national examination after completing 6 years at a school of medicine and a license to practice medicine will be granted if they pass the examination. In parallel with this, they write a thesis while they are students, and obtain the degree of MD at the same time as the medical license. Since the thesis is not linked to the medical license, students who complete their studies at a school of medicine without submitting a thesis and who passed the national examination will become non-MD doctors. There are many non-MD doctors particularly among younger persons. Many of the specialist doctors, who are not family doctors, are degree holders (MD).

5. Financial/Organizational Independence of University Hospitals in Japan

5-1. System Background

In Chapter 4, the financial independence of university hospitals (or faculties of medicine and university hospitals) is listed as a characteristic common to all countries. At Harvard University, Erasmus MC and Seoul National University, the university hospitals were separated as corporations. Such financial/organizational independence determined the fundamental structure of the medical R&D platform and affected the detailed policies on management, research, HR, education etc.

In Japan, financial/organization independence of national university hospitals has been a hot topic for discussion. For example, the "investigation and review meeting concerning turning national university hospitals into independent administrative corporations" held by the MEXT was compiled into a final report "new 'national university corporations'" on March 26, 2002. The report regards national university hospitals as being inseparable from the educational activities of universities and are to be included in the universities. On the other hand, it also states the following: "Considering the actual status of management, the possibility of self-sufficiency etc., specific facilities etc. among university facilities shall be separated from the national university corporations (tentative name) and be turned into different types of corporations, and if necessary, the national university corporations (tentative name) shall be allowed to invest in these corporations."[71] At the meeting of the 151st Committee on Education, Culture, Sports, Science and Technology[72] held on June 05, 2001, Osamu Fujimura, a member of the Democratic Party of Japan, raised the following question: " In the plenary session of the House of Councilors on May 11, Prime Minister Koizumi answered a question saying that it was important to consider privatization where it is possible even in national universities. (snip) The MEXT drafted a proposal for review based on this response. The draft proposal contains no idea of the privatization of national universities but considers whether some institutions such as national university hospitals and university research institutions may be privatized and incorporated." Atsuko Toyama, the Minister of Education, Culture, Sports, Science and Technology at that time, answered as follows: "This does not mean that everything will be privatized. The point was to consider privatization or to transfer what is feasible to the local government. (snip) Even when privatizing national universities, it is legitimate to entrust those national university functions, which the private sector can fulfil, to the private sector and incorporate." In other words, at this point, there was "a possibility that national university hospitals might be separated as separate corporations rather than being considered as one organization of a university as an independent corporation." (Maeda

[71] The final report cannot be viewed on the MEXT HP. There are descriptions on "new 'national university corporation' state (draft)" on pp.11-12.
(http://www.mext.go.jp/b_menu/shingi/chukyo/chukyo4/gijiroku/__icsFiles/afieldfile/2014/09/24/1266090_003.pdf)
[72] http://www.shugiin.go.jp/internet/itdb_kaigiroku.nsf/html/kaigiroku/009615120010605015.htm

2002, p.2)

It has been said that the authority of hospital directors, specifically in HR, needs to be strengthened to promote autonomous management while not going so far as financial/organizational separation of university hospitals.[73] In 2016, the MHLW held a "meeting on the governance of university hospitals etc." (chair = Shigeru Tanaka, Emeritus Professor, Keio University) and the opening remarks from Yasuhisa Shiozaki, Minister of Health, Labour and Welfare (at the time) at the beginning of the first meeting showed the need to reform the selection process for hospital directors as follows: "The most important thing is the process used to select the administrator who holds ultimate responsibility. By any means, an appropriate person should be selected as the administrator and undertake the management and operation of the hospital with authority and responsibility instead of being selected via an election process (called intentional voting) as implemented in many university hospitals. To ensure medical safety, it is essential to review the governance reform including whether any of the hospital's decision-making processes are the most appropriate for ensuring medical safety. In the meeting, I expect that governance reform such as reviewing the qualifications of and processes for selecting an administrator and a system for appropriate decision-making will be discussed in detail from scratch."[74] The background to this are the ongoing problems concerning medical safety at Gunma University Hospital and Tokyo Women's Medical University Hospital. In December 2016, the MHLW proposed a draft revision of the Medical Care Act, such as the administrative authority of university hospital directors, to the Medical Council of Social Security Council (chair = Ryozo Nagai, President of Jichi Medical University). Finally in June 2017, the revised Medical Care Act,[75] which aims at strengthening the administrative system in advanced treatment hospitals, was enacted.

In parallel with the governance reform of university hospitals, laws to incorporate university hospitals as separate corporations had also been developed. On March 28, 2014, in the 7th Medical Care/Nursing Care Group, Industrial Competitiveness Council, the headquarters for Japan's Economic Revitalization, Kiyoshi Morita, the President, Okayama University announced the "Okayama University Medical Center Concept" that would make Okayama University Hospital a separate corporation and one that would include neighboring hospitals.[76] Mr. Morita reorganized the Okayama University Hospital of Medicine so that it became Okayama University Hospital, an independent department within the university, when he was the hospital Director, and the intention "to obtain some degree of freedom from the university" is considered to be consistent with these moves.[77] The Okayama University

