# A Study on the Development of a Research-based Hospital Model in Korea

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# A Study on the Development of a Research-based Hospital Model in Korea

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## **Table of Contents**

Abstract	x ii
I. Introduction	1
1. Background	
Concept of Health Technology	
2) Value of Health Technology	
3) Potential of Hospital-based HT Research	
(a) Completion of the R&D System	
(b) Enhancement of R&D Productivity	
(c) Activation of R&D Specialization	8
(d) R&D Value Maximization	9
(e) Coping with Crisis and Advancement	10
4) Current Situation of the Korean Hospitals in HT Research	12
2. Purpose	16
3. Methodology	18
1) Research Objective	18
2) Analysis Factors	19
(a) Government Investment in Health Sector R&D	19
(b) Hospital Research Infrastructure	19

(c) R&D Implementation of Hospitals	19
(d) Case Study of Hospital-based Research of Domestic and Foreign Hospitals-	-20
3) Analysis Methods	20
(a) Questionnaire Survey and Analysis Targeting Hospitals (Researchers, Management and Supporting Departments)	-20
(b) Bibliography Analysis Related to Health R&D	-21
(c) HT R&D Statistics Analysis per Research Subject and Institution	-21
(d) Comparative Analysis of Open Data including Website and Guidance Information	23
(e) Interviews with Health R&D-related people	-23
4) Main Research Details	-23
(a) Health R&D Investment in Hospitals	-23
(b) Analysis of the Status of Hospitals' R&D Performance, Investment, and Utilization of Hospitals	-24
(c) Analysis of the Current Situation of Hospitals in terms of HT R&D	24
(d) The Direction of R&D Development in Terms of HT in Hospitlas	-24
	-25
1. Health Technology R&D	25
2. Hospital-based R&D	31
1) Status and Performances of Hospital R&D Support	-31

2) Major Hospital-based R&D Projects	35
(a) Promotion of Research-based Hospitals	35
(b) Formation of Clinical Research Network	37
(c) Korea National Enterprise for Clinical Trials (KONECT)-	40
(d) Medical Device Clinical Trial Center	41
(e) Disease-Oriented Translational Research	41
(f) Medical Genomics	44
3. Cost-effectiveness Analysis of Hospital-based Health Technology I	R&D46
□. Issues on the Achievement of Research-based Hos     in Korea	-
	53
	53
in Korea  1. Survey Result Analysis	53 53
<ol> <li>Survey Result Analysis</li> <li>Survey on the Research-based Hospital Model in Korea</li> </ol>	53 53 53
in Korea  1. Survey Result Analysis  1) Survey on the Research-based Hospital Model in Korea  (a) Survey through the Delphi Method	53 53 53 53
in Korea  1. Survey Result Analysis  1) Survey on the Research-based Hospital Model in Korea  (a) Survey through the Delphi Method  (b) Result Analysis	5353535353 ountries66
<ol> <li>Survey Result Analysis</li></ol>	5353535353 ountries66
<ol> <li>In Korea</li> <li>Survey Result Analysis</li></ol>	53535353 ountries6666

IV. Conclusion	73
1. Discussion	73
1) Concept and Element of Research-based Hospitals	73
(a) Operational Concept	73
(b) Elements of Research-based Hospitals	73
2) Is it possible to develop a world-class research-based hospital in Korea?	75
(a) Key Success Factors of RBHs	75
(b) Major Barriers to RBHs in Korea	79
3) Discussion	85
2. Suggestions for Research-based Hospitals	87
1) Systematic Reform Related to the Hospitals	87
(a) Strong Leadership	87
(b) Strong Commitment of Employees	88
(c) Strategic Management System	89
(d) Close Team Collaboration and Open Innovation	90
(e) Mandatory Re-investment Policy	91
2) Reinforcement of the Infrastructure of the Hospitals	92
(a) Capacity Building of TTO	92
(b) Strategic Allocation of Resources	92
(c) Integrated Information System	93
(d) Strengthening Clinical Trial Research Facilities	03

3) Empowering human resources	-93
(a) Dual-track System for Physicians	-93
(b) Exchange Training Courses	-94
(c) Career Management Program for Researchers	-94
4) Social Recognition and Policy Framework to Support Hospitals	-95
(a) Advocacy for RBH Framework	-95
(b) Legislation for RBH	-95
(c) Deregulation	-96
(d) Active Support of the Government Grant for HT R&D	97
(e) Coordination in the Government	-98
5) Implementation strategy	-99
(a) Initial Stage: Group A and Selected Hospitals with Specialities	99
(b) Second Stage: Expansion to Group B Hospitals	100
References1	101
Appendix: Survey Questionnaire with Results1	106
Abstract in Korean1	124

### List of Tables

Table	1.	Employment Multiplier in Greater Philadelphia and Jobs Created in 2008	
Table	2.	Sales Size and Growth Rate of Global New Bio Drugs	-5
Table	3.	Size of R&D Investment in the Health Sector (2004-2008)	26
Table	4.	Investment in the BT Sector per Individual Ministries	26
Table	5.	Health R&D Investment Ratios of the Ministries in Charge of Health of Major Countries	
Table	6.	Support for Hospital R&D (2005-2009)	32
Table	7.	Hospital R&D Grants per Region (2005-2009)	32
Table	8.	HT R&D Funds Status Per Major Project (2005-2009)	33
Table	9.	Status of R&D Achievements per Hospital (2005-2009)	34
Table	10.	Support for Hospital-based R&D Projects	36
Table	11.	Support for Clinical Research Network	38
Table	12.	Support for Clinical Research Centers	.39
Table	13.	Contents of Support for KONECT	40
Table	14.	Support for Medical Device Clinical Trial Center	42
Table	15.	Support for Disease-Oriented Translational Research	43
Table	16.	Support for Medical Genomics	44
Table	17.	R&D Support per Hospital (2007-2009)	-47

Table	18.	Recognition on Current Role of Hospitals in HT R&D54
Table	19.	Potential Area by Competent Hospitals in Korea to Contribute for HT R&D Development54
Table	20.	Major Barriers to becoming Research-based Hospitals with Suitable Competence56
Table	21.	Significant Factors Generating Crucial Barriers to Becoming Research-based Hospitals56
Table	22.	Systematic Issues for Promoting Hospital-based R&D58
Table	23.	Issues on Infrastructure Refinement60
Table	24.	Issues on Human Resources in Hospitals62
Table	25.	Issues on the Government Policy for Supporting Research-based Hospitals64
Table	26.	Performance Change of MDACC (2005-2009)67
Table	27.	MDACC Research Fund68

## List of Figures

Figure	1.	The Categories of Health Technology2				
Figure	2.	Problems of the Current R&D System6				
Figure	3.	Completion of the R&D System through Hospital-based Translational Research6				
Figure	4.	Technological Hindrance in New Medicine Development7				
Figure	5.	Status of Drug Reposition Candidates10				
Figure	6.	Status of Global New Drug Development Productivity11				
Figure	7.	Growth Opportunities through Short and Long Term Generics(2008)11				
Figure	8.	Investment Amount Ratio per Economic and Social Goal(2008)27				
Figure	9.	Status of Investment per Science and Technology Standard Classification (2008)28				
Figure	10.	Research Expenses in Major Technology Sectors per Region(2008)29				
Figure	11.	Comparison of Medical Technology Levels in Terms of Research Subsidy Size50				
Figure	12.	Research Subsidy of Five Institutions in Group A and their Performance Analysis51				
Figure	13.	Comparison of Performances of Groups A, B and C52				
Figure	14.	Team Collaboration Model of MDACC79				

#### List of Abbreviations

BT Biotechnology

C&D Connect and Development

DH Department of Health (UK)

DHHS Department of Health and Human Services (USA)

DT Diagnosis and Treatment

GDP Gross Domestic Product

HIRA Health Insurance Review & Assessment Service

HT Health Technology

INAHTA International Network of Agencies for Health Technology

Assessment

JHU Johns Hopkins University

KFDA Korea Food and Drug Administration

KHIDI Korea Health Industry Institute

KISTEP Korea Institue of Science and Technology Evaluation and

Planning

KoNECT Korea National Enterprise for Clinical Trials

KRW Korea Won (1 US dollar is 1,217 Won on 10 June, 2010)

MDACC MD Anderson Cancer Center

MHLW Ministry of Health, Labor, and Welfare (Japan)

MOHW Ministry of Health and Welfare

MEST Ministry of Education, Science and Technology

MKE Ministry of Knowledge Economy

NIH National Institute of Health (USA)

NHI National Health Insurance

NSCR National Strategic Coordinating Center for Clinical Research

NSTC National Science and Technology Council

NTIS National Technical Information Service

OECD Organization of Economic Cooperation Development

RBH Research-based Hospital

R&D Research & Development

R&BD Research & Business Development

RDA Rural Development Administration

TTO Technology Transfer Organization

TWIns Tokyo Women's Medical University Waseda University Joint

Institution for Advanced Biomedical Sciences

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#### <Abstract>

# A Study on the Development of a Research-based Hospital Model in Korea

Noting the increasing public attention on health care maintenance and the following cost under the long-term low economic growth, Korean society has shown greater attention to the significance of the health technology (HT) development. As a result, the HT attracts various interests in Korea as one of economy growth engines of the next generation. In order to promote HT competitiveness, the role of research-based hospitals (RBHs), in producing new ideas as well as utilizing final outcomes, has grown increasingly significant. Despite high quality health care professionals, state-of-the-art equipment, and well developed information technology, few hospitals in Korea are successful leaders in HT development.

In order to understand HT research and development (R&D) programs in Korea as well as hospital-based R&D investment performance, this study has analyzed a recent three-year R&D investment of the Korean government. Also, the R&D performance has been reviewed using a numbers of patents, technical transfers and papers. In addition, a survey on how to promote RBHs in Korea has been proceeded through adopting the Delphi method. Several model cases of RBHs abroad have been also studied to understand key success factors in formulating a development model of RBH in Korea.

This study proposes suggestions for the promotion of RBHs in Korea based on the survey and case studies: systematic reform related to the hospitals, reinforcement of the infrastructure of the hospitals, empowering human resources and policy framework to support the hospitals. Regarding systematic reform, concrete leadership and strong commitment of all hospital employees who understand of the value of HT R&D within the hospitals are essential. Other priorities include both a strategic management system to encourage hospital-based R&D, and strong multi-disciplinary collaboration via team approach.

In terms of strengthening hospital infrastructure, capacity building of technology transfer organization, strategic allocation of hospital resources, researcher-friendly integrated information system, and improving clinical trial facilities are required to be RBHs in Korea. In order to empower human resources, the following measurements are suggested; a dual-track system for physicians in which they can develop their career in both research and medical service, exchange programs with training courses between scientists and physicians, and career management programs for researchers and technicians.

The most significant requirement is the full support of the government, the support based in social recognition of the value of RBHs in Korea. With legislative backing for RBHs, deregulatory measurements are necessary. Expanded support of the government grant for HT R&D is also requested not only for increased funding but also allowance of longer-term support for R&D. In addition, an inter-government coordination body is suggested for enhancing the efficiency of HT R&D implementation and formulating R&D investment strategy.

Key words: health technology, research and development, research-based hospital, health industry

#### I. Introduction

#### 1. Background

#### 1) Concept of Health Technology

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (WHO, 2006). The technology for maintaining our health is called health technology (HT). In reality, HT is defined as "the devices, drugs, medical and surgical procedures and knowledge associated with their use in the prevention, diagnosis, and treatment of diseases as well as in rehabilitation, and organizational and supportive systems within which the care is provided" Health Technology encompasses an associated knowledge classified into various categories as seen in Figure 1 (INAHTA, 2009).

#### 2) Value of Health Technology

Korea is one of the most rapidly aging societies in the world (Statistics Korea, 2006). The country will enter an aging society by 2018 and a super-aging society by 2026. About 38 percent of Korea's total population is forecasted to be more than 65 years old by 2050.

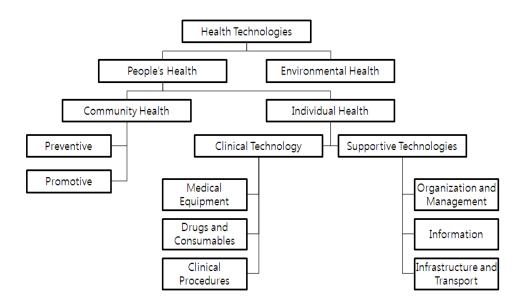


Figure 1. The Categories of Health Technology<sup>1)</sup>

In this context, chronic diseases such as cancer, obesity, and cardiovascular diseases along with medical expenses for health maintenance are projected to jump rapidly, due mainly to westernized dietary habits and lifestyle changes. Korea's national medical expenditure in 2007 stood at 6.8 percent of the gross domestic product (GDP), which was lower than the Organization of Economic Cooperation Development (OECD) member countries' average 8.9 percent. However, it should be noted that the speed of health expenditure increase is nearly three times higher than that of OECD countries (1.55%; OECD Health Data, 2009). With the rapid increase in old population

<sup>1)</sup> source: International Network of Agencies for Health Technology Assessment. HTA glossary. 2009

aged 65 years and older, the financial burden from healthcare is expected to be continuously augmented in the future.

Therefore, efficient development and a sustained supply of innovative health and medical technologies including new drugs are essential in effectively controlling the various social expenses arising from emerging and reemerging diseases along with rapidly increasing health expenses for the older population. Despite the cost incurred from new drug development, the total expense of treatment including the reduction of total treatment duration, activities, and hospitalization period have actually declined (Lichtenberg, 2001). For AIDS patients, according to a comparison of the gross treatment expenses at the time when there was no treatment medicine for AIDS with those after the advent of a treatment drug, treatment drug expenses rose by 35 percent, but the other expenses dropped by 41 percent. As a result, the total expense has been reduced by 16 percent (Bozette et al., 2001). In the case of Alzheimer's, the annual average medical expense of Alzheimer's patients who used medication were 8,056 US dollars, but those who did not take medication spent 11,947 US dollars, that is about a difference of 4,000 US dollars (Hill et al., 2002). The development of a new treatment method through HT research and development (R&D) reduced the total expense per relevant disease; also the effect of treatment is expected to improve with HT R&D outcomes.

The advancement of the healthcare industry has huge ripple effects on employment in various fields and on the production of diverse commodities (Devol *et al.*, 2009). The Employment Multiplier<sup>2)</sup> of HT-related industries

and R&D activities in Philadelphia is 4.0 on average, as shown in Table 1; the individual score of HT R&D is 2.8, and that of the medical service sector is 2.2 (Ross *et al.*, 2009).

Table 1. Employment Multiplier in Greater Philadelphia and Jobs Created in 2008

	Direct-effect employment muliplier	Total impact (Thousands)	Direct impact (Thousands)	Indirect + induced (Thousands)
Biotech	7.3	27.0	3.7	23.3
Pharmaceuticals	7.3	192.8	26.4	166.4
Medical devices	3.6	24.0	6.7	17.3
R&D	2.8	54.0	19.5	34.6
Health-care services*	2.2	83.0	38.1	44.8
Total life sciences	4.0	380.8	94.4	286.4

Source: BLS, BEA, Milken Institute

Reflecting its insufficient HT industrial infrastructure and investment, Korea posted a deficit of 17.8 billion US dollars in the pharmaceutical and medical devices sectors during the period between 2003 and 2008. The deficit in technology balance stood at 100 million dollars (KHIDI, White Paper of Health Industry, 2009). Such continuous trade and technology deficits can be solved through improvement in HT R&D productivity. In particular, the deficit mentioned above can be reduced simply with the development of 2 or 3 globally-used new innovative drugs (Table 2). Specifically, the development of

<sup>\*</sup> Inlcudes only portion of health-care services not consumed locally (exported outside the region).

<sup>2)</sup> The employment multiplier refers to the size of jobs additionally created in the associated industry when one unit of employment was injected into the field concerned. An average multiplier of 4.0 means that four-fold employment in the HT industry is induced in the total associated industry

a smartly targeted anti-cancer medicine and the research on the molecular biology action mechanism are forecasted to grow in the global market in a short period of time, due to the huge spectrum of needs awaiting for these innovative HT R&D outcomes (Stegmeir *et al.*, 2010).

Table 2. Sales Size and Growth Rate of Global New Bio Drugs

(unit: USD 100 m, %)

Product	US FDA Approval Date	Sales in 2008	Sales Growth Rate
Rituxan	1997.11	50.4	16
Avastin	2004.02	44.3	37
Herception	1998.09	43.3	12
Glivec	2001.05	36.7	20
Tarceva	2004.11	10.5	23

(Source: Korea Drug Research Association and KHIDI)

#### 3) Potential of Hospital-based HT Research

#### (a) Completion of the R&D System

Translational research, a hot topic in the health industry since the beginning of the 2000s, has been designated as a top priority by the US government's National Institute of Health (NIH Roadmap for Medical Research; Woolf, 2008), which is a hub of HT R&D worldwide (KISTEP, 2009). Korea has also been paying much attention to translational research in order to improve HT R&D efficiency, which increases the commercialization of R&D outcomes through successful clinical application in the target fields (Lee, 2008).

Hospital-based HT translational research may be able to address R&D system problems such as severance barrier in R&D activities interconnection among major R&D players and R&D productivity enhancement by establishing a close cooperative R&D system between clinical and basic researchers.



Figure 2. Problems of the Current R&D System

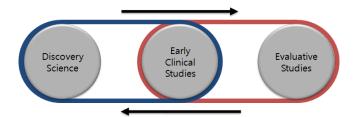


Figure 3. Completion of the R&D System through Hospital-based Translational Research

#### (b) Enhancement of R&D Productivity

The global pharmaceutical industry has been faced with the deterioration of R&D productivity since 1996. Korea has gone through a similar deterioration. Although various ministries of the Korean government have aggressively invested into health R&D, inefficiency has prevented the HT R&D industry from new drug development, which would be key in reducing health-related expenses. (NSTC, 2008).

The fundamental reason for such low R&D productivity in the health sector lies in the limitations of the currently usable science & technology and diseases. Due to the lack of correlations between the animal models used for disease treatment studies and those of human's, additional development is not carried out in the clinical stage although many new drug candidates are verified in terms of their efficacy and safety in animal models. In other words, those drug candidates are not applied to humans in reality (KISTEP, 2009).

