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Commentary

Clinical pharmacology and therapeutics in South Korea: 30 years with the Korean Society of Clinical Pharmacology and Therapeutics

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The Korean Society of Clinical Pharmacology and Therapeutics (KSCPT) celebrated its 33rd anniversary in 2024. In 1992, the KSCPT was founded against the backdrop of increasing global focus on drug development. Since its establishment, the society has played a leading role in advancing clinical pharmacology in Korea, promoting personalized therapy, and supporting the development of clinical trial and regulatory systems for drug development. As the field now transitions from its growth phases into a period of maturity, we take this opportunity to reflect on the history of clinical pharmacology in Korea and explore its future role and development in an evolving landscape.

THE INCEPTION OF CLINICAL PHARMACOLOGY IN SOUTH KOREA AND THE EARLY ACTIVITIES OF KSCPT

The academic field of clinical pharmacology began with intensive research on the appropriate use of antimalarial drugs during World War II. In the United States, clinical pharmacology research and training programs flourished in the 1950s and 1960s, supported by the National Institute of General Medical Sciences, leading to the establishment of 10 clinical pharmacology centers within university hospitals. Concurrently, in Western Europe, clinical pharmacology emerged as a distinct discipline, with significant development centered around Huddinge Hospital in Sweden in the 1960s [1,2].

Clinical pharmacology was introduced to the Korean medical community when Professor Sang-Goo Shin, then an associate professor of pharmacology at Seoul National University, returned to Korea in 1988 after completing a clinical pharmacology fellowship at Northwestern University [3].

In the early 1990s, there was a global shift towards more efficient drug development focusing on clinical development. The United States, Europe, and Japan took the lead in discussions to harmonize global drug approval systems through the establishment of the International Conference of Harmonization. These changes in the drug development landscape significantly influenced not only the Korean government and pharmaceutical industry but also academia. In January 1992, 83 professors specializing in pharmacology and clinical medicine from medical schools, along with industry professionals, founded the KSCPT, with

Professor Chung-Kyoon Lee from Seoul National University College of Medicine serving as the inaugural president. The inaugural meeting of the KSCPT, attended by approximately 300 participants including clinical pharmacologists, basic pharmacologists, and clinicians, marked the beginning of active clinical pharmacology activities in Korea [3].

Since its establishment, the KSCPT has actively promoted research and activities related to personalized drug therapy. Studies have been conducted in various areas such as clinical pharmacokinetics and pharmacodynamics, pharmacogenetics and drug-drug interactions. As experts in the field of optimal drug therapy, the members of KSCPT have provided advice on personalized drug therapy within clinical settings.

Furthermore, the KSCPT has made various efforts to enhance and advance clinical trials and to establish advanced clinical research environments. The KSCPT participated in the publication of the Korean Good Clinical Practice (KGCP) in October 1995, making Korea the second country in Asia, after Japan, to implement Good Clinical Practice (GCP). The KSCPT also actively contributed to the revision of the KGCP in 2001 to manage clinical trials at a global standard. Starting from 1993, the KSCPT encouraged major university hospitals in Korea to establish Institutional Review Boards (IRBs) and initiated IRB reviews for clinical research, raising awareness of clinical research ethics. Through continuous education, the KSCPT improved the standards of IRBs and contributed to the standardization of IRB operations. The KSCPT played a crucial role in the establishment of the Korean Association of IRBs in 2002, with Professor Sang-Goo Shin serving as its first president [4].

The KSCPT also provided opportunities for medical and pharmaceutical industry professionals to broaden their understanding of clinical trials for drug development through symposiums and discussions on topics such as clinical trials and GCP systems of advanced countries and IRBs. For instance, the KSCPT organized the GCP symposium in 1992 to discuss the historical background of GCP and the responsibilities and roles of investigators and sponsors. In 1996, the KSCPT held workshops on clinical trials to introduce the preparation of the pharmaceutical industry for KGCP implementation, the perception of researchers on clinical trials, and the drug approval process. In 1997, the KSCPT hosted the first IRB training education in Korea, sponsored by the Korean Medical Association (KMA) and the Ministry of Health and Welfare [4]. The history of 30 years of KSCPT was presented in **Table 1**.