[73] An article states that selection of directors of university hospitals by an election based on HR organization by the clinical department is a problem (2005) etc. http://www.cdi-medical.co.jp/common/uploads/2005/04/20050401.pdf
[74] http://www.mhlw.go.jp/stf/shingi2/0000116878.html
[75] The following was stipulated concerning selection of the hospital director: "the organization of an advanced treatment hospital shall establish a collegiate body, which consists of other members than those who have special relationships stipulated by the MHLW ordinance with the organizer, to select the administrator, and select a candidate who has the skills and experience necessary to perform activities related to management and operation of an advanced treatment hospital as the administrator of the advanced treatment hospital, based on the results of deliberations by the collegiate body."
[76] https://www.kantei.go.jp/jp/singi/keizaisaisei/bunka/iryou/dai7/siryou1.pdf
[77] From the minutes of the Group meeting (https://www.kantei.go.jp/jp/singi/keizaisaisei/bunka/iryou/dai7/gijiyousi.pdf)

Medical Center Concept was developed based on "establishment of a nonprofit holding company corporation system that integrally provides medical care, nursing care etc." as proposed in the "Revision of Japan Revitalization Strategy 2014 – Challenge to the future –."[78][79] This document referred to the separate incorporation of university hospitals as follows: "With a view to taking steps to maintain and improve the educational, research and clinical functions of university hospitals, a conclusion shall be reached within this year and institutional measures shall be established … (snip) … so that university hospitals can be separated from the university as separate companies to realize integrated management with other hospitals, utilizing the nonprofit holding company corporation system (tentative name)" (pp.92-93).

Furthermore, the "Japan Revitalization Strategy 2016 – Toward the 4th Industrial Revolution –"[80](June 02, 2016) mentioned the realization of a "regional medical care coordination promotion corporation" system and combining it with separate incorporation of university hospitals stating as follows: "Following the enactment of a law (Law No. 74, 2015) to partially revise the Medical Care Act, which includes the establishment of a "regional medical care coordination promotion corporation" system to allow integrated management of multiple medical corporations etc., government ordinances etc. will be developed to make the system easy to use (snip). Necessary institutional revision will be implemented within this year and preparation will be promoted steadily in collaboration with all the parties involved so that university hospitals, which wish to integrate their management with other hospitals, can be separated from universities and start operating smoothly at the same time in conjunction with the regional medical care coordination promotion corporation system." (pp.77-78)

On the other hand, the MEXT, which has jurisdiction over university hospitals, reviewed requirements for university hospitals to become separate corporations, which had been proposed in the "Japan Revitalization Strategy 2014". In the 35th Implementation Realization Inspection Meeting, Industrial Competitiveness Council on March 23, 2016, the following drafts were presented.[81]

- The form of the corporation, which wishes to establish a hospital to be treated as a university hospital (hereinafter, "quasi-university hospital"), shall be a general incorporated association and its essential purpose and business should be "to establish a hospital that can provide the necessary functions for education and research in a faculty of medicine in the university at the request of the organizer of the university". Moreover, the organizer of the university shall retain majority of voting rights concerning matters related to education and research in the faculty of medicine.

[78] https://www.kantei.go.jp/jp/singi/keizaisaisei/pdf/honbunJP.pdf
[79] The concept was first proposed in the social security reform national congress report of August 06, 2013 (https://www.kantei.go.jp/jp/singi/kokuminkaigi/pdf/houkokusyo.pdf) p.28
[80] https://www.kantei.go.jp/jp/singi/keizaisaisei/pdf/zentaihombun_160602.pdf
[81] The underlined parts are the same as the source. https://www.kantei.go.jp/jp/singi/keizaisaisei/jjkaigou/dai35/siryou10.pdf

- The organizer of the university, the corporation which plans to establish a quasi-university hospital, and regional medical care coordination promotion corporation shall conclude an agreement on the following matters and comply with it to secure the functions of the hospital as a vital institution for education and research in the faculty of medicine.

In November 2016, the enactment of an ordinance to partially revise the criteria for establishing universities was decided as shown in Table 12 and the ordinance came into effect on the same day (April 02, 2017) as the revised Medical Care Act, which created the regional medical care coordination promotion corporation system. The establishment of these systems allowed university hospitals to become separate corporations.

Table 12 MEXT Material Concerning Enactment of Ordinance to Partially Revise the Criteria for Establishment of Universities[82]

Enactment of Ordinance to Partially Revise the Criteria for Establishment of Universities
(Measures to allow university hospitals, which wish to integrate management with other hospitals that use the regional medical care coordination promotion corporation system, to become separate corporations from universities.)

1 Purposes

Realization of separation of university hospitals, which wish to integrate management with other hospitals that utilize the regional medical care coordination promotion corporation system is requested in the "Japan Revitalization Strategy 2016 – Toward the 4th Industrial Revolution –" (cabinet approval on June 02, 2016) etc. Based on this and the stipulation in the criteria for establishment of universities (Ordinance No. 28, the Ministry of Education, Science, Sports and Culture, 1956) that hospitals are vital facilities for education and research in faculties related to medicine or dentistry, necessary measures will be taken.

2 Summary of the partially revised ordinance

As cases where hospital functions necessary for education and research in faculties related to medicine or dentistry are ensured, hospitals established by participant companies[83] as stipulated in Paragraph 1, Article 70, Medical Care Act (Law No. 205, 1948) are included as university hospitals only when separately stipulated by the Minister of Education, Culture, Sports, Science and Technology.

3 Summary of announcement

When hospital functions necessary for education and research in faculties related to medicine and dentistry are ensured, the following requirements shall be fulfilled.