Therefore, the following technical assistance of physicians are needed to improve the success rate in the following ways: understanding of diseases, examination of correlations between pharmaceuticals and diseases, and bio marker search and verification. Toward this end, competent hospitals, with world-class bed-side scientists, need to form a research-oriented environment beyond the clinical service dominant framework.

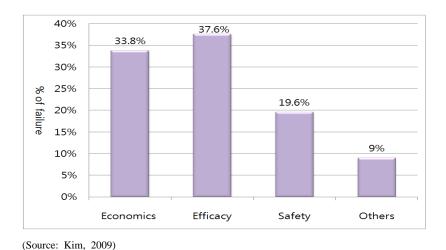


Figure 4. Technological Hindrance in New Medicine Development

#### (c) Activation of R&D Specialization

Despite the Korean government's continuous and huge investment in R&D of the health sector since the 1990s, it is difficult to successfully commercialize or to produce globally bestselling drugs such as "Lipitor®" (hyperlipidemia drug), developed and released by Pfizer (KISTEP, 2009; NSTC, 2008). This can be attributed to the lack of strategic and intensive investment in R&D with high potential for commercialization success utilizing limited research resources through close cooperation among R&D players compared to advanced countries.

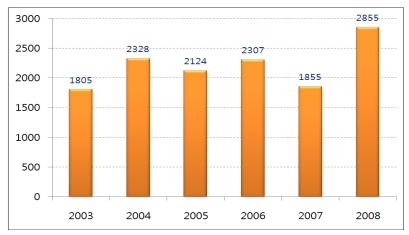
Korea's relatively small pharmaceutical industry desperately conducts both basic and clinical studies with limited financial resources. Thus, it has not secured world-class technology evaluation capacity, which can only be established through extensive research experience. For this reason, rational decisions based on clinical development are not easily made. This would necessitate considerable funding along with essential follow-up investments to commercialize the outcomes of health technology research done by universities or state-funded research institutions. All of this is needed in order for the Korean pharmaceutical industry to be a major supplier of various new drug candidates.

Hospital-based HT research can quickly establish a virtuous cycle and an organic cooperative system among R&D players to effectively develop a globally competitive core technology and to accomplish tangible outcomes of R&D in the near future in Korea.

#### (d) R&D Value Maximization

There are some cases of global bestselling pharmaceuticals, where the original R&D goal in the clinical research process was not reached, that have been found to have another hidden value different from the original target diseases and have created new markets worldwide. For example, Pfizer's Viagra®, an impotence drug, or Thalidomide, which was suspended due to serious genotoxicity when it was developed as a sleeping pill but was found to be a treatment of Hansen's disease and multiple myeloma by repositioning R&D (KISTEP, 2009). To discover the hidden values of basic research achievements and commercialize them, clinical doctors should strengthen scientific and technological capacity through bed side research that uses HT instead of being limited to traditional clinical trials.

Hospitals can also forecast new revenue sources (cash cow) through "Drug Reposition", which is regarded as an astute R&D strategy in advanced countries through translational research (Barton, 2007). Also, this new methodology of R&D can be implemented through technology evaluation capacity, utilizing physicians to be fostered via hospital-based HT research. Companies such as Gene Logics (US) and Sosei (Japan) are developing blue ocean area using extensive Drug Reposition candidate materials (Kim, 2009) on the basis of translational research and evaluation capacity are emerging as growth engines of the pharmaceutical industry in the advanced countries.



(Source: Kim, 2009)

Figure 5. Status of Drug Reposition Candidates

#### (e) Coping with Crisis and Advancement

The pharmaceutical industry, located at the center of the health industry, has grown largely through generic products. Owing to the global decline in new drug development productivity that has continuously deteriorated since 1996, a growth crisis is expected after 2012, in view of the reduction in growth opportunity because of the generics market (Kim, 2009).

Compared to advanced countries, it is impossible for the Korean pharmaceutical industry to build excellent R&D pipelines equipped with global competitiveness in all new drug development processes, considering its limited investment capacity due to the small size of the industry. Therefore, it is required for the Korean health industry to move towards the global competitive industrial structure, focused on innovative new drug development beyond the

generics. This can be realized through hospital-based HT research, which makes qualified clinical physicians shift from diagnosis and treatment (DT)-oriented medical service provision to research-based activities.

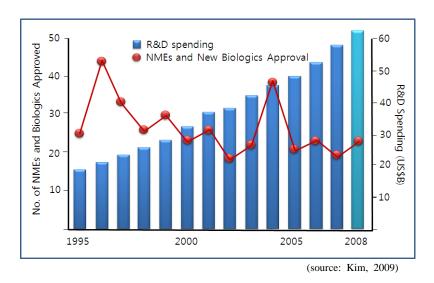


Figure 6. Status of Global New Drug Development Productivity

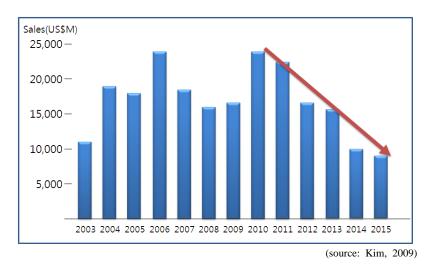


Figure 7. Growth Opportunities through Short and Long Term Generics(2008)

#### 4) Current Situation of the Korean Hospitals in HT Research

The conditions for hospital HT research, including abundant human resources and high clinical technology level, are considered to be mature. The highest scoring students of the university entrance exam in Korea during 2003 until 2005 unanimously applied to the Medical School of Seoul National University. This implies that the top intellectuals in Korea are recently concentrated in medical schools (Chosun Ilbo, Dec. 2009). Some of the competent hospitals, especially top-level university-affiliated hospitals, are estimated to have world-class clinical research capacity because they have a large number of patients, much more than leading hospitals in advanced Because of this large patient population, Korean hospitals have countries. world-class competence in clinical treatment. On the other hand, the expenses for medical service in the Korean hospital is comparatively lower than that of the advanced countries. This factor of low cost and high competence for R&D in Korean leading hospitals is possible under the National Health Insurance (NHI) system<sup>3)</sup>, which strictly controls the medical cost and ensures accessibility to essential healthcare for the Korean people.

Compared to advanced countries, Korea has relatively cheaper clinical and research expenses but it has competitive clinical research capacity with ample experiences in patient DT<sup>4</sup>). Coupled with the demand for competitive

<sup>3)</sup> NHI was introduced in 1977 and it has achieved the universal coverage in 1989. Currently, 96.3 percent of the Korean people are covered by NHI, and the rest 3.7 percent are eligible for Medical Aid program. Both of NHI and Medical Aid policy compose health security system on Korea. Under this scheme, the Korean people can easily access to essential health-care services with only 5. 33 percent of contribution rate, which is comparatively low than OECD countries.

hospitals that are equipped with cutting-edge technology, many competent Korean hospitals are increasing the number of state-of-the-art equipment such as CT and MRI along with PetCT and Cyclotron. Korea's cutting-edge equipment holding rate<sup>5)</sup> is on par with the world's best hospitals. The information technology environment of Korea also provides a digitalized clinical information system<sup>6)</sup> for the hospitals, facilitating the analysis of extensive clinical information.

Nonetheless, Korean hospitals still focus on medical service provision activities, owing to the lack of R&D investment and incentives along with systematic problems (Park, 2009). Due to the revenue structure that keeps hospitals focused on clinical services, Korea's research personnel within hospitals only had about 7,000 persons in 2006; that is only 8 percent of the total number of physicians, which is extremely low compared to 44 percent of physicians participating in research activities at Harvard Medical School (Ryu, 2008). Only 39 general hospitals out of 268 carry out R&D projects. Even in excellent hospitals in Korea, potential R&D infrastructure including

<sup>4)</sup> Size of the world clinical market: KRW 40 trillion (Korea accounts for KRW 300 billion and ranks 10th in terms of trial number and 11th in pharmaceuticals consumption in the world.) (JoongAng Ilbo, Feb. 2010)

<sup>5) 37.1</sup> units of CT per 1 million people (Britain: 8.1units; US: 34.3 units); MRI: 16.1 units (Britain: 8.2units; Canada: 6.7 units)

<sup>6)</sup> Most of university-affiliated hospitals and many specialized hospitals in Korea have following IT applied systems: Electronic Medical Record (EMR), Picture Archiving Communication System (PACS), Clinical Decision Support System (CDSS), and Order Communication System (OCS). In addition, every Korean has individual identification code containing information about gender, date of birth, and place of birth, that is compulsory assigned by the government. This ID code system enables hospital management more efficient and effective compared to the other countries without a compatible ID system in their countries.

prominent human resources, medical facilities, and cutting-edge equipment are hardly used for R&D activities. Most companies and hospitals tend to only use generic productions with low risk and low return, rather than to invest in the R&D for new medication and technology development with high risk and high return. For this reason, the financial resources and incentive mechanism to induce them to invest in R&D are insufficient compared to advanced countries<sup>7)</sup>. Moreover, the government's budget for R&D in the HT sector<sup>8)</sup> is inadequate, and the national health insurance (NHI) manages a very rigid system that regulates medical service types and details; thus, the NHI works as a barrier to new technology and product development as well as reducing the hospital's impetus to engage in R&D. In this context, despite the very high connections "service", "industry", and "clinical and/translational among research", which are HT's 3 major axes, hospitals do not play a central role. As a result, company development of pharmaceuticals and medical devices are not effectively linked to the hospitals' demand for them. Neither a synergy effect nor a target-oriented value chain are formed in the HT R&D framework in Korea, thereby causing an asymmetric industrialization of HT.

Hospitals are the source of technology development since they offer ideas based on clinical experiences and as the end-users of the developed

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<sup>7)</sup> Funding structure: US (public: 32%; nonprofit organizations: 3%; firms: 57%), Japan (government: 10%; universities: 31%; firms: 55%), UK (government: 23%; firms: 69%; charity organizations: 9%)

<sup>8)</sup> Korea's R&D investment in the BT sector was KRW 1.5 trillion (2007), which accounted for about 15.7% of the total national R&D budget. Of the total, HT R&D amounted to only KRW 580 million or 5.9% (US: HT R&D took up about 21.8% of the total national R&D investment).

technologies; they are at the center of the value chain for HT industry development (KHIDI, 2006). Therefore, it is highly requested for competent hospitals to connect industrialization with medical services and to develop HT (this is referred to as "C&D" by the Task Force Team of MOHW). They also need to be equipped with sufficient research capacity to play such a role. Note, however, that actively stimulating medical personnel and hospital research is very important in view of the current income structure of the hospitals, which depends largely upon medical service provision. The improvement of the hospital's situation to encourage research by physicians is considered a matter of urgency, with regard to improving their own financial stability and further development.

This study tries to draw the hospital's R&D potential into the HT industry's innovation capacity, and prepare for general and systematic development measures to foster hospitals as a leading group for a balanced health industry wherein hospitals are linked with clinical activities and research. Also this study will try to present a Korean-style research-based hospital model in the process.

#### 2. Purpose

The health sector is an industry with a strong emphasis on "The Public Good" as an essential social service. Health-related laws, including the Medical Act or the Pharmaceutical Affairs Act, have strictly restricted capital procurement and profit distribution in health and medical service industries<sup>9</sup>). Considering that lower economic growth rate in Korea is expected in the future<sup>10</sup>) while the health sector's potentialities<sup>11</sup>) through which high-quality job creation might be possible, the health industry is seriously recognized as a future growth engine<sup>12</sup>). As in any other industry, gaining technological advantage through R&D is a key factor to success in the health care industry.

This study seeks to search for a method to shape research-based hospitals as a framework tool for Korea's R&D capacity, a key factor in the health industry's development. Hospitals are the end-users in the value chain in the health industry as well as the supplier generating and maturing new ideas on products and technologies, including pharmaceuticals and medical devices (KHIDI, 2006). In such a context, this study aims to draw a model of

9) The Medical Act does not allow for-profit hospital entities; neither does the Pharmaceutical Affairs Act acknowledge the establishment of drug store corporations.

<sup>10)</sup> According to KDI, Korea's economic growth rates in 2020 and 2030 are forecast to be 2.91% and 1.6%, respectively: low growth rate of less than 3% of economic growth is projected (Economic and Social Ripple Effects of Aging Population and Policy Tasks, Dec. 2006).

<sup>11)</sup> According to Business Week (Dec.2006), "What's Really Propping Up the Economy," increases of 1.7 million jobs, 940,000 jobs, and 900,000 jobs were recorded in the health, construction/real estate, and public sectors, respectively, after 2001, but the IT industry recorded a decline of 1.2 million jobs.

<sup>12)</sup> Of the government's 17 major projects as new growth engines, 2 in the health industry were selected (May 27, 2009, New Growth Engine General Implementation Plan).

research- based hospitals in Korea and also to propose suggestions for hospitals, industry, and policy-makers to accomplish such a model. This study intends to encourage the investment in the R&D of health and medical services by positioning the hospitals at the center of HT R&D within close coordination and strong connection between beds and benches. This study tries to search for alternative suggestions concerning systems, human resource training and management structure, and the policy environment of many hospitals, in order to build a Korean-style research-based hospital model. This type of hospital model would allow many clinical service provision dominant hospitals with potentiality of HT R&D to possibly transfer to balanced hospitals in research and medical service provision.

#### 3. Methodology

#### 1) Research Objective

This study attempts to analyze the capacity and the situation of human resources, facilities, equipment, organization, network, and management system of Korean hospitals. In particular, this paper tries to analyze the direction of change as to how a hospital's incentive structure related to human resources and remuneration can stimulate physicians and basic scientist in hospitals to concentrate better on research. Moreover, systematic change to reach an appropriate balance between a hospital's medical service provision and R&D will be pursued, along with perceptual changes concerning medical personnel (*i.e.* physicians) and chief executive officers (CEO) of hospitals with regard to R&D.

Also, this study will try to discuss various suggestions to accomplish what is necessary to attain successful RBHs in Korea. This study examines the government's policy in relation to the promotion of hospital R&D in terms of maximizing the Korean medical institutions' R&D capacity and augmenting the overall efficiency of R&D in the health care industry. Meanwhile, case studies on research-based hospitals in advanced countries will be analyzed to extract implications for the development of the Korean model of research-based hospitals.

#### 2) Analysis Factors

#### (a) Government Investment in Health Sector R&D

The status of the Korean government vis-a-vis R&D is examined in this study, particularly in its attempts to examine the recent data of the R&D investment status with regard to HT. It is noteworthy that the study more specifically examines the status of investment in R&D by the Ministry of Health and Welfare (MOHW) for the past 3-5 years.

#### (b) Hospital Research Infrastructure

This study examines the essential factors of R&D such as hospital human resources, facilities, equipment, organization, systems, and networks from the perspective of activation of the health sector R&D.

#### (c) R&D Implementation of Hospitals

As measurable variables to analyze the R&D achievements of hospitals, papers, patents, technology transfer results, and royalty payment records that were produced through projects supported by government R&D grants are examined. Specifically, correlations between R&D investment and achievement indicators are analyzed per hospital in order to examine hospital R&D results, efficiency, and effectiveness versus investment.

## (d) Case Study of Hospital-based Research of Domestic and Foreign Hospitals

This study analyzes the amount of investment input in research, outcomes, and medical technology level of domestic hospitals while investing successful foreign research-based hospital model cases to draw policy implications and suggestions.

#### 3) Analysis Methods

#### (a) Questionnaire Survey and Analysis Targeting Hospitals

This study targeted approximately 30 experts including researchers at hospitals who have actively participated in R&D, CEOs of hospitals, and technology transfer organization directors to study whether Korea's hospitals have the capacity for HT R&D and play a pivotal role. This paper also surveys the system, human resources, institutions, and policy factors hindering research-based hospital management and collects opinions on how to compel hospitals towards a research balanced model. For the questionnaire survey and analysis, a qualitative analysis method, applying the Delphi technique (Kwon *et al.*, 2004), is used in view of the small size of samples. Above all, the first questionnaire survey with 30 experts is carried out based on prior interviews with 10 experts. This survey uses an open question in the first round (attached in Appendix); thus, a respondent describes his or her opinion on the questionnaire. The first round of replies are categorized into several groups

for each question, with the results and the frequency sent again to the experts panelists. They must reply with their opinions once again after reviewing feedback from the others' reply to the first questionnaire (attached in Appendix). Through this progress, the final results of the opinions are gathered and analyzed. The panelists were selected from major HT R&D leaders, prominent researchers, physicians with rich research experiences, directors of supporting units for major R&D projects, and key members of advisory committees for HT R&D in MOHW.

#### (b) Bibliography Analysis Related to Health R&D

This study refers to existing reports on health R&D: reports of various R&D management institutions, state-funded research institutes and government agencies; discussed agenda and reviewed papers by the Health Technology Policy Deliberation Committee of the government; released papers by the HT forum of MOHW (MOHW, 2009; MOHW, 2010); and internal reports of the HT Strategic Planning Organization of MOHW (MOHW, 2008; MOHW, 2009) and the Task Force Team of MOHW on Research-based Hospital (MOHW, 2010). Moreover, papers and reports of various institutions on research-based hospitals in advanced countries and mission reports by researchers and government agencies are also referenced to for the foreign case study (MOHW, 2010).

#### (c) HT R&D Statistics Analysis per Research Subject and Institution

To examine the recent research achievements of major research hospitals, this paper analyzes the amount of R&D investment in the health sector supported by MOHW by classifying each hospital grant for the past 3 years (NTIS data; KHIDI data; MOHW 2008; MOHW 2009), whose data was available and categorized based on the amount of R&D fund spent by each hospital. Although a head of a research team of a single project posts the statistics of the total research expenses to his/her institution in general for large-scale projects, this paper examines which hospitals have executed research investment per detailed project for the analysis of the actual research investment amount.

Along with the analysis above, this study also investigates the papers, patents and technology transfer, and royalty amount produced by the recent MOHW research subsidies per hospital (KHIDI data). Through this, the amount of research investment made for one paper and research investment made per patent are examined to measure each hospital's R&D efficiency. Note, however, that this study analyzes R&D achievements such as papers and patents in a quantitative method; qualitative analysis such as the impact factor of an individual paper or a patent's industrial values has been excluded from this study.

