History of clinical pharmacology in Korea

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Rudolph Buchheim introduced the concept of optimum drug therapy and optimal use of drugs in the treatment of disease in 1849. However, clinical pharmacology as an academic discipline began after intensive researches into the appropriate use of antimalarial drugs during World War II. The word “Clinical Pharmacology” was first used in the title “Clinical Pharmacology Laboratory” led by Albert Sjoerdsma, with the support of James Shannon of the US National Heart Institute, in the early 1950s. There was also a clinical working group within the Department of Pharmacology at Cornell University College of Medicine led by Harry Gold and Walter Modell. In the US, during the 1950s and 1960s, clinical pharmacological research and programs fostering clinical pharmacologists expanded greatly, with the establishment of 10 clinical pharmacology centers within university hospitals supported by NIGMS. Simultaneously, in Western Europe, there was a rapidly growing need for collaboration between the pharmaceutical industry and academia for the clinical development of new drugs, and clinical pharmacology was dawning as a discipline at Hammersmith Hospital and University College Hospital in the UK. The thalidomide tragedy in the late 1950s demonstrated the urgent need to develop clinical pharmacology departments in universities. In the 1960s, the Karolinska Institute of Sweden established a clinical pharmacology department in Huddinge Hospital, which became the epicenter of clinical pharmacology development throughout Western Europe.

Among Asian countries, the pharmaceutical industry developed early only in Japan. The Japanese pharmaceutical industry developed early only in the 1960s. Scholars who received clinical pharmacology training in Europe and the US during this period facilitated the establishment of clinical pharmacology programs in medical institutes from the late 1960s to the 1970s. However, despite the WHO’s endeavor to expand clinical pharmacology to other countries in the early 1970s, this did not extend to the Asian medical world beyond Japan. The notion of clinical pharmacology was first introduced in the Korean medical community in the early 1970s by professor KS Lee from SUNY Downstate Medical Center in New York while he was working as a visiting professor in the Department of Pharmacology at Seoul National University (SNU) College of Medicine. Dr. YW Cho became the Chair of the Pharmacology Department of Chung-Ang University College of Medicine in 1974 after finishing fellowship training in clinical pharmacology in the US. Though he introduced clinical pharmacology to Korea and conducted clinical pharmacology studies, he did not make a large impact in academia. However, since then, more young pharmacologists and clinicians have begun to recognize the importance of clinical pharmacology in the development and optimal use of new and existing drugs.

Burgeoning of Clinical Pharmacology in Korea (1988-1994, before KGCP enforcement)

Beginning in the mid-1980s, some of Korean pharmaceutical companies began to establish in-house research institutes to foster new drug development capabilities. SNU and Yonsei University started to send their junior faculty members to the West under the initiative of the Departments of Pharmacology, so that the young scientists could receive clinical pharmacology training. I was an assistant professor at SNU in 1986 and received fellowship training as a visiting scholar at the Clinical Pharmacology Center of Northwestern University Memorial Hospital (Dr. Arthur A Atkinson Jr as supervisor) in Chicago, IL. After returning to Korea, I commenced clinical pharmacology activities in 1988; this was the beginning of clinical pharmacology in Korea. Later, Dr. YJ Bang, who majored in Oncology at the Department of Internal Medicine of SNU, received fellowship training at a clinical pharmacology branch of NCI in 1989. Dr. BJ Park of the Department of Preventive Medicine at SNU received training in pharmaco-epidemiology at Washington University in 1991. Dr. MH Lee of the Department of Internal Medicine of Hanyang University received fellowship training in the Clinical Pharmacology Division of Vanderbilt University. Dr. IS Lee, medical director at a pharmaceutical company (Han-Dok), finished his fellowship in Clinical Pharmacology at Cornell in 1992.

In the early 1990s, new drug development, especially that focusing on efficiency of clinical development, had become a global issue. The WHO Drug Committee initiated a related discussion in 1991. In 1992, the US, Europe, and Japan led discussions about system reform under the title of ICH (International Conference of Harmonization) for the globalization of a new drug approval system. This change in the drug development process had a significant influence not only on Korean government and drug industries, but also in academia, as evidenced by the growing interest in clinical pharmacology within the Korean medical societies. In spite of the small number of trained clinical pharmacologists in Korea, 83 medical professors studying pharmacology and clinical medicine, along with members of the pharmaceutical industry, established...
the KSCPT (Korean Society for Clinical Pharmacology and Therapeutics) on January 15, 1992. The academic society’s activities will be mentioned later in this document.