1 The organizer of the university of the department concerned has concluded an agreement to ensure that the functions of the hospital concerned necessary for education and research in the faculty concerned can be set up.
2 The corporation, which establishes a hospital, shall fulfill the following.
   a. Complies with the agreement and sets establishment of a hospital as the primary objective.
   b. Matters necessary for compliance with the agreement are stipulated in the

[82] http://www.mext.go.jp/b_menu/shingi/chukyo/chukyo4/siryo/attach/1380615.htm
[83] Article 7, Medical Care Act "regional medical care coordination promotion corporation": A (nonprofit) corporation, which establishes an institution/establishment engaging in the hospital or nursing care business, is defined as a "participant company." A general incorporated association for medical care coordination promotion operations ("regional medical care coordination promotion corporation") shall be certified by the governor of the prefecture (one prefecture if encompassing more than one prefecture) to which the area (medical care coordination promotion area) promoting the coordination stipulated in the articles of incorporation belongs.

articles of incorporation of the corporation concerned or other memoranda of association.

3 Smooth and steady implementation of education and research in the faculty concerned is expected.

4 Effective date

April 02, 2017 (the same date as the revised Medical Care Act)

5-2. Challenges in the Pioneering Examples

Though the revised Medical Care Act enacted on April 02, 2017 institutionalized the regional medical care coordination promotion corporations, only a limited number of hospitals actually became regional medical care coordination promotion hospitals. Keiju Medical Center (Nanao-shi, Ishikawa), the CEO of which participated in the 35th Implementation Realization Inspection Meeting, Industrial Competitiveness Council (March 23, 2016) as an expert, did not apply to become a part of the corporation system. The "healthcare partners network" composed of Hakuaikai Sagara Hospital (Kagoshima city, Kagoshima) and Niimura Hospital (Kagoshima city) withdrew their applications on March 31, 2016. According to news reports, the participant medical corporations would become equal regardless of the relative size and financial status of the hospitals (one employee one voting right), making free access to the promotion corporations and prohibition on the payment of a dividend from a surplus the bottlenecks.[84] The Okayama University Medical Center Concept for Okayama University, which has been examined from the beginning, is still being reviewed after the establishment of the Okayama medical care coordination promotion committee.

For separate incorporation of university hospitals utilizing the regional medical care coordination promotion corporation system, economies of scale in management and research through scale-up can be a major incentive. Most of the surveyed institutions were far larger than Japanese national university hospitals. Expansion of the scale is essential to realize medical care/research that can compete with these advanced institutions. This is a benefit that cannot be achieved solely by an initiative to turn a hospital into a department, which Okayama University has already done. The Okayama University Medical Center Concept aimed to significantly expand human resources, facilities and reference area by having a total 3200 beds in six hospitals. However, some experts have pointed out that there is a risk that the reduced diversity in the medical institutions/human resources due to concentration of resources may suppress innovation.

Furthermore, if a university hospital is separately incorporated and separated from the decision-making system of a university, this will aid prompt decision-making supportive of industry-government-academia collaboration. Private companies are aware that there is a lack of flexibility/freedom in universities when considering implementing industry-academia collaboration such as joint research and contract research. Increased responsiveness/freedom in hospitals are expected benefits from separate incorporation. In a similar manner, freedom in decision-making in relation to HR is expected to be enhanced. This can also be realized to a certain extent by turning hospitals into departments (for HR, whether this would be effective depends on how the relationship with faculties of medicine is defined.)

Economies of scale through scale-up and improvement in freedom of hospitals may lead to improvement in clinical services, the fundamental function of hospitals. The overseas

[84] https://www.mixonline.jp/Article/tabid/55/artid/57355/Default.aspx

institutions surveyed employ doctors with superior clinical expertise in clinical faculty positions and are equipped with many advanced medical facilities as a result of hospitals being scaled up.[85] In Japan, increases in clinical services may be an important benefit through separate incorporation of university hospitals.

On the other hand, there are many disadvantages associated with separate incorporation of university hospitals utilizing the regional medical care coordination promotion corporation system. The biggest disadvantage is the temporary loss of being designated as advanced treatment hospitals or as clinical trial core hospitals. According to the revised Medical Care Act, regional medical care coordination promotion corporations are defined as general incorporated associations. Therefore, it is necessary to confirm the requirements and regain approval to be requalified as advanced treatment hospitals. Even though it is temporary, losing the designations of advanced treatment hospital or clinical trial core hospital, which requires the designation of advanced treatment hospital under the condition that requires autonomous management separate from the university, may be still a challenge leading to hesitation despite the benefits. Furthermore, the funding for strengthening university hospital functions related to the university hospital, which were included in the university management expense grants, cannot be obtained. The income lost due to loss of these designations is said to reach a total of 1,200 million yen according to an expert, who participated in the interview. For the University of Tokyo, for instance, it means a loss of financial support of 2.4% of the total budget of the Faculty of Medicine and the university hospital.

Separate incorporation of university hospitals may affect the quality of medical care. Separately incorporated hospitals may consider eliminating unprofitable therapeutic areas to improve their financial condition. In Japan, national university hospitals are the core of regional medical care and have the role of providing medical education. This report does not discuss whether a high concentration of difficult patients and the provision of medical education are related to the financial condition of university hospitals.[86] It is true that there are apprehensive voices being raised about the risk that university hospitals may not play the role of "the hospital of last resort for regional medical care." Ultimately, it is desirable that improvement of the quality of medical care and the promotion of medical R&D are in a win-win relationship and undermining the quality of medical care to prop up medical R&D will make it extremely difficult to build a political and social consensus. Damaging the brand of "university hospital" may bring about disadvantages such as impacts on the willingness of patients to come to hospital and eventually on the hospital management coupled with hospital staff becoming less motivated to work at hospitals (or even to consider employment at hospitals).

[85] Severance Hospital Yonsei University (≥ 2000 beds) in South Korea has expanded the scale and increased the number of surgical procedures aided by the "da Vinci" robot. Currently five robots are in use at the hospital.