By analyzing the number of cases of high-level surgical procedures released by the Health Insurance Review & Assessment Service (HIRA, 2009), this paper has researched them in combination with each hospital's R&D size. In other words, this study tries to analyze indirectly the correlation between

R&D investment and the quality level of medical technology by examining the research investment amount and high-level surgical achievements per major hospital.

# (d) Comparative Analysis of Open Data including Website and Guidance Information

The data and information publicly disclosed by major domestic and foreign research hospitals on their websites have been investigated as basic data to determine the size of R&D investment, major investment directions, and achievements.

#### (e) Interviews with Health R&D-related people

In this study, interviews have been conducted with health R&D-related researchers, research planning experts, hospital top management, administrative staff, people connected with pharmaceutical and medical equipment firms, health journalists, and related government officials.

## 4) Main Research Details

#### (a) Health R&D Investment in Hospitals

This study analyzes the government's investment in R&D particularly the amount of R&D investment in the health sectors of hospitals.

# (b) Analysis of the R&D Performance, Investment, and Utilization of Hospitals

To analyze a hospital's R&D performance, this paper examines recent papers, patents, and technology transfer results.

# (c) Analysis of the Current Situation of Hospitals in terms of HT R&D

This study tries to identify the hindrance factors in the operation of research-based hospitals and improvement measures by investigating various conditions and systems related to hospital R&D.

### (d) The Direction of R&D Development in Terms of HT in Hospitals

The future direction of HT R&D within hospitals has been reviewed to find out major trends of development in hospital-based researches.

# II. The Current Status of Hospital-based R&D in Korea

## 1. Health Technology R&D

The government's annual budget for the biotechnology (BT) sector over the past 5 years (2004~2008) has risen 22.3 percent, which is higher than the total government R&D budget increase of 16.4 percent during the same period (Table 3). In view of BT R&D budget allocation among ministries in the Korean government during the same period (Table 4), the Ministry of Education, Science, and Technology (MEST) accounted for 36.7 percent (KRW 633.4 billion), followed by 18.5 percent (KRW 319.8 billion) from the Rural Development Administration (RDA), 16.2 percent (KRW 279.3 billion) from the Ministry of Health and Welfare (MOHW), and 14.6 percent (KRW 251.1 billion) from the Ministry of Knowledge Economy (MKE).

The government budget for the health and medical field, specifically for the BT R&D budget, shows a slightly different range from KRW 545.8 billion or 4.96 percent (health sector per science and technology standard classification table) to KRW 991.2 billion or 9.0 percent (health enhancement and health sectors per social and economic goal) in fiscal year 2008, according to the classification criteria. In particular, MOHW's R&D budget was only KRW 288.1 billion or 2 percent in 2008, and the ratio of the total R&D budget to what was allocated for BT R&D was 16.2 percent. The Korean government prioritizes R&D on industrial production and (continued page 27)

Table 3. Size of R&D Investment in the Health Sector (2004~2008)

(unit: KRW 100 million, %)

Category	2004	2005	2006	2007	2008	Annual Avg. Rate of Increase
Total Govt. R&D	59,846.6 (59,847)*	77,904.3 (72,218)*	87,639.1 (80,393)*	95,745.4 (87,704)*	109,935.9 (98,362)*	16.4
BT R&D	7,717 (12.9%)	10,968 (14.01%)	13,019 (14.8%)	15,063 (15.7%)	17,257 (15.7%)	22.3
HT R&D 13)	5,735 (9.58%)	6,992 (8.97%)	7,256 (8.28%)	8,017 (8.37%)	9,912 (9.0%)	14.7
HT R&D 14)	3,633 (6.07%)	4,189 (5.80%)	5,324 (6.62%)	5,774 (6.58%)	5,458 (5.54%)	10.7
MOHW R&D (including KFDA)	1,928	2,106	2,420	2,389	2,881	10.6

(Source: NTIS DB)

( )\* Total Government R&D budget for "health sector per science and technology standard classification". In this case, budgets for research on policy, humanities, etc. are excluded.

Table 4. Status of Investment in the BT Sector per Individual Ministries

Ministry	2004		200	2005		2006		2007		2008	
1vanasti y	Subsidy Amount	Ratio (%)	Subsidy Amount				Subsidy Amount		Subsidy Amount		Avg. Rate of Increase
MEST	3,284	42.6	4,701	42.9	4,851	37.3	5,798	38.5	6,334	36.7	17.8
RDA	823	10.7	1,564	14.3	2,119	16.3	2,924	19.4	3,198	18.5	40.4
MKE	1,350	17.5	2,073	18.9	2,210	17.0	2,180	14.5	2,511	14.6	16.8
MOHW	1,592	20.6	1,843	16.8	2,130	16.4	2,185	14.5	2,793	16.2	15.1
Others	668	8.7	787	7.2	1,709	13.1	1,976	13.1	2,423	14.0	38.0
Total	7,717	100	10,968	100	13,019	100	15,063	100	17,259	100	22.3

(Source: NTIS DB)

13) Health enhancement and health sector per economic and social goal

<sup>14)</sup> Health sector per science and technology standard classification table

technology, a field that can directly lead to economic growth; therefore, R&D investment in health technology has been relatively lower<sup>15</sup>).

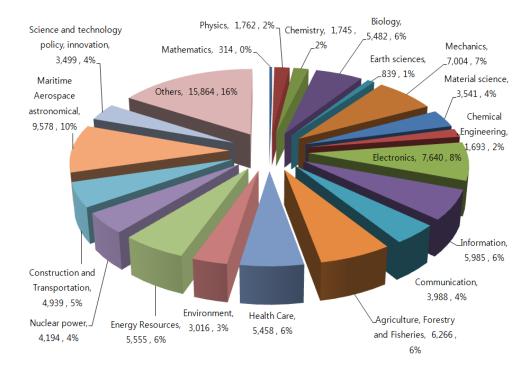


Figure 8. Investment Amount Ratio per Economic and Social Goal (2008)

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<sup>15)</sup> The R&D investment of Korea in the health enhancement and health sectors was about 9%, which was relatively smaller than the 40% in the industrial production technology sector. In the case of the US, health R&D accounts for the second largest portion with 22.7% next to defense's 56.7%.

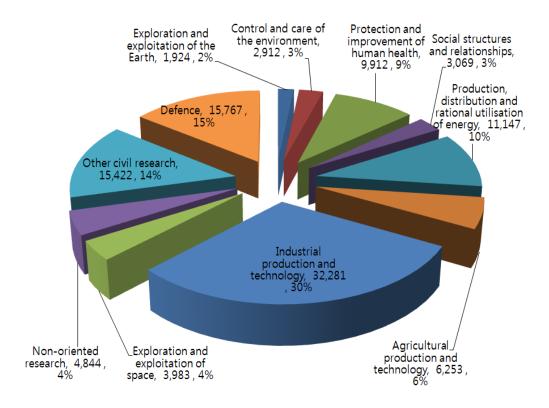
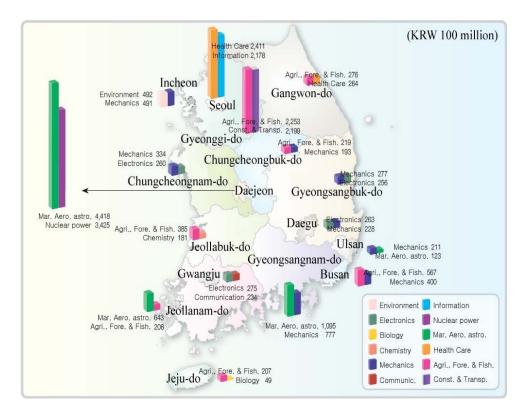


Figure 9. Status of Investment per Science and Technology Standard Classification (2008)

According to the survey results on the research investment of each region in major technology fields (Figure 10), R&D investment in the health sector was concentrated in Seoul; investment in the Gangwon region was one tenth of the investment made in Seoul.



(Source: NTIS Data)

Figure 10. Research Expenses in Major Technology Sectors per Region (2008)

Meanwhile, looking into major countries' HT R&D investment (Table 5), the US invested about KRW 30 trillion, Japan, KRW 3 trillion, and UK, about KRW 2.5 trillion; their investment was about 1.7~20 times larger than the Korean government's investment in health technology R&D. Although investment in the BT sector of Korea has constantly increased, investment in the health sector is still insufficient compared to that of advanced countries.

In the US, Department of Health and Human Services (DHHS), the main department of the US government in charge of the health sector, plays a leading role in the management of HT R&D along with policies on public health and health related industries in connection with clinical trials and clinical research. In Korea, MEST, RDA, MOHW, and MKE have invested 38.5 percent, 19.4 percent, 14.5 percent, and 14.5 percent respectively (Table 4). Note, however, that the investment ratio of MOHW, the ministry in charge of the health sector, was somewhat on the decline from 16.8 percent in 2005 to 14.5 percent in 2007.

Table 5. Health R&D Investment Ratios of the Ministries in Charge of Health of Major Countries

	US	UK	Japan	Korea
Ministry in Charge of Health	Department of Health and Human Services (DHHS, NIH)	Department of Health (DH)	Ministry of Health, Labor, and Welfare (MHLW)	
Health R&D Investment Amount	KRW 30 trillion (2007)	KRW 2.5 trillion (2005)	KRW 3 trillion (2007)	KRW 1.5063 trillion (2007) <sup>16)</sup>
Relevant Ministry's R&D Investment Amount	KRW 29 trillion (2007)	KRW 1.3 trillion (2005)	KRW 1.3 trillion (2007)	KRW 218.5 trillion (2007) <sup>17)</sup>
Relevant Ministry's Investment Amount Ratio	96%	51%	42%	14.5%

<sup>16)</sup> BT budget out of 6Ts

<sup>17)</sup> The investment amount of MOHW excludes KFDA's investment.

### 2. Hospital-based R&D

#### 1) Status and Performances of Hospital R&D Support

To analyze Korean hospitals' current research capacity, this study examines the status of research grants and performances (particularly examines papers, product commercialization cases, technology transfer cases, etc.) supported by MOHW for hospitals (including medical colleges, colleges of dentistry, and colleges of Korean traditional medicine) from MOHW's R&D budget for the past 5 years (2005-2009)<sup>18</sup>).

The hospital-based R&D investment ratio among the total R&D fund of MOHW shows an upward trend from 45 percent in 2005 to 67 percent in 2009. The number of supported projects has also risen as well, with 486 projects or 60 percent of the total projects as of 2009 (Table 6). Hospitals and medical colleges located in Seoul and the Metropolitan Seoul Area received about 80 percent of total R&D grants for hospitals; this data shows the concentration of HT R&D grants by MOHW in the greater Seoul region (Table7). Table 8 shows the project types and grant sizes offered mainly to hospitals in Korea.

<sup>18)</sup> Through NTIS data, the actual size of R&D grants for hospitals cannot be identified. For this reason, this study attempts to find out the entire trend through an analysis of the budget investment status of soley by MOHW. Thus, this analysis does not include R&D grants from the other ministries.

Table 6. Support for Hospital R&D (2005-2009)

(unit: KRW million)

Cat	tegory	2005	2006	2007	2008	2009
Health R&D	Subsidy amount	103,297	123,197	92,750	144,717	185,892
support	Number of projects	422	473	242	597	806
Hospital*	Subsidy amount	45,980	63,529	63,516	83,918	122,294
subsidy amount	Number of projects	171	238	137	344	486
Datia	Subsidy amount	45%	52%	62%	60%	67%
Ratio	Number of projects	41%	50%	57%	58%	60%

<sup>\*</sup> Subsidies to hospitals include colleges of medicine, dentistry, and traditional medicine.

Table 7. Hospital R&D Grants by Region (2005-2009)

(unit: KRW million)

D	2005		2006		2007		2008		2009	
Region	No. of Cases	Subsidy Amount								
Seoul	113	33,708	161	49,194	96	51,735	225	66,434	331	10,0157
Capital Metropolitan Area <sup>19</sup> ) except Seoul	13	3,100	15	2,992	11	3,062	28	3,090	42	4,808
The Other Province	45	9,172	62	11,343	30	8,719	91	14,394	113	17,329
Total	171	45,980	238	63,529	137	63,516	344	83,918	486	122,294

<sup>19)</sup> Gyeonggi, Incheon, Daejeon

Table 8. HT R&D Funds Status Per Major Project (2005-2009)

(unit: KRW million)

	2005			2006		2007		2008			2009				
Category	No. of Cases	Subsidy	Ratio												
Clinical research infra.(KONECT,. Clinical Research)	14	10,345	22%	18	14,487	23%	17	19,166	30%	19	17,732	21%	33	32,507	27%
Translational research (rare diseases, biotechnology)	79	6,868	15%	158	10,198	16%	77	4,562	7%	285	24,014	29%	391	32,863	27%
Leading Research-based Hospitals (leading type /hospital specialization)				2	8,000	13%	2	9,000	14%	8	20,481	24%	7	24,333	20%
Medical Genomics	16	10,787	23%	16	10,977	17%	16	11,472	18%	9	6,550	8%	13	9,850	8%
Health Info.	1	2,170	5%	5	5,249	8%	5	5,824	9%	2	987	1%	6	5,160	4%
Medical Device <sup>20)</sup>	5	3,515	8%	8	3,900	6%	7	3,845	6%	4	1,472	2%	6	2,384	2%
New Drug <sup>21)</sup>	3	2,884	6%	3	2,625	4%	3	2,920	5%	4	2,845	3%	4	2,807	2%
Bio Organ	1	3,535	8%	1	3,716	6%	1	3,699	6%	1	3,370	4%	1	3,370	3%
Bio Chip	2	1,700	4%	2	1,876	3%	2	1,408	2%	2	1,276	2%	2	1,212	1%
Others	50	4,176	9%	25	2,501	4%	7	1,620	3%	10	5,191	6%	23	7,808	6%
Total	171	45,980	100 %	238	63529	100 %	137	63,516	100 %	344	83,918	100 %	486	122,294	100 %

<sup>20)</sup> Mostly company-targeted projects as a commercialization project

<sup>21)</sup> Mostly company-targeted projects as a commercialization project

Looking into the performances of hospital-based R&D funded by MOHW (Table 9), the number of papers are higher than R&D programs not funded to ultimately serve hospitals (considering that only 45 percent of HT R&D has been invested into hospitals, 59 percent of papers produced by hospital-based R&D projects); however, the number of patents and product commercialization show comparatively lower result. Maybe, the reason for this lower achievement of reaching patent attainment and commercialization is that R&D these projects aiming for commercialization mostly support pharmaceuticals or medical equipment companies. For patents and technology transfer, however, the interests of hospital researchers or hospital-based technology transfer organizations (TTOs) are estimated to be insufficient so far. The fact that paper achievements of hospitals are far more excellent than non-hospital institutions implies that the R&D potential of hospitals has already matured to some degree. Moreover, in the future, if proper support is offered for the insufficient parts, hospital R&D potential can be upgrade rapidly to an innovative level in order to boost HT-based industries in Korea.

Table 9. R&D Achievements per Hospital (2005-2009)

			Paper			Patent	tent Commercialization		ion	Tech	
		SCI	Non SCI	Total	Appli- cation	Regist- ration	Total	Devt. Com- pleted	Product Launch ed	Total	Tran sfer
Health R&D	A chieve- ments	7,659	3,109	10,768	2,182	1,017	3,199	284	209	493	
Hospital	A chieve- ments	4,791	1,573	6,364	812	427	1,239	80	8	88	31
R&D	Ratio	62%	50%	59%	37%	42%	39%	28%	4%	18%	

#### 2) Major Hospital-based R&D Projects

#### (a) Promotion of Research-based Hospitals

RBHs equipped with an optimal research environment and core research capacity have been promoted and supported since 2006. This promotion and support is a result of two shifts in priority: placing importance on R&D aimed at improving productivity and technological exchanges through building up a tripartite partnership among industry-academe-research, an associated Medi-cluster and open innovation networks based in hospitals.

The first clinical application-feasible translational research is being subsidized through cooperative research between basic researchers and clinical medical doctors. The goal is to apply basic research achievements and ideas drawn from clinical experiments to industrialization or clinical application. The system for shaping the research environment is improving within hospitals, such as hiring exclusively research-committed professors and gaining support for research activity from clinical doctors. Furthermore, the hospital's infrastructure assists the establishment of RBHs including support for an independent research space within hospitals, research personnel expansion, and bureau establishment within medical institutions.

Since Seoul National University (SNU) Hospital and Asan Medical Center were launched as innovative research-based hospitals with KRW 4 billion in investment in 2006, they were categorized as leading RBHs and hospital specialization research centers when there was a measure to expand

research-based hospitals in 2008. By 2009, 5 leading research-based hospitals<sup>22)</sup> and 7 hospital specialization research centers<sup>23)</sup> have been designated and supported by MOHW.

Table 10. Support for Hospital-based R&D Projects

Category	Project Name	Research Institute	Research Duration (Y/M)	Cumulative Total of Government Subsidy(KRW million)
	Innovative cancer research-based hospital through new functional anticancer medication development	ASAN Medical Center	2006.12- 2011.11	17,600
Leading	Development of a cutting-edge cell treatment method of the next generation	Seoul National University Hospital	2006.12- 2011.11	17,400
research- based	Brain/Cardiovascular Disease Conversion Research Organization	Severance Hospital	2008.12- 2013.11	9,000
hospital –	Open, research-based hospital for bio new drug development for intractable cancer treatment	Samsung Medical Center	2009.12- 2014.11	4,500
	Immune Disease Conversion Research Organization	Seoul St. Mary's Hospital	2009.12- 2014.11	4,500
	New-concept treatment drug development for intractable lung damage	Chonbuk National University Hospital	2008.11- 2013.3	1.416
	Treatment technology development for step-by-step problem-solving for burns	Hallym University Medical Center	2008.11- 2013.3	1.416
Hospital	Treatment Technology Development Specialization Center for Heart Disease	Chonnam National University Hospital	2008.11- 2013.3	1.416
specialization research center	Research-oriented Sterility Treatment Specialization Hospital	CHA Hospital	2008.11- 2013.3	1.416
	Urogenital Disease Specialization Research Center	Chung-Ang University Hospital	2008.12- 2013.3	1.317
	Osteoarthritis Specialization Center	Ajou University Hospital	2009.5- 2014.3	916
	Cholangiohepatitis Specialization Hospital Specialization Research Center	Yangsan Pusan National University Hospital	2009.5- 2014.3	917

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<sup>22)</sup> Supporting within the limit of KRW 4.5 billion annually up to 5 years (2+3 yrs.)

