CURRICULUM VITAE

Name: Howard (Hyeong Ki) Lee, MD, PhD
Nationality: USA
Current Position: **Professor**, Department of Clinical Pharmacology and Therapeutics, Seoul National University Hospital and College of Medicine
Professor, Department of Molecular Medicine and Biopharmaceutical Sciences, Graduate School of Convergence Science and Technology, Seoul National University
Founder and Director, the Center for Convergence Approaches in Drug Development (CCADD)
Founder and Chief Executive Officer, PMATCH. Inc., Korea
Address in Korea: 101 Daehak-ro, Jongno-gu
Department of Clinical Pharmacology and Therapeutics
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Web Sites:
http://mmbs.snu.ac.kr/bbs/board.php?bo_table=Research_23
http://www.snuh.org/pub/ihosp/sub03/sub01/sub01/viewDoctor.jsp?drcd=86154&deptcd=CPU
http://ccadd.snu.ac.kr/bbs/board.php?tbl=people
http://cpt.snu.ac.kr/en/Leadership/Members/Faculty
http://convergence.snu.ac.kr/bbs/board.php?bo_table=peopl_professor_en&wr_id=129

Latest GCP Training:
- Advanced education for clinical trial investigators (8 hrs, Seoul National University Hospital, November 21, 2016)
- Investigator Refresher education of Clinical Trials Professionals (4hrs) on 29 Nov 2017
- Investigator Refresher education of Clinical Trials Professionals (4hrs) on March 29, 2018
- Investigator Refresher education of Clinical Trials Professionals (4hrs) on March 21, 2019
- Investigator Refresher education of Clinical Trials Professionals (4hrs) on June 19, 2020
- Investigator Refresher education of Clinical Trials Professionals (4hrs) on March 25, 2021

EDUCATION

1982 - 1984	Seoul National University College of Natural Sciences, Seoul, Korea	Premed	Premedical Sciences
1984 - 1988	Seoul National University College of Medicine, Seoul, Korea	MD	Medicine
1989 - 1991	Seoul National University College of Medicine Graduate School, Seoul, Korea (Supervisor: Yoon Ok Ahn, MD, PhD)	MSc	Epidemiology
1994 - 1998	Seoul National University College of Medicine Graduate School, Seoul, Korea (Supervisor: Yoon Ok Ahn, MD, PhD)	PhD	Epidemiology
1988 - 1989	Seoul National University Hospital, Seoul, Korea	Intern	Medicine
1989 - 1991	Seoul National University Hospital, Seoul, Korea	Resident	Family Medicine
1997 - 1997	Graduate School of Public Administration Sejong University, Seoul, Korea	Diploma	Public Health
2000 - 2002	Center for Drug Development Science	Clinical Fellow	Clinical Pharmacology

Department of Pharmacology
School of Medicine, Georgetown University
Washington, DC, USA
(Supervisor: Carl C. Peck, MD, PhD (hon.))

LICENSES, CERTIFICATION:

1988	Medical License (No. 36075), Ministry of Health and Welfare, Seoul, Korea
1991	Board Certificate, Family Medicine (No. 2257), Korean Academy of Family Medicine, Seoul, Korea
2005	Medical Licensure, Institutional (LT-000580), Commonwealth of Pennsylvania, State Board of Medicine, USA
2016	Board Certificate, Clinical Pharmacology, Korean Soceity for Clinical Pharmacology and Therapeutics

PRINCIPAL POSITIONS HELD:

1991 - 1992	Cheju Radar Unit, Air Force Chejudo, Korea	Head, Medical Squadron
1992 - 1994	Air Force Seoul Hospital	President
1992 - 1994	Seoul National University College of Medicine Seoul Cohort	Researcher, Preventive Medicine
1994 - 1994	Seoul National University College of Medicine	Lecturer, Epidemiology
1994 - 1996	MSD Korea	Senior Manager, Medical Department
1998 - 1999	Chong Kun Dang Pharmaceutical Corp.	Director, Medical Department
2002 - 2004	Georgetown University	Assistant Professor, Medicine
2004 - 2005	University of California San Francisco	Assistant Clinical Professor
2005 - 2006	University of Pittsburgh	Assistant Professor, Medicine
2006 - 2012	University of California San Francisco	Associate Adjunct Professor
2012 - 2014	Seoul National University Hospital	Clinical Professor
2012 - 2017	Global Strategy and Planning, Clinical Trials Center, Seoul National University Hospital	Head
2014 - present	Seoul National University Hospital and College of Medicine	Professor
2014 - 2020.2	Department of Transdisciplinary Studies, Graduate School of Convergence Science and Technology, Seoul National University	Professor
2017 - present	Advanced Course in Pharmaceutical Medicine, Seoul National University Hospital	Chair
2017.8 – 2021. 7	Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University	Chair
2020.3 - present	Department of Molecular Medicine and Biopharmaceutical Sciences, Graduate School of Convergence Science and Technology, Seoul National University	Professor

OTHER POSITIONS HELD CONCURRENTLY:

1998 - 1999	Ulsan Medical Cohort Department of Family Medicine Asan Medical Center Ulsan Medical School Seoul, Korea	Consultant, Epidemiology
1999 - 1999	Division of Clinical Pharmacology Chonnam University College of Medicine Kwangju, Korea	Adjunct Associate Professor
1999 - 1999	Clinical Trial Center	Clinical Trial Consultant

	Seoul National University Hospital Seoul, Korea	
2001 - 2001	Division of Cardio-Renal Products Center for Drug Evaluation and Research Food and Drug Administration Rockville, Maryland, USA	Guest Medical Reviewer
2004 - 2005	Office of Clinical Pharmacology and Biopharmaceutics Center for Drug Evaluation and Research Food and Drug Administration Rockville, Maryland, USA	Guest Researcher
2004 - 2005	University of California San Francisco Center for Drug Development Science	Associate Director for Research
2005 - 2006	University of Pittsburgh Center for Clinical Pharmacology Clinical Investigation Core	Associate Director
2005 - 2006	University of Pittsburgh Center for Clinical Pharmacology	Fellowship Director
2006 – 2008	University of California San Francisco Diagnostic and Therapeutic Regulatory Consultation Service, Regulatory Knowledge Service, Clinical Translational Science Institute	Director
2006 - 2012	University of California San Francisco Center for Drug Development Science	Director
2010 - present	Inje University College of Medicine Division of Clinical Pharmacology	Distinguished Visiting Professor

HONORS AND AWARDS:

April, 1991	The Most Honorable Air Force Officer Award, Air Force, Korea
December, 1999	The Kochon Excellent Award for International Research in Pharmaceutical Medicine and Drug Development Science, Kochon Foundation, Seoul, Korea
January, 2003	2003 Faculty Colloquium, Center for New Designs in Learning and Scholarship (CNDLS), Georgetown University, Washington, DC, USA
October, 2003	Young Investigator's Travel Award, The Pharmacokinetics, Pharmacodynamics and Drug Metabolism Section, The American Association of Pharmaceutical Scientists, USA
May, 2005	Fellow, The Summer Institute in Maternal-Fetal Pharmacology, Mont-Tremblant, Quebec, Canada
March, 2015	Member Award, American Society for Clinical Pharmacology and Therapeutics, USA

KEYWORDS/AREAS OF INTEREST:

clinical trials; drug development science; clinical pharmacology; regulatory science; pharmacometrics; pharmacokinetics; pharmacodynamics; pharmacokinetic-pharmacodynamic modeling; clinical trial simulation; disease progression model; FDA; biosimilars

PROFESSIONAL ACTIVITIES:

CLINICAL

Principal Investigator	2012-Present	Seoul National University Hospital
Principal Investigator	2005-2006	University of Pittsburgh School of Medicine
Associate Director, Clinical Investigation Core	2005-2006	University of Pittsburgh School of Medicine

PROFESSIONAL ORGANIZATIONS

Memberships:

1989 - present	Korean Academy of Family Medicine
1994 - present	Korean Society for Clinical Pharmacology and Therapeutics
1995 - 1995	American Heart Association
1996 - present	Drug Information Association
1996 - present	Korean Academy of Pharmaceutical Medicine
2001 - present	American Society for Clinical Pharmacology and Therapeutics
2001 - present	American Association of Pharmaceutical Scientists

Service to Professional Organizations:

1996 - 1998	Korean Society for Clinical Trial	President
1999 - 1999	Korean Academy of Pharmaceutical Medicine	Director, General
2002 - 2004	Korean Society for Clinical Pharmacology and Therapeutics	Director, Foreign Affairs
2012 - 2020	Korean Society for Clinical Pharmacology and Therapeutics	Director, Foreign Affairs

SERVICE TO PROFESSIONAL PUBLICATIONS:

2006 - 2016	Editorial Board, *Therapeutic Drug Monitoring*
2015 - present	Editorial Board, *The Korean Circulation Journal*
2017 - present	Editorial Board, *International Journal of Clinical Pharmacology & Pharmacotherapy (IJCPP)*
2017 - present	Editorial Board, *Translational and Clinical Pharmacology*

INVITED PRESENTATIONS (incomplete list):

INTERNATIONAL (newer one first, incomplete)