GROWTH OF CLINICAL PHARMACOLOGY IN SOUTH KOREA

Expansion of clinical trials and increased demand for clinical pharmacologists

Since the 2000s, the clinical trial market has globalized and expanded significantly both quantitatively and qualitatively. In 2004, the Ministry of Health and Welfare initiated the Regional Clinical Trial Center (RCTC) establishment support program to fundamentally improve the clinical trial environment for new drug development. Consequently, from 2004 to 2010, 15 RCTCs were established in major university hospitals nationwide [4], leading to an increased demand for clinical pharmacologists. Additionally, in the 2000s, 2 government policies—the separation of investigational new drug (IND) applications and new drug applications, and the separation of prescription and dispensing—further underscored the necessity of clinical pharmacologists. In this context, clinical pharmacology in Korea

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Table 1. History of KSCPT

Year	Events
1991	Establishment preparation committee of the KSCPT
1992	Inaugural general meeting of the KSCPT
1993	Launch of the society journal (*Journal of Korean Society for Clinical Pharmacology and Therapeutics*)
1994	Launch of the Pharmacoepidemiology Research Group
1996	Workshop on KGCP and clinical trials
1997	First IRB training course
1999	Discussion on changes in new drug approval and clinical trial environment
2000	Workshop on generic substitution and classification of pharmaceutical products First Investigator Support Initiative Workshop DIA2000 Seoul Conference
2001	Launch of the Pharmacogenomics Research Group
2002	10th anniversary conference of KSCPT
2005	First KSCPT-JSCPT joint symposium
2006	Launch of the Population Approach Group in Korea
2007	*Journal of Korean Society for Clinical Pharmacology and Therapeutics* indexed in Scopus Launch of the Korea National Enterprise for Clinical Trial
2009	First KSCPT-ASCPT joint conference
2011	Launch of the certification system for clinical pharmacology specialists 20th anniversary conference of KSCPT KSCPT-ASCPT-JSCPT joint conference
2013	*Journal of Korean Society for Clinical Pharmacology and Therapeutics* indexed in KCI
2014	Transition of the journal to "*Translational and Clinical Pharmacology*" (*TCP*) *TCP* indexed in KCI Opening of the Society's secretariat
2015	Establishment of the Woo-Chon Award
2017	First KSCPT-EACPT joint symposium
2019	MOU with the National Institute of Food and Drug Safety Evaluation
2020	*TCP* indexed in PubMed Central
2022	*TCP* indexed in Web of Science
2022	30th anniversary conference of KSCPT

KSCPT, Korean Society for Clinical Pharmacology and Therapeutics; KGCP, Korean Good Clinical Practice; IRB, Institutional Review Board; JSCPT, Japanese Society for Clinical Pharmacology and Therapeutics; ASCPT, American Society for Clinical Pharmacology and Therapeutics; KCI, Korean Citation Index; EACPT, European Association for Clinical Pharmacology and Therapeutics; MOU, Memorandum of Understanding.

experienced significant growth. Clinical pharmacologists led early phase clinical trials in Korea, transforming the country into one of the top ten global leaders in conducting over 300 global clinical trials annually in 2014.

Establishment of clinical pharmacology departments and training of clinical pharmacologists

The increase in domestic clinical trials and globalization not only improved the quality of clinical trials but also advanced system operations, expanded education, and led to the establishment of clinical pharmacology departments within hospitals, along with the training of clinical pharmacologists. Following the establishment of the first clinical pharmacology department at Yonsei University Severance Hospital in 1996, when 2 young doctors returned from Europe after completing clinical pharmacology training, clinical pharmacology departments began to be set up at university hospitals in the 2000s. The Clinical Pharmacology Center at Inje University Busan Paik Hospital, established in 2005, is the first center founded by a clinical pharmacologist trained in Korea. Professor Jae-Gook Shin, who established the Center, is one of the first 2 clinical pharmacologists trained by Professor Sang-Goo Shin at Seoul National University College of Medicine, along with Professor In-Jin Jang of Seoul National University's Department of Clinical Pharmacology [3]. As of 2023, there are independent clinical pharmacology departments or as a subdivision

within another department in 19 hospitals, with 8 institutions having independent department within medical schools.