<sup>23)</sup> Supporting within the limit of KRW 1.0 billion up to 5 years (2+3 yrs.)

#### (b) Formation of Clinical Research Network

This project was launched in an effort to carry out the following objectives: to establish evidence-based medicine suitable for Korean including the expansion of a clinical research base, which is weak in Korea, and the establishment of standard practice guidelines; to develop clinical methods befitting Koreans' characteristics by securing scientific evidence for medical technology efficacy, enhancement of people's health, and improvement of the quality of medical services; to address the most urgent and long-term problems in each disease group through evidence that was created through clinical To establish standard clinical practice guidelines, clinical research research. centers (CRCs)<sup>24)</sup> for each disease have been supported since 2004. This way, the base has been established for clinical R&D support, academic activities, and information network development and clinical trial unit.

Aside from disseminating clinical research achievements, reflective individual clinical research demands more information beyond disease-oriented, top-down support; clinical research support center (CRSC)<sup>25)</sup> and advanced medical technology R&D based on evidence creation<sup>26)</sup> were established in 2008 and have been supported ever since (Table 11).

<sup>24)</sup> Limited to KRW 700 million annually/support up to 6 years(3+3 yrs.) or 9 years

<sup>25)</sup> Limited to KRW 700 million annually/support up to 6 years(3+3 years.)

<sup>26)</sup> Limited to KRW 60 million annually/support up to 2 years

Table 11. Support for Clinical Research Network

Support Field	Details
Clinical Research Center (CRC)	<ul> <li>■ Create a foundation through clinical research to solve the most urgent and long-term problems by disease group; establish standard DT guidelines based on such.</li> <li>- clinical research support (R&amp;D support)</li> <li>- academic activation (academic activity)</li> <li>- infomation network development (networks)</li> <li>- clinical trial (clinical trial unit)</li> </ul>
Clinical Research Support Center (CRSC)	<ul> <li>IIT (Investigator-Initiated Trial) support</li> <li>adjustment of CRSC's research direction support for research, collection of patient data, registration of diseases</li> <li>CPG (Clinical Practice Guideline) support</li> <li>develop and supplement clinical practice guidelines through organic cooperation with individual CRCs.</li> <li>authorize, educate, distribute, and publicize through the relevant academic societies.</li> <li>organize symposiums of CRC through the clinical research council</li> </ul>
Evidence Creation/ R&D of Advanced Medical Technologies	<ul> <li>Research-creating evidence by clinically applying at the DT site to verify medical technologies' efficacies and effects</li> <li>Research-examining efficacies and effects of medical technologies whose safety and validity have been ensured</li> <li>Patient's DT result change research and extent calculation after using the medical technology in question</li> <li>Prepare for policy measures to utilize scientific clinical research results and establish the means of using them in connection with the existing systems.</li> </ul>

The clinical research centers for each disease have been carrying out clinical research for 11 diseases such as cancers and respiratory and circulatory organ diseases (Table 12). Advanced medical technology R&D based on evidence creation supports 10-20 projects annually and ensures the development of new medical technologies. To enhance the efficiency of clinical research projects by coordinating and integrating all projects beginning in 2010, the existing clinical research (support) centers have been consolidated and converted into a type of project organization<sup>27)</sup> like the Korea National Enterprise for Clinical Trials (KONECT).

Table 12. Status of Support for Clinical Research Centers

Center Name	Research Institute	Selection Year	Cumulative Total of Govt. Subsidy (KRW million)
Adult Solid Cancer Treatment Clinical Research Center (CRC)	National Cancer Center	2004	2,785
Ischemic Heart Disease CRC	Asan Medical Center	2004	3,004
Chronic Obstructive Airway Diseases CRC	Asan Medical Center	2004	3,003
Hepatic Cirrhosis CRC	Severance Hospital	2005	2,478
Diabetes 2 CRC	Kyung Hee Medical Center	2005	2,618
Depression CRC	St. Mary's Hospital	2005	2,610
Stroke CRC	Seoul National University Hospital	2006	2,006
Senile Dementia CRC	Samsung Medical Center	2005	2,136
Terminal Renal Failure CRC	Kyungpook National University Hospital	2008	700
Antimicrobial Adequate Use CRC	Samsung Medical Center	2008	700
Rheumatoid Arthritis CRC	Hanyang University Medical Center	2008	700
Clinical Research Support Center	Korea Centers for Disease Control and Prevention	2008	700

<sup>27)</sup> National Strategic Coordinating Center for Clinical Research (NSCR)

#### (c) Korea National Enterprise for Clinical Trials (KONECT)

The project to support regional clinical trials centers by establishing clinical trials facilities, equipment, human resources, and technologies at the level of advanced countries was launched in 2004 for the following purposes: to lay down the foundation of the advanced medical industry for health and medical service development, to become a hub of world-class clinical trials and to consolidate international competitiveness for the pharmaceutical industry. For the maximization of the project's efficiency and synergy effect, the project had been converted into KONECT in 2007.

KONECT subsidizes regional clinical trials centers for major regions, builds clinical trials center facilities and equipment, develops base technology for clinical trials, and conducts clinical trials at the level of advanced countries. Furthermore, KONECT fosters professionals to manage the centers and develops clinical trials technologies (Table 13).

Table 13. Contents of Support for KONECT

	Govt. Contribution			
Category	1st phase (2007.11 ~ 2009.3)	2nd phase (2009.4 ~ 2010.5)	Remarks	
Regional clinical trial center	9,400	8,932	14 centers	
Fostering clinical trial specialists	4,400	3,980	20 detailed projects	
Developing clinical trial technology	3,000	3,065	20 detailed projects	
Total	16,800	15,977	Support for a total of 54 projects	

#### (d) Medical Device Clinical Trial Center

The medical device industry is a growth engine for the next generation with huge potentiality. Along with the increase in the aged population, Koreans have a growing sense of interest in the quality of life, constant augmentation of clinical trial demand for new medical equipment development because Korea's infrastructure related to medical device clinical trials (essential in the validation of the safety and effectiveness of new technology and products) is weak. In this context, the consolidation of clinical trial capacity of medical device is urgently needed.

Due to the obstacle of clinical trials in the development process and in receiving permission, product commercialization is delayed. Otherwise, the lack of scientification and insufficient competitiveness would work as a critical hindering factor in entering domestic or foreign markets.

Five medical device clinical trials centers have been selected and supported to establish medical device clinical trials at the level of advanced countries for the development and competitiveness consolidation of the industry since 2008 (Table 14).

#### (e) Disease-Oriented Translational Research<sup>28)</sup>

Disease-oriented translational research is supported to improve the diagnosis, treatment, and prevention technologies of diseases through creative disease-oriented and patient-oriented research.

<sup>28)</sup> Disease-Oriented Translational Research (DOTR) aims at clinically applying the concepts, knowledge, and technologies identified through basic science research to diagnosis, treatment, and prevention of the relevant diseases and damages. (Academic Medicine, 1996)

Table 14. Support for Medical Device Clinical Trial Center

Center	Research Institution	Selection Year	Cumulative Total of Govt. Subsidy (KRW million)
Medical Device Clinical Trials Center	Severance Hospital	2008	2,307
Establishment and Operation of Medical Device Clinical Trial Center at the Level of Advanced Countries thru Consortium	Samsung Medical Center	2008	2,308
Medical Device Clinical Trials Center (Yeungnam University)	Yeungnam University Medical Center	2008	2,308
Medical Device Clinical Trials Center (Korea University)	Korea University Guro Hospital	2009	917
Establishment of Medical Device Clinical Trials Center and Clinical Trials Support	Chonbuk National University Hospital	2009	917

The scope of translational research is presented as follows: research to examine the biological effects of therapeutics among patients; research to examine the biology and natural history of disease and to lay down the scientific foundation for developing new technologies (diagnosis, treatment, prevention) for diseases; research to study principles and rules for the development of DT technology of diseases and their application to non-clinical and clinical models of relevant diseases; research to develop translational research (*i.e.* molecular biological analysis method, imaging technology, drug, biological medication and methodology for prevention, early detection, diagnosis, prognosis and treatment of diseases) and review clinical feasibility;

and research to lay down the biological foundation on the phenomena observed in patients or disease risk groups. Translational research using HT is funded in four types depending on the research objects and goals for 13 diseases.

Table 15. Support for Disease-Oriented Translational Research

Category	Support Details	Object	Subsidy Size
Fostering translational researchers (STEP 0)	Translational research capacity consolidation of new researchers	New researchers	KRW 35 million annually /within a year
Exclusive translational research (STEP   )	Research to discover new clinical phenomena from the research studies or patients (or disease risk groups) using cytological, structural, biochemical, genetic, or appropriate experimental approaches to identify new biological principles or mechanisms for disease-related translational technology development	Individual researchers	KRW 60 million annually /within 2 years
Cooperative translational research (STEP 11)	Research to identify the biological principles or mechanisms of new clinical phenomena found from research studies that develop disease- related translational technology and verify clinical feasibility based on new biological knowledge or clinical phenomena or from patients (or disease risk groups)	Cooperative research between clinical doctors and basic scientists	KRW 200 million annually /within 2 years
Translational research center (STEP III)	Development and clinical application research of new disease-related translational technology	Joint research by a research team composed of 3-4 members	KRW 500 million annually /within 4 years (2+2 yrs.)

# (f) Medical Genomics

Table 16 shows the government support for medical genomics. The genome research centers for each disease have been carrying out genomic research projects for 12 diseases.

Table 16. Support for Medical Genomics

Center Name	Research Institution	Selection Year	Cumulative Total of Govt. Subsidy (KRW million)
Cardiovascular Genome Research Center (GRC)	Severance Hospital	2000	5,053
Neuro-degenerative Disorders GRC	Catholic University St. Mary's Hospital	2000	4,301
Diabetes and Endocrine Disease GRC	SNU Hospital	2000	5,332
Lung and Respiratory Disease GRC	Soonchunhyang Bucheon Hospital	2001	5,116
Lung Cancer, Breast Cancer, and Ovarian Cancer GRC	Korea University Anam Hospital	2001	4,600
Immune Disorder GRC	Wonkwang University Medical Center	2001	4,422
Musculoskeletal System Disorder GRC	Kyungpook National University Hospital	2001	4,961
Cutaneous Disorder GRC	Samsung Medical Center	2001	4,586
Liver and Digestive System GRC	Ajou University Hospital	2001	3,663
Sterility and Genital Disorder GRC	CHA Hospital	2001	3,863
Hematopoietic Disease GRC	Chonnam National University Hospital	2001	4,366
Anomaly and Prenatal Disease GRC	ASAN Medical Center	2001	4,259
Korea Pharmacogenomics Research Network	SNU College of Medicine	2003	18,865
Skin Infectious Bacteria GRC*	SNU College of Medicine	2001	4,174
Intestine Infectious Bacteria GRC*	Chonnam National University	2001	4,271
Respiratory Organ Infectious Bacteria GRC*	Yonsei University	2001	4,322

By intensively supporting research centers that research specific disease groups, research centers located in university-affiliated hospitals equipped with research capability in the human genome field, this project seeks to improve the genome research level, to foster specialized personnel, and to develop those hospitals as specialized clinical trial institutions.

The diverse types of genome research have been performed according to the individual disease, technique and cause of disease. The genome research is categorized as the dynamics research of disease genome, research on pursuing disease-related genes and Korean-specific genes along with searching for functions of genes and the genetic research for family disease.

# 3. Cost-effectiveness Analysis of Hospital-based Health Technology R&D

To examine more specifically the status of HT R&D programs in hospitals in Korea, this study classifies R&D grants from MOHW for the past 3 years (2007~2009) when data was available based on the actual amount spent by hospitals<sup>29)</sup> (Table 17). Likewise, the produced papers, patents, product commercialization, and technology transfer cases have been investigated.

For the past three years, a total of 45 hospitals carried out at least one project, subsidized by MOHW<sup>30</sup>). The difference in research subsidies was a whopping 2.5 times that figure with KRW 63.8 billion as the largest subsidy given to a hospital for the past 3 years followed by KRW 26.0 billion. Five medical institutions received more than KRW 20 billion in subsidies for the past three years. At least 23 medical institutions were located in provincial areas. Of these provincial hospitals, the largest subsidy was KRW 8 billion over the past three years.

29) By analyzing which hospitals spent research subsidies per detailed project of a main project, the actually used research subsidies were examined for each hospital. In this survey table, however, only serial numbers were written, not the actual hospital names.

<sup>30)</sup> The college of medicine and the hospital are classified into the same university (or hospital; the Catholic University of Daegu is separately classified, however).

Table 17. R&D Support per Hospital (2007-2009)

(unit: KRW million)

	2007		2008		2009		Total	
University Hospitals <sup>31)</sup>	No. of Cases	Subsidy Amount						
A	109	19,461	126	17,231	208	27,141	443	63,834
В	44	6,485	60	7,589	102	11,977	206	26,051
С	31	6,418	51	6,143	75	9,203	157	21,763
D	35	6,899	35	4,057	65	10,432	135	21,388
Е	26	3,820	53	5,316	90	11,178	169	20,308
F	14	2,660	18	1,467	36	3,990	68	8,117
G	18	2,303	22	1,749	28	3,740	68	7,792
Н	14	3,035	15	1,922	20	2,165	49	7,121
I	14	2,470	16	1,035	24	2,938	54	6,442
J	7	2,039	9	1,690	13	1,917	29	5,646
K	6	1,617	9	1,054	17	2,771	32	5,442
L	10	1,754	7	867	15	1,837	32	4,458
M	7	891	16	2,533	11	934	34	4,358
N	6	689	11	1,066	16	1,639	33	3,394
О	4	1,220	5	320	10	1,735	19	3,275
P	4	720	9	1,642	8	566	21	2,928
Q	1	128	9	765	13	1,872	23	2,765
R	2	255	7	1,586	6	474	15	2,314
S	4	568	3	424	9	1,215	16	2,206
Т	4	462	6	727	9	911	19	2,100
U	3	286	11	783	14	945	28	2,013
V	4	480	9	802	8	619	21	1,901
W	3	240	8	706	9	881	20	1,827

X	6	618	8	908	14	1,271	28	2,797
Y	4	609	3	584	3	608	10	1,801
Z	3	566	3	588	3	588	9	1,742
AA		-	1	41	5	1,134	6	1,175
AB	1	200	4	450	6	440	11	1,090
AC	1	57	2	366	3	588	6	1,011
AD	2	160	5	518	5	304	12	982
AE	1	383		-	1	415	2	798
AF		-	8	394	6	349	14	743
AG		-	3	145	4	394	7	539
АН	2	95	3	190	3	220	8	505
AI	1	60	3	160	4	270	8	490
AJ	1	100	4	274	1	70	6	444
Ak		-	1	160	1	222	2	382
Al		-		-	1	200	1	200
AM		-	1	30	3	160	4	190
AN	1	55	1	55	1	60	3	170
AO		-	1	35	1	34	2	69
AP	1	60		-		-	1	60
AQ		-	1	20	1	18	2	38
AR		-	1	35		-	1	35
AS		-		-	1	35	1	35
Total	394	67,862	568	66,426	873	108,454	1,835	242,741

<sup>31)</sup> Including university-affiliated hospitals, colleges of dentistry and colleges of Korean traditional medicine.

Along with the above-mentioned research subsidies, this study analyzes the data of high-level surgery cases generated by HIRA (HIRA, 2008)<sup>32)</sup> and examines the data in combination with the R&D subsidies of each hospital. By analyzing the research subsidy size per major hospital and high-level surgery cases in combination, this paper indirectly examines the correlations between R&D investments and quality level of medical technologies. The analysis results are shown in Figure 11.

In Group A,<sup>33)</sup> there are five medical institutions - Seoul National University(SNU), Yonsei University, ASAN Medical Center, The Catholic University of Korea, and Seoul Samsung Medical Center. The research subsidies for these institutions were the largest for the past 3 years, and their technologies were the best. Figure 12 shows the comparison of these institutions' research performances and research investment size for the past 3 years. The average research investment of the five institutions was KRW 30.7 billion, and SCI papers numbered 2 per KRW 100 million. An average of four cases was recorded in terms of technology transfer.

At least 13 hospitals belonged to Group B, and they held 3-4 technologies; the largest research subsidy was KRW 8.1 billion, with the largest subsidy recipient a provincial hospital holding all 4 technologies.

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<sup>32)</sup> Survey-targeted operation types in 2008: 7 operations such as PCI, CABG, hip joint partial substitution surgery, stomach cancer operation, esophageal cancer, pancreatic surgery, stem cell transplant surgery; of these, PCI and hip joint partial substitution surgery and stem cell transplant surgery have been excluded from the analysis objects in this paper. \*2008 DT volume indicator evaluation results (See website of the Health Insurance Review & Assessment Service)

<sup>33)</sup> Names of Group A hospitals have been disclosed. Other hospitals remain anonymous.

Meanwhile, two hospitals did not receive any research subsidy. A total of 26 hospitals belonged to Group C, and they held 1-2 technologies. The largest research subsidy was KRW 5.6 billion, and 5 institutions did not receive any subsidy.

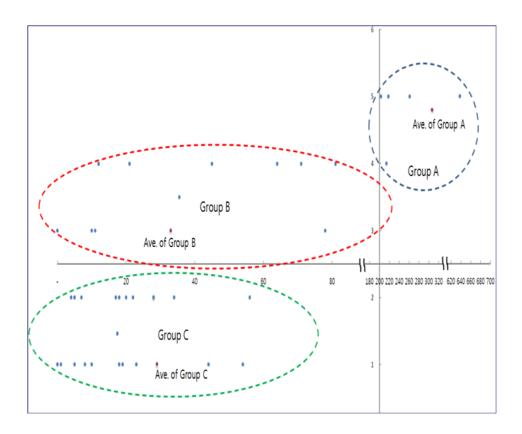


Figure 11. Comparison of Medical Technology Levels in Terms of Research Subsidy Size

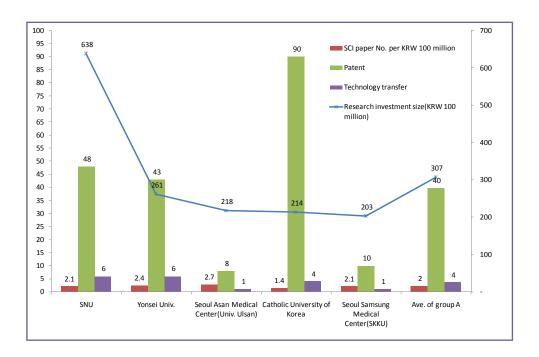


Figure 12. Research Subsidy of Five Institutions in Group A and their Performance Analysis

In an effort to compare research efficiency among these three groups, this paper compares each item's average of each group; the results are shown in Figure 13. Generally, hospitals whose R&D subsidies are larger have higher medical technology level. Although some medical institutions that did not receive any subsidies for projects over the past 3 years, they had 1-3 excellent surgery cases.