1. Can the COVID-19 Pandemic Disrupt the Current Drug Development Practices? International Conference for Future Dentistry 2021, December 2021 (Seoul, Korea)
2. Biosimilarity in the orphan world, The 6th Gaucher Disease Forum, 2020 (Asia)
3. Current status of advanced therapeutics development in Korea, New Approaches to Immuno-Oncology Webinar, 2020 (UK)
4. Early phase clinical trials in Korea. 2020, ACCP 2020 Workshop (US)
5. Biosimilarity in the orphan world. 2019, The Gaucher Symposium, Kuala Lumpur, Malaysia
6. Polypharmacy in Korea, 2019, European Society for Clinical Pharmacology and Therapeutics, Stockholm, Sweden
7. HOW DISSIMILAR ARE BIOSIMILARS? THE LATEST CLINICAL EVIDENCE, Hong Kong Pharmacy Conference, 2017, Hong Kong, China
8. A pharmacogenomic study on the pharmacokinetics of tacrolimus in healthy subjects using the DMET™ Plus platform, Hokkaido University, 2016
9. RMP in Korea, 10th DIA Asia New Drug Conference in Japan, 2016, Tokyo, Japan
10. 2015 Investigator Network Meeting: Quality Collaboration, 2015 Sanofi-Aventis Investigator Network Meeting, 2015, New Jersey, USA
11. Capture Data from Where They Are and When Their Transaction Happens, REACTA Forum, 2015, Tokyo, Japan
12. Enabling Advanced Clinical Research [in Korea], OmniComm Open Innovation Forum, 2015, Fort Lauderdale, Florida, USA
13. Extrapolation of Indications for Biosimilars: Scientific Limitations, 5th Latin American Forum on Biosimilars (FLAB), 2015, Brasilia, Brazil
14. What defines a biosimilar?, 2015, ESMO Asia, Singapore
15. How the South Korean Government, Academia and Industry are Working to Stimulate Productivity, 2015, CCDRS, Peking, China
16. Recent Experiences of SNUH in Microtracer Studies, 2015, 3rd International Microdosing Symposium, Seoul, Korea
17. Building a Global Phase I Unit, 2013.9.14, REACTA Forum, Busan, South Korea, Regional East Asian Clinical Trial Annual Forum
18. Introduction to GREATS @SNUH, 2013.9.13, REACTA Forum, Busan, South Korea, Regional East Asian Clinical Trial Annual Forum
19. Drug Lag, Regulatory Innovation and the Role of the Academic Center in East Asia, 2013.6.26, DIA 2013, 49th Annual Meeting, Boston, MA, USA
20. Chinese Course in Drug Development and Regulatory Sciences, Peking University, Peking, China, 2010 (invited lecture

series)
21. Drug safety - physician's perspective, American College of Clinical Pharmacology, Orlando, Florida, USA; 2003
22. American Society for Clinical Pharmacology and Therapeutics; 2006 (invited oral presentation)
23. Yonsei International PK-PD Symposium, Seoul, Korea, 2006 (invited talk)
24. International Conference on Pharmaceutical Medicine; Seoul, Korea, 2006 (invited talk)
25. Global Cooperation and Technical Update; Seoul, Korea, 2004 (invited talk)
26. CDER Academic; 2004 (invited talk, session chair, moderator)
27. Annual IIR Conference on Faster and More Efficient Phase I Clinical Trials; 2003 (invited talk)
28. East Coast Population Analysis Group Conference; Baltimore, MD, USA, 2002 (invited talk)
29. Food and Drug Administration; Rockville, MD, USA, 2001 (invited talk)
30. Asia Business Forum; Seoul, Korea, 1997 (invited talk); Seoul, Korea, 1998 (invited talk)

NATIONAL (newer one first, incomplete)
1. Bottle of Lies: Issues in the quality management of generics in Korea. Galvus symposium, February, 2022
2. Dimensionality reduction model for efficient clinical trial feasibility assessments. Korean Society for Pharmacy, 2021
3. Role of physicians and physician scientists in commercialization of medica products: experiences in US FDA and academia. November, 2020, Seoul, Korea
4. Lessons Learned from Recent AMS-based Microtracing Studies in Humans to Streamline New Drug Development. Microdosing Symposium, KIRAMS, Seoul, Korea, 2017
5. AMS-based Microdosing/Microtracing Studies in Drug Development: Recent Advances @SNUH, Annual Conference in Radiopharmaceuticals, Daejeon, Korea
6. Biosimilar 101, 2014.7.5, Roche Korea Breast Cancer Forum, Yeosu, South Korea
7. Pharmacogenomics in Hypertension: Focus on ADRB1 and CACNB2 genes, 2014.5.9, Korean Society for Hypertension, Seoul, Korea
8. Metabolomics in Clinical Drug Development: Hype or Reality?, 2014.4.3, Korean Society for Metabolomics, Seoul, Korea
9. Clinical Platform for the Microdosing Study at Seoul National University Hospital, 2014.1.23, 1st International Microdosing Symposium, Seoul, Korea, Seoul National University Hospital Clinical Trials Center
10. To Use or Not To Use Generics: Points to Consider for Practicing Anesthesiologists, 2014.1.18, Ultiva Winter Academy, Yeosu, South Korea
11. Scientific and Clinical Challenges in Extrapolation of Data across Indications for Biosimilar Products, 2013.5.22, Korean Society for Clinical Pharmacology and Therapeutics, Seoul, Korea
12. Maximizing Mutual Benefits through Effective Industry-Academia Communications/Collaborations in Clinical Drug Development, 2012.12.6, Korean Society for Clinical Trials, Seoul, Korea
13. Envisioning a Transformed Clinical Trials Enterprise in Korea, 2012.10.19, Dong-A Hospital, Busan, Korea
14. South Korean Drug Regulatory Process, Practice and Activities to Stimulate Innovation and Harmonization
15. 2010.11
16. Strategies for the Korean Food and Drug Administration, Korea, 2010 (invited plenary session speaker)
17. Drug Development Strategy for the Korean Pharmaceutical Industry, Seoul National University College of Medicine Graduate School, Seoul, Korea, 2009 (invited talk)
18. Doctors without a white-coat, Inje University College of Medicine, 2009, Pusan, Korea, 2009 (invited talk)
19. Will we do what we are doing now in 10 years, Annual Meeting of the Korean Society for Pharmaceutical Medicine, Seoul, Korea, 2009 (invited talk)
20. Pharmaceutical Medicine, Seoul National University College of Medicine Graduate School, Seoul, Korea, 2008 (invited talk)
21. Early clinical drug development, Seoul National University College of Medicine Graduate School, Seoul, Korea, 2007 (invited talk)
22. Pharmaceutical Medicine, Seoul National University College of Medicine Graduate School, Seoul, Korea, 2006 (invited talk)
23. Asan Medical Center Clinical Research Center Symposium; 2002 (invited talk); 2005 (invited talk); Seoul, 2004 (invited talk)
24. Korean Society for Pharmaceutical Medicine; 2002 (invited talk); 2005 (invited talk)
25. Korean Society for Pharmacology and Therapeutics; 1995 (invited talk); 1997 (invited talk); 1998 (invited talk); 1999 (plenary talk); 2002 (plenary talk)
26. Public Health Policy Forum; Seoul, 2005

REGIONAL AND OTHER INVITED PRESENTATIONS (incomplete list)

1995 Seminar on Korean Good Clinical Practice
1997 Clinical Trial Workshop
1997 Symposium on Post Marketing Surveillance
1997 Department of Family Medicine, Seoul National University Hospital
1998 Clinical Trial Workshop
1998 Korea Food and Drug Administration
1998 New Drug Development and Clinical Trial Workshop
1998 GCP Workshop for Family Medicine
1998 Clinical Trial Workshop, Catholic Medical Science Research Center
1999 Chonnam University College of Medicine
1999 GCP Workshop
1999 Global C&R Seminar
1999 Annual Symposium of Seoul National University Hospital Clinical Trial Center
1999 Clinical Trial Workshop
1999 Gacheon Medical School
1999 Korean Society for Clinical Trial
2003 Thomas Jefferson University, Jefferson Medical College, Department of Clinical Pharmacology
2003 Maximizing Clinical Efficiency PHASES
2003 Korean Pharmaceutical Development Forum
2004 Department of Family Medicine, Seoul National University Hospital
2005 Korea University Medical Center
2006 Clinical Trial Center, Kyungbook University College of Medicine
2007 Baik University College of Medicine
2009 Biomarkers in Drug Development (invited seminar), The Uniformed Services University of the Health Sciences (USUHS), the Walter Reed Army Institute of Research (WRAIR)
2009 Population Pharmacokinetic Analysis: Concepts, Implications, and Applications, Johns Hopkins Clinical Pharmacology Research Conference

GOVERNMENT AND OTHER PROFESSIONAL SERVICE:

1994 - 1999 Consultant, Committee on Statistics, Korean Academy of Pediatrics, Seoul, Korea
1995 - 1999 Member, Good Clinical Practices Committee, Korean Pharmaceutical Manufacturers Association, Seoul, Korea
1998 - 1999 Member, Advisory Committee, New Drug Reevaluation, Central Pharmaceutical Affairs Council, Korea Food and Drug Administration, Seoul, Korea
1998 - 1999 Secretary General, Expert Working Group & Committee for Clinical Trial Regulation Modernization, Korea Food and Drug Administration, Seoul, Korea
1998 - 1999 Secretary General & Director of General Affairs, The Korean Academy of Pharmaceutical Medicine, Seoul, Korea
2013 - present External consultant, Ministry Food and Drug Safety, Korea

UNIVERSITY AND PUBLIC SERVICE:

UNIVERSITY SERVICE

2017 - present Department Chair, Graduate Program in Clinical Pharmacology, College of Medicine, Seoul National University