[86] In the surveyed overseas hospitals, there was no discourse that the quality of regional medical care was reduced due to separate incorporation of university hospitals at least during the interviews. It was rather logic that separate incorporation helped make management efforts to improve the quality of medical care.

While freedom of HR is increased in separately incorporated hospitals, it becomes difficult to thoroughly reflect universities' intentions in hospital HR management. This is a risk that stands in opposition to the benefit and may affect the relationship between the university and university hospital in the long run. In the 7th Medical Care/Nursing Care Group, Industrial Competitiveness Council, Headquarters for Japan's Economic Revitalization (March 28, 2014), where Okayama University mentioned the Okayama University Medical Center Concept for the first time, Hiroya Masuda (visiting professor, Graduate School of Public Policy, the University of Tokyo), Head of the Group, raised a number of discussion points on the university-hospital relationship stating that "university hospitals will become separate corporations and the organizers will be changed. Then, questions may arise from the MEXT viewpoint on whether functions, as general universities, can be carried out in an integrated manner. What do you think about this? What approaches should be taken to successfully secure integrity of functions?"[87] Furthermore, in the 35th Implementation Realization Inspection Meeting, Industrial Competitiveness Council (medical care/nursing care, March 23, 2016), Kazuhito Hashimoto (professor, School of Engineering, the University of Tokyo), Head of the Group, raised a discussion point on the university-hospital relationship while showing an understanding regarding the separate incorporation of university hospitals commenting that "doctors of regional university hospitals said that a strong relationship with faculties of medicine of universities is a restriction when it comes to contributing to regional medical care. Human resources are related, and basic research is very important for faculties of medicine, consequently, the balance between basic research and regional medical care needs to be considered. Therefore, it is difficult to see things from the viewpoint of the regional contribution of hospitals. Therefore, many doctors strongly assert that university hospitals should be separately incorporated."[88] Yutaka Tokiwa, Director-General, Higher Education Bureau, MEXT responded saying that "there were many HR and financial challenges" and showed an awareness of these challenges.

Hospitals that became separate corporations are required to be self-sufficient in terms of their management. However, depending on the position of the assets and the setting of financial collateral after separation from universities, they may be burdened with unfavorable conditions. For example, in Stanford University, while the university and the School of Medicine/hospital are financially separate, the assets including the buildings and facilities are the property of the university. Various legal solutions have been implemented in each country to realize independent management of R&D. Measures for assets etc. are essential in Japan for a discussion about financial/organizational separation.

When utilizing the regional medical care coordination promotion corporation system, more than one hospital is assumed to participate in a corporation. Even if there are differences in the services and financial conditions between these hospitals, it is difficult for universities, which became separate organizations, to take measures responsibly. Participant hospitals have

[87] https://www.kantei.go.jp/jp/singi/keizaisaisei/bunka/iryou/dai7/gijiyousi.pdf
[88] http://www.kantei.go.jp/jp/singi/keizaisaisei/skkkaigi/kaisai.html

different management organizations (for example, national universities, Saiseikai and other social welfare corporations, Japanese Red Cross Society, etc.) and different missions. Coordination between participant hospitals is not easy.

In the National University Corporation Evaluation Committee (56th, March 02, 2017) immediately before the enforcement of the regional medical care coordination promotion corporation system, committee member Takaaki Kirino (the University of Tokyo, emeritus professor) stated that "when separately incorporating university hospitals, there are still many outstanding problems such as various legal revisions, financial responsibility and rights/obligations in relation to other corporations." The Secretariat of the MEXT responded by saying that "institutionally, the regional medical care coordination promotion corporation system and separate incorporation are feasible. However, as pointed out, there is still insufficient coordination with other hospitals, HR and budgets."[89] Benefits and disadvantages of these discussion points are summarized in Table 13.

Since most of the forward-thinking parties, which plan to utilize the regional medical care coordination promotion corporation system, are still carefully investigating benefits and disadvantages, it cannot be said that the current policy is directly linked to the advancement of financial/organizational separation in Japan. It is important to discuss benefits from various viewpoints such as tax benefits, separate accounting, medical fees of Group I of Diagnosis Procedure Combination (DPC) hospitals, etc. when considering if hospitals are to be separately incorporated, and to establish a system in the same manner as the "national university hospital corporation system."

These were the discussion points on the benefits and disadvantages of separate incorporation of university hospitals utilizing the regional medical care coordination promotion corporation system from the hospital perspective. There are also discussion points from the university perspective. If a university hospital, which is virtually the only source of its own income, becomes a separate corporation, the effect on the university management will be a significant problem. In the 35th Implementation Realization Inspection Meeting (medical care/nursing care), Industrial Competitiveness Council, Mr. Hashimoto, Head of the Group, pointed out one of the challenges stating that "specifically in regional universities, the percentage of the hospital income allocated to university management is significantly high. (Snip)… separating university hospitals is very difficult in terms of university management." Mr. Tokiwa, Director-General, Higher Education Bureau, mentioned that university hospitals are not necessarily in a favorable financial situation in terms of revenue and stated that "problems of hospitals need to be considered as problems of hospitals." In terms of university profitability, there was a comment that "university hospitals are not profitable" in some of the countries surveyed,[90] suggesting that the separation of university hospitals could be financially

[89] http://www.mext.go.jp/b_menu/shingi/kokuritu/gijiroku/1385313.htm
[90] For example, South Korea and Germany.

beneficial. However, in terms of profitability that can be improved by the management/asset sizes and management efforts, it makes sense for universities to own university hospitals.