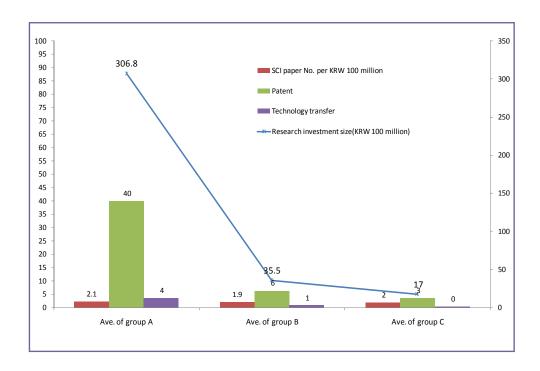


Figure 13. Comparison of Performances of Groups A, B, and C

# **Ⅲ.** Issues on the Achievement of Research-based Hospitals in Korea

# 1. Survey Result Analysis

#### 1) Survey on the Research-based Hospital Model in Korea

#### (a) Survey through the Delphi Method

Based on interviews with researchers, relevant experts, CEOs of hospitals, reporters and relevant government officials, a set of questionnaires was developed (Appendix). This questionnaire was circulated to 30 panelists who were selected among leaders of major Health Technology R&D projects, CEOs of major hospitals, prominent researchers, and government officials. For this survey, the Delphi method is used (Kwon *et al.*, 2004).

#### (b) Result Analysis

## (a) Perspectives on the Current Role of Major Hospitals in HT R&D

Overall, a large number of panelists (63%) answered that several hospitals are taking a major role in health technology R&D in Korea, whereas thirty-seven percent of panelists answered that roles of major hospitals are not sufficient in HT R&D despite the meaningful development in this field.

Table 18. Recognition on the Current Role of Hospitals in HT R&D

Answers		
Several hospitals are taking major role in HT R&D	63%	
Improved, but still insufficient	37%	

Many of the panelists (48%) saw that several major hospitals with R&D capability could connect basic research and industrialization through translational research. Also, thirty-seven percent of panelists answered that these hospitals could lead health industries and yield economic values. These answers show that, at least, several hospitals in Korea could advance the health industry, especially through translational research.

Table 19. Potential area by competent hospitals in Korea to contribute for HT R&D development

answers	percent
Link basic research and commercialization through translational research	48%
Lead HT industry with increased economic value	37%
Develop clinical trial and clinical research	11%
Develop and evaluate new HT, drug and medical equipment	4%

#### **(b)** Major Barriers for Research-based Hospitals

The following is a list of significant answers for crucial barriers of becoming RBHs with suitable competence: lack of commitment from CEOs, lack of time for research due to the excessive burden of clinical work, and insufficient supply of R&D fund. From the perspective of CEOs of hospitals, major hospitals are surveyed as follows: the uncertainty of outcomes from R&D investment (41%), evaluation system based on short-term performance for CEOs (31%), and financial restriction by insufficient reimbursement for the Nationa Health Insurance (15%).

Significant barriers for devoting medical doctors in hospitals to R&D are listed as follows: medical service dominant hospital management and revenue-driven policy of CEOs (37%), inadequate incentive for R&D (24%), and lack of time for research due to the overwhelming burden of medical treatment and teaching (22%).

Also, the replies of non-medical hospital staff to the question regarding the major barriers to becoming research-oriented hospitals are as follows: a lack of recognition by both hospital and staff members of the value of R&D in terms of revenue increase (46%), lack of R&D experience (14%), and lack of sufficient R&D funds (14%).

From the perspective of the health industry, such as pharmaceutical and medical equipment companies, major barriers are reported as follows: irrational relationship between hospitals and companies such as illegal rebate practice between medical doctors and pharmaceutical companies (30%), prematurity of related companies, such as insufficient investment capacity and lack of R&D experience (26%); and deficiency of mutual trust and collaboration experience (12%).

Table 20. Major Barriers to Becoming Research-based Hospitals with Suitable Competence

Answers	Percent
Lack of recognition of CEOs of hospitals on the value of R&D	28%
Limited time for R&D due to overwhelming burden of medical service provision	24%
Insufficient R&D resource including fund/space/equipment	22%
Poor human resources of research and research support in hospitals	11%
Insufficient incentive system for researchers	9%
Absence of long-term R&D visionary plan and strategy in hospitals	4%
Lack of communication between scientists and physicians	2%

Table 21. Significant Factors Generating Crucial Barriers to Becoming Research-based Hospitals

Danling	Significant factors generating crucial barriers				
Replies	Answers				
	Uncertainty of outcomes from R&D investment	41%			
	Short-term based evaluation for CEOs	31%			
CEOs	Financial restriction by insufficient reimbursement from the NHI	15%			
	Insufficient resources (funds and space, etc)				
	Lack of recognition of R&D value	6%			
	etc.	2%			
	Medical service dominant hospital management and revenue-driven policy of CEOs	37%			
Medical doctors	Inadequate rewards (salary, promotion, etc) for R&D	24%			
	Lack of time for R&D due to overwhelming burden of medical service provision and education	22%			

	Insufficient research human resources		
etc.			
	Insufficient recognition of the value of R&D in terms of revenue increasement both of hospital and staff members		
Non-medical	Lack of R&D experience	14%	
staff members	Lack of sufficient R&D fund	14%	
in hospitals	Recognition that little rewards will be given to non-medical staff	12%	
	etc.	14%	
	Irrational relationship between hospitals and companies (illegal rebate practice)	30%	
	Prematurity of related companies (insufficient investment capacity, lack of R&D experience)	26%	
	Deficiency of mutual trust and collaboration experience		
Health industry	Lack of experts and TTOs to connect hospitals with industries		
	Medical service dominant hospital culture		
	Regulation of NHI and related law	6%	
	etc.	6%	

# © Issues with Hospital Systems in Promoting Hospital-based R&D

Regarding government R&D grants, the following changes are instituted for effective performance: allowance for long-term projects (35%); financial, legal and institutional assistance for R&D investment by hospitals (20%); and increased R&D grants from the government (17%). Regarding R&D overhead cost policy, the following is reported to be revised: allowance for using R&D grant for personal expense (36%); increase of overhead cost ratio (30%); and introduction of compulsory regulation of using certain portion of overhead cost directly for research (17%). In terms of crucial regulations

hindering hospital-based research, the following is listed: excessive regulation on usage of R&D grant (37%); inefficient services by the Korean Food and Drug Administration for clinical trial approval (17%); and prohibition of establishing for-profit organizations by major hospitals (13%); along with relevant regulations of bioethics, health insurance, etc. (13%).

Table 22. Systematic Issues for Promoting Hospital-based R&D

T	Most urgently required for an effective performance		
Issues	Answers	Percent	
	Allowance for long-term projects	35%	
	Financial, legal and institutional assistance for R&D investment by hospitals	20%	
	Increased government R&D grants	17%	
Government R&D Management	Government grants for setting up R&D system of a whole hospital	15%	
	Support hospitals according to their individual needs rather than a unified support model	5%	
	Correct and reasonable evaluation of R&D performance	4%	
	etc.	4%	
	Allowance for using R&D grant for personnel expenses	36%	
	Increase R&D overhead cost ratio	30%	
R&D overhead cost policy	Introduction of compulsory regulation of using certain portion of overhead cost directly for research	17%	
	Differentiated overhead cost ratio according to characteristics of each R&D project	14%	
	No change is required	3%	

	Excessive regulation on usage of R&D grants	37%
	Inefficient services by KFDA for clinical trial approval	17%
Pagulation	Insufficient tax exemption for R&D investment of hospitals	13%
Regulation	Excessive legal regulation including NHI, bioethics, etc.	13%
	Prohibition of establishment of company by major hospitals	9%
	etc.	11%

#### d Issues on Infrastructure Refinement

The survey shows that the following is required in the area of hardware for promoting hospital-based R&D: sufficient space for R&D including rooms for administrative services (53%); clinical trial facilities for animal testing (15%); and biobank system for blood and tissues (12%). In addition, the following items for human capital reinforcement are summarized: recruiting competent researchers (29%); financial assistance (23%); and recruiting research assistants and technicians (20%).

Considering an incentive system for clinical physicians devoting themselves to research, reinforced incentives for research (including income, job stability, promotion, etc.) is most significant (44%), followed by revised income calculation system, which guarantees at least the same income level for researchers (mainly, medical doctors) with less medical treatment service

provision due to research (30%), and a portion of R&D grants for the researcher's own salary (16%). For accelerating health technology R&D based in hospitals, the following is identified as critical factors in the area of industrial cooperation supporting organization for hospital researchers: recruitment of experts in intellectual property and international technical trend information (37%); establishment of a hospital-based independent industrial cooperation supporting organization from medical schools such as the Technology Transfer Organization, or the TTO (26%); and administrative support staff for researchers (17%).

Table 23. Issues on Infrastructure Refinement

Issues	Most urgently required for encouraging R&D in hospitals		
Issues	answers		
	Sufficient space for R&D	53%	
	Pre-clinical research facility (for animal trial)	15%	
Hardware of	Bio bank of blood, tissues, etc	12%	
Hardware of Hospitals	Lab. facility for gene research, etc	9%	
	Equipments for joint use	6%	
	Clinical trial facilities	6%	
	Recruitment of competent researchers	29%	
	Financial support of recruitment		
Human Resources	More R&D assistant staff	20%	
	Increase job security and salary	15%	
	Establishment of independent R&D organization with administrative staffs	12%	

	Reinforced incentives for researchers (including income, job stability, promotion, etc)	44%	
	Revised income calculation method (guarantee the same income for researchers with less medical service provision due to R&D)		
Incentive System	Allowance of spending a portion of R&D grant for researcher's own salary		
	Allowance of spending a portion of R&D grant for improving R&D facilities	6%	
	Acceptance of overall outcome of R&D instead of counting number of papers, patents, etc.	4%	
	Recruitment of experts (especially on IP, international technical information, etc)	37%	
	Independent TTO within hospitals	26%	
TTOs	Capacity building of TTO in supporting commercialization		
	Adoption of mandatory re-investment policy of R&D profit on further R&D	15%	
	etc.	6%	

# (e) Issues on Human Resources in Hospitals

The panelists indicated that the following kinds of human resources are most necessary for incubating research-based hospitals in Korea: qualified researchers with doctoral degrees (39%), scientists with the capacity for collaboration with medical doctors (26%), and clinical trial and clinical research experts including coordinators and clinical nurses (18%). Also, the following human resources are identified as critical requirements to be trained by the government for successful establishing research-based hospitals: medical doctors with research capability (37%); qualified researchers for bridging basic study and clinical application (30%); and scientists with the capacity for collaborating with medical doctors (22%).

With regards to the education system, medical colleges and schools with capacity-building to become research-based hospitals, a joint program of medical and scientific curriculum (Joint program of M.D. and Ph.D.) is identified as a key factor by the panelists (28%), followed by strengthening research-related subjects in the medical college curriculum (20%); and total reform of medical schools in the direction of research orientation (15%). For non-medical schools and colleges, the following changes are recognized for the successful establishment of RBHs in Korea: introduction of co-education program for basic science departments with medical colleges (42%); expansion of opportunities for cooperation between medical doctors and basic scientists at universities (24%); and enhancing job security of scientists and technicians hired by medical colleges and research centers (17%).

Table 24. Issues on Human Resources in Hospitals

Issues	Answeis		
	Researchers with more than doctoral degrees	39%	
Which human	Basic scientists to cooperate with physicians in R&D	26%	
resource is most required for RBH?	Clinical research experts (coordinator, clinical nurse, etc)	18%	
	Experts to lead planning of R&D projects, IP, license, etc	8%	
	etc.	10%	
Which human	MD with research capacity	37%	
resource is required to be trained by the government for RBH?	Qualified researchers for bridging basic study and clinical application	30%	
	Scientists with capacity of collaborating with MDs	22%	
	etc.	12%	

	Introduction of joint program of MD and PhD	
	Strengthening research related subjects in the curriculum of medical colleges	
The most suitable	Total reform of medical schools in the direction of research orientation	15%
change in the system of medical schools	Introduction of research leave for clinical research physicians	13%
Schools	Improved treatment for scientists	
	Allowance of incentive for military service to hospital-based researchers	7%
	etc.	8%
	Introduction of co-education programs for basic science departments with medical colleges	42%
The most suitable change in the system of non-medical schools and colleges	Expansion of cooperation opportunity between medical doctors and basic scientists at universities	24%
	Enhancing job security of scientists and technicians hired by medical colleges and research centers	17%
	Opening of special courses on required expertise by hospital-based researches	15%
	etc.	2%

# (f) Government Policy Issues Concening the Support of RBHs

Regarding economic incentives from the government for fostering research-based hospitals (RBH), two main responses were (i) additional incentives, i.e. reimbursement from the National Health Insurance (43%) and (ii) enhancing R&D grants from the government along with long-term infrastructure investment for qualified hospitals. In addition, suggested incentives for human resources include allowing military service substitution for researchers and introducing a government-certified researcher program (14%).

The following answers are regarding the question about serious regulatory barriers for accomplishing RBHs: regulations by NHI including revision of approval systems for new research-based techniques and medicine (72%). Also, the prohibition of establishing a for-profit venture company via research-based hospitals is indicated for revision (16%) along with introduction of a fast track in the KFDA approval procedure for newly developed medicine and equipment (12%).

Table 25. Issues on the Government Policy for Supporting Research-based Hospitals

Issues	Answers	Percent
	Additional incentive by reimbursement of National Health Insurance	43%
Economic Incentives	Enhancing R&D grant of the government with long-term infrastructure investment for the qualified hospitals	40%
	Allowance substitution of military service for researchers	14%
	Adoption of R&D as a criteria of the government accreditation of hospitals	3%
	Revision of approval system for newly developed medical technique, and elaborating pilot-based non-reimbursed system for RBHs	72%
Legal Deregulation	Allowance of venture companies by RBHs	16%
	Fast track approval of KFDA	12%

	Special incentive for outstanding researchers (supporting oversea training programs, etc)	53%
	Regular accreditation for RBHs	32%
The other Supportive Measures	Different support system according to R&D investment amount/ratio	7%
	Provision of MD in substitution of military service	4%
	Allowance of flexible requirement of staffs for RBHs	4%

# 2. Case Studies on Advanced Research-based Hospitals of Other Countries

## 1) M. D. Anderson Cancer Center (MDACC)

The University of Texas M. D. Anderson Cancer Center was created by an act of the Texas Legislature in 1941. It is a component of The Texas Medical Center which is composed of 49 institutions including 13 hospitals, 2 specialty institutions, 2 medical schools, 4 nursing schools, and schools of dentistry, public health, and pharmacy<sup>34</sup>). MDACC is world-renowned hospital that specializes in cancer care, treatment and research. *US News & World Report's* "America's Best Hospitals" survey has ranked MDACC the nation in cancer care for six of the past eight years<sup>35</sup>). In 2009, MDACC invited more than 100,000 people, over one-third of them being new patients, who sought high-quality cancer care. Of those patients, more than 11,000 participated in clinical trials exploring novel treatments<sup>36</sup>).

The hospital also conducts innovative health research to rapidly help translate important scientific knowledge gained from the laboratory into clinical care. MDACC is designated as one of the nation's 40 Comprehensive Cancer Centers by the National Cancer Institute and it attracts research grant awards—nearly \$510 million including \$111 million from NCI. The research

<sup>34)</sup> http://www.texasmedicalcenter.org

<sup>35)</sup> U.S. News & World Report

<sup>36)</sup> http://www.mdanderson.org

program at MDACC is considered one of the most productive in the world aimed solely at cancer<sup>37</sup>).

Table 26. Performance Change of MDACC (2005-2009)

Clinical Activity	FY05	FY09	% Change
Hospital admissions	20,728	23,277	12%
Hospital patient days	153,615	174,740	14%
Average number of hospital beds	475	507	7%
Outpatient clinic visits, treatments, procedures	831,025	1,055,092	27%
Pathology/laboratory medicine procedures	7,465,264	10,112,244	36%
Diagnostic imaging procedures	384,872	519,150	35%
Surgery hours	50,442	62,587	24%
Total active clinical research protocols	951	1,073	13%

(source: http://www.mdanderson.org)

Although the economic impact of MDACC is not as well known as its cancer treatment and research, it is highly significant. The total annual impact of operations and collateral spending associated with MDACC was estimated to be \$7.3 billion in annual total spending, \$3.8 billion in annual output, and 51,960 permanent jobs. The overall effects of MDACC activity represent approximately 2% of the Houston economy (THE PERRYMAN GROUP, 2009)

<sup>37)</sup> http://www.mdanderson.org

Table 27. MDACC Research Fund

Research Funding	FY05	FY09	% Change
Federal grants and contracts	\$160,953,853	\$194,632,638	21%
Private industry grants and contracts	\$26,766,196	\$43,688,603	63%
Philanthropy and foundations	\$43,062,200	\$83,046,345	93%
Institutional and local funds	\$90,536,075	\$167,219,478	85%
State-appropriated general revenue and tobacco settlement	\$20,660,355	\$21,685,677	5%
Total research funding	\$341,978,679	\$510,272,741	49%

(source: http://www.mdanderson.org)

The exceptional performance of MDACC is based on its research capacity, and the research competitiveness of MDACC is an effect of the thousands of researchers (nearly 1,500 faculty and 1,600 research trainees). Extensive reform to transform MDACC into a RBH started 15 years ago. The main cause of this reform's success was the excellent leadership of the president Mendelsohn. All departments of MDACC shifted towad a research-oriented system under consistent direction by the reform, which eventually led to having world-class research capacity. Ultimately, this reform created a lot of innovative cancer treatments.