UNIVERSITY SERVICES, PREVIOUS AFFILIATIONS

2002 - 2004 Institutional Review Board, Committee B, Georgetown University Medical Center
2002 - 2004 Clinical Pharmacology Course Planning Committee, 4th year medical student, Georgetown University Medical Center

2001 - 2004	Strategic Planning Committee, Center for Drug Development Science, Georgetown University Medical Center
2002 - 2003	Curriculum Development Committee, Initiative for New School of Medicinal Products Development, in collaboration with Virginia Tech.
2005 - 2006	Voting Member, GCRC Advisory Committee, University of Pittsburgh Medical Center, General Clinical Research Center
2005 - 2006	Member, Pharmacy and Therapeutics Committee, University of Pittsburgh Medical Center
2005 - 2006	Member, eRecord PUH/SHY Physician Advisory Committee, University of Pittsburgh Medical Center
2006 - 2012	Department of Biopharmaceutical Sciences, UC Washington Center for Drug Development Science, Fellowship Committee, School of Pharmacy, University of California San Francisco
2014 - 2016	Member, Institutional Review Board, Seoul National University Hospital
2019 - present	Member, Institutional Review Board, Seoul National University Hospital

TEACHING AND MENTORING:

UNIVERSITY TEACHING

1990	*Principles of Community Based Medicine*, 4th year medical students (n=170), 100 contact hours, Seoul National University College of Medicine, Seoul, Korea
1990	*Introduction to Outpatient Care in Family Medicine*, 4th year medical students (Seoul National University College of Medicine, n=170) and pharmacists in PharmD course (Seoul National University Hospital, n=5), 50 contact hours, Seoul, Korea
1992	*Statistics for Nursing*, 2nd year nursing students (n=60), 2 semesters (3 credits), Danguk School of Nursing, Chungcheongnamdo, Korea
1993	*Medical Statistics*, 1st year medical students (n=100), 2 semesters (4 credits), Danguk Medical School, Chungcheongnamdo, Korea
1992 - 1994	*Epidemiology*, 2nd year medical students (n=170), 1 semester (3 credits), Seoul National University College of Medicine, Seoul, Korea
2002 - 2004	*Clinical pharmacology*, 4th year medical students (n=100), elective course (1 full week), Georgetown University School of Medicine, Washington, DC
2005	*Clinical pharmacology*, selective for 4th year medical students, workshop moderator (renal module), University of Pittsburgh School of Medicine
2005	*Research Design Seminar (CLRES 2071/2072)*, Clinical Research Training Program, small group moderator
2006	*Clinical pharmacology*, selective for 4th year medical students, workshop moderator (renal module), University of Pittsburgh School of Medicine
2006	*Clinical pharmacology*, selective for 4th year medical students, Drugs Use in Pregnancy and Lactation, University of Pittsburgh School of Medicine
2006 (Jan-Apr)	*Introduction to Pharmacometrics (CLRES 2340)*, Clinical Research Training Program, Course Director, Moderator, and Lecturer, University of Pittsburgh School of Medicine (n=6)
2007 April	Biomarkers in Drug Development, UCSF School of Pharmacy (n=2)
2007 June	Regulatory Education Seminar, UCSF CTSI, Role of Academic Investigators in Drug Development (n=~60)
2007 October	Regulatory Education Seminar, UCSF CTSI, Dose Selection for the First-Time-In-Human Study (n=~60)
2007 December	UC Davis/UCLA Undergraduate Research Conference (12/4/07), "Got Drugs? Issues Affecting the Mental Health Community"
2008 1st Half	Introduction to Pharmacometrics (weekly lecture/hands-on series for fellows at CDDS, Washington, DC)
2009 1st Half	Advanced Pharmacometrics (weekly intensive lecture/hands-on series for fellows at CDDS, Washington, DC)

2012 - presentHow to write the INTRODUCTION, Seoul National University College of Medicine
2012 - presentHow to write the RESULTS, Seoul National University College of Medicine
2012 - presentHow to write the DISCUSSION, Seoul National University College of Medicine
2012 - presentRole of FDA in drug development, Seoul National University College of Medicine

2012 - present	Population pharmacokinetic-pharmacodynamic analysis, Seoul National University College of Medicine
2013 - present	Drug Interaction 101 (Clinical Pharmacology for 4th year medical students), Seoul National University College of Medicine
2015 - 2019	Adverse Drug Reactions (Clinical Pharmacology for 4th year medical students), Seoul National University College of Medicine
2015 - 2019	Understanding Drug Labels and Good Prescription Practices (Clinical Pharmacology for 4th year medical students), Seoul National University College of Medicine
2015, 1st semester	Use of Radiation Technology in Drug Development, Graduate School of Convergence Science and Technology, Seoul National University
2015, 2nd semester	Introduction to Systems Clinical Pharmacology, Graduate School of Convergence Science and Technology, Seoul National University
2016, 1st semester	Understanding New Health Technology Development, Graduate School of Convergence Science and Technology, Seoul National University
2016, 2nd semester	Nonlinear Mixed Effects Modeling for Clinical Pharmacology, Graduate School of Convergence Science and Technology, Seoul National University
2017, 1st semester	Drugs and Society, College of Liberal Arts, Seoul National University
2017, 1st semester	Introduction to Convergent Radiological Biomedical Science, Graduate School of Convergence Science and Technology, Seoul National University
2017, 2nd semester	Clinical Trials Seminar 2, Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University College of Medicine
2017, 2nd semester	Understanding Drugs, Seoul National University College of Medicine
2018, 1st semester	Understanding New Health Technology Development, Graduate School of Convergence Science and Technology, Seoul National University
2018, 1st semester	Theme Exploration Seminar 4, Seoul National University College of Liberal Arts
2018, 1st semester	Drug Therapy, Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University College of Medicine
2018, 2nd semester	Nonlinear Mixed Effects Modeling for Clinical Pharmacology, Graduate School of Convergence Science and Technology, Seoul National University
2018, 2nd semester	Drug Therapy in Special Populations, Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University College of Medicine
2019, 1st semester	Clinical Pharmacokinetics and Pharmacodynamics to Clinical Drug Development, Graduate School of Convergence Science and Technology, Seoul National University
2019, 1st semester	Principles of Drug Action, Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University College of Medicine
2019, 1st semester	Theme Exploration Seminar 4, Seoul National University College of Liberal Arts
2019, 1st semester	Clinical Drug Interactions, Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University College of Medicine
2019, 2nd semester	Application of AI to Clinical Drug Development and Optimal Use of Drugs, Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University College of Medicine
2019, 2nd semester	Understanding Drugs, Seoul National University College of Medicine
2019, 2nd semester	Adverse Drug Events and Hypersensitivity, Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University College of Medicine
2020, 1st semester	Drug Regulatory Science Seminar, Graduate School of Convergence Science and Technology, Seoul National University
2020, 1st semester	Advanced Theme Seminar 3, Seoul National University College of Liberal Arts
2020, 1st semester	Principles of Drug Action, Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University College of Medicine
2020, 1st semester	Exploratory New Drug Development, Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University College of Medicine
2020, 2nd semester	Nonlinear Mixed Effects Modeling for Clinical Pharmacology, Graduate School of Convergence Science and Technology, Seoul National University
2020, 2nd semester	Drug Therapy in Special Populations, Interdisciplinary Graduate Program in Clinical Pharmacology, Seoul National University College of Medicine

INFORMAL TEACHING

2006 - 2012 American Course in Drug Development and Regulatory Sciences (break-out session moderators)

SUPERVISION OF POST-DOCTORAL FELLOWS

2002 - 2003 Covariate model development project (Stacey Tannenbaum, PhD)
2003 - 2003 Phase III trial failure project (Christine Garnett, PharmD),
2003 - 2003 Oncology drug development project (Seth Berry, PharmD)
2003 - 2005 Disease progress modeling for Rheumatoid Arthritis (Dong-Seok Yim, MD, PhD)
2003 - 2003 Accuracy of PDA-based prescription software programs (David Min, MD)
2004 - 2004 Mentoring on IRB review for Drs. Brendan Smyth, MD, PhD and Karl Kim, MD, PhD, NIGMS Clinical Pharmacology Fellows, School of Medicine, Georgetown University
2002 - 2004 Post-doctoral fellows mentoring for Drs. Stacey Tannenbaum, PhD, Seth Berry, PharmD, Christine Garnett, PharmD, Bruce Green, PharmD, PhD, Dong-Seok Yim, MD, PhD, Center for Drug Development Science, School of Medicine, Georgetown University
2004 - 2005 Post-doctoral fellows mentoring for Drs. Bruce Green, PharmD, PhD, Dong-Seok Yim, MD, PhD, Center for Drug Development Science, School of Pharmacy, University of California San Francisco
2005 - 2006 Nathalie Zgheib, MD, Post-doctoral fellow, Center for Clinical Pharmacology, Department of Medicine, University of Pittsburgh
2006 - 2007 Thuy Vu, PharmD, Post-doctoral fellow, Center for Drug Development Science
2007 Hyou-Young Rhim, MD, Senior Visiting Scholar, CDDS, UCSF
2008 - 2008 Hong-Guang Xie, MD, PhD, Post-doctoral fellow, Center for Drug Development Science, UCSF
2008 - 2009 Rose-Marie Crombag, Visiting fellow, Center for Drug Development Science, UCSF
2008 - 2011 Haritha Mandula, PhD, Post-doctoral fellow and Visiting Scientist, Center for Drug Development Science, UCSF
2008 - 2010 Siromi Weerasuriya, PhD, Visiting Scientist, Center for Drug Development Science, UCSF
2009 - 2010 Yuhong Chen, MD, PhD, Post-doctoral fellow and Visiting Scientist, Center for Drug Development Science, UCSF
2009 - 2012 Ayyappa Chaturvedula, PhD, Visiting Scientist, Center for Drug Development Science, UCSF
2013 - 2014 Jiang Fen, PhD, Hanmi-SNUCPT Clinical Pharmacology Fellow, Seoul National University College of Medicine
2013 - 2015 Sojeong Yi, PhD, Hanmi-SNUCPT Clinical Pharmacology Fellow, Seoul National University College of Medicine
2017 - 2019 Jeong-An Gim, PhD, Senior Postdoctoral Researcher, Center for Convergence Approaches in Drug Development, Graduate School of Convergence Science and Technology, Seoul National University
2017 - 2018 Soohyun Kim, PhD, Senior Postdoctoral Researcher, Center for Convergence Approaches in Drug Development, Graduate School of Convergence Science and Technology, Seoul National University
2019 - 2019 Hyun-A Lee, PhD, BK21 Postdoctoral Researcher, Center for Convergence Approaches in Drug Development, Graduate School of Convergence Science and Technology, Seoul National University