Table 13 Benefits and Disadvantages of Separate Incorporation of University Hospitals Utilizing the Regional Medical Care Coordination Promotion Corporation System

Benefits	**Disadvantages**
Economies of scale through scale-up → Improvement in research functions	Reduced diversity of medical institutions, suppression of innovation
Prompt decision-making to facilitate industry-government-academia collaboration (This can be realized by turning a hospital into a department.)	
Management ups and downs of a university hospital will not affect university management	Reduction in income and loss of rights due to resetting which institutions will be designated as clinical trial core hospitals and which as advanced treatment hospitals
	Separation of unprofitable therapeutic areas placing the priority on management (difficult to play the role of the hospital of last resort in the region)
Increased freedom of HR	Difficulty in thoroughly reflecting the university's intentions in HR management Risk of reduced relationship with the university in the long run
	Damage to the brand of the university hospital Reduced motivation of staff
	Positioning of assets, setting of financial collateral
Improvement in clinical services	If more than one hospital is involved, services and management conditions vary (the university cannot take the responsibility)

6. Conclusions

6-1. Conclusions

In this study, a case study analysis was conducted in advanced university hospitals in the US, Netherlands, Germany, South Korea and Japan. In each institution, systems for medical R&D (medical R&D platforms), including organization, financing and governance, were examined. As a result, elements that help medical doctors (MDs) and non-MD researchers (PhDs) perform research were identified and structuralized (Table 14). The organizational or financial independence of university hospitals was the common fundamental element observed in all the overseas cases. For example, Stanford University is said to have relatively strong university governance in the US. Stanford University Medical Center, which is composed of the School of Medicine and university hospitals, maintains a certain financial independence from the university. In the Netherlands, the integration (University Medical Center = UMC, a separate corporation from the university) of the faculties of medicine and university hospitals (teaching hospitals) proceeded from the 1990s, and all faculties of medicine in the Netherlands had become UMCs by 2008. In South Korea, Seoul National University incorporated the university hospital as a separate corporation in 1978 in advance of other countries. These separations had a significant influence on policies as shown in Table 14.

Table 14 Elements and Structure of Medical R&D Platforms Covered in the Overseas Case Study

Research promoting factor		Policy in each country
Promotion of clinical research by MDs	Reduction in clinical workload	Clinical faculty positions → improvement of medical functions by recruiting outstanding clinicians Branch hospital → functional independence of research/education/medical care Financial/organizational independence of university hospitals → increases in the number of MDs employed
	Increases in research resources	Research laboratories under the hospital organization/JV research laboratories, cross-appointments → strengthening collaboration between MDs and PhDs Industry-government-academia collaboration, financial and organizational independence of university hospitals → increases in research budgets or improvement of research environment
	Improvement of skills and incentives	System to foster MDs with research skills → Industry-government-academia collaboration, cross-appointments → patent/ventures etc. Project positions → increased income
Promotion of clinical research by PhDs	Systems/positions for research in the clinical setting	Financial/organizational independence of university hospitals → industry-government-academia collaboration, cross-appointments, research laboratories under the hospital organization/JV research laboratories, project positions
	Increases in the number of research topics	Industry-government-academia collaboration, branch hospitals → creation of research sites, diversity MD-PhD collaboration → more clinical research being undertaken

Reductions in clinical workload, increases in research resources and improvement of skills and incentives are effective ways to promote research by MDs. Various policies have been adopted in the institutions in each country to reduce the clinical workload of MDs so that MDs with research skills and motivation can invest their time in research. For example, the US, Germany and South Korea have introduced clinical faculty positions. This policy can improve the clinical functions of a hospital by recruiting MDs with outstanding skills in clinical care, thereby allowing other MDs to invest more time in research and improve hospital management. The title of “clinical faculty” can work as an incentive for MDs with superior clinical skills to obtain positions in universities. This is an important element especially in universities like Harvard University that has many affiliates. For instance, Stanford University has established the Clinician Educator Line positions as the clinical faculty positions that focus on medical care and education, and employs 1200 doctors, slightly over half of the overall faculty members. These clinician educators produce resources that allow slightly less than 500 faculty members of the Academic Council Professoriate and 500 faculty members of the Medical Center Line to engage in research. In the interview at Seoul National University, the interviewee commented that there was a kind of competition between MDs hired for these clinical faculty positions and faculty members of College of

Medicine, and there is a possibility to become professors, the top of lecturers in the College of Medicine, from any position. This is also a factor that can make clinical faculty positions an incentive for talented MDs, and from the perspective of the institution, the clinical faculty positions are drivers that ensure the recruitment of as many research personnel as possible. The clinical faculty positions in these countries can be flexibly operated according to the management/R&D strategy of the hospital as university hospitals are organizationally/financially independent.

Having branch hospitals and affiliates is also effective in promoting research performed by MDs. Harvard University, Erasmus MC and Seoul National University have branch hospitals and affiliates, and the research, education and clinical functions can be divided between the faculties of medicine, main hospital, branch hospital(s) or affiliates. In Japan, Nihon University established Nihon University Hospital (formerly Surugadai Nihon University Hospital), which is placed directly under the university corporation and focuses on medical care, separately from Nihon University Itabashi Hospital. Such branch hospitals and affiliates can contribute to the overall management by utilizing the brand power of the university, and increase resources that allow MDs and PhDs of faculties of medicine and main hospitals to invest their time in research. Furthermore, an increasing pool of human resources, (big) data etc., which can be easily utilized strategically, will contribute to the promotion of research.