Another cause of success is the Dual Career Path System. This system gives physicians who are awarded enough research grants opportunities to select a research career instead of a clinical career. Research career physicians can reduce their clinical work to one-third of the time, leaving the

rest of the time for research. Therefore, many physician-scientists, who are the essential factors of a RBH, have been trained in MDACC.

The third cause of success is government support. MDACC has had the benefit of not only receiving research grants from the National Cancer Institute (NCI) but also experiencing Medicare's flexible insurance system, e.g. compensation of therapy for patients enrolled in clinical trial, and exemption of diagnosis related group (DRG) payment.

#### 2) Johns Hopkins University (JHU)

Johns Hopkins University is an American private research university located in Baltimore, Maryland. The university opened in 1876 and the Johns Hopkins Hospital was established in 1889. From its earliest period, JHU has successfully formulated the concept of combining medical research, education and patient care and now it is particularly famous for its world-renowned affiliated hospital and medical school.

Johns Hopkins Hospital has been ranked number one in the United States for 19 consecutive years by *U.S. News & World Report* and 20 current or former School of Medicine scientists have won the Nobel Prize including 2009 Nobel Prize in Physiology or Medicine. Johns Hopkins scientists received 437 million dollars in federal research grant money in 2008, the largest amount among U.S. medical schools. The National Science Foundation has ranked the university number one among U.S. academic institutions in

total science, medical and engineering R&D spending for the 30th year in a row<sup>38)</sup>. In addition, Johns Hopkins is among Maryland's largest private employers employing 32,700 employees. Johns Hopkins' annual economic impact on Maryland totals \$6.4 billion.

## 3) Tokyo Women's Medical University

Tokyo Women's Medical University and its teaching hospital is one of the leading health research complex in Japan. The university was founded in 1900 and the teaching hospital of the original medical school opened in 1908. After several decades, Tokyo Women's Medical University Hospital is now an advanced state-of-the-art hospital with 1,423 beds (as of September 2004). The hospital has a dedicated staff of 6,358, comprised of 1,775 doctors, 1,684 nurses, 735 medical technicians, and 2,164 logistics personnel. The hospital has 9 medical centers with 38 departments and 13 independent clinical departments<sup>39</sup>).

The university was awarded the "Center of Excellence" in research for regenerative medicine in 2003 and has maintained Japan's top position in various basic and clinical research fields. The driving force behind the achievement in health research is its high-quality research institutes.

The Institute of Advanced Biomedical Engineering and Science opened in 2001. The Institute has focused on regenerative medicine and genetics research, and has built up world-class research capacity in these field. In 2008,

<sup>38)</sup> http://www.hopkinsmedicine.org

<sup>39)</sup> www.twmu.ac.jp

Tokyo Women's Medical University Waseda University Joint Institution for Advanced Biomedical Sciences (TWIns) was established. TWIns has successfully facilitated interdisciplinary and innovative research and contributed to the forming of strong research enterprises.

TWIns has developed many useful health technologies and commercialized products such as the cell sheet developed by Cell Sheet Tissue Engineering Center in TWIns. What explains the successful story of TWIns is over 30 years of experience of collaborative research experience between the two universities. They developed a significant cooperative relationship that makes the team approach possible.

In addition, strong government support is a critical factor of success. Even before the establishment of TWIns, the government of Japan funded approximately 14 US million dollars annually for the collaborative research of the two universities over 10 years, and it provides about 90 percent of total TWIns research funding. Due to the long term support of the government, TWIns was able to build up world-class research capacity.

#### 4) Implications

Research-oriented hospitals that have made significant achievement have some common key factors of success.

First, they have a strong research institute to enhance translational research conducted by interdisciplinary or multidisciplinary research teams. Both

MDACC and Johns Hopkins have several research institutes composed of world-class multidisciplinary research teams. Tokyo Women's Medical University also has top-notch research institute such as TWIns. These research-oriented institutes could acts as an incubator of innovative health research.

Second, good research integration and supporting staffs such as financial administrators, contract managers and experts of intellectual property are critical. The role of the physician-scientist who can translate various research languages and subserve communication between clinicians and basic researchers is especially essential. To foster qualified physician-scientists, MDACC introduced Dual Career Path System, which permitted physicians to choose a career between research and patient care. Also, MDACC offers education to support career development, such as Clinician-Investigator Program.

Third, strong government support is needed. Direct funding for health research is just part of the broad range of government support. In the U.S., health care insurance partially covers treatment costs of clinical trials and helps more patients to enrol in clinical trials. In addition, strong government leadership is very important in facilitating the transformation of the older patient care-oriented hospitals to newer research-oriented ones.

# **IV.** Conclusion

# 1. Discussion

#### 1) Concept and Element of Research-based Hospital

## (a) Operational Concept

For the discussion on policy initiatives, it is required to define the concept of the RBH. The Task Force Team on the RBH at the Ministry of Health and Welfare defines it as "a world-class research-based hospital which leads the development of health industry through research and business based development (R&BD) on the state-of-the-art health technology, based upon accumulated knowledge through clinical experiences within the hospital" (MOHW, 2010)<sup>40)</sup>. This concept of a RBH has several elements: ⓐ world-class hospital, ⓑ leader of the health industry, ⓒ core of R&BD in HT, and ⓓ user of accumulated knowledge from clinical experiences.

## (b) Elements of Research-based Hospitals

(a) World class hospital: A RBH is expected to provide world-class services in terms of high technology. Patients can receive the most advanced medical treatment, which is possible through vigorous research activity. MDACC has a reputation of excellent care through continuous research efforts (http://www.mdanderson.org)<sup>41)</sup>.

<sup>40)</sup> Ministry of Health and Welfare, Working Paper of the Task Force Team on Research Based Hospital, 2010

b Leader of the health industry: The RBH is not only a provider of high quality medical services but also a leader of the health industry in medical services, pharmaceutical goods, and medical devices and equipments by providing ideas on patients need, products design, product feedback and future development. Massachusetts General Hospital (MGH) has lead the health industry by providing 140 cases of technology transfer to companies with income of 63 million US dollars of royalty income per R&D-inspired products. Also, MGH has established more than fifty venture companies based on R&D outcomes.

© Core of R&BD in HT: The RBH is the core of HT research as well as business-based development. This element is also known as the "Core of C&D" (Connect and Development), "Pipeline of Translational Research", and "Center of Clinical Research" (MOHW, 2010)<sup>42</sup>). This means that the RBH should take a role of accelerating the efficiency of HT research by incubating the production process of research outcomes. Thus, the hospital could be a hub of health technology as well as the health industry. MDACC has three units for advocating R&BD: The Office of Technology Discovery, Technology Review Committee, and Office of Technology Commercialization. These units assist researchers and companies in evaluating appropriate

<sup>41)</sup> MDACC have been ranked the top hospital in the field of cancer treatment 4 times out of 6 years by annual evluation of the US News and World Report.

<sup>42)</sup> Ministry of Health and Welfare, Working Paper of the Task Force Team on Research Based Hospital, 2010

technology for commercialization, attaining patents and licenses, and establishing venter companies.

d User of accumulated knowledge from clinical experiences: A research-based hospital has a huge knowledge base coming from clinical experiences, which can be applied to R&D. For this purpose, a well-designed information system is required for storaging and analyzing a huge amount of information from clinical experiences.

# 2) Is it possible to develop a world-class research-based hospital in Korea?

#### (a) Key Success Factors of RBHs

Based upon the collective opinion revealed by the experts' surveys, several factors are recognized as crucial for an efficient and effective research-based hospital. Even though there are significant differences in terms of the financial environment, national health security system, educational structure and value and framework of the national economy, the case studies on advanced RBHs abroad also show that there should be universal key success factors that can be benchmarked into the Korean context. On the whole, the most significant factor is the hospital system. The system covers not only the operational management of the hospital but also the incentive system for all staff members, the structure of human resources management,

the criteria of resources allocation and the networking capability of industrial and academic societies. The entire hospital system should be oriented for research and medical service provision equivalently.

The second factor is the goal of the hospital, which is being research-oriented. As shown in the case study on MDACC, the priority of the hospital's mission is research and development. This orientation is encouraged by an incentive system for staff members. Every employee is given a predictable incentive of income and status based upon research performance as well as provision of medical services. Even for physicians, their income and job security are determined both by research and performance of medical services. In MDACC, physicians with R&D grants are responsible for fewer patients while those without grants will be responsible for more<sup>43</sup>). In other words, there is no negative incentive for employees to devote themselves to research activities or reduce their amount of medical service.

This research-oriented model also has supported by the consensus of all the stakeholders in the hospital. From the CEO to medical doctors and technicians, there is firm belief that their hospital should be developed through research and development as well as provide first-rate medical services, as shown in the case studies of MDACC and Johns Hopkins. Strong commitment and leadership of CEOs are especially resent in all the advanced research-oriented hospitals including MDACC, Johns Hopkins and TWIns.

Another factor is a research-friendly arrangement of infrastructure. For example, inadequate space and equipment are frequently mentioned in the experts survey as an important barrier to overcome for an RBH, which is described in Chapter III. In the case study of the TWIns, a 22,000 m<sup>2</sup> building is solely dedicated to this research institute. Also, this building has its own GMP facilities along with other relevant laboratories and equipment Another crucial factor is human resources. for research and development. The case study shows that all successful models have a proper combination of the following human resources: R&D program coordinators, technicians, research nurses, financial managers, intellectual property specialists, government relations experts, legal affairs managers, secretaries for R&D, research-oriented scientists and medical doctors.

In addition, adequate investment of R&D funding is crucial in the achievement of a research-based hospital. For example, MD Anderson spent \$488,654,827 in 2008 (Table 18), which is more than double the amount of total R&D funding from the Ministry of Health and Welfare of Korea (MOHW) in the same fiscal year<sup>44</sup>). The top-ranked hospital in terms of receiving R&D grant money from MOHW in 2009 received 27,141 million Won, and the average MOHW R&D grant to the top 5 hospitals was 6,140 million Won during 2007 to 2009. To maintain a hospital, R&D is a high-risk investment, considering that hospitals have an extremely low-risk

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<sup>44)</sup> Total amount of R&D fund of Ministy of Health and Welfare was 288 billion Won in 2008 (NTIS DB)

investment in the provision of medical services. Thus, hospitals cannot invest in research activities if there is insufficient R&D grant money given by the government. Hospitals cannot bear uncertain risk-high investment in R&D, which should be sponsored by a government-backed risk pool.

The final factor successful team collaboration, including interdisciplinary and multidisciplinary approaches. The Cancer Prevention and Research Institute of Texas (CIPRIT) requires multidisciplinary collaboration as a prerequisite condition for application. The hospital of the University of California at San Francisco established an R&D building for hosting multidisciplinary research teams. Also, TWIns itself is an interdisciplinary R&D entity between Tokyo Women's Medical University and Waseda University, which does not have a medical college. TWIns is a joint team of a medical school and science department of two schools for HT R&D. team collaboration also requires experts of integrating diverse sectors. experts are called integrators, translators, or coordinators, many of whom are medical doctor-scientists with deep understanding in pathology, biochemistry, and physiology.

Strong leadership for R&D, a reasonable incentive system for researchers, adequate resource allocation for R&D, capable human resources, appropriate R&D funds, and well-organized team collaboration are key success factors identified through the survey and case studies. Although there may be variations between hospitals, those key success factors can also be applied in Korea to establish successful RBHs.

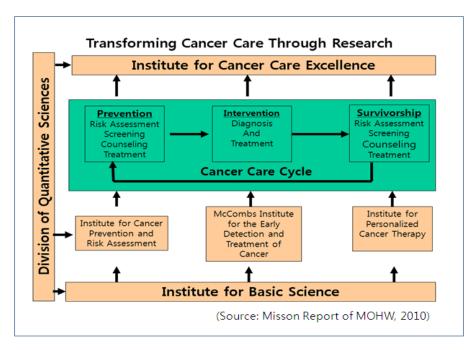


Figure 14. Team Collaboration Model of MDACC

# (b) Major Barriers to RBHs in Korea

The above-mentioned requirements are considered to be essential for the accomplishment of research-based hospitals, while a number of potential hospitals in Korea are still in need of several key success factors. As those key success factors are derived from the case studies of advanced RBHs abroad, application of those factors into the Korean context should be reviewed with consideration to the financial, political, educational, and cultural systems of Korea. Particularly, some determining elements deeply affect the management of hospitals. In this study, four aspects of determinants will be reviewed as barriers for realizing research-centered hospitals.

## a Systematic problems of the hospitals

To set up a research-based hospital, the most important feature is that hospital system operations should be holistically research-oriented. To meet this goal, strong leadership of the CEOs of hospitals is crucial. Without strong commitment to and advocating of research-oriented operations, the hospital cannot move in the direction of R&D. Unfortunately, many of the panelists on the experts survey answered that lack of understanding of R&D value by the CEO is the most serious barrier to the establishment of RBHs in Korea<sup>45</sup>). Considering their duties and burdens as CEOs, it is natural to focus more on the direct income of hospitals rather than long-term and uncertain income from R&D activities. Furthermore, a large number of CEOs are evaluated on their short-term performances including financial balance sheets<sup>46</sup>). In this situation, a hospital cannot adopt R&D plans effectively.

For hospital employees, including physicians, the incentive management of the hospital is another barrier in setting up RBHs. The panelists answered that the dominant medical service provision system and insufficient incentive for R&D are two main reasons for physicians not to devote themselves to research activities. In the experts survey, it is reported that researchers and other research-related staff members are deeply concerned with job security along with economic incentive for R&D performance. Only with a suitable

45) Twenty-eight percent of panelists answered that recognition of CEOs is the most significnt barrier.

<sup>46)</sup> Thirty-one percent answer that short-term evaluation is serious barrier for CEOs to focus on R&D supporting policy.

reward system will researchers be motivated properly. Furthermore, they cannot focus on a research program in an atmosphere where R&D is considered as extra activity, outside of the mainstream direction of hospitals. For physicians, scientists, technicians and other staff members working on R&D projects, an incentive system composed of economic reward, promotion and job security is significantly important, all of which is described as deficient in the Korean situation by the survey<sup>47)</sup>.

Weak team approach is another barrier for Korean hospitals in achieving a research-oriented model. Interviews with leaders at advanced research-oriented hospitals abroad unanimously commented that solid team collaboration is the most critical element of hospital-based research (MOHW, 2010)<sup>48</sup>). In Korea, poor team approach is one of the major barriers in establishing a RBH. Even though this point did not surface during the experts survey, certain reports on HT R&D performance describe the necessity of a team approach (KISTEP, 2009). During training courses and educational programs, researchers seem to have not experienced team collaboration fruitfully, which is also applied to physicians and basic scientists in Korea.

#### **(b)** Deficiency in the Infrastructure of the Hospitals

The second barrier is the infrastructure of hospitals. Appropriate

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<sup>47)</sup> Forty-four percent answer that salary, job security, and promotion are most important factors of incentives to encourage R&D activities for physicians.

<sup>48)</sup> Ministry of Health and Welfare (MOHW), Misson Report on the Successful Cases of Leading Oversea Research Based Hospitals, 2010

allocation of space and equipment is a basic condition to maintain a research project for every researcher. Half of the panelists who participated in the experts survey replied that researchers in the hospital need more space to conduct research. Researchers also need to be provided with essential equipment for experiment and analysis. In addition, many of the panelists answered that they are in need of facilities for animal testing and a biobank of blood and tissue. Also, gene analysis facilities and a HT information center within the hospital are regarded as necessary infrastructure for hospital-based research.

Moreover, a well-developed technology transfer organization (TTO) is crucial for a RBH. To utilize hospital-based research effectively, a TTO should be the link between research and industry. The beauty of hospital-based research is its application to real practice. In this sense, a competent TTO can raise the efficacy of research in a hospital. Many researchers in hospitals feel that current hospitals require more sophisticated TTOs<sup>49</sup>). The panelists repeatedly mentioned a need for experts on intellectual property and international technical information as well as TTOs within hospitals independent from universities.

#### © Lack of Sufficient Human Resources

In order to implement and assist research projects effectively, competent human resources is one of the basic requirements. In the experts survey, the

<sup>49)</sup> See the Analysis on Survey Result.

panelists replied that a research-based hospital requires various experts, such as physicians with R&D capacity, scientists with an understanding of the medical field, technicians, coordinators and clinical research nurses, diverse assistant staff members for information process, administrative management, and specialists for TTOs. In addition, the case study on MDACC indicates that expert assisting researchers are very important for an outstanding performance of hospital-based research. Those experts are master coordinators of an R&D program, financial specialists, intellectual property experts, contract specialists, research program secretaries, and research nurses. Compared to advanced hospitals, most Korean hospitals carrying out research projects seem to be in need of diverse and competent human resources, inferred from the expert survey and the case study.

#### **d** Insufficient Government Investment

As mentioned earlier, the total amount of R&D funding for HT investment in Korea is comparatively small. The amount of HT R&D investment of the government in 2008 was 991.2 billion Won, which is 9 percent of the total R&D fund of the government. Despite the difference in economy magnitude, the size of R&D investment for bio-technology (BT) in Korea was one-fifteenth of the U.S. BT investment in 2007. Also, it was half of the Japanese BT investment in 2007. Because of financial limitations, the government cannot provide enough grants to HT researchers, many of whom are physicians and basic scientists of the HT field. The shortage of

government grants is a serious barrier to a generation of HT R&D in Korea.

Another issue is its coordination and integration within the government on HT R&D. In the U.S., the Department of Health and Human Services spent 96 percent of the total HT R&D fund allotted by of the U.S. government in 2007. The British Department of Health executed 51 percent in 2005, while the Japanese Ministry for Health, Welfare and Labour invested 42 percent in 2007. As for the Korean government, the Ministry for Health and Welfare spent only 14.5 percent of the total BT R&D allotted in 2007<sup>50</sup>). This could be a barrier in the strategic investment of HT R&D by the government because each ministry's missions and strategies may be ineffectively coordinated compared to one single dominant player situation. In this sense, if the government's coordinating structure were more productive, the effectiveness of the HT R&D investment of the Korean government could be increased.