The KSCPT has designated training institutions and standardized training processes since 2008. The training curriculum covers personalized drug therapy consultation, regulations and ethics of clinical trials, trial design, pharmacokinetic/pharmacodynamic data analysis, population pharmacokinetic/pharmacodynamic modeling and simulation, consultancy on new drug development, and review of approval documents. Until 2020, the training period was 4 years, which was shortened to 3 years after 2021. Upon successful completion of clinical pharmacology training and the qualification examination, the KSCPT confers certification in clinical pharmacology. As of 2023, a total of 156 individuals have been granted clinical pharmacology certification since January 2011.

MATURATION OF CLINICAL PHARMACOLOGY IN SOUTH KOREA

The current activities of clinical pharmacologists

Clinical pharmacologists, trained through rigorous programs, are active in academia, healthcare institutions, pharmaceutical companies, and regulatory agencies, engaging in various activities to advance personalized medicine and drug development. Their contributions span patient care, drug development, education, collaboration with regulatory agencies, and international collaboration.

Patient care

Clinical pharmacologists play a vital role in patient care within hospitals. Through Therapeutic Drug Monitoring (TDM), they provide personalized drug therapy by analyzing patients' drug concentrations, clinical laboratory test results, and demographic information to recommend optimal drug regimens, thereby minimizing side effects and maximizing therapeutic efficacy. TDM is conducted for various drugs, including antibiotics such as vancomycin and aminoglycosides, antiepileptics like valproic acid and carbamazepine, immunosuppressants such as cyclosporine and tacrolimus, as well as drugs like theophylline and lithium. Some hospitals also offer services to determine the initial dose of warfarin and certain neuropsychiatric drugs based on genotype and clinical information. In addition, clinical pharmacologists provide consultations on drug responses based on various information including clinical information, genetic factors and drug-drug interactions. They also provide advice to help understand and resolve adverse drug reactions.

Drug development

Drug development activities often involve collaboration with the pharmaceutical industry. Clinical pharmacologists collaborate with the pharmaceutical industry, serving as investigators in early-phase clinical trials, responsible for planning, conducting, and analyzing trial data. They also provide consultation on drug development strategy through interpreting preclinical data, designing clinical trial or pharmacokinetic and pharmacodynamics modeling-simulation. Many clinical pharmacologists directly engage in pharmaceutical companies, leading drug development by formulating development strategies, planning and managing clinical trials, and overseeing drug safety information. The involvement of clinical pharmacologists in most of the 36 new drugs developed in Korea underscores the significance of their role in drug development. Analysis of IND application

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database from the Ministry of Food and Drug Safety (MFDS), along with information from KSCPT members highlights the contributions of clinical pharmacologists to new drug development through various studies including first-in-human studies, pharmacokinetic studies in special populations, drug-drug interaction studies, bioequivalence studies and ethnic difference studies. Clinical pharmacologists have also contributed to the development of new drugs for chronic diseases, antibiotics and various anti-cancer agents, and participated in the development of vaccines and therapeutics for coronavirus disease 2019 (COVID-19) during the pandemic crisis (**Table 2**) [4].

Education

Clinical pharmacology education is offered in both undergraduate and graduate courses for medical students, as well as in advanced courses for professionals in the pharmaceutical industry. Undergraduate courses cover the variability in drug responses, individualized therapy, pharmacokinetics in special populations (such as the elderly, children, and pregnant women), the impact of impaired renal and hepatic function on pharmacokinetics and pharmacodynamics, and the role of genetic variabilities as biomarkers for drug responses. These courses include both lectures and problem-based learning in small groups, where students learn to select and prescribe appropriate medications for patients. Graduate-level courses cover basic concepts of clinical pharmacology, pharmacogenomics, clinical trial design, drug development process, and regulatory process for drug management. Advanced courses for pharmaceutical industry professionals aim to enhance drug development expertise, offering lectures on topics such as drug design, process development for drug development, clinical trial management, drug development strategies, and regulatory process for drug management.