These changes resulted in increased interest in the area of clinical pharmacology among young medical scientists. In 1991, Dr. Sohn of the Pharmacology Department at Soonchunhyang University College of Medicine, received training in clinical pharmacology at the International Hospital, Japan. Dr. HK Roh, from Inha University, with a background in both pharmacology and internal medicine, received clinical pharmacology training at the Karolinska Huddinge Hospital of Sweden. Yonsei University College of Medicine sent Dr. MS Park (pediatrician) and Dr. NC Yu (oncologist) to the University of Aberdeen in UK and Hoechst Clinical Pharmacology Center in Germany, respectively, for training. In 1996, the first Korean Clinical Pharmacology Department was established at Severance Hospital, and Professor KH Kim, the Chairman of the Department of Pharmacology, was invited to be the founding Chairman of the Clinical Pharmacology Department Hospital.

**Korean Society for Clinical Pharmacology & Therapeutics**

In the early 1990s, the medical society and pharmaceutical industry that embarked on R&D for new drug development recognized clinical pharmacology as an essential area of research for new drug development and optimum use of drugs. In November 1991, approximately 20 experts from SNU and Yonsei University College of Medicine gathered to discuss the establishment of a Korean clinical pharmacology society. The inaugural meeting of the KSCPT (Korean Society for Clinical Pharmacology and Therapeutics) was held in the Grand Ballroom of the Grand Intercontinental Hotel Seoul on January 25, 1992, attended by approximately 300 participants. This year, 2014, marks the 23rd anniversary of KSCPT’s inception.

KSCPT was founded for broad participation, including a small number of clinical pharmacologists, basic pharmacologists, and many clinicians. For the past two decades, KSCPT has played a leading role not only in the academic development of clinical pharmacology, but also in the progress of clinical development of new drugs in Korea, fostering clinical trials for new drugs and clinical regulatory systems. Additionally, KSCPT initiated clinical researches and trials within medical institutions of Korea. To further explore the activities and implications of KSCPT, please refer to the detailed review by Professor Roh in the first issue of 2012 Journal of Korean Society for Clinical Pharmacology & Therapeutics. However, since this review is written in Korean, the historical significance and important

![Figure 1. Overseas Clinical Pharmacology Training: before 1994](image-url)
contributions of KSCPT’s activities are described here.

Immediately after its foundation, the KSCPT discussed clinical trials, the GCP systems of advanced countries, and IRBs as topics in its first annual meeting, in order to enhance new drug clinical trials in Korea and improve hospitals’ clinical trial environments. This served as an opportunity to enable those working in the medical and pharmaceutical industries to broaden their understanding on clinical trials. KSCPT modified the draft version of the Korean GCP prepared by the Ministry of Health and Welfare in line with practical clinical environment and advanced regulations of the US and the WHO. The KSCPT continued to provide a venue for IRB settlements in Korea, clinical trial ethics, and changes in the role of hospital governance in clinical trials. Since 1993, KSCPT has encouraged major university hospitals in Korea to establish IRBs and start IRB reviews of new drug clinical trials. To keep pace with such changes in academia, the Korean government mandated the enforcement of the Korean GCP regulation in October 1995. Korea was the second Asian country to implement GCP, after Japan.

With the number of trained clinical pharmacologists increasing after 1995, the academic activities of KSCPT became more focused on core knowledge for clinical pharmacology. KSCPT held symposiums on optimal drug therapy, therapeutic drug monitoring, new drug post-marketing surveillance (PMS), clinical evaluation of new drugs, clinical trial methodology, and DUR. Along with the progress of ICH, clinical studies of new drugs and approval systems became more scientific and globalized. In response, KSCPT organized workshops and symposia related to guidelines, such as ICH E5 and E6, in an effort to lead the change in Korea’s medical and pharmaceutical environment. As such, even when global clinical trials were not legally allowed in Korea, KSCPT played a role as one of the most essential medical societies to improve the national capacity to prepare for the future, including globalization of the medical environment and drug development of local pharmaceutical companies.