Research laboratories under the hospital organizations or joint research laboratories with other institutions and cross-appointments between hospitals and other university departments or external institutions are policies widely noted in the surveyed cases. Research laboratories employ PhDs who are not medical doctors, and have established systems in which internal and external PhDs can obtain cross-appointments in the hospitals or faculties of medicine and promote research in collaboration with MDs. Charité-Universitätsmedizin Berlin jointly established the BIH with the MDC (affiliate of Helmholtz Association) and has increased the number of cross-appointments between Charité and the BIH or between the MDC and the BIH. This is expected to facilitate collaboration between MDs of Charité and PhDs of the MDC. In Erasmus MC, under the Medical Delta system, PhDs of Delft University of Technology, Leiden University and neighboring companies can obtain cross-appointments at Erasmus MC and MDs of Erasmus MC can obtain cross-appointments in these institutions. Although the number is limited, in Seoul National University, three non-MD PhDs are enrolled as principal investigators in the SNUH Biomedical Research Institute, which belongs to the main hospital of Seoul National University Hospital, and are conducting research in collaboration with MDs.

Although details were not deeply investigated in the surveyed cases, industry-government-academia collaboration also supports the promotion of research performed by MDs. As described above, Erasmus MC collaborates with neighboring companies in research under the Medical Delta system. There are ventures funded by sources other than Erasmus MC under the umbrella of Erasmus MC Holding BV and these ventures

support practical application of the research results of MDs of Erasmus MC. Furthermore, public-private collaboration is promoted at the EU level and, for example, resources are concentrated under the European Institute of Innovation and Technology (EIT) and EIT Health, a consortium to support medical care/health innovations and start-ups, has been established and is being operated. Rotterdam, where Erasmus MC is located, is one of the six locations of EIT Health. As can be seen from these examples, systems to utilize human and economic resources outside hospitals through industry-government-academia collaboration have been developed to promote research by MDs. While it cannot be said that financial/organizational independence of university hospitals is a necessary condition, it is estimated to improve responsiveness and speed of decision-making in hospitals and contribute to the promotion of industry-government-academia collaboration.

Financial/organizational independence of university hospitals can bring about the strategic operation of medical fee-based revenues and establishment of staff positions (especially, the clinical faculty position described earlier) in hospitals, thereby facilitating the promotion of R&D in these hospitals. The UMC in the Netherlands is the most notable example. All budgets from medical fees, VWS and OCW (via the university) are collectively provided to the UMC and the UMC has sole discretion on their use. The UMC is not fully accountable to funders as to how these funds are used and can manage budgets flexibly from the perspective of management of the UMC. In the Netherlands, the health insurance system based on the concept of “management competition” is implemented and hospitals negotiate prices with insurers regarding healthcare services that the hospitals provide. In this system, because hospitals are constantly exposed to competition in terms of innovation creation and thereby strategic budget operation of the UMC, which is separately incorporated, becomes an essential condition for prompt entry into R&D that meets the needs of MDs and PhDs of the UMC. In South Korea, Seoul National University Hospital, Severance Hospital Yonsei University and other university hospitals, which are designated under the research-driven hospital system introduced in 2013, are financially or organizationally separate from the universities. Therefore, a condition whereby a specific percentage of hospital income is invested in research, in other words, a mechanism that channels the income from medical practice back into research funds, could be embedded in the system.

Enhancement of the research skills of MDs or incentives for engaging in research are important for establishing a medical R&D platform. Germany and the Netherlands, in particular, enthusiastically promote a policy to develop MDs with research skills. The clinician-scientist system introduced in Charité-Universitätsmedizin Berlin in collaboration with the BIH is a contract whereby the research institution (BIH) pays half of the salary for 3 to 4 years and the MD will spend half of his/her working hours on scientific research. In other words, it is a contract to “buy the time” of young doctors. The BIH provides a budget of 4 million euros a year for this system. This system is highly evaluated by Charité MDs and the gate to becoming a clinician-scientist is getting harder to pass through. Therefore, Charité established the junior clinician-scientist system for young medical students. Erasmus MC has

a similar system called the research MD system, for which Erasmus MC supplies the funds to "buy time." These initiatives are based on the awareness that it is of vital importance to secure young talents, who determine the quality of medical care and research in hospitals, under the competitive environment that characterizes top-ranking universities in the US, UK and other countries. If the ranking of a university (faculty of medicine) is raised by increasing the numbers of papers, citations and HCPs through the development of MDs with research skills, young talents will emerge. These young talents will create high-quality research results with the effect that the cycle repeats itself. At the national level, it is a policy to aggregate MDs with research skills and divide functions with members of the clinical faculty. However, development of MDs with research skills is no longer the main focus in the US. The interview revealed that Stanford University used to promote the MD-PhD double degree program in the past, but it is becoming obsolete.

Industry-government-academia collaboration and cross-appointments with other institutions can incentivize MDs to engage in research through the acquisition of patents and involvement in venture start-ups. Erasmus MC has over 25 affiliates and faculty members of Erasmus MC participate in clinical research and practical commercialization of research results through cross-appointments. Revenues and patent revenues generated by these ventures act as incentives to MDs to engage in TR and clinical research.

In the US and EU, it is common to pay salaries (partial or additional salaries)[91] of researchers from the external research funds. The fringe benefits related to medical insurance etc. can be also paid from the external research funds and the ratio relative to the total research funds is stipulated by the university in the same manner as that of the indirect costs. It goes without saying that for tenured faculty positions, even for project positions with restrictions, the motivation to win positions from direct incentives, i.e., increases in income, will be developed, if someone has the capacity to obtain funds for research from an external source. Furthermore, if a specific amount from an external research fund can be continuously obtained even if the fund is changed, the project's position can be maintained virtually without a finite term. Project positions operated under such a system can act as effective incentives for MDs with the ability to conduct research.