Clinical pharmacology training for physicians involves acquiring knowledge and skills for personalized drug therapy consultation, regulations and ethics for clinical trial, trial design, pharmacokinetic/pharmacodynamic data analysis, population pharmacokinetic/pharmacodynamic modeling and simulation, consultancy on new drug development, and review of approval documents.

Collaboration with regulatory agency

The KSCPT has contributed to improving public health through personalized drug therapy and enhancing national capabilities in drug development and management, through various research projects conducted in collaboration with the Ministry of Health and Welfare and the MFDS. For example, the KSCPT operated the 'Korean Pharmacogenomics Research Network' from 2003 to 2012, focusing on predicting drug responses and developing pharmacogenomic diagnostic technologies, laying the foundation for personalized drug therapy. This project involved genome research on drug metabolism enzymes and drug transporters, as well as pharmacogenomic studies in therapeutic categories such as respiratory and psychotropic drugs. With the pharmaceutical industry increasingly utilizing modeling and simulation for new drug development, and with regulatory agencies becoming more aware of model-informed drug development, the KSCPT developed a shared modeling-simulation library at the request of the MFDS in 2018. This initiative has facilitated more efficient drug development and regulatory management. Additionally, in this project, the open-source web platform for non-compartmental analysis, compartmental modeling, prediction of phase 1 dosing using allometric scaling, and the estimation of hepatic clearance based on in-vitro study results was developed. Recently, the KSCPT has been working on a project supported by the MFDS to address regulatory changes required for clinical trials in the post-COVID-19

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era, focusing on the decentralized clinical trials (DCTs) and use of advanced technologies such as IoT and big data in clinical trials.

Table 2. The list of domestic new drug approvals contributed by Korean Society of Clinical Pharmacology and Therapeutics