As the number of clinical studies for NDA in Korea started to increase in the 1990s, more medical doctors engaged in work for pharmaceutical companies. In addition, KSCPT supported the foundation of the KSPM (Korean Society of Pharmaceutical Medicine) in 1996. The number of medical doctors working in pharmaceutical companies has now risen to about 150. With the expansion of global clinical trials in Eastern Europe, Latin America, and Australia after the mid-1990s, there has been a growing request to change the government’s regulations banning clinical trials within Korea for new drugs developed overseas. In the late 1990s, there were a series of venues for discussion of globalization among the KSCPT, KSPM, and MFDS (Ministry of Food and Drug Safety). This served as an opportunity to rapidly change Korea’s drug regulations in line with the global standard in the 2000s.

Korea’s new drug clinical trials were formally globalization in 2002, which brought about a remarkable change in terms of quantitative and qualitative expansion of Korean clinical trials. The increase in global clinical trials in Korea led to the advancement of not only clinical trials themselves, but also the related education and robust IRB operations. Accordingly, there was greater need for clinical pharmacologists, primarily in university hospitals. Key members of the KSCPT supported the inception of the Korean Association of IRB under the KAMS (Korean Academy of Medical Sciences) in March 2002 to improve IRB operations nationwide. They also made great contributions to the standardization of IRB operations in view of ethical and scientific management of clinical trials and improved them to the level of IRBs in advanced countries through consistent educational activities.

In 2004, the Ministry of Health and Welfare considered the clinical trial sector for new drug development as a knowledge-based industry; they initiated programs to support the establishment of the RCTC (Regional Clinical Trial Center) to bring fundamental improvement to the clinical trial environment for Korea’s new drug development. This was the result of continuous communication among leading clinical pharmacologists, pharmaceutical physicians, and the government. This state-sponsored program made the greatest contribution to the global expansion of Korea’s clinical trial sector. The establishment of 15 RCTCs in large university hospitals in Korea between 2004 and 2010 generated a greater need for clinical pharmacologists and accelerated the foundation of clinical pharmacology in hospitals (clinical pharmacology departments in hospitals or clinical pharmacology divisions in clinical trial centers) as a research-oriented and consulting entity for optimum drug therapy, thereby increasing the number of clinical pharmacology training programs in Korea.

In addition, a large number of clinical pharmacologists lead RCTCs as center heads. Such changes transformed Korea from a country without any global clinical trial experience prior to 2000 to the world’s 10th leading global clinical trial country in 2014, with more than 300 global trials per year. Korea also emerged as a global conductor of early-stage clinical trials. With the increase in local clinical pharmacology training programs and scientists who have completed clinical pharmacology fellowships overseas, academic research activities have rapidly increased in the KSCPT, such as PK-PD modeling simulation and pharmacogenomics. PAGE (Population approach group in Korea) and pharmacogenomics study group were founded as interest groups affiliated with the KSCPT. This increase in Korean clinical pharmacologists after 2000 led to greater involvement in international academic activities. In 2008, the International Pharmacogenomics Congress was held in Busan, and in September 2012, the 1st World Congress in pharmacometrics was held in Seoul.

Recently, about 50 Koreans participated in the annual meeting of the ASCPT (American Society for Clinical Pharmacology and Therapeutics), which is the...
largest clinical pharmacologist meeting in the world. Korean attendees represented the second largest delegation, following the US, at this meeting. The KSCPT has hosted annual joint conferences with its Japanese counterparts (JSCPT) since 2005 and also organized a joint conference with ASCPT in Seoul in 2009. A trilateral joint conference involving Korea, the US, and Japan was held in Hamarnatsu, Japan, in 2011.

Slowly Emerging Clinical Pharmacology Training and Educational Programs

Between the late 1980s and early 1990s, eight Korean medical scientists returned to Korea after receiving clinical pharmacology training overseas. In addition, with the founding of the KSCPT in 1992, many activities were pursued to promote the development of clinical research and clinical trials aimed at new drug development in Korea. However, the establishment of clinical pharmacology curricula and training programs within medical schools in Korea was a daunting task.

The first clinical pharmacology program was established by Dr. SG Shin of the Pharmacology Department of SNU College of Medicine. Dr. Shin created a clinical pharmacology unit within SNU Hospital in 1988 to provide TDM consulting services and clinical pharmacology research. At that time, a 4-year clinical pharmacology training program was initiated to allow MDs to work as research and educational assistants in the clinical pharmacology section of the Pharmacology Department. Two young doctors who first started training at SNU in 1988 were IJ Jang and JG Shin. Afterward, the program added one or two clinical pharmacologists every year.