FACULTY MENTORING

Dates	Name	Position while Mentored	Mentoring Role	Current Position
2005-2006	Nathalie Zgheib, MD	Postdoctoral Fellow	Academic Advisor, Teacher	Instructor, University of Pittsburgh School of Medicine
2005-2006	Rhonda Rea, PharmD	Asst. Prof.	Collaborator, Academic Advisor	Asst. Prof., University of Pittsburgh School of Pharmacy
2005-2006	Capitano Blair, PharmD	Asst. Prof.	Collaborator, Academic Advisor	Asst. Prof., University of Pittsburgh School of Pharmacy
2017-2017	Yuchae Jung, PhD	BK21 Assistant Prof.	Academic Advisor	Graduate School of Convergence Science and Technology, Seoul National University
2018-2019	Jung-An Gim, PhD	Post Doc	Academic Advisor	Graduate School of Convergence Science and Technology, Seoul

				National University
2019-2019	Hyun-A Lee, PhD	BK21 Post Doc	Academic Advisor	Graduate School of Convergence Science and Technology, Seoul National University

TEACHING AWARDS AND NOMINATIONS:

January, 2003 2003 Faculty Colloquium, Center for New Designs in Learning and Scholarship (CNDLS), Georgetown University, Washington, DC

SUMMARY OF TEACHING HOURS (in the US)

2008 - 09 350 total hours of teaching (including preparation).
Formal class or course teaching hours: 20 hours
Informal teaching hours: 110 hours (2 hours/week)
Mentoring hours: 220 hours (~ 1.5 hours/week/fellow, 3 fellows)

2009 - 10 280 total hours of teaching (including preparation).
Formal class or course teaching hours: 20 hours
Informal teaching hours: 110 hours (2 hours/week)
Mentoring hours: 150 hours (~ 1.5 hours/week/fellow, 2 fellows)

2010 - 11 (est.) 280 total hours of teaching (including preparation).
Formal class or course teaching hours: 20 hours
Informal teaching hours: 110 hours (2 hours/week)
Mentoring hours: 150 hours (~ 1.5 hours/week/fellow, 2 fellows)

PEER REVIEWED PUBLICATIONS (Newest first):

1) Kim Y, Kim S, Park J, **Lee H**. Clinical Response and Hospital Costs of Therapeutic Drug Monitoring for Vancomycin in Elderly Patients. Journal of Personalized Medicine. 2022; 12(2):163. https://doi.org/10.3390/jpm12020163 (**Corresponding author**)
2) Kim S, Choi Y, Won J-H, Mi Oh J, **Lee H**. An annotated corpus from biomedical articles to construct a drug-food interaction database. J Biomed Inf. 2022;126: 103985. doi: 10.1016/j.jbi.2022.103985. Epub ahead of print. PMID: 35007753. (**Corresponding author**)
3) Jeon Y, Lee N, Baek S, Choi JD, Jhee S, **Lee H**. A Randomized, Double-Blind, Placebo- and Active-Controlled, Escalating Single-Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetic, Pharmacodynamic Profiles of Subcutaneous Eflapegrastim in Healthy Japanese and Caucasian Subjects. Drugs R&D (2022) 1-17. https://doi.org/10.1007/s40268-021-00397-8 (**Corresponding author**)
4) Huh KY, Hwang JG, Shin W, Baek S, Choi J, Lee N, Cho YM, **Lee H**. A double-blind, placebo-controlled, single-ascending dose study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of HM15136, a novel long-acting glucagon analogue, in healthy subjects. Diabetes Obes Metab. 2021 Nov 2. doi: 10.1111/dom.14590. (**Corresponding author**)
5) Jung JH, Huh KY, Jin XY, Ha A, Park KH, Park JS, Kim EJ, Lee JH, Jang IJ, **Lee H**. A phase I study to evaluate the safety, tolerability, pharmacodynamic and pharmacokinetic profiles of ocular GLH8NDE in healthy male subjects. Clinical and Translational Science, 2021. https://doi.org/10.1111/cts.13150 (**Corresponding author**)
6) Kim S, Lee HA, Jang SB, **Lee H**. A population pharmacokinetic-pharmacodynamic model of YH12852, a highly selective 5-hydroxytryptamine 4 receptor agonist, in healthy subjects and patients with functional constipation. *CPT Pharmacometrics Syst Pharmacol*. 2021 Jun 4. doi: 10.1002/psp4.12664. Epub ahead of print. PMID: 34085769. (**Corresponding author**)
7) Moon BS, Park HS, Sunwoo J, Lee IH, Kim A, Moon SJ, Lee H, Son MH, Kim SB, Park SM, Woo SK, Jang JH, Kim BS, Kim JH, Kim SE, **Lee H**. Tissue pharmacokinetics of DHP107, a novel lipid-based oral formulation of paclitaxel, in mice and patients by positron emission tomography. *Clin Transl Sci*. 2021 Jun 4. doi: 10.1111/cts.13003. Epub ahead of print. PMID: 34085761. (**Corresponding author**)

8) Won JH, **Lee H**. Can the COVID-19 Pandemic Disrupt the Current Drug Development Practices? Int J Mol Sci. 2021 May 21;22(11):5457. doi: 10.3390/ijms22115457. PMID: 34064287; PMCID: PMC8196831. (**Corresponding author**)
9) Huh KY, Choi Y, Nissel J, Palmisano M, Wang X, Liu L, Ramirez-Valle F, **Lee H**. Pharmacokinetics and tolerability of apremilast in healthy Korean adult men. *Clin Transl Sci*. 2021 May 1. doi: 10.1111/cts.13013. Epub ahead of print. PMID: 33932093. (**Corresponding author**)
10) Choi Y, **Lee H**. Policy Suggestions to Improve Patient Access to New Drugs in Korea. *Korean J Clin Pharm*. 2021;31:1-11. https://doi.org/10.24304/kjcp.2021.31.1.1 (**Corresponding author**)
11) Chung TK, Lee HA, Park SI, Oh DY, Lee KW, Kim JW, Kim JH, Woo A, Lee SJ, Bang YJ, Lee H. A target-mediated drug disposition population pharmacokinetic model of GC1118, a novel anti-EGFR antibody, in patients with solid tumors. *Clin Transl Sci*. 2021 May;14(3):990-1001. doi: 10.1111/cts.12963. (**Corresponding author**)
12) Won J-H, **Lee H**. The Current Status of Drug Repositioning and Vaccine Developments for the COVID-19 Pandemic. *Int. J. Mol. Sci.* 2020, 21(24), 9775; https://doi.org/10.3390/ijms21249775 (**Corresponding author**)
13) Lee HA, Moon SJ, Yoo H, Kim MK, Jang SB, Lee S, Kim S, **Lee H**. YH12852, a Potent and Selective Receptor Agonist of 5-hydroxytryptamine, Increased Gastrointestinal Motility in Healthy Volunteers and Patients with Functional Constipation. Clinical and Translational Science, 2020. https://doi.org/10.1111/cts.12924 (**Corresponding author**)
14) Lien Ngo, Jaeseong Oh, Anhye Kim, Hyun-moon Back, Won-ho Kang, Jung-woo Chae, Hwi-yeol Yun, **Lee H.** Development of a Pharmacokinetic Model Describing FcRn-Mediated Recycling of HL2351, a Novel Hybrid Fc-Fused IL1Ra, to Optimize Dosage Regimen. CPT Pharmacometrics Syst Pharmacology. 2020. Oct:9(10):584-595. doi: 10.1002/psp4.12555 (**Corresponding author**)
15) Anhye Kim, Stephen R Dueker, Jun Gi Hwang, Jangsoo Yoon, Sang-Won Lee, Hye Suk Lee, Byung-Yong Yu, Kyung-Sang Yu, **Lee H**. An investigation of the metabolism and excretion of KD101 and its inter-individual differences: a microtracing mass balance study in humans. Clinical and Translational Science. 2020. doi: 10.1111/cts.12848 (**Corresponding author**)
16) Kim SH, Kim SU, **Lee H**. A critical review of the United States regulatory pathways for determining the equivalence of efficacy between CT-P13 and original infliximab (Remicade ®). Drug Des Devel Ther. 2020. doi: 10.2147/DDDT.S254776 (**Corresponding author**)
17) Wilson JL, Cheung KWK, Lin L, Green EAE, Porrás AI, Zou L, Mukanga D, Akpa PA, Darko DM, Yuan R, Ding S, Johnson WCN, **Lee H**, Cooke E, Peck CC, Kern SE, Hartman D, Hayashi Y, Marks PW, Altman RB, Lumpkin MM, Giacomini KM, Blaschke TF. Scientific considerations for global drug development. Science Translational Medicine. 2020. doi:10.1126/scitranslmed.aax2550
18) Jeon Y, Choi Y, Kim EH, Oh S, **Lee H**. Common data model-based real-world data for practical clinical practice guidelines: clinical pharmacology perspectives. Transl Clin Pharmacol. 2020;28(2):67-72. doi:10.12793/tcp.2020.28.e11 (**Corresponding author**)
19) Lee JH, Faderl S, Pagel JM, Jung CW, Yoon SS, Pardanani AD, Becker PS, **Lee H**, Choi J, Lee K, Kim M, Cortes JE. Phase 1 study of CWP232291 in patients with relapsed or refractory acute myeloid leukemia and myelodysplastic syndrome. Blood Adv.2020;4(9):2032-2043. doi:10.1182/bloodadvances.2019000757
20) Jang K, Tong T, Lee J, Park T, **Lee H.** Altered Gene Expression Profiles in Peripheral Blood Mononuclear Cells in Obese Subjects. Obes Facts 2020 Jun 16;1-11. doi:10.1159/000507817 (**Corresponding author**)
21) Lee SW, Choi D, Heo M, Shin EC, Park SH, Kim SJ, Oh YK, Lee BH, Yang SH, Sung YC, **Lee H.** HIL-7-hyFc, a long-acting IL-7, increased absolute lymphocyte count in healthy subjects. *Clin. Transl. Sci.* 2020; doi:10.1111/cts. 12800 (**Corresponding author**)
22) Gim JA, Kwon Y, Lee HA, Lee KR, Kim S, Choi Y, Kim YK, **Lee H**. A Machine Learning-Based Identification of Genes Affecting the Pharmacokinetics of Tacrolimus Using the DMET™ Plus Platform. *Int. J. Mol. Sci.* 2020, *21*(7), 2517; https://doi.org/10.3390/ijms21072517 (**Corresponding author**)
23) Kim A, Dueker S, Dong F, Roffel AF, Lee S, **Lee H**. Human ADME for YH12852 using wavelength scanning cavity ring-down spectroscopy (WS-CRDS) after a low radioactivity dose. Bioanalysis. 2020; doi:10.4155/bio-2019-0119 (**Corresponding author**)
24) Choi J, Gim JA, Oh C, Ha S, **Lee H**, Choi H, Im HJ. Association of metabolic and genetic heterogeneity in head and neck squamous cell carcinoma with prognostic implications: integration of FDG PET and genomic analysis. EJNMMI Res. 2019 Nov21;9(1):97. doi:10.1186/s13550-019-0563-0.
25) Oh J, Huh KY, Cho YG, Cha JE, Kim SJ, Yoon SH, Park SS, Yoon H, Lee J, **Lee H**. Safety, tolerability and pharmacokinetics and pharmacodynamics of HL2351, a novel hybrid Fc-fused IL-1 receptor antagonist, in healthy subjects: a first-in-human study. 2020 Feb;86(2):372-379. doi: 10.1111/bcp.14161. Epub 2020 Jan 3. (**Corresponding author**)