Brand name	Company	Active ingredient	Indication	Approval date	Contributions
ENVLO TAB	Daewoong Pharmaceutical Co., Ltd.	Enavogliflozin	Anti-diabetics	22.11.30	FIH study, special population study (renal impairment), drug-drug interaction study, etc.[5]
SKYCOVIONE MULTI INJ	SK Bioscience Co., Ltd.	Recombinant SARS CoV-2 spike protein	COVID-19 vaccine	22.6.29	Phase III study, etc.[6]
FEXUCLUE TAB	Daewoong Pharmaceutical Co., Ltd.	Fexuprazan	GERD medication	21.12.30	FIH study, pharmacogenomics study, ethnic difference study, drug-drug interaction study, bioequivalence study, etc.[7-9]
ROLONTIS PFS INJ	Hanmi Pharmaceutical Co., Ltd.	Eflapegrastim	Neutropenia medication	21.03.18	FIH study, etc.[10]
REGKIRONA INJ	Celltrion, Inc.	Regdanvimab	COVID-19 medication	21.02.05	FIH study, etc.[11]
LECLAZA TAB	Yuhan Corp.	Lazertinib	Anti-cancer agent	21.01.18	Ethnic difference study, food effect study, etc.[12]
K-CAB TAB	CJ HealthCare Corp.	Tegoprazan	Anti-ulcer agent	18.07.05	FIH study, food effect study, drug-drug interaction study, bioequivalence study, etc.[13-16]
BESIVO TAB	Ildong Pharmaceutical Co., Ltd.	Besifovir	HBV hepatitis medication	17.05.15	Food effect study, special population study (renal impairment), etc.[17]
OLITA TAB	Hanmi Pharmaceutical Co., Ltd.	Olmutinib	Anti-cancer agent	16.05.13	Ethnic difference study, food effect study, patient PK study, etc.[18]
SUGANON TAB	Dong-A ST Co., Ltd.	Evogliptin	Anti-diabetics	15.10.02	FIH study, special population study (renal /hepatic impairment), bioequivalence study, drug-drug interaction study, etc.[19-23]
SIVEXTRO TAB/INJ	Dong-A ST Co., Ltd.	Tedizolid	Antibiotics	15.04.17	FIH study, absolute bioavailability study, ethnic difference study, etc. [24]
ZABOLANTE TAB	Dongwha Pharmaceutical Co., Ltd.	Zabofloxacin	Antibiotics	15.03.20	Bioequivalence study, PK/PD study, etc.[25]
ACELEX CAP	CrystalGenomics, Inc.	Polmacoxib	Osteoarthritis medication	15.02.05	FIH study, drug-drug interaction study, bioequivalence study, etc.[26,27]
DUVIE TAB	Chong Kun Dang Pharmaceutical Corp.	Lobeglitazone	Anti-diabetics	13.07.04	FIH study, drug-drug interaction study, bioequivalence study, special population study (renal /hepatic impairment), food effect study, etc.[28-32]
ZEMIGLO TAB	LG Life Sciences, Ltd.	Gemigliptin	Anti-diabetics	12.06.27	FIH study, drug-drug interaction study, bioequivalence study, special population study (renal impairment), food effect study, etc.[33-37]
ZEPEED TAB	JW Pharmaceutical Corp.	Avanafil	Erectile dysfunction medication	11.08.17	FIH study, etc.[38]
PYRAMAX TAB	Shinpoong Pharmaceutical Co., Ltd.	Pyronaridine	Anti-malarial agent	11.08.17	Bioequivalence study, etc.
KANARB TAB	Boryung Pharmaceutical Co., Ltd.	Fimasartan	Anti-hypertensive agent	10.09.09	Bioequivalence study, drug-drug interaction study, special population study (renal /hepatic impairment), absolute bioavailability study, etc.[39-43]
NOLTEC TAB	Il-Yang Pharmaceutical Co., Ltd.	Ilaprazole	Anti-ulcer agent	08.10.28	Bioequivalence study, pharmacogenomics study, drug-drug interaction study, etc.[44,45]
MVIX TAB	SK Chemicals Co., Ltd.	Mirodenafil	Erectile dysfunction medication	07.07.18	FIH study, special population study (renal /hepatic impairment), patient PD study, bioequivalence study, etc. [46-49]
PELUBI TAB	Daewon Pharmaceutical Co., Ltd.	Pelubiprofen	Osteoarthritis medication	07.04.20	Food effect study, drug-drug interaction study, etc.
ZYDENA TAB	Dong-A Pharmaceutical Co., Ltd.	Udenafil	Erectile dysfunction medication	05.11.29	Drug-drug interaction study, special population study (renal impairment, geriatrics), etc.[50-55]
REVANEX TAB	Yuhan Corporation	Revaprazan	Anti-ulcer agent	05.09.15	Drug-drug interaction study, pharmacogenomics study, etc. [56]
CAMTOBELL INJ	Chong Kun Dang Pharmaceutical Corp.	Belotecan	Anti-cancer agent	03.10.22	Patient PK study, etc.[57]
PEUDOVACCIN INJ	CJ CheilJedang Co., Ltd.	Pseudomonas aeruginosa purified cell wall protein	Pseudomonas vaccine	03.05.28	FIH study, etc.
FACTIVE TAB	LG Life Sciences, Ltd.	Gemifloxacin	Antibiotics	02.12.27	Bioequivalence study, etc.[58]
SUNPLA INJ	SK Chemicals Co., Ltd.	Heptaplatin	Anti-cancer agent	99.07.15	Patient PK study, etc.

FIH, first in human; PK, pharmacokinetic; PD, pharmacodynamics, SARS CoV-2, severe acute respiratory syndrome coronavirus-2; COVID-19, coronavirus disease 2019; GERD, gastroesophageal reflux disease; HBV, hepatitis B virus.