SNU started to offer ten hour clinical pharmacology education programs to medical students, teaching the concepts of clinical pharmacology for optimum drug therapy as a 0.5-credit formal lecture in 1989. Meanwhile, Dr. HK Roh received training in both pharmacology and internal medicine after graduating from Yonsei University College of Medicine. He became an instructor in the Department of Internal Medicine of Inha University in 1991 and received training in clinical pharmacology at the Huddinge Hospital of Karolinska Institute. After returning, he achieved dual appointments in internal medicine and basic pharmacology at Inha University. He also opened a clinical pharmacology division within the Department of Internal Medicine at Inha University Hospital and initiated pharmacogenomics research and training programs. At that time, Prof. YN Cha, the chairman of the Pharmacology Department, was active in promoting clinical pharmacology. Dr. KH Lee joined the clinical pharmacology section of Inha University after finishing training at SNU. Professor HK Roh moved to Gachon
University Gil Medical Center in 2007, where he established a new clinical pharmacology division.

Meanwhile, Severance (Yonsei University) Hospital sent two young doctors to Europe for clinical pharmacology training. Immediately after they returned to Korea, Severance Hospital began operations in its new Clinical Pharmacology Department in 1996. This was the first independent Clinical Pharmacology Department at a university hospital in Korea. Professor DR Sohn at Soonchunhyang University College of Medicine returned from training at the Clinical Pharmacology Laboratory of Tokyo International Hospital (with Dr. Takashi Ishizaki as supervisor). Sohn changed the name from the Department of Pharmacology to the Department of Clinical Pharmacology, establishing the first Clinical Pharmacology Department in a Korean medical school in 1996. After clinical pharmacology training at SNU College of Medicine, Dr. JG Shin joined the Pharmacology Department of Inje University College of Medicine, where he graduated and became a faculty member. He established the Clinical Pharmacology Center at Inje University Busan Paik Hospital and was soon joined by Dr. YE Kim. As a faculty member, Dr. Shin established TDM services and a clinical pharmacology training program. He also designed a clinical pharmacology course for medical students. The center was expanded to a government-funded RCTC in 2004. Inje University's clinical pharmacology team actively embarked on pharmacogenomics research and established the globally recognized Pharmacogenomics Center (PGx) with continuous governmental grants.

Between 1988 and 2000, very few institutions had training programs for young clinical pharmacologists. SNU usually generated the largest number of new clinical pharmacologists. Inje University and some other universities also produced a small number. After 1995, young doctors who finished clinical medicine training (their training experiences were diverse, including family medicine, pediatrics, internal medicine, anesthesiology, and pharmaceutical medicine) went abroad for fellowship training in clinical pharmacology. After returning to Korea, they made great contributions to the country’s clinical pharmacology activities.

Those who received clinical pharmacology training between 1995 and 2000 are specified in Figure 2. During this period, many Korean clinical pharmacologists received advanced training at the clinical pharmacology division of Georgetown University in Washington, DC, US by working with Drs. Carl Peck, Abernetlay, and Flokhart.

**Establishment of Clinical Pharmacology Organizations in Korea**

In the 1990s, clinical pharmacology organizations often started with 1–2 professors at SNU Hospital, Inha University Hospital, Yonsei University Severance Hospital, Inje University Busan Paik Hospital, or Soonchunhyang University College of Medicine. Their informal training programs generated a few young clinical pharmacologists. Clinical pharmacology education for undergraduate students was established only at a few universities. However, entering the 2000s, two governmental policies enacting separation of IND and NDA and separation of prescription and dispensing, clearly identified the need for clinical pharmacologists within the medical society in Korea. In 2004, the government began to support the establishment of clinical trial infrastructures within university hospitals to promote clinical trials (RCTC programs). Accordingly, large university hospitals in the Seoul metropolitan area and major local cities began to realize that it was essential to secure clinical pharmacologists and establish clinical pharmacology departments within their hospitals to host the RCTC. Thus, there has been active recruitment of young clinical pharmacologists and the establishment of clinical pharmacology organizations after 2004. As shown in Table 1 and Figure 3, 15 independent clinical pharmacology departments were established at university hospitals, and 7 clinical pharmacology organizations were opened as divisions of internal medicine or as departments of CTCs. Currently, there are 64 clinical pharmacology professors, including those with dual appointments. There are also several clinical pharmacologists who are working as faculty members in pharmacology departments or clinical trial centers without officially established clinical pharmacology organizations.