26) Drelichman G, Castaneda-Hernandez G, Ar C, Dragosky M, Garcia R, **Lee H**, Moiseev S, Naderi M, Rosenbaum H, Znidar I, Zuluaga AF, Freisens S, Mistry PK. The Road to Biosimilars in Rare Diseases - Ongoing Lessons from Gaucher Disease. Am J Hematol. 2019; doi:10.1002/ajh.25701
27) Lee HA, Yu KS, Park SI, Yoon SH, Onohara M, Ahn YJ, **Lee H**. URC102, a potent and selective inhibitor of hURAT1, reduced serum uric acid in healthy volunteers. Rheumatology. 2019. 2019 Nov 1;58(11):1976-1984. doi: 10.1093/rheumatology/kez140 (**Corresponding author**)
28) Oh DY, Lee KW, Han SW, Kim JW, Shin JW, Jo SJ, Won J, Hahn S, **Lee H**, Kim WH, Bang YJ. A First-in-Human Phase I Study of GC1118, a Novel Anti-Epidermal Growth Factor Receptor Antibody, in Patients with Advanced Solid Tumors. The Oncologist. 2019; 0294. doi:10.1634/theoncologist.
29) Son H, Jang K, Lee H, Kim SE, Kang KW, **Lee H**. Use of molecular imaging in clinical drug development: a systematic review. Nucl Med Mol Imaging. 2019; 1-8. doi: 10.1007/s13139-019-00593-y (**Corresponding author**)
30) Kim Y, Hatley O, Rhee SJ, Yi S, Lee HA, Yoon S, Chung JY, Yu KS, **Lee H**. Development of a Korean-specific virtual population for physiologically-based pharmacokinetic modeling and simulation. Biopharm Drug Dispos. 2019; doi: 10.1002/bdd/2178. (**Corresponding author**)
31) Polasek TM, Rostami-Hodjegan A, Yim D-S, Jamei M, **Lee H**, Kimko H, Kim JK, Nguyen PTT, Darwich AS, Shin J-G. What Does it Take to Make Model-Informed Precision Dosing Common Practice? Report from the 1st Asian Symposium on Precision Dosing. The AAPS Journal. 2019;21(2):17. dos: 10.1208/s12248-018-0286-6
32) Lee HA, Lee KR, Jang SB, Chung SY, Yu KS, **Lee H**. A Physiologically-based pharmacokinetic model adequately predicted the human pharmacokinetic profiles of YH4808, a novel K+-competitive acid blocker. *Eur J Pharm Sci.* 2019; 130:1-10. doi: 10.1016/j.ejps.2019.01.009 (**Corresponding author**)
33) Rhee SJ, **Lee H**, Ahn LY, Lim KS, Yu KS. Lack of a Clinically Significant Pharmacokinetic Interaction Between Pregabalin and Thioctic Acid in Healthy Volunteers. *Clin Ther*. 2018. [Epub ahead of print]
34) **Lee H**. Data exclusivity through New Drug Reexamination in Korea: sibutramine hydrochloride (Reductil®) vs. sibutramine mesylate (Slimmer®) as an example. Translational and Clinical Pharmacology 2018;26(2) 49-55. doi: 10.12793/tcp.2018.26.2.49 (**first and corresponding author**)
35) **Lee H**, Lee H, Baik J, Kim H, Kim R. Failure mode and effects analysis drastically reduced potential risks in clinical trial conduct. *Drug design, development and therapy*. 2017;11:3035-3043. (**first and corresponding author**)
36) Kim YK, Kim A, Park SJ, **Lee H**. New tablet formulation of tacrolimus with smaller interindividual variability may become a better treatment option than the conventional capsule formulation in organ transplant patients. *Drug design, development and therapy*. 2017;11:2861-2869. (**Corresponding author**)
37) Kim Y, Kim A, Lee S, Choi SH, Lee DY, Song JS, **Lee H**, Jang IJ, Yu KS. Pharmacokinetics, Safety, and Tolerability of Tedizolid Phosphate After Single-dose Administration in Healthy Korean Male Subjects. *Clin Ther*. 2017;39(9):1849-1857.
38) Lee H, Chung H, Lee S, **Lee H**, Yang SM, Yoon SH, Cho JY, Jang IJ, Yu KS. LBEC0101, A Proposed Etanercept Biosimilar: Pharmacokinetics, Immunogenicity, and Tolerability Profiles Compared with a Reference Biologic Product in Healthy Male Subjects. *BioDrugs*. 2017;31(4):349-355.
39) Yi S, **Lee H**, Jang SB, Byun HM, Yoon SH, Cho JY, Jang IJ, Yu KS. A novel K+ competitive acid blocker, YH4808, sustains inhibition of gastric acid secretion with a faster onset than esomeprazole: randomised clinical study in healthy volunteers. *Aliment Pharmacol Ther*. 2017;46(3):337-346.
40) Oh J, Lee S, **Lee H**, Cho J-Y, Yoon SH, et al. The novel carboxylesterase 1 variant c.662A>G may decrease the bioactivation of oseltamivir in humans. *PloS one.* 2017;12(4):e0176320.
41) Rhee SJ, Lee JW, Yu KS, Hong KT, Choi JY, Hong CR, Park KD, Shin HY, Song SH, Kang HJ, **Lee H**. Pediatric patients undergoing hematopoietic stem cell transplantation can greatly benefit from a novel once-daily intravenous busulfan dosing nomogram. *Am J Hematol*. 2017;92(7):607-613. (**Corresponding author**)
42) Kim A, Yu BY, Dueker SR, Shin KH, Kim HS, Ahn H, Cho JY, Yu KS, Jang IJ, **Lee H**. An Accelerator Mass Spectrometry-Enabled Microtracer Study to Evaluate the First-Pass Effect on the Absorption of YH4808. *Clin Pharmacol Ther.* 2017;102(3):537-546. (**Corresponding author**)
43) Choi Y, Jiang F, An H, Park HJ, Choi JH, **Lee H.** A pharmacogenomic study on the pharmacokinetics of tacrolimus in healthy subjects using the DMET™ Plus platform. *The pharmacogenomics journal*. 2017;17(2):174-179 (**Corresponding author**)
44) Suh HY, Peck C, Yu K-S, **Lee H**. Determination of the starting dose in the first-in-human clinical trials with monoclonal antibodies: a systematic review of papers published between 1990 and 2013. *Drug Des Devel Ther*. 2016;Volume 10:4005-4016. (**Corresponding author**)
45) Kim A, Lim KS, **Lee H**, Chung H, Yoon SH, Yu KS, Cho JY, Jang IJ, Chung JY. A thorough QT study to evaluate the QTc prolongation potential of two neuropsychiatric drugs, quetiapine and escitalopram, in healthy volunteers. *Int Clin Psychopharmacol.* 2016;31(4):210-217.