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In addition to research projects, the KSCPT play active roles as drug-related advisory members of KMA and MFDS, and it maintains close ties with related institutions such as the Korea National Enterprise for Clinical Trial and the Korea Drug Development Fund.

International collaboration

The KSCPT maintains collaborative relationships with international clinical pharmacology societies, including the Japanese Society for Clinical Pharmacology and Therapeutics (JSCPT), the American Society for Clinical Pharmacology and Therapeutics (ASCPT), the European Association for Clinical Pharmacology and Therapeutics (EACPT), the International Union of Basic and Clinical Pharmacology (IUPHAR), and the American College of Clinical Pharmacology (ACCP).

Since 2005, the KSCPT has held annual joint symposia with JSCPT, with the 17th joint symposium scheduled for 2024. These regular joint symposia have facilitated the exchange of information on global issues and sharing of research findings on common topics. The collaboration between KSCPT and JSCPT has led to joint research projects between Korea and Japan [59,60].

The KSCPT has strengthened its relationship with ASCPT through active participation in its annual meetings. In 2009, the KSCPT and ASCPT held a joint symposium titled "Personalized Health Care for the Global Community" discussing topics such as pharmacogenomics in personalized drug therapy, integrating pharmacogenomics and biomarkers for efficient drug development, and regulatory science related to modeling-simulation.

The KSCPT has held joint sessions with EACPT at its annual meetings in 2017 and 2019. In 2017, the sessions covered the education and training of clinical pharmacology in Korea and role for clinical research and dissemination to industry in Korea, focusing on pharmacometrics. In 2019, the sessions focused on drug safety, discussing topics such as the clinical pharmacology perspectives for optimal polypharmacy and prioritizing hospital patients at high risk of medication harm: development and validation of a predictive risk model.

The KSCPT's members actively have participated in IUPHAR's clinical pharmacology council, solidifying the relationship between the 2 organizations. The KSCPT is a key partner society for IUPHAR's clinical pharmacology division and actively participates in the annual World Smart Medication Day event held every May. The society has also translated IUPHAR's publication, "Clinical Pharmacology in Health Care, Teaching and Research," into Korean.

In 2024, the KSCPT plans to hold a joint symposium with ACCP on the topic of DCTs and clinical pharmacology. The symposium will explore the opportunities and complexities of DCTs from a global perspective.

At the individual researcher level, international collaboration is also active. For example, from 2020, a 5-year government-funded project called the "International Network for Infectious Disease Research and Development of Korea" has been implemented, involving 16 institutions from 15 countries (Bhutan, Chile, Indonesia, Laos, Malaysia, Mexico, Mongolia, Nepal, Pakistan, Paraguay, Peru, Saudi Arabia, Thailand, Uzbekistan, and Vietnam). This project has established an international network for infectious disease research.

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Growth of academic journal

In 1993, the KSCPT began publishing an official journal named the "*Journal of Korean Society for Clinical Pharmacology and Therapeutics*" to showcase the research findings from clinical pharmacologists. This journal attracted contributions not only from academia but also from industry and government stakeholders. Research topics predominantly focused on pharmacokinetics/pharmacodynamics, pharmacogenomics and pharmacometrics, with additional contributions in areas such as pharmacoepidemiology and regulatory science. In 2013, the *Journal of Korean Society for Clinical Pharmacology and Therapeutics* was indexed in the Korean Citation Index. In 2014, it transitioned into an English-language journal and was renamed "*Translational and Clinical Pharmacology* (*TCP*)." *TCP* was indexed in PubMed Central in 2020, and the editorial management system and the website was updated. Since its transition, *TCP* has covered various topics related to clinical pharmacology, with a predominant focus on pharmacokinetics/pharmacometrics, followed by bioanalysis research, statistical analysis research, and pharmacogenomics. Notably, recent publications have increasingly utilized real-world data, reflecting a trend towards diversified research topics.