In 2005, the University of Ulsan (Asan Medical Center) and Inje University established independent departments at medical schools (‘Gyosil’ in Korean), following such a development at Soonchunhyang University in 1996. In Inje University, the clinical pharmacology department at the medical school has been established in line with the clinical pharmacology department at its affiliated hospital. Since its development in 1996, the department has performed research, consulting, and educational activities in clinical pharmacology.

In later years, Kyung Hee University, SNU, and Inha University established clinical pharmacology departments within their medical schools. More recently, independent clinical pharmacology departments were established in both CHA Medical School and Bundang CHA Medical Center. Currently, 7 medical schools have such independent departments. In Yonsei University, clinical pharmacology remains a division of the Pharmacology Department of the medical school (Table 1). With the growing number of RCTC establishments in major hospitals nationwide, independent clinical pharmacology departments have been established in hospitals, and the demand for clinical pharmacologists far exceeded the supply until recently. Young doctors trained in the 1990s served as professors of clinical pharmacology for several universities in the early 2000s. Some of them began their professorial activities based on RCTCs.

**Changes of Educational and Training Activities in Korea**

In the 1990s, clinical pharmacology organizations were established in SNU,
Table 1. Clinical Pharmacology Organizations established in University Hospitals and Medical Schools

<table>
<thead>
<tr>
<th>Department of Clinical Pharmacology in Hospital</th>
<th>Year of Establishment</th>
<th>Number of Faculty (Dual Appointment)</th>
<th>Remarks (Organizations other than department)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Severance Hospital</td>
<td>1996. 03</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>2 Inha University Hospital</td>
<td>1999. 04</td>
<td>3(2)</td>
<td></td>
</tr>
<tr>
<td>3 Asan Medical Center</td>
<td>2004. 09</td>
<td>5(3)</td>
<td></td>
</tr>
<tr>
<td>4 Inje University Busan Paik Hospital</td>
<td>2005. 02</td>
<td>6</td>
<td>1996.02-2005.01 Clinical Pharmacology Center</td>
</tr>
<tr>
<td>5 Seoul St. Mary’s Hospital</td>
<td>2006. 08</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>6 Korea University Anam-Hospital</td>
<td>2006. 09</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>7 Seoul National University Hospital</td>
<td>2007. 12</td>
<td>6</td>
<td>1988-2007.11 Clinical Pharmacology Unit</td>
</tr>
<tr>
<td>8 KyungHee University Hospital</td>
<td>2008. 01</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>9 Samsung Medical Center</td>
<td>2009. 09</td>
<td>4(2)</td>
<td></td>
</tr>
<tr>
<td>10 Inje University Haeundae Paik Hospital</td>
<td>2010. 02</td>
<td>2(2)</td>
<td></td>
</tr>
<tr>
<td>11 Konkuk University Hospital</td>
<td>2012. 03</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>12 Dongguk University Ilsan Hospital</td>
<td>2013. 07</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>13 Donga University Medical Center</td>
<td>2013. 09</td>
<td>2(1)</td>
<td></td>
</tr>
<tr>
<td>14 Kyungpook National University Hospital</td>
<td>2014. 03</td>
<td>2(1)</td>
<td>2005.03-2104.02 Clinical Pharmacology Division, clinical Trial Center</td>
</tr>
<tr>
<td>15 CHA Bundang Medical Center, CHA University</td>
<td>2014. 03</td>
<td>2(1)</td>
<td></td>
</tr>
<tr>
<td>16 Gachon university Gil Medical Center</td>
<td>2007. 03</td>
<td>1</td>
<td>Clinical Pharmacology division at Dept. of Internal Medicine / Clinical Trial Center</td>
</tr>
<tr>
<td>17 Chonnam National University Hospital</td>
<td>2007. 11</td>
<td>6</td>
<td>Clinical Pharmacology Division clinical Research Institute</td>
</tr>
<tr>
<td>18 Ewha Womans University Mokdong Hospital</td>
<td>2008. 12</td>
<td>1</td>
<td>Clinical Pharmacology Division Clinical Trial Center</td>
</tr>
<tr>
<td>19 Chonbuk National University Hospital</td>
<td>2011. 04</td>
<td>2</td>
<td>Clinical Pharmacology Team clinical Trial Center</td>
</tr>
<tr>
<td>20 Busan National University Hospital</td>
<td>2011. 09</td>
<td>1</td>
<td>Clinical Pharmacology Division Clinical Trial Center</td>
</tr>
<tr>
<td>21 Seoul National University Bundang Hospital</td>
<td>2012. 03</td>
<td>1</td>
<td>Clinical Pharmacology Division Clinical Trial Center, CRI</td>
</tr>
<tr>
<td>22 Chungnam National University Hospital</td>
<td>2012. 05</td>
<td>3</td>
<td>Clinical Pharmacology Division Clinical Trial Center</td>
</tr>
</tbody>
</table>