46) Yoon S, Shin D, **Lee H**, Jang IJ, Yu KS. Pharmacokinetics, pharmacodynamics, and tolerability of LC350189, a novel xanthine oxidase inhibitor, in healthy subjects. *Drug design, development and therapy*. 2015;9:5033-5049.
47) Chung H, **Lee H**, Han H, et al. A pharmacokinetic comparison of two voriconazole formulations and the effect of CYP2C19 polymorphism on their pharmacokinetic profiles. *Drug design, development and therapy.* 2015;9:2609-2616. (**Co-first author**)
48) Oh J, Ji S, **Lee H**, Yu KS, Jang IJ. Response to "Induction of both P-glycoprotein and specific cytochrome P450 by Aspirin eventually does not alter the antithrombotic effect of clopidogrel". Clin. Pharmacol. Ther. 2015;97(4):325
49) Park SI, **Lee H**, Oh J, Lim KS, Jang IJ, Kim JA, Jung JH, Yu KS. A fixed-dose combination tablet of gemigliptin and metformin sustained release has comparable pharmacodynamic, pharmacokinetic, and tolerability profiles to separate tablets in healthy subjects. *Drug design, development and therapy*. 2015;9:729-736. (**Co-first author**)
50) **Lee H**. Erratum to: Is Extrapolation of the Safety and Efficacy Data in One Indication to Another Appropriate for Biosimilars? *AAPS J*. 2015;17(6):1520-1521 (**First author**)
51) Chung I, Yoon S, Yi S, Kim B-H, Yim S-V, Jang I-J, **Lee H**. A bioequivalence study of two levofloxacin tablets in healthy male subjects. *Translational and Clinical Pharmacology.* 2014;22(2):102. (**Corresponding author**)
52) Lee J, **Lee H**, Jang K, Lim KS, Shin D, KS Yu. Evaluation of the pharmacokinetic and pharmacodynamic drug interactions between cilnidipine and valsartan in healthy volunteers. Drug design, development and therapy, 2014 Oct 8;8:1781-8. doi: 10.2147/DDDT.S68574. (**Co-first author**)
53) Yi S, An H, **Lee H**, Lee S, Ieiri I, Lee Y, Cho JY, Hirota T, Fukae M, Yoshida K, Nagatsuka S, Kimura M, Irie S, Sugiyama Y, Shin DW, Lim KS, Chung JY, Yu KS, Jang IJ. Korean, Japanese, and Chinese populations featured similar genes encoding drug-metabolizing enzymes and transporters: a DMET Plus microarray assessment. *Pharmacogenetics and genomics.* 2014;24(10):477-485.
54) Lee J, Yoon S, Shin D, Han H, An H, Lee J, Lim KS, Yu KS, **Lee H**. Predictive performance of gentamicin dosing nomograms. *Drug design, development and therapy.* 2014;8:1097-1106. (**Corresponding author**)
55) Jang K, Yoon S, Kim SE, Cho JY, Yoon SH, Lim KS, Yu KS, Jang IJ, **Lee H**. Novel nanocrystal formulation of megestrol acetate has improved bioavailability compared with the conventional micronized formulation in the fasting state. *Drug design, development and therapy*. 2014;8:851-858. (**Corresponding author**)
56) Kim TE, **Lee H**, Lim KS, Lee S, Yoon SH, Park KM, Han H, Shin SG, Jang IJ, Yu KS, Cho JY. Effects of HM30181, a P-glycoprotein inhibitor, on the pharmacokinetics and pharmacodynamics of loperamide in healthy volunteers. *Br J Clin Pharmacol.* 2014;78(3):556-564. (**Co-first author**)
57) Kim A, Chung I, Yoon SH, Yu KS, Lim KS, Cho JY, **Lee H**, Jang IJ, Chung JY. Effects of proton pump inhibitors on metformin pharmacokinetics and pharmacodynamics. *Drug Metab Dispos.* 2014;42(7):1174-1179.
58) Shin D, Cho YM, Lee S, Lim KS, Kim JA, Ahn JY, Cho JY, **Lee H**, Jang IJ, Yu KS. Pharmacokinetic and pharmacodynamic interaction between gemigliptin and metformin in healthy subjects. *Clin Drug Investig.* 2014;34(6):383-393.
59) Oh J, Shin D, Lim KS, Lee S, Jung KH, Chu K, Hong KS, Shin KH, Cho JY, Yoon SH, Ji SC, Yu KS, **Lee H**, Jang IJ. Aspirin decreases systemic exposure to clopidogrel through modulation of p-glycoprotein but does not alter its antithrombotic activity. *Clin Pharmacol Ther.* 2014;95(6):608-616.
60) Shin KH, Lim KS, **Lee H**, Jang IJ, Yu KS. An assessment of the pharmacokinetics, pharmacodynamics, and tolerability of GCPGC, a novel pegylated granulocyte colony-stimulating factor (G-CSF), in healthy subjects. *Invest New Drugs*. 2014;32(4):636-643.
61) Yoon S, **Lee H**, Kim TE, et al. Comparative steady-state pharmacokinetic study of an extended-release formulation of itopride and its immediate-release reference formulation in healthy volunteers. *Drug design, development and therapy*. 2014;8:123-128. (**Co-first author**)
62) **Lee H**. Is Extrapolation of the Safety and Efficacy Data in One Indication to Another Appropriate for Biosimilars? *AAPS J.* 2014;16(1):22-26, Epub 11 Oct 2013 DOI: 10.1208/s12248-013-9534-y (**first and corresponding author**)
63) Chaturvedula A, Sale ME, **Lee H**. Genetic algorithm guided population pharmacokinetic model development for simvastatin, concurrently or non-concurrently co-administered with amlodipine. *Journal of Clinical Pharmacology.* 2014;54(2):141-149, Epub 21 SEP 2013 DOI: 10.1002/jcph.176 (**corresponding author**)
64) Kim DW, Gu N, **Lee H**, Jang IJ, Chu K, Yu KS, et al. Usefulness of oral loading of oxcarbazepine suspension in selected patients with epilepsy. Int J Clin Pharmacol Ther. 2013 Oct;51(10):780-6. doi: 10.5414/CP201896.
65) Cha Y-J, **Lee H**, Gu N, Kim T-E, Lim KS, Yoon SH, Chung J-Y, Jang I-J, Shin S-G, Yu K-S, Cho J-Y. Sustained Increase in the Oral Bioavailability of Loperamide after a Single Oral Dose of HM30181, a P-glycoprotein Inhibitor, in Healthy Male Participants. Basic Clin Pharmacol Toxicol. 2013;113(6):419-424. (**co-first author**)
66) **Lee H**, Jang I-J, Yu K-S, Choi J, Oh B-H. A Population Pharmacokinetic Analysis of Fimasartan, a Selective Angiotensin II Receptor Antagonist, in Healthy Caucasian Subjects and Korean Patients With Hypertension. *Clinical Pharmacology in Drug Development*. 2013;2(2):162-72. doi: 10.1002/cpdd.10. (**first & corresponding author)**