Expansion of clinical pharmacology research areas and advancement of clinical trials

Clinical pharmacologists are actively engaged in a wide range of research activities, serving as experts in personalized medicine, early-phase drug development, and regulatory science. Clinical pharmacokinetic/pharmacodynamic studies exploring the pharmacokinetics and pharmacodynamics of new drugs, investigating drug-drug interactions and identifying ethnic differences in pharmacokinetics/pharmacodynamics have been continuously conducted by clinical pharmacologists. Pharmacogenomics, a traditional research area within clinical pharmacology, remains a significant focus, with ongoing efforts in Korea aimed at understanding the impact of genetic polymorphisms on drug responses and adverse effects. With the development of new technologies, the research areas and methodologies in clinical pharmacology have diversified and evolved. Pharmacogenomics has expanded into related fields such as pharmacometabolomics and pharmacoproteomics. In particular, pharmacometabolomic studies are actively being conducted to identify biomarkers for drug response and disease prognosis. Collaboration with clinical departments is strong in this field. Translational research is also a key focus for many clinical pharmacologists in Korea. This includes *in vitro* and *in vivo* studies investigating the activity of metabolizing enzymes and drug transporters, as well as the development of new models that mimic patients' pharmacokinetics or drug responses. Pharmacometrics has been increasingly utilized in drug development since the 2010s, leading to a growing number of research groups. Particularly, with advancements in *In Vitro In Vivo* Extrapolation technology and increasing interest in Physiology-Based Pharmacokinetics modeling and simulation, pharmacometrics is being used to predict drug effects and drug-drug interactions, as well as to exploring optimal regimen, expanding into Quantitative System Pharmacology. Founded in 2006 as a subgroup of the KSCPT, the Population Approach Group in Korea has grown from 62 initial members to over 300 active members as of 2023.

Meanwhile, clinical pharmacologists are striving for increased efficiency in clinical trials by adopting various technologies. Efforts include the implementation of clinical trial management systems to facilitate multi-center clinical trials, direct integration of electronic health records (EHRs) with electronic case report forms to minimize errors during data recording, and designing clinical trials using real-world data. Additionally, as the COVID-19 pandemic unfolded, clinical pharmacologists expanded their research focus to include DCTs and the use of real-world data for clinical trial design, moving beyond traditional clinical trial formats.

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FUTURE DIRECTIONS OF CLINICAL PHARMACOLOGY

Clinical pharmacologists in Korea been at the forefront of research and clinical support for personalized therapy. They also have played a significant role in establishing the infrastructure for new drug clinical trials and advancing global competitiveness through the development of early phase clinical trial methodologies. Clinical pharmacology is currently facing new phases. Therapeutics is diversifying beyond chemical and biological drugs to include cell therapy, gene therapy, and digital therapeutics. Advancements in technology such as artificial intelligence and data science are reshaping the drug development environment. Clinical pharmacologists face the challenge of embracing the development of these new disciplines and applying them effectively to clinical practice and drug development.

Artificial intelligence and machine learning, core elements of artificial intelligence, hold potential for predicting dose finding, drug-drug interactions, and adverse drug events. They may also assist in identifying suitable patients for clinical trials and dose allocation in adaptive clinical trials [61]. The widespread use of digital health technology such as EHRs and mobile applications is generating real-world data that can be extensively used for drug-drug interaction assessments, dose recommendations for patients with organ impairment, pediatric dosing optimization, identification of prognostic biomarkers and providing evidence for regulatory decisions [62,63].

In addition to adopting innovative technologies, the field of clinical pharmacology must redefine its scope to thrive in the changing environment. Korean clinical pharmacologists have established a specialized domain in new drug development through active early-phase clinical trials and have conducted robust translational research for personalized drug therapy. However, in patient care, the scope of activities has been relatively limited. There is a need for more proactive involvement in patient care, including education on drug prescribing practices.

Moreover, the future of clinical pharmacology involves assuming a leadership role in planning, strategizing, and coordinating development across the entire drug development cycle, establishing specialized expertise in clinical practice areas, and expanding interdisciplinary research and collaboration among basic medicine/clinical medicine, academia/industry/research institutions/regulatory agencies, and related academic fields [4].

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