Some government regulations are considered barriers to the nurturance of HT R&D and the HT-based industry, as shown in the experts survey. At the micro-level, researchers replied that many of the rules and regulations regarding the administration of the R&D grants are too tight to manage their R&D projects effectively. Also, the panelists pointed out that strict restriction of the government grant to spend on salary of the researchers is another obstruction. Researchers are a significant factor in HT R&D because large

<sup>50)</sup> See Table 5: The portion of HT R&D fund of the responsible department in the total government R&D investment.

number of physicians can yield definite income from provision of medical services instead of research activities. In order to devote themselves more on research, physicians hope to reduce the income deficit of each hospital by allocating a portion of the R&D grant to the hospital as an overhead cost. Even though there could be an ethical hazard if this policy is adopted, this limitation of spending the grant is one of hindrances to establishing RBHs in Korea.

At the macro-level, a hospital, founded by a non-commercial foundation, cannot establish a for-profit venture company to incubate HT application. In the Korean legal system, medical service industry is regarded as part of the charity-based sector, where it is not desirable to yield economic profit. In this regard, this restriction is also applied to HT development. However, this regulation is a significant obstacle when trying to connect the outcomes of HT research with industrialization. Particularly, this limitation on HT R&D is significant in hospital-based research because the role of HT R&D within the hospital is translating the basics to the industries.

#### 3) Discussion

As described in Chapter I, some hospitals in Korea have high potentiality for HT R&D. With top-quality human resources including medical experts, state-of-the-art medical equipments in quantity, large numbers of patients groups, and digitalized information system, these hospitals could turn

into research and development leaders in HT improvement. However, many experts replied that the Korean hospitals are not taking a leadership role in R&D despite their high potentiality of HT R&D innovation. In this regard, there are key factors to stimulate hospital-based research and to nurture hospitals to become the hubs of HT R&D. Those key success factors can be identified as "tipping points", critically affecting and changing hospitals in the direction of R&D.

The discussion should be focused on how to utilize potentiality of Korean hospitals along with their positive factors, while the focus will continue to be on how to overcome the negative aspects of the hospitals as well as deficient factors in the Korean context. This study will propose a set of policy suggestions for the establishment of RBHs in Korea based upon the analysis and discussion above. Although the goal cannot be accomplished solely through government policies, this study focuses on policy initiatives. For a fundamental change in research-based hospitals, there should not only be an internal activity but also a shift of environmental conditions. In the realm of hospital-based HT R&D, exterior factors are very significant because a large portion of the R&D funds comes from the government and industry. Also, hospitals are deeply affected by regulations, institutions and systems of society in terms of financial stability, human resource recruitment, and relationships with industry and academia.

# 2. Suggestions for Research-based Hospitals

In order to effectively establish RBHs in Korea, the systematic reform of the hospital is the most significant factor. Not only the reform of each part, but that of the whole system of the hospital, which should turn the focus of the hospital toward research. A crucial point is that all staff members seriously regard R&D as a priority and non-R&D staffs as well as researchers fully understand the value and the necessity of HT R&D in the hospital. This goal of the RBH model cannot be reached without multi-dimensional collaboration of the hospitals, the government, health industries, universities and research institutions. In this study, a set of policy initiatives, required for the strategic reform of the hospitals, is discussed, which is composed of systematic reform related to hospitals, reinforcement of infrastructure and human resources, and revision of government policies.

# 1) Systematic Reform Related to the Hospitals

# (a) Strong Leadership

Leadership of a hospital is a critical factor in determining the management and performance of the hospital. A successful RBH should be guided by a CEO with clear understanding of R&D of their role in leadership. Without solid leadership towards research, a hospital cannot transfer into a RBH. However, CEOs of hospitals in Korea are usually evaluated on a comparatively short-term basis which is reported to affect the management

direction of CEOs to focus on short-term outcomes especially in financial performance. In this regard, a policy is required to encourage selected hospitals to adopt a long-term basis evaluation system along with a revision of evaluation factors including bigger portions for research activities and strategic management of hospitals. This arrangement can be stimulated through a guideline for RBH, which can be possibly proposed to candidate hospitals aspiring to become RBHs by the government.

# (b) Strong Commitment of Employees

While strong leadership is essential, voluntary cooperation from all hospital employees is also critical for a successful RBH. Physicians, scientists, technicians, nurses, coordinators and anyone related to either R&D or clinical services are significant. As shown in the expert survey result (Chapter III-1), many physicians recognize the value of R&D in a hospital whether they are working on R&D programs or not. However, a major problem is that they cannot find enough time and resources for R&D within the hospital. Furthermore, physicians are not motivated to devote themselves to R&D mainly due to a lack of incentives, which is oriented by the instant and reliable income of the hospital. Because R&D is a long-term and unpredictable investment, researchers are not appropriately motivated under the current incentive system, which significantly affects researchers' income, organizational status and job security. On the other hand, it is estimated that many researchers could feel a heavy burden from medical treatment

assignments and they may think R&D activity is extra work. Because dramatic improvement in policy changes or managerial guidelines is expected to be difficult in this situation, a gradual approach toward R&D-orientation is a more practical course of action. A couple of conditions are required for this proposal: a strong commitment of hospital employees to R&D, and a strategic management system to support this commitment of staff members.

#### (c) Strategic Management System

Employees are profoundly affected by incentive structure of income, promotion, and job stability. In order to guarantee continuous cooperation of all members of the hospitals for R&D, a strategic management system should be predictable and persistent, instead of counting on personal-base commitment. Regarding a salary arrangement system, the hospitals should apply a policy of equivalent treatment between profit from R&D and medical services. Thus, a physician can expect the same income incentive from R&D activities by the hospital. Also, the other employees of the hospital may consider the R&D program as one of the main activities of the hospital under this policy. In this circumstance, a researcher can devote oneself to a research project without considering income deficiency from research activities.

In addition, a performance evaluation for employees should not only include medical service, but also outcomes of R&D. Based on this comprehensive evaluation system, a researcher may have incentives for promotion and tenure-track according to research performance. Economic

incentives along with non-economic favors can encourage R&D activities of the hospitals, which is a primary factor in founding an RBH. Instead of relocating direct employees to research, this kind of indirect incentive policy may lead to becoming a research-oriented hospital.

## (d) Close Team Collaboration and Open Innovation

One of the key success factors of a research-based hospital is close team collaboration among related units of the hospitals. The multi-dimensional approach is essential because a competent R&D hospital not only needs the existence of specialized sub-units but also a framework for multi-disciplinary collaboration. Neither health industry companies nor research institutions have all of the required specialists as do hospitals. A competent hospital, however, may have almost all of the required experts including physicians with diverse specialties, scientists, technicians, nurses and dietitians. As the goal of health technology is to overcome disease and to improve health condition, a hospital may be a suitable milieu for health technology research and business To stimulate team collaboration, a hospital may impose development. incentives for multi-disciplinary projects in an investment decision guideline. Also, a hospital should support this by providing regular meetings of diverse experts, financing multi-units training courses, and recruiting required staffs to aid the team approach.

Another cultural characteristic required for RBH is openness of the hospital system. Not only internal cooperation among sub-units of a hospital

but also close collaboration with external resources, such as health industries and research institutions, are essential to RBHs. As shown in MDACC and TWIns, many venture companies share research infrastructure with hospitals. In Korea, Seoul Asan Hospital works with a couple of bio-venture companies within its campus. In this setting, both hospital and the company enjoy mutual benefit through close collaboration between physicians and researchers of the two institutions. Their work together on developing new items based on accumulated knowledge of clinical experiences has been accelerated. This type of open renovation is required for bridging clinical knowledge and commercialization of health technology, which is a major mission of the RBH. A hospital should formulate a system to collaborate with relevant partners including private companies and research institutions to be a successful RBH.

#### (e) Mandatory Re-investment Policy

Some of the hospital-based research projects may succeed in commercialization, which brings income to hospitals. It is recommended to adopt an obligatory policy to re-invest a certain portion of the profit made from R&D outcome of the hospital, to ensure continuous investment in R&D. Even though the amount of re-invested funds may be insignificant considering the whole size of the R&D fund of the hospital, it is important to reinforce commitment for R&D in the hospital itself. Also, it is meaningful to introduce this policy in the initial stage of RBH development, considering that the entire R&D fund of Korea is limited and the social recognition of

hospital-based R&D is lacking.

# 2) Reinforcement of the Infrastructure of the Hospitals

# (a) Capacity Building of TTO

It is essential to build a strong technology transfer organization (TTO) to support close and efficient communication between researchers of the hospitals and relevant companies. In-hospital researchers have knowledge, experience, and ideas for managing an R&D project; on the other hand, most of them require assistance from experts on how to apply their research outcomes into the industry. In addition, health industries (mainly drug and medical equipment companies) and investment funds may not easily be able to identify R&D procedures in hospitals although they, as potential investors, are eager to discover appropriate items. Strong TTOs located in hospitals will contribute in bridging research and industry, which will result in building the concrete value chain of HT R&D.

# (b) Strategic Allocation of Resources

As discussed, pertinent allocation of space and equipment for researchers is imperative for a successful RBH. Pertinent allocation will not only benefit research activities but also administrative support.

### (c) Integrated Information System

A comprehensive and well-organized information system for all stakeholders of hospital-based R&D is recommended. For efficiency and effectiveness of R&D project management, an improved information system is necessary to provide all relevant information to researchers, assistants, and managers of the hospitals about real-time processes of research projects, potential resources such as government grants, non-government funds, and details on researchers.

#### (d) Strengthening Clinical Trial Research Facilities

Clinical trial research is increasingly important as the market size grows by 3 percent annually and globally (Evaluate Pharma, 2009). Reliable clinical trial research facilities must be established in order to ensure the implementation of successful research programs within hospitals. Strong clinical trial research facilities will help the researchers of the hospitals conduct research more efficiently. In addition, health industry companies will be able to communicate successfully with researchers.

### 3) Empowering Human Resources

### (a) Dual-Track System for Physicians

In an RBH, a dual-track career development system for phsicians is recommended. In this system, a physician can choose his or her own major

career track between research and medical service. A physician can consult with the management organization about the work ratio of research to medical service provision. The decision will be made according to their own capacity, available R&D funding, approved R&D projects, and the other resources of the hospitals. Even though a physician can choose the research track, he or she is recommended to invest a certain portion of his or her time on medical service provision. Without clinical experience and knowledge, a physician cannot successfully carry out research projects because their main role is to direct and coordinate the whole projects based upon clinical knowledge.

#### (b) Exchange Training Courses

Training course exchanges are recommended to educate physicians and scientists. Exchanges between medical colleges and life sciences colleges will increase the understanding of each other, which will strengthen professional relationships and development of research projects of the hospitals. For this area, there should be an earmarked government grant to increase funding, which is at a primitive stage in Korea<sup>51</sup>).

#### (c) Career Management Program for Researchers

A career management program is required to encourage basic scientists and technicians to work in hospital-based research. Job stability is the most

51) The M. D. - Ph, D. Training Program by the Korean Institute for Health Industry Development has less than one year grant program for ?? physicians and scientists annually with 10 million KRW per a recipient from 2009

sensitive issue for them in determining their career as part of a hospital research staff because there are no stable positions for scientists and technicians participated in R&D. If a tenure track is offered based on research performances, motivation and commitment will be highly reinforced.

### 4) Social Recognition and Policy Framework to Support Hospitals

### (a) Advocacy for RBH Framework

The most serious challenge is to advocate for the value of RBH in Korea. Without the social recognition and adequate support measurements necessary, RBHs, cannot be arranged effectively. The value of health technology and industry should be recognized along with the role of RBH in HT R&D. In this regard, an accreditation of RBH can be developed as well as a social recognition system for renowned HT researchers.

### (b) Legislation for RBH

For systematic support of RBHs, legislation is required. The legislation should prescribe the legal concept, elements, and authorization of diverse policy support for RBHs. Revising the Health Industry and Technology Promotion Act will provide the legal framework for RBH. The RBH Task Force Team at MOHW proposes a draft of a revision of the Act, which covers relevant articles on concepts, eligibility, accreditation, obligation of RBHs along with provision of legal framework to support RBHs.

### (c) Deregulation

Deregulation is definitely required for fostering RBHs. First of all, the overhead cost allowed in government grants needs to be raised because hospitals will take a significant financial loss from investing in physicians for research activities instead of medical services. Although an increased overhead cost cannot fully cover all financial loss expected, this policy will allow the government to share the burden of the economic loss of hospitals. Otherwise, physicians cannot devote themselves intensively to research, and CEOs will regard R&D as a secondary mission of the hospital<sup>52</sup>). In addition, more flexibility regarding the use of the R&D grant is required, under the condition that the final evaluation has a mandatory close auditing. Just as the proposal cannot cover all the detailed contents of R&D projects, the regulations on the use of the R&D grants cannot predict all of the situations that could occur during the implementation of the project.

Another required deregulatory action concerns National Health Insurance (NHI). If NHI allows temporary non-reimbursable coverage for drugs, medical equipment, or techniques newly developed by an RBH, the health industry will improve significantly through hospital-based researches. Because expensive costs are required for researchers to apply outcomes of R&D to the clinical practice, this kind of deregulation will help to nurture

52) The current level of 20 percent of overhead cost is proposed to raise up to 30 - 40 percents by the RBH Task Force at MOHW.

RBHs in Korea effectively. For example, if a medical device developed by an RBH is used by a hospital and it is deemed non-reimbursable by NHI (directly paid by the patients who have given informed-consent) for three years, the device can be fully examined in the clinical setting. NHI may review cost-efficiency based on a three-year trial by the hospital. This means that a new item is not tried for safety, but for cost-efficiency, which is currently high in cost.

Also, the restriction on the establishment of venture companies by an RBH for the commercialization of R&D outcomes is necessary. Under the current regulation, most hospitals that are non-for-profit entities cannot establish venture companies, which may be a barrier in the commercialization of R&D outcomes. Despite expected negative effects, carefully developed deregulation can boost research and business development (R&BD) in hospitals.

### (d) Active Support of the Government Grants for HT R&D

As in the cases of "World-Class University (WCU)" and "World-Class Institutions (WCI)" projects guided by the Ministry of Education, Science and Technology, a bold resolution to dramatically increase the investment of R&D for RBHs is required<sup>53</sup>). If a World-Class Research-based Hospital (WCRBH) project can be initiated by the government, the hospitals with R&D capacity will take more concrete actions towards RBH establishment. Without financial

<sup>53)</sup> WCU is a R&D project initiated from 2008 for 5 years by the Korean government for the advanced research-based universities by supporting the invitation of worldwide prominent scholars, of which amount is 825 billion KRW for 5 years. WCI is another program for research institutions.

risk sharing by the government, the hospitals do not have enough to invest in resources for R&D activities. As shown in the case studies, a huge amount of funds have been invested to advanced research-oriented hospitals in US and Japan. Sharply increasing the investment in HT R&D by launching the "WCRBH" project, hospital-based HT research can be the core framework for HT R&D.

#### (e) Coordination in the Government

With regard to coordination of the government investment on HT R&D, the role of the health ministry should be enforced. In spite of the small portion of MOHW in the whole government investment on HT R&D, MOHW should lead HT R&D mainly through an RBH project. As the final goal of HT R&D is to overcome diseases and to improve health, which is a major mission of MOHW, HT R&D needs to be coordinated according to the priorities of disease control targets and health promotion of the government, which is decided by MOHW. For this purpose, a governmental coordination body, or an HT R&D committee, is required for the increase of efficiency and effectiveness of HT R&D. This committee should be responsible for determining priorities of HT R&D target items, in collaboration with relevant experts and related government officials from MOHW, MEST, and MKE<sup>54</sup>).

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<sup>54)</sup> MEST: Ministry of Education, Science and Technology, MKE: Ministry of Knowledge Economy

### 5) Implementation Strategy

### (a) Initial Stage: Group A and Selected Hospitals with Specialties

With limited resources for RBHs in Korea, a 'select and focus' strategy is required. In Figure 11, Group A is considered leaders in the Korean hospitals for HT R&D, and Group B is potential contributor. It will be practical to focus on several big hospitals affiliated to medical colleges and some competent specialized hospitals in the initial stage.

For a reasonable selection of RBHs, an evaluation process can be applied to all R&D proposals submitted by candidate hospitals. Also, all designated RBHs need to be accredited and regularly evaluated according to their performance and goals. This competitive accreditation system should emphasize not only the current capacity of a hospital but also its potentiality and commitment.

In the implementation process of RBHs, it is expected that candidate hospitals reduce medical service provision in order to achieve success in the R&D clustering function. By the reduction of medical service provision, RBHs can devote themselves more to R&D activities; physicians especially can allocate more time for R&D. As a result, it is expected that a portion of patients with comparatively minor diseases may be transferred to non-RBHs, if implementation proceeds as intended. This may be a side-effect of this plan, which may be positive for the settlement of the medical service delivery system in Korea.

### (b) Second Stage: Expansion to Group B Hospitals

After the settlement of the initial stage, the next step would be the expansion of RBHs to Group B hospitals. As seen in Figure 11, hospitals in Group B tend to have a high quality of clinical technology; however they usually do not have enough R&D experience compared to Group A. In this situation, it is required to select RBHs among Group B on the basis of the following criteria: willingness of the hospital to change its entire system to be an RBH, a concrete plan to fund R&D, a plan to strengthen TTO within the hospital; and other related requirement mentioned in this chapter.

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Appendix : Survey Questionnaire

## Questionnaire for a Study on the Development of Research-based Hospitals in Korea

I am a Ph.D. candidate, Kim, Ganglip, in the Department of Medical Law and Bioethics at the Graduate School of Yonsei University.

This questionnaire will be used as a basic data source for the study of the development of research-based hospitals in Korea. I cordially ask for your honest opinion based on your expertise and experience. This research is planned to be carried out using the delphi technique, in which first phase responses to the open questions are collected and then the respondents are asked to reply the closed questions in the second phase questionnaire survey.

It would be greatly appreciated if you could respond to the first phase questions. I will send the questionnaire for the second phase survey along with the response results of the first phase respondents. The results of this questionnaire survey will be used only to draw up a doctoral degree thesis and will not be used for any other purposes.

Thank you for your sincere cooperation.

This questionnaire is designed for the study of the development of research-based hospitals in Korea, which aims to formulate a model of a hospital as the hub of health technology (HT) R&D with balanced capacity between research and medical service provision.