Table 2. Department of Clinical Pharmacology at Medical Schools (“Gyosil”)

<table>
<thead>
<tr>
<th>Department of Clinical Pharmacology at Medical Schools (“Gyosil”)</th>
<th>Year of Establishment</th>
<th>Number of Faculty (Dual Appointment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Soonchunhyang University College of Medicine</td>
<td>1996. 03</td>
<td>3</td>
</tr>
<tr>
<td>2 University of Ulsan College of Medicine</td>
<td>2005. 03</td>
<td>4(2)</td>
</tr>
<tr>
<td>3 Inje University College of Medicine</td>
<td>2005. 02</td>
<td>6(3)</td>
</tr>
<tr>
<td>4 KyungHee University School of Medicine</td>
<td>2005. 06</td>
<td>3</td>
</tr>
<tr>
<td>5 Seoul National University College of Medicine</td>
<td>2012. 03</td>
<td>7</td>
</tr>
<tr>
<td>6 Inha University School of Medicine</td>
<td>2013. 03</td>
<td>1</td>
</tr>
<tr>
<td>7 CHA University School of Medicine</td>
<td>2014. 03</td>
<td>2(1)</td>
</tr>
<tr>
<td>8 Yonsei University College of Medicine</td>
<td>2004. 03</td>
<td>1</td>
</tr>
</tbody>
</table>
Yonsei University, and Inje University Hospitals. The training for clinical pharmacologists was provided informally in several universities by linking the pharmacology departments in medical schools with the hospitals’ clinical pharmacology organizations. Formal clinical pharmacology residency training was initiated at SNU Hospital in 1999, with two residents per year. Dr. KS Yu of SNU and Drs. KS Bae and HS Lim currently working at Asan Medical Center were trainees at that time.

In the 1990s, only a few universities (SNU, Inje University, and Kyung Hee University) provided clinical pharmacology lectures or offered practicums for formal credit (0.5-4.0 credits). Such limited educational and training activities have improved remarkably due to the increasing need for clinical pharmacology in Korea starting in the 2000s. This was attributed to the gradual increase of formal clinical pharmacology organizations within hospitals and medical schools. Regarding the education of undergraduate students, the number of courses or total lecture time on clinical pharmacology increased gradually. An official clinical pharmacology Ph.D. track was introduced after 2000 as a postgraduate program. Currently, a clinical pharmacology Ph.D. track or a collaborative Ph.D. course is available in 5 medical schools, reinforcing academic research activity. In the 2000s, a 4-year resident training course in clinical pharmacology was established after internship. Now, there are training courses for specialty in at least 6 university hospitals or clinical trial centers (SNU Hospital, Yonsei University Hospital, Seoul Asan Medical Center, Seoul St. Mary’s Hospital, Kyungpook National University Hospital, and Chonnam National University Hospital). In addition, at least 5 hospitals (SNU Hospital, Yonsei University Hospital, Seoul St. Mary’s Hospital, Samsung Medical Center, and Asan Medical Center) operate clinical pharmacology fellowship programs that provide subspecialty training for doctors with clinical board experience after training in other clinical specialties. With an increase in the number of young doctors who received formal clinical pharmacology training, the KSCPT (Korean Society for Clinical Pharmacology & Therapeutics) has been making an effort to establish a specialty board system in Korea similar to the systems that have existed in the US, Europe and Japan since 2008. The KSCPT established training contents and minimum requirements that were standardized according to residency training years and for the 4-year training program. In 2011, the KSCPT introduced the clinical pharmacology specialist qualification examination to generate certified clinical pharmacologists. As such, the KSCPT is making an effort to qualify new clinical pharmacologists in Korea. The society initially issued the certification for 79