67) **Lee H**, Kim KS, Chae SC, Jeong MH, Kim DS, Oh BH. Ambulatory Blood Pressure Response to Once-Daily Fimasartan: An 8-Week, Multicenter, Randomized, Double-Blind, Active-Comparator, Parallel-Group Study in Korean Patients With Mild To Moderate Essential Hypertension. *Clin Ther*. 2013;35(9):1337-49. doi: 10.1016/j.clinthera.2013.06.021. (**first author**)
68) **Lee H**, Yang H-M, Lee H-Y, Kim J-J, Choi D-J, Seung K-B, Jeon E-S, Ha J-W, Rim S-J, Park JB, Shin J-H, Oh B-H. Efficacy and Tolerability of Once-Daily Oral Fimasartan 20 to 240 mg/d in Korean Patients with Hypertension: Findings from Two Phase II, Randomized, Double-Blind, Placebo-Controlled Studies. Clin Ther. 2012;34(6):1273-1289. (**first author**)
69) **Lee H**, Equivalence Margin of the Biosimilar Product. *J Korean Soc Clin Pharmacol Ther.* 2012;20(1):17-33
70) Chi YH, **Lee H**, Paik SH et al. Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Fimasartan, a Novel Angiotensin II Receptor Antagonist, Following Single and Repeated Oral Administration in the Fasted and Fed States in Healthy Subjects. *Am J Cardiovasc Drugs* 2011 Oct 1;1(5):335-46
71) Xie HG, Cao YJ, Gauda EB, Agthe AG, Hendrix CW, **Lee H.** Clonidine Clearance Matures Rapidly during the Early Postnatal Period: A Population Pharmacokinetic Analysis in Newborns with Neonatal Abstinence Syndrome, *J Clin Pharmacol*, 2011:51:502-511 (**corresponding and senior author**)
72) Park CG, **Lee H**, Choi JW, Lee SJ, Kim SH, Lim HE., Non-concurrent Dosing Attenuated Pharmacokinetic Drug Interaction between Amlodipine and Simvastatin. *Int J Clin Pharmacol Ther*, 2010; 48(8):497-503 (**co-first, corresponding, & senior author**)
73) Xu Z, **Lee H**, Vu T, Hu C, Yan H, Baker D, Hsu B, Pendley C, Wagner C, Davis HM, Zhou H. Population Pharmacokinetics of Golimumab in Patients with Ankylosing Spondylitis: Impact of Body Weight and Immunogenicity, *Int J Clin Pharmacol Ther*, 2010;48(9):596-607 (**co-first author**)
74) H. G. Xie, Y. J. Cao, A. G. Agthe, E. B. Gauda, C. W. Hendrix, J. Nelson, C. C. Peck, **H. Lee**. Population Pharmacokinetics (PPK) of Multiple Doses of Oral Clonidine in Newborns. *Clinical Pharmacology & Therapeutics* 2009;85:S56.
75) Xu Z, Vu T, **Lee H**, Hu C, Ling J, Yan H, Baker D, Beutler A, Pendley C, Wagner C, Davis HM, Zhou H. Population Pharmacokinetics of Golimumab, an Anti-Tumor Necrosis Factor-α Human Monoclonal Antibody, in Patients with Psoriatic Arthritis. *J Clin Pharmacol*, 2009;49:1056-1070
76) Rea RS, Capitano B, Bies R, Bigos KL, Smith R, **Lee H**. Suboptimal Aminoglycoside Dosing in Critically Ill Patients, *Ther Drug Monit*, 2008;30:674–681 (**last and corresponding author**)
77) **Lee H**, Romkes M, Branch R, Backer L, Lan Q, Blount B, Nuckols J, Lyu C, Kieszak S, Brinkman M, Gordon S, Cantor K: Glutathione-S-transferase theta 1 (GSTT1) and CYP2D6 null genotypes have a lower clearance for chloroform absorbed during a shower. *Clinical Pharmacology & Therapeutics* 2007;81:S115-S116.
78) O'brien S, **Lee H**, Ritchey, AK. Once-Daily Enoxaparin in Pediatric Thromboembolism: A Dose Finding and Pharmacodynamics Study, *Journal of Thrombosis and Haemostasis*, 2007 Sep;5(9):1985-7
79) **Lee H**, Yim D. Disease progression model is useful to characterize the pattern of placebo response in patients with rheumatoid arthritis (RA) using the numeric American College of Rheumatology Improvement Criteria (ACR-N). Clinical Pharmacology & Therapeutics. 2006;79:3.
80) Tannenbaum S, Holford NHG, **Lee H**, Peck C, Mould DR. Simulation of Correlated Continuous and Categorical Variables using a Single Multivariate Distribution. *Journal of Pharmacokinetics and Pharmacodynamics*, 2006 Dec;33(6):773-94
81) Knollmann BC, Smyth B, Garnett C, Salessiotis A, Gvodjan D, Berry NS, **Lee H**, Min FD. Personal Digital Assistant-Based Drug Reference Software as Tools to Improve Rational Prescribing: Benchmark Criteria and Performance *Clin Pharmacol Ther* 2005 Jul;78(1):7-18.
82) **Lee H**, Yim D-S, Zhou H, Peck CC. Evidence of Effectiveness: How Much Can We Extrapolate From Existing Studies? AAPS Journal. 2005 Oct 5;7(2):E467-74
83) Yim D, Zhou H, Peck CC, **Lee H**. Population pharmacokinetic-pharmacodynamic (PK-PD) modeling of etanercept in patients with juvenile rheumatoid arthritis (JRA) using a dichotomous clinical endpoint. *Clin Pharmacol Ther* 2005;77(2): P92
84) Green B, **Lee H**, Lack N, et al. A population pharmacokinetic/pharmacodynamic model for the mobilization of progenitor cells by AMD3100. CLINICAL PHARMACOLOGY & THERAPEUTICS 77 (2): P92-P92 Suppl. S FEB 2005
85) **Lee H**, Yim D, Green B, Peck C. Modeling circadian rhythm of diastolic blood pressure in hypertensive patients using 24-hour ambulatory blood pressure monitoring. *Clin Pharmacol Ther* 2005;77(2): P57
86) Lack NA, Green B, Dale DC, Calandra GB, **Lee H**, MacFarland RT, Badel K, Liles WC, Bridger G, A Pharmacokinetic/Pharmacodynamic Model for the Mobilization of CD34+ Hematopoietic Progenitor Cells by AMD3100, *Clin Pharmacol Ther* 2005;77(5): 427-36

87) Yim DS, Zhou H, Buckwalter M, Nestorov I, Peck CC, **Lee H**. Population Pharmacokinetic Analysis and Simulation of the Time Concentration Profile of Etanercept in Pediatric Patients with Juvenile Rheumatoid Arthritis, *Journal of Clinical Pharmacology*, 2005;45(3):246-256 (**last and corresponding author**)
88) **Lee H**. Good Review Practices are the first step forward for the Korea Food and Drug Administration, *Drug Information Journal* 2005;39: 185-192
89) Yim D, **Lee H**, Nestorov I, Zhou H, Buckwalter M, Peck CC. A population pharmacokinetics of etanercept in patients with juvenile rheumatoid arthritis. *Clin Pharmacol Ther* 2004;75(2):P53
90) **Lee H**, Yim D, Nestorov I, Zhou H, Buckwalter M, Peck CC. 0.8 mg/kg once weekly subcutaneous regimen of etanercept will yield an overlapping steady state time-concentration profile with 0.4 mg/kg twice weekly dosing in pediatric patients with juvenile rheumatoid arthritis. *Clin Pharmacol Ther* 2004;75(2):P53
91) Berry NS, Yim D, Peck CC, Weiner DL, **Lee H**. A systematic approach to identifying and modeling the source of pharmacokinetic nonlinearity. *Clin Pharmacol Ther* 2004;75(2):P90
92) Min FD, Smyth B, Berry N, **Lee H**, Knollmann BC. Critical evaluation of handheld electric prescribing guides for physicians. *Clin Pharmacol Ther* 2004;75(2):P92
93) **Lee H**, Tannenbaum S, Peck C. A Novel Method for Deriving Intersubject Variability for Baseline Hazard Rates and Relative Risks for Secondary Vascular Events. *Clin Pharmacol Ther* 2003;73(2):P88
94) Tannenbaum S, Mould DR, Holford NHG, **Lee H**, Peck C. Validation of a novel method of combining both continuous and categorical covariates in a single joint function for clinical trial simulation. *Clin Pharmacol Ther* 2003;73(2):P87
95) **Lee H**, Kimko H, Rogge M, Wang D, Nestorov I, Peck CC. Population pharmacokinetic and pharmacodynamic modeling of etanercept using logistic regression analysis. *Clin Pharmacol Ther* 2003;73(4): 348-365
96) Cross J, **Lee H**, Westelinck A, Nelson J, Grudzinskas C, Peck C. Postmarketing Drug Dosage Changes of 499 FDA-Approved New Molecular Entities, 1980-1999, *Pharmacoepidemiology and Drug Safety*, 2002;11:439-446
97) **Lee H**, Kimko HC, Rogge M, Wang D, Nestorov I, Peck CC. 50 Mg Once Weekly Subcutaneous Regimen of Etanercept Will Yield an Overlapping Steady State Time-Concentration Profile with 25 mg Twice Weekly Dosing. *Clin Pharmacol Ther* 2002;71(2): P90
98) Nestorov I, **Lee H**, Kimko HC, Rogge M, Wang D, Peck CC. Clinical trial simulation of a 50 mg once weekly subcutaneous dosing regimen with etanercept (Enbrel). Ann Rheum Dis 2002;61 Suppl 1:71.
99) **Lee H**, Kimko HC, Rogge M, Wang D, Nestorov I, Peck CC. Population Pharmacokinetic and Pharmacodynamic Modeling of Etanercept Using Logistic Regression Analysis. *Clin Pharmacol Ther* 2002;71(2): P84
100) **Lee H**, Application of foreign clinical trial data by using pharmacokinetic-pharmacodynamic modeling and simulation technique in Korea: a regulatory point of view. *Kor J Clin Pharmacol Ther*, 2002; 10(2): 193-9
101) **Lee H**, C Kim, S Shin. Changes in Clinical Trial Practice and the Working Environment in the Korean Pharmaceutical Industry Since the Implementation of Good Clinical Practice, *Drug Info J,* 2001;35:203-210
102) Cross J, **HK Lee**, JS Nelson, CV Grudzinskas, CC Peck. One in Five Marketed Drugs Undergoes a Dosage Change: 1980-1999. *Clin Pharmacol Ther* 2001;69(2): P63
103) Yoon YR, Cha IJ, Shon JH, Kim KA, Kim MJ, Shin JG, Park SW, Seo SS, Choi JS, **Lee HK**. Clinical Pharmacokinetics of Transdermal Absorption of Diclofenac Diethylammonium Plaster in Healthy Volunteers, *Kor J Clin Pharmacol Ther,* 2000;8(1): 101-112
104) **Lee HK**. Categorical Data Analysis II. *Pediatric Infection*, 1999;6(1):136-141
105) **Lee HK**. Comparison of Two Means, *Pediatric Infection*, 1998; 5(1): 152-7
106) **Lee HK**. KW Lim, JH Park et al. A Survey of Industrial Perspectives on the Central Pharmaceutical Affairs Council's Review of Clinical Trial Protocols and Study Reports, *Kor J Clin Pharmacol Ther*, 1998; 6(1): 11-28
107) **Lee HK.** Categorical Data Analysis I. *Pediatric Infection*, 1998; 5(2): 313-9
108) MS Park, NC Yu, DR Na, YS Kim, **HK Lee**, KH Kim. Bioequivalence Study of CIPOL-N (Cyclosporine Microemulsion Preparation) in Healthy Adults, *Transplantation Proceedings,* 1998; 30:3541-6
109) Lee JM, Lee JH, Kim JK, Shin HJ, **Lee HK**, Lee SJ, Hong CI. Pharmacokinetic Study of CKD-602, A New Camptothecin Derivative. *Journal of the Pharmaceutical Society of Korea*, 1998;42(4):437-46
110) Lee JM, Lee JH, Kim JK, Shin HJ, **Lee HK**, Lee SJ, Hong CI. Pharmacokinetic Study of CKD-602, A New Camptothecin Derivative. *Journal of the Pharmaceutical Society of Korea*, 1998;42(4):431-36
111) **Lee HK**. The Principle of Hypothesis Testing II. *Pediatric Infection*, 1997; 4(2): 314-9
112) **Lee HK**. The Principle of Hypothesis Testing I. *Pediatric Infection*, 1997; 4(1): 183-92
113) **Lee HK**, MG Kim, SY Kim, HY Koh, CJ Kim. The Reliability of Translated Korean Psychological General Well-being Index, *Kor J Clin Pharmacol Ther*, 1996; 4(2): 148-65
114) **Lee HK**. Medicine and Statistics: Introduction. *Pediatric Infection*, 1996; 3(2): 222-4