On the other hand, it is effective in the promotion of research by PhDs to increase systems/positions that allow non-MD PhDs to conduct research in the clinical setting, and to increase research themes where PhDs can be effectively utilized. As described above, the financial/organizational independence of university hospitals will affect the promotion of industry-government-academia collaboration and cross-appointments, strategic

[91] It varies depending on the university. For example, 9 months, which corresponds to the academic year, are paid as the salary stipulated by the university and 3 months, which corresponds to the summer holiday period, are paid as additional salary from the external research funds. In the US, the ratio is generally determined according to the efforts related to the external research funds concerned. In Harvard University, it is stipulated that salaries provided via external research funds is □ 25% of the total salary and other universities have a similar upper limit though the ratios differ.
(https://research.fas.harvard.edu/supplemental-salary)

establishment/utilization of research laboratories, and the flexible operation of project positions etc. If non-MD PhDs are to conduct research in the clinical setting, collaboration between MDs and PhDs or positions that allow PhDs to conduct research independently are necessary. Industry-government-academia collaboration and research laboratories where MDs and PhDs get together may be effective ways to bring about collaboration between MDs and PhDs and positions at hospitals for PhDs through cross-appointments and making project positions available may be effective in the latter case. As already stated, the Netherlands, Germany and South Korea have introduced these policies, though at different levels, to promote research led by PhDs.

The cases in each country suggested that intensive development or diversification of research sites through industry-government-academia collaboration and establishment of branch hospitals/affiliates are effective ways to increase research themes in which PhDs can actively participate. The Dana-Farber Cancer Institute, an affiliate of Harvard Medical School, has 479 full-time researchers, and 93 of them are non-MD PhDs. Also, in other affiliates of Harvard University, many non-MD PhDs are employed. Various science and engineering PhDs are employed in each institution according to the diseases and therapeutic areas that the affiliates research, and all of them are concentrated in a specific area of Boston. In addition to that, MD-PhD collaboration is expected to increase TR and clinical research. For example, in Germany, R&D related to medical devices through industry-academia collaboration is being actively pursued, and clinical MDs and PhDs of medical device manufacturers or PhDs of research associations collaborate in the clinical setting. Even if there are restrictions so that development of systems does not proceed and PhDs cannot work independently on research themes closely related to the clinical areas, advancement of collaboration with MDs will provide sufficient scope for PhDs to play an active part.

6-2. Policy Suggestions

Taking the above conclusions reached based on the surveys into consideration, policy suggestions for the establishment of a medical R&D platform were evaluated with Japanese national university hospitals in mind.

As seen in each country, financial independence of university hospitals can be an important policy when hospital management develops/implements a strategy that integrates management and research/education as one. In Japan, there has been a movement to bring about the financial/organizational independence of university hospitals. In particular, separate incorporation of university hospitals utilizing the regional medical care coordination promotion corporation system is the most forward-thinking effort. The Okayama University Medical Center Concept for Okayama University, which led the discussion and attracted attention as a pilot case, has not been realized yet due to a lack of evidence that supports benefits for the university and hospital and legal evidence on avoiding/addressing risks. Cases

that separately incorporated university hospitals through structural reforms of universities, such as the UMC in the Netherlands and Seoul National University Hospital in South Korea, as an independent corporation, considered systems that allow hospitals to operate independently and the legal systems that guarantee that this can be created. The financial/organizational independence of university hospitals is not necessarily the only avenue, and there are other measures such as clarification of separated accounting, establishing university hospitals as a department, etc. that can be implemented before financial/organizational separation. Furthermore, the feasibility and effect of financial/organizational separation is affected by the regional characteristics of the location of the target university hospital and its history. If still considering organizational separation, systems such as those covered in the "National University Hospital Corporation Act" need to be discussed.

Not only the systems concerning university hospitals but also the meta-systems, for example the health insurance system and university system, may become targets for discussion. It is estimated that introduction of "management competition" in the health insurance system gave a strong incentive to the UMC management to promote R&D in the Netherlands. In South Korea, the research-driven hospital system that requires medical practice income to be returned to augment research funds and the direction to provide medical fee benefits to research-driven hospitals in the medium term may become the basis for a social system wherein medical expenses and research funds are able to circulate. In Japan, the open-door policy, meaning that non-MD researchers can actively participate in medical R&D and that medical expenses (medical fees), which have not previously been a source of research funds and will be partially linked to the research funds, will be important in the long run. For this to come about, consolidation or organic collaboration of the research departments of national R&D corporations, educational reform of science/engineering and other meta-systems should also be considered to reduce vertical segmentation within or between universities, ministries and research institutions. For expensive new drugs and advanced treatments including cancer drugs, measures to link medical expenses and research funds in medical fees, for instance, considering the costs incurred in clinical research related to efficacy etc., are necessary.

Financial/organizational independence of university hospitals is not easily realized and does not necessarily guarantee a satisfactory level of benefits. Therefore, it is important to consider policies that contribute to the promotion of medical R&D without depending on financial/organizational independence. First, it is necessary to establish an environment in which non-MD PhDs can play an active part in medical R&D. As widely seen in the surveyed cases, a platform where MDs and PhDs can collaborate and PhDs can independently engage in medical R&D is needed. For example, it is effective to promote cross-appointments within the university (faculties of science/engineering and graduate schools) under collaborations between faculties of medicine and engineering or between faculties of medicine, science and engineering. Eliminating the therapeutic area from the degree name and simplifying it as "PhD" may motivate MDs to pursue a doctorate in graduate schools of engineering or

students of graduate schools of science and engineering to receive education on the human body, diseases etc. in graduate schools of medicine. However, some experts point out that discretion in choice of subjects that was reinforced after the strategic focus on graduate schools/shift of national universities to independent administrative corporations was the background to the insufficient effect of various systems including the dual-position system. Some argue that it is necessary to support the dual-position system and other collaborations in a top-down manner from the dean of graduate of school and hospital director.