## 1. Please provide your opinion briefly on the current R&D capacity of the Korean hospitals.

## (1-1) Do you think competent hospitals in Korea play a major role in HT R&D?

Answers	1st Ro	ound	2nd Round		
Allsweis	frequency	percent	frequency	percent	
Yes	9	31	10	37	
Improved, but still insufficient	7	24	10	37	
Only limited hospitals do	6	21	7	26	
No	7	24	0	0	

## (1-2) To which area of HT R&D development do you think competent hospitals in Korea are contributing?

ancword	1st Ro	1st Round		ound
answers	frequency	percent	frequency	percent
Lead HT industries with	16	39	10	37
increased economic value	10	39	10	37
Link basic research and				
commercialization through	11	27	13	48
translational researches				
Develop clinical trial and	6	15	3	11
clinical research	0	13	3	11
Develop and evaluate new HT,	5	12	1	4
drug and medical equipment	3	12		4
Develop clinical guideline and	2	7	0	0
improve clinical quality	3	/	U	U

### 2. Quesions on barriers to hospital-based HT R&D

(2-1) Which is the most significant barrier to encouraging R&D in competent hospitals whose R&D performances are not sufficient compared to their potentiality?

oneware	1st Ro	ound	2nd R	ound
answers	frequency	percent	frequency	percent
Insufficient R&D resource including fund/space/equipment	17	21	12	22
Lack of recognition of CEOs of hospitals on the value of R&D	14	17	15	28
Limited time for R&D due to overwhelming burden of medical service provision	13	16	13	24
Insufficient incentive system for researchers	10	12	5	9
Poor human resources of research and research support in hospitals	10	12	6	11
Lack of communication between scientists and physicians	5	5	1	2
Absence of long-term R&D visionary plan and strategy in hospitals	5	5	2	4
Insufficient government R&D grant	5	5	0	0
Poor capacity of commercialization of R&D outcome	2	2	0	0

# (2-2) Which is the most serious problem to manage a hospital to be R&D oriented from the perspective of CEO of hospitals?

	1st Ro	1st Round		1st Round 2nd R		ound
answers	frequency		frequency	percent		
Short-term based evaluation for CEOs	15	32	17	31		
Uncertainty of outcomes from R&D investment	11	23	22	41		
Financial restriction by insufficient reimbursement from the National Health Insurance (NHI)	8	17	8	15		
Absence of capacity to formulate visionary plan of R&D and commercialization	4	9	1	2		
Insufficient resources (funds and space, etc)	4	9	3	6		
Lack of recognition of R&D value	3	6	3	6		
Few competent R&D human resources	2	4	0	0		

## (2-3) What is the most significant factor for physicians to invest on medical service provision rather than R&D activity?

A	1st Ro	1st Round		ound
Answers	frequency	percent	frequency	percent
Inadequate rewards (salary, promotion, etc) for R&D	16	24	13	24
Medical service dominant hospital management and revenue-driven policy of CEOs	14	21	20	37
Lack of time for R&D due to overwhelming burden of medical service provision and education	11	17	12	22
Insufficient research human resources	6	9	5	9
Poor infrastructure for R&D (space, equipment, supporting organization, etc.)	6	9	2	4
Lack of R&D experience and training	6	9	2	4
Insufficient R&D fund	3	5	0	0
Lack of recognition of R&D value	2	3	0	0
Unstable and short-term based R&D funding	2	3	0	0

# (2-4) Which is a major barrier to becoming RBHs as a non-medical staff member of hospitals?

A =	1st Ro	ound	2nd Round		
Answers	frequency	percent	frequency	percent	
Insufficient recognition of the value of R&D in terms of revenue increase both of hospital and staff members	13	41	23	46	
Lack of R&D experience	6	16	7	14	
Lack of sufficient R&D fund	5	13	7	14	
Uncertainty of short-term performance	3	9	3	6	
Recognition that little rewards will be given to non-medical staff	2	6	6	12	
Lack of communication between clinical researchers and staff	2	6	4	8	
Additional workload from R&D	1	3	0	0	

(2-5) Which is the most serious barrier in coopeating with hospitals from the perspective of health-related industries such as pharmaceutical and medical equipment companies?

Answers	1st Ro	ound	2nd Round	
Answers	frequency	percent	frequency	percent
Irrational relationship between hospitals and companies (illegal rebate practice)	7	20	15	30
Prematurity of related companies (insufficient investment capacity, lack of R&D experience)	5	14	13	26
Deficiency of mutual trust and collaboration experience	4	11	6	12
Lack of experts and TTOs to connect hospitals with industries	3	9	4	8
Lack of communication between researchers and companies	3	9	1	2
Regulation of NHI and related law	3	9	3	6
Insufficient R&D capacity of clinical physicians	3	9	1	2
Absence of incentives in hospitals to encourage open innovation with industries	3	9	1	2
Medical service dominant hospital culture	2	6	4	8
Poor commercialization support system within hospitals	2	6	2	4

### 3. Questions on systematic issues for promoting hospital-based R&D

(3-1) Regarding government R&D, which changes are required for an effective performance?

	1st Ro	1st Round		ound
Answers	frequency	percent	frequency	percent
Allowance of long-term projects	7	25	19	35
Increased R&D government grants	5	18	9	17
Correct and reasonable evaluation of R&D performance	3	11	2	4
Government grant for setting up R&D system of a whole hospital	3	11	8	15
Financial, legal and institutional assistance for R&D investment by hospitals	3	11	11	20
Increased support for research grant rather than for infrastructure	2	7	1	2
Support hospitals according to their individual needs rather than a unified support model	2	7	3	5
Support R&D projects through their entire process	2	7	1	2
Provision of social application of R&D outcome	1	4	0	0

## (3-2) What is your opinion about the current policy of the government on the overhead cost of R&D?

Answers	1st Ro	ound	2nd R	ound.
Allsweis	frequency	percent	frequency	percent
Increase R&D overhead cost ratio	10	36	11	30
Allowance for using R&D grant for personnel expenses	5	18	13	36
Differentiated overhead cost ratio according to characteristics of each R&D project	5	18	5	14
Introduction of compulsory regulation of using certain portion of overhead cost directly for research	4	14	6	17
No change is required	4	14	1	3

## (3-3) Please select the most significant regulation for hospital-based R&D and commercialization of R&D outcome.

Answers	1st Ro	ound	2nd Round	
Allsweis	frequency	percent	frequency	percent
Excessive regulation on usage of R&D grant	7	26	20	37
Inefficient services by KFDA for clinical trial approval	4	15	9	17
Prohibition of company establishment by major hospitals	4	15	5	9
Insufficient tax exemption for R&D investment in hospitals	3	11	7	13
Inappropriate R&D evaluation criteria	2	7	3	5
Excessive legal regulation including NHI, bioethics, etc.	2	7	7	13
No incentive in military service obligation for researchers	2	7	2	4
Irrational regulation on R&D outcome	1	4	0	0
Prohibition of staff exchange between medical colleges and hospitals	1	4	1	2
Unified regulation without considering different level of publicity of R&D projects	1	4	0	0

### 4. Issues on infrastructure of hospitals for better R&D

(4-1) Which one is the most urgently required for encouraging R&D in hospitals?

### <About hardware of hospitals>

Answers	1st Ro	ound	2nd R	ound
Allswers	frequency	percent	frequency	percent
Sufficient space for R&D	8	35	18	53
Lab facility for gene research, etc.	5	22	3	9
Pre-clinical research facility (for animal trial)	3	13	5	15
Biobank of blood, tissues, etc.	3	13	4	12
Information center with library	2	9	0	0
Equipment for joint use	1	4	2	6
Clinical trial facilities	1	4	2	6

### <About human resources>

Answers	1st Ro	ound	2nd Round	
Allsweis	frequency	percent	frequency	percent
More R&D assistant staff	7	23	7	20
Recruitment of competent researchers	6	20	10	29
Provision of more R&D staff	4	13	0	0
Financial support of recruitment	4	13	8	23
Establishment of independent R&D organization with administrative staffs	4	13	4	12
More education and training	3	10	0	0
Increase job security and salary	2	7	5	15

# (4-2) What is the most effective change of an incentive system for clinical physicians to devote themselves to R&D?

A	1st Round		2nd R	ound
Answers	frequency	percent	frequency	percent
Reinforced incentives for researchers (including income, job stability, promotion, etc.)	14	35	22	44
Revised income calculation method (guarantee the same income for researchers with less medical service provision due to R&D)	12	30	15	30
Allowance of spending a portion of R&D grant for researcher's salary	5	13	8	16
Allowance of spending a portion of R&D grant for improving R&D facilities	4	10	3	6
Acceptance of overall outcome of R&D instead of counting number of papers, patents, etc.	3	8	2	4
Provision of incentive according to performance of each researcher	1	3	0	0
Allowance of providing incentive from hospitals related to R&D outcome	1	3	0	0

# (4-3) Which is the most urgently required in TTOs for research-based hospitals in Korea?

Amorrono	1st Round		2nd Round	
Answers	frequency	percent	frequency	percent
Recruitment of experts (especially on IP, international technical information, etc)	9	31	20	37
Independent TTO within hospitals	8	28	14	26
Capacity building of TTO in supporting commercialization	5	17	9	17
Adoption of mandatory re-investment policy of R&D profit on further R&D	2	7	8	15
Encouraging small & mid-sized hospital to cooperate with TTOs of leading hospitals	1	3	0	0
Concrete joint agreement between TTOs of universities and hospitals	1	3	0	0
Establishment of an exclusive TTO subunit for hospitals in universities	1	3	1	2
Decrease overhead cost collected by TTO	1	3	0	0
Adoption of mandatory re-investment policy of overhead cost of TTO on researchers	1	3	2	4

### 5. Issues on human resources in hospitals

## (5-1) Which human resource is most required for RBH?

	1st Round		2nd Round	
Answers	frequency	percent	frequency	percent
Researchers with doctoral degrees	25	33	21	39
Clinical research experts (coordinator, clinical nurse, etc)	11	14	10	18
Basic scientists to cooperate with physicians in R&D	11	14	14	26
Experts to lead planning of R&D projects, IP, license, etc	8	11	4	8
Technicians with master degrees or higher	7	9	1	2
MDs working on R&D only	6	8	2	4
Administrative assistant staff	5	7	1	2
Research assistant staff	2	3	0	0
Engineers for medical equipment and devices	1	1	1	2

# (5-2) Which human resource is required to be trained by the government for RBH?

A	1st Rou	ound	2nd R	ound
Answers	frequency	percent	frequency	percent
MD with research capacity	18	38	20	37
Qualified researchers for bridging basic study and clinical application	9	19	16	30
Scientists with capacity of collaborating with MDs	9	19	12	22
Technicians for assisting R&D	4	9	2	4
Clinical pharmacologists	2	4	1	2
Clinical research coordinators	2	4	0	0
Clinical trial experts	1	2	2	4
Experts on developing medical equipment and devices	1	2	1	2
Bio-statisticians	1	2	0	0

# (5-3) Please select the most suitable change in medical schools system for capacity building of hospital-based R&D.

	1st Round		2nd Round	
Answers	frequency	percent	frequency	percent
Strengthening research related subjects in the curriculum of medical colleges	8	27	11	20
Introduction of joint program of MD and Ph D	5	17	15	28
Total reform of medical schools in the direction of research orientation	5	17	8	15
Recruitment of more clinical physicians in basic science departments	3	10	2	4
Allowance of training students of medical colleges in research lab of hospital-based research professors	2	7	0	0
Improved treatment for scientists	2	7	5	9
Introduction of research leave for clinical research physicians	2	7	7	13
Allowance of incentive for military service to hospital-based reseachers	2	7	4	7
Adoption of dual-track program both of R&D and medical service for physicians	1	3	2	4

(5-4) Please reply your opinion on significant improvement measures on education system of non-medical schools and colleges in terms of capacity building of R&D in hospitals.

A # 2222 # 2	1st Round		2nd Round	
Answers	frequency	percent	frequency	percent
Introduction of co-education programs for basic science departments with medical colleges	14	54	23	42
Opening of special courses on required expertise by hospital-based research	4	15	8	15
Expansion of cooperation opportunity between medical doctors and basic scientists at universities	4	15	13	24
Provision of incentives for required human resources in medical schools applications	1	4	1	2
Enhancing job security of scientists and technicians hired by medical colleges and research centers	1	4	9	17
Introduction of re-training program for researchers	1	4	0	0
Focus on commercialization of hospital-based R&D outcome rather production of papers, no connection with commercialization	1	4	0	0

### 6. Issues on the government policy for supporting research-based hospitals

(6-1) Please select the most effective economic incentive measure of the government to encourage RBHs.

Amorrono	1st Ro	ound	d 2nd Ro	
Answers	frequency	percent	frequency	percent
Additional incentive by reimbursement of NHI (national health insurance)	15	32	15	43
Enhancing R&D grant of the government with long-term infrastructure investment for the qualified hospitals	11	23	14	40
Allowance substitution of military service for researchers	6	13	5	14
Adoption of R&D as a criteria of the government accreditation of hospitals	4	9	1	3
Tax exemption for R&D	4	9	0	0
Providing incentive in selection process of R&D recipients	3	6	0	0
Expansion of NHI coverage to clinical research patients in RBHs	2	4	0	0
Increase the ratio of overhead cost	1	2	0	0
Introduction of fast track in the approval process of KFDA for R&D outcomes	1	2	0	0

### (6-2) Please answer the most effective legal deregulation for RBHs.

Answers	1st Round		2nd Round	
Allswers	frequency	percent	frequency	percent
Revision of approval system for newly developed medical technique, and elaborating pilot-based non-reimbursed system for RBHs	12	57	23	72
Fast track approval of KFDA	3	14	4	12
Allowance of venture companies by RBHs	3	14	5	16
No special deregulation is required	2	10	0	0
Expansion of tax exemption	1	5	0	0

## (6-3) Please select the other supportive measures that the government could perform for RBHs.

Answers	1st Round		2nd Round	
Answers	frequency	percent	frequency	percent
Special incentive for outstanding researchers (supporting oversea training programs, etc.)	6	36	15	53
Regular accreditation for RBHs	4	24	9	32
Advocacy and training for RBHs	2	12	0	0
Different support system according to R&D investment amount/ratio	1	6	2	7
Provision of MD in substitution of military service	1	6	1	4
Allowance of flexible requirement of RBH staff	1	6	1	4
Deregulation of the single hospital attache policy for MDs	1	6	0	0
Introduction of national certification for new HT researchers	1	6	0	0

#### Abstract in Korean

## 한국형 연구중심병원 모형개발에 관한 연구

보건의료관련 기술(Health Technology, HT)은 건강에 대한 사회적관심의 증가, 의료비용의 증가 및 저성장 경제기조의 정착 등 사회경제적변화에서 그 중요성이 더욱 증가하고 있다. 이러한 HT 경쟁력 제고 및 관련 산업의 발전을 위해서는 HT가치사슬의 중심에서 아이디어를 생산하고연구, 개발하며 최종적으로는 성과물을 소비하는 병원의 역할이 무엇보다중요하다. 우리나라의 병원들은 우수한 인적자원이 집중되어 있으며, 첨단의료기기의 확보, 뛰어난 정보화 인프라 등 연구를 위한 잠재적 역량을 갖추고 있음에도 불구하고 실제 HT 연구개발(R&D) 과정에서 중추적 역할을수행하고 있지 못하다는 지적이 있다.

HT R&D 전문가들을 대상으로 델파이기법을 활용한 설문조사 및 우수한 외국의 연구중심병원 사례연구 결과를 분석한 결과, 우리나라 병원들의 일부가 RBH가 되기 위해서는 크게 병원의 시스템 개편, 병원의 연구개발 인프라 강화, 인적자원 확충, 그리고 정부의 지원 및 사회적 인식개선의 측면에서 개선이 필요하다. 병원의 전반적 시스템의 개편은 RBH를 향한 강력한 리더십과 모든 병원 종사자들의 인식전환, R&D가 장려되고 목표가 될 수 있는 관리체계의 획기적 개편, 다학제적 협력과 개방적 혁신의추구 등을 포함하고 있다. 병원의 전반적인 시스템이 진료뿐 아니라 R&D가 병원의 핵심사업이며 지향점이라는 인식을 갖고 움직일 수 있도록 모든병원 임직원의 의식과 행태를 바꾸는 것이 관건이다.

병원의 인프라 강화는 병원의 특성에 적합한 산학협력단을 구성, 운영하여야 하며 병원의 시설, 장비 등을 R&D에 전략적으로 배분할 수 있 고 연구자 중심의 통합적 정보시스템을 구축하고 병원의 임상시험 인프라의 확충을 골자로 하고 있다. 한편, 인적자원과 관련하여 임상의사들에게연구와 임상을 선택적으로 또는 균형되게 수행할 수 있는 경로 (Dual-track system)를 마련하고, 의사들과 기초과학자들이 서로 교류하며 훈련받을 수있는 교환교육 프로그램이 필요하다고 본다. 또한 병원내 연구를 뒷받침하는 연구원들의 안정적 신분보장을 포함한 경력관리제도의 도입도 요청된다.

가장 중요한 것은 RBH가 미래 한국의 HT 발전 및 건강산업의 주역이 될 수 있다는 사회적 인식의 확산을 기초로 한 정부의 전폭적 지원이다. 우선, 안정적 RBH 지원을 위한 법적 기반을 갖추고 병원중심 연구의활성화를 위하여 건강보험, 의료법 등의 규제완화가 필수적이다. 그리고 무엇보다 HT 분야에 대한 R&D 투자를 세계적 수준의 RBH가 육성될 수 있는 수준으로 장기간에 걸쳐 획기적으로 증액하여 투자하여야 한다. 이러한제안은 우선 제한된 국가적 자원을 고려하여 선택과 집중의 원칙에 따라R&D 역량을 갖추고 있으며 임상수준도 상대적으로 우수한 병원들과 일부역량 있는 전문병원을 대상으로 지원하되 정기적 평가를 통하여 철저한 검증을 거쳐 관리하여야 할 것이다. RBH에 대한 제도적 기반이 성숙되는시기에는 다소 연구역량과 경험은 부족하나 임상수준이 높은 병원들을 대상으로 RBH 모델을 확산하는 단계적 접근방식이 효과적일 것으로 본다.

\* 핵심되는 말: 보건의료 기술 (HT), 연구중심병원 (RBH), 연구개발 (R&D), 보건의료관련 산업 (Health Industry)