Figure 3. Clinical Pharmacology Organization at Univ. Hospitals, as of Sep, 2014

- Clinical Pharmacology Unit:
  - 1988, SNU Hospital as a unit (2007, upgraded to department)

- Clinical Pharmacology Center at Busan Paik Hospital – later integrated to CTC
  - 1996, Inje University

- Clinical Pharmacology as Department (15), Division*(1) or others(6) at Univ. Hospitals
  - 1996, 1st Dept. in Severance Medical Center

- Clinical Pharmacology Department(7), Division(1) at Medical Schools
  - 1996 1st Dept. at Soonchunhyang University College of Medicine

- Clinical Pharmacology Center at Seoul National Univ. Hosp
- Clinical Pharmacology Center at Inha Univ. Hosp
- Clinical Pharmacology Center at Asan Med. Center
- Clinical Pharmacology Center at Inje Univ. Haeundae Baik Hosp
- Clinical Pharmacology Center at ChungNam Univ. Hosp
- Clinical Pharmacology Center at Samsung Med. Center
- Clinical Pharmacology Center at Ewha Womans Univ. Hosp
- Clinical Pharmacology Center at Gachon Univ. Hospital Division*
- Clinical Pharmacology Center at Soonchunhyang Univ. College of Medicine

Korea Univ. Anam Hosp
KyungHee Univ. Hosp
Catholic Univ. Hosp
CHA Bundang Hosp
Seoul Natl Univ. Bundang Hosp

Cheju

Seoul

Inje Univ. Haeundae Baik Hosp, Busan Baik Hosp,

Korea Univ. Anam Hosp
KyungHee Univ. Hosp
Catholic Univ. Hosp
CHA Bundang Hosp
Seoul Natl Univ. Bundang Hosp

Cheju
doctors in 2011; to date, there are 107 certified clinical pharmacologists in Korea.

In the late 1990s or early 2000s, young doctors who completed clinical pharmacology training in Korea, as well as many young medical scientists who were interested in clinical pharmacology after obtaining another clinical specialty, received advanced training in leading global medical centers in pharmacometrics, pharmacogenomics, pharmacometabolomics, and regulatory science. Such organizations include Pfizer Clinical Research Center (San Diego, US), CDER of the FDA, Queensland University in Australia (Brisbane) and the Center for Human Drug Research of Leiden University in the Netherlands.

Korea’s clinical pharmacology commenced with a burgeoning period in the 1990s, followed by increasing numbers of clinical pharmacologists, clinical pharmacology organizations within institutes, and the stabilization of education and training programs in the 2000s. Through this process, the roles of clinical pharmacologists in Korea can be broadly summarized as follows.

First, in terms of academic activities, clinical pharmacology education for optimum drug therapy in medical schools has become popular. Second, research activities have been outstanding in the areas of pharmacogenomics and pharmaco-metrics, and a large number of clinical pharmacologists are actively conducting research in these areas. Recently, research areas have been expanded to pharmacometabolomics, system pharmacology, and early phase clinical trial technologies. Third, various clinical pharmacology activities have been performed within hospitals. The scope of these activities differs by hospital but includes TDM consulting services, ADR monitoring, and optimum drug therapy consulting as services for optimal patient treatment. Clinical pharmacologists in Korea are also contributing to the development of hospital systems as key members of therapeutic committees and IRBs. The fourth important role of clinical pharmacologists is to conduct clinical trials for new drug development through collaboration with the pharmaceutical industry. Most clinical pharmacologists in Korea play crucial roles as core investigators of early phase clinical trials for new drug development. They also develop clinical trial platforms within university hospitals in order to enhance industry-academy collaborations. Many Korean scholars lead new drug development and provide consultation for

Figure 4. Overseas Clinical Pharmacology Training Since 2002
new drug development in the pharmaceutical industry. Additionally, in terms of public services, they play active roles as drug-related advisory members of the Korean Medical Association and Ministry of Food and Drug Administration. Clinical pharmacology was introduced to Korea in the 1990s, much later than in Western countries. However, its growth has been so intense, especially since the 2000s, that Korean activities have since caught up or surpassed activities in other countries. Despite this success, there are still an insufficient number of clinical pharmacologists in academia and hospitals. Moreover, clinical pharmacologists are desperately needed to work at MFDS or in the pharmaceutical industry as well as in academia. To this end, clinical pharmacology must be acknowledged as an essential discipline throughout Korean society.

References