It is also important to employ PhDs with well-developed research expertise, and who can obtain an abundance of external research funds, in faculties of medicine and hospitals. To serve this purpose, incentives for PhDs need to be created. As seen in the overseas cases, a policy to virtually abolish a finite term for project positions (the employment is continued so long as certain external research funds are continuously obtained regardless of the funder) can be considered. Flexible operation of project positions in university hospitals will be affected by whether or not the organization that has authority over HR of a hospital and faculty of medicine has a certain level of discretionary power. The indirect costs and overheads are said to be related to this discretionary power. In the US, the rate of indirect costs relative to the external research funds is considerable. For Stanford University, 28.5% to 57% (rate to the MTDC, where necessary costs are subtracted from the total funds) are paid to the university. The obtained external research funds were approximately 1,000 million dollars (660 million dollars in the School of Medicine) for the entire university, of which the indirect costs were approximately 250 million dollars (2015). For Harvard University, the rate of indirect costs reaches 26% to 69.5%. For Stanford University, in addition to the indirect costs, 110 million to 120 million dollars of overheads (FY2015-2016), 2.3% to 2.5% of the total income of 4,873.1 million dollars (2016 budget plan) of Stanford University Medical Center, were paid to the accounting department of the university. The rate of indirect costs and overhead will be important discussion points in the formulating the strategy to obtain research resources in Japan.

As stated in Chapter 4, HR departments in Japanese universities tend to value IFs in relation to the recruitment of faculty members and the dominant research promotion strategy may be described as that of “big game hunters.” This will impair diversity in research and reduce the possibility of innovation. Furthermore, as described in Chapter 1, it may be a cause of the medical care workload being unevenly distributed among young doctors. On the other hand, research promotion strategies that value the number of citations and HCPs, which are considered to contribute to the recent assessments of universities, including their ranking, have been adopted in the countries surveyed. In order to acquire young talents to further globalize higher education and research fields, IFs, the number of citations and HCPs, HR management and intelligent allocation of research budgets that place value on research achievements, such as IFs, the number of citations and HCPs, contributing to the international reputation of the university may be effective approaches.

The above-described MD-PhD collaboration mainly discussed policies in universities. The overseas cases reveal the measures taken to promote MD-PhD collaboration under industry-government-academia collaboration and collaboration with external institutions. Although rigidity of decision-making and accounting due to the vertically segmented structure of universities is an issue that needs to be resolved, the policy to establish a site for promotion of industry-government-academia collaboration has already been implemented in many Japanese universities. It is necessary to increase opportunities to employ persons with PhDs and implement research that allows MDs-PhDs to work together to further promote collaboration. One example is an affiliate agreement with external hospitals and research institutions as seen in Harvard University. However, only a limited number of university hospitals in Japan have the resources and the capability to conclude affiliate agreements with external institutions and collaborate in research, education, medical treatment etc. Given these circumstances, increasing the availability of researchers by reviewing the concept of a national R&D corporation will also contribute to the promotion of MD-PhD collaboration.

Finally, the primary challenge of any medical R&D platform is securing research funds, human resources, time and incentives. Financially, in addition to policies to increase the circulation of medical expenses and boost investment by the private sector, policies to effectively operate resources limited by concentration and competition are important. To secure human resources and time, an effective approach is to expand the career path of MDs in research hospitals by adopting appropriate policies including the introduction of clinical faculty positions, proceed with the division of functions among MDs, and to promote the activities of PhDs through cross-appointments and affiliate agreements with external institutions. Promotion of clinical research with the collaboration of co-medicals such as pharmacists and physiotherapists can also be considered. Like the agreement to “buy the time” of young doctors under the clinician-scientist system in Charité-Universitätsmedizin Berlin, it is expected to be an effective way to secure research time through an employment agreement. Improvement of systemic/institutional schemes such as research achievement evaluation criteria, job titles/positions (including clinical faculty etc.)/degrees and medical specialist systems are necessary to create incentives. Approval and licensing of applied medical techniques/technologies for special research achievements can also be incentives. This policy has been partly implemented in highly advanced medical treatment scenarios in Japan. An efficient healthcare provision system utilizing information technologies such as big data and AI and cycle-type R&D based on that system will be important for the continuous development of the medical system. On the basis of the above, not only for advanced medical institutions but also when regional medical institutions implement a healthcare provision system based on IoT, medical fee policies that take into account the results of research/technology development in such system and the approval and licensing of pioneer cases may be effective ways to expand medical R&D.

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■ Individuals Involved in the Development of the Study Report ■

Ryozo Nagai	Principal Fellow	(Life Science and Clinical Research Unit)
Shunsaku Komatsuzaki	Fellow	(Life Science and Clinical Research Unit)

Please contact the Unit below for inquiries etc.

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Life Science and Clinical Research Unit,
Center for Research and Development Strategy,Japan Science and Technology Agency

7, Gobancho Chiyoda-ku, Tokyo 102-0076 JAPAN
TEL +81-3-5214-7481
E-mail crds@jst.go.jp
https://www.jst.go.jp/crds/

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