115) Kim SW, JK Chung, DS Lee, C Kwark, JM Jeong, MK Kim, MC Lee, CS Koh, **HK Lee**, KY Yoo, YO Ahn. Cutoff values of serum CEA in normal Korean adults and factors influencing serum CEA level, *Kor J Nuclear Med*, 1994; 28(3): 391-6
116) Shin MH, DH Kim, JM Bae, **HK Lee**, MS Lee, JY Noh, YO Ahn. The effect of coffee consumption on serum total cholesterol level in healthy middle-aged men. *Kor J Prev Med*, 1994;27(2):200-16
117) **Lee HK**, YO Ahn. An assessment of methodological and statistical validity of medical articles published in Korea, from 1980 to 1989. *Kor J Med Edu*, 1991; 3(1): 52-69
118) Ahn YO, **HK Lee**. Development of a checklist for assessing the methodological and statistical validity of medical articles. *Kor J Med Edu*, 1991; 3(1): 19-35
119) **Lee HK**, BR Huh, YO Ahn. An assessment of methodological and statistical validity of medical articles. *J Kor Acad Fam Med*, 1991;12(6):46-27
120) Ahn YO, **HK Lee**. Research methodologies in medical studies. *Kor J Epidemio*, 1990; 12(2):107-14
121) Choi JH, KS Lee, **HK Lee**, S Sunwoo, BR Huh. Graduate follow-up in the family practice residency programs. *J Kor Acad Fam Med,* 1989; 10(9): 19-27
122) Seo HG, SP Chung, HS Park, **HK Lee**, YS Kim, YM Han, BR Huh. A study on the stress amount and life event according to family life cycle. *J Kor Acad Fam Med*, 1989; 10(3):1-11

BOOKS:

1) **Lee H** et al. There is no such thing as K-quarantine. Golden Time. Seoul, Korea, 2021 (ISBN: 9791197167843)
2) Kim S and **Lee H**. The age of biopharmaceuticals is coming. The Young Physicians Press. Seoul, Korea, 2019 (ISBN: 8991232817)
3) **Lee H.** Let Us Not Forget Woo-Suk Hwang. The Young Physicians Press. Seoul, Korea, 2007 (ISBN: 8991232124)
4) **Lee H**. FDA vs. KFDA. The Young Physicians Press. Seoul, Korea, 2005 (ISBN : 8991232043)
5) Ahn YO, DH Kim, MH Shin, JM Bae, **HK Lee**, MS Lee, JY No. Korean Cancer Research Survey; Seoul Male Cohort Construction, Dept. of Preventive Medicine, Seoul National University College of Medicine, 1994
6) Ahn YO, **HK Lee**. The Understanding of Statistical Methods in Health Sciences, 1st ed., Chung-Moon Sa, Seoul, 1992

BOOK CHAPTERS:

1) **Lee H.** Chapter 1. Disappearance of Biomedical Science, Destruction of Research Ethics. In: Hwang Woo Suk's Scandal. Hannarae Publishing Co., Seoul, Korea (ISBN: 8955660480 93330)
2) **Lee H**. Chapter 12. Utilizing the Preclinical Database to Support Clinical Drug Development. In: Preclinical Drug Development, edited by Mark Rogge and David R. Taft, Taylor & Francis, Boca Raton, London, New York, Singapore, 2005 & 2009 (2nd ed.) (ISBN: 978-1420084726)
3) **Lee H.** Chapter 13. Regulation for Drug Development and Competition. In: Introduction to Pharmaceutical Medicine, Novo Consulting, Seoul, 2009

PROCEEDINGS (Incomplete):

1) Z. Xu, **H. Lee**, T. Vu, C. Hu, J. Ling, D. Baker, M. Rahman, C. Pendley, C. Wagner, H. M. Davis, H. Zhou. Population pharmacokinetics of golimumab, an anti-tumor necrosis factor-a human monoclonal antibody in patients with rheumatoid arthritis, 2008 EULAR, Paris, France
2) Z. Xu, **H. Lee**, T. Vu, C. Hu, J. Ling, D. Baker, M. Rahman, C. Pendley, C. Wagner, H. M. Davis, H. Zhou. Population Pharmacokinetics of Golimumab, an Anti-tumor Necrosis Factor-α Human Monoclonal Antibody in Patients with Psoriatic Arthritis, 2008 EULAR, Paris, France
3) Tannenbaum S, Holford NHG, **Lee H**, Peck CC, Mould D, A Novel Method for Simulation of Correlated Continuous and Categorical Variables Using A Single Multivariate Distribution, PAGE, June 2006
4) Green B, **Lee H**, Lack N, Dale D, Calandra G, MacFarland R, Badel K, Liles W, Bridger G, Peck C. A Population Pharmacokinetic/Pharmacodynamic Model for the Mobilization of Progenitor Cells by AMD3100, 2005 Page Meeting, Pamplona, Spain
5) Yim DS, **Lee H**, Peck CC. Population pharmacokinetics and simulated time above MIC of meropenem in febrile neutropenic patients in Korea. Accepted for poster presentation at the Annual Meeting of the American Association of Pharmaceutical Scientists, October, 2004, Baltimore, Maryland, USA
6) **Lee H**, Zhou H, Yim DS, Peck CC. A Comparison of Demographic and Baseline Disease Status Variables among Various Placebo Response Patterns for the American College of Rheumatology 20% Improvement Criterion (ACR20) in

Patients with Rheumatoid Arthritis (RA). Accepted for poster presentation at the Annual Meeting of the American Association of Pharmaceutical Scientists, October, 2004, Baltimore, Maryland, USA

7) Stangier J, Garnett C, Liesenfeld KH, Tillmann C, Troconiz I, **Lee H**, Schaefer HG. PK/PD-Modeling (PK/PD) and Clinical Trial Simulation (CTS) of Early Clinical Data of a New Oral Direct Thrombin Inhibitor (Dabigatran Etexilate). At the Pharmaceutical Sciences World Congress, May 2004, Kyoto, Japan
8) Min FD, Smyth B, Berry N, **Lee H**, Knollmann BC. Critical evaluation of handheld electric prescribing guides for physicians. At the 2004 Annual Meeting of ASCPT, Miami Beach, Florida, USA, March, 2004
9) Berry NS, Yim D, Peck CC, Weiner DL, **Lee H**. A systematic approach to identifying and modeling the source of pharmacokinetic nonlinearity. At the 2004 Annual Meeting of ASCPT, Miami Beach, Florida, USA, March, 2004
10) **Lee H**, Yim D, Nestorov I, Zhou H, Buckwalter M, Peck CC. 0.8 mg/kg once weekly subcutaneous regimen of etanercept will yield an overlapping steady state time-concentration profile with 0.4 mg/kg twice weekly dosing in pediatric patients with juvenile rheumatoid arthritis. At the 2004 Annual Meeting of ASCPT, Miami Beach, Florida, USA, March, 2004,
11) Yim D, **Lee H**, Nestorov I, Zhou H, Buckwalter M, Peck CC. A population pharmacokinetics of etanercept in patients with juvenile rheumatoid arthritis. At the 2004 Annual Meeting of ASCPT, March 2004, Miami Beach, Florida, USA
12) Garnett C, Liesenfeld KH, Tillmann C, Troconiz I, Schaefer HG, Stangier J, **Lee H**. Clinical Trial Simulation of the Effect of Renal Impairment on the Dose-Response Relationship of a Direct Thrombin Inhibitor, BIBR 1048, in Hip Replacement Patients, Accepted for poster-podium presentation at the Annual Meeting of the American Association of Pharmaceutical Scientists, Salt Lake City, Utah, USA, October, 2003
13) **Lee H**, Wang D, Nestorov I, Rogge M, Peck C. Disease Progress Models for Simulation that Employ the American College of Rheumatology 20% Improvement Criterion (ACR20) in Patients with Rheumatoid Arthritis (RA) using Logistic Regression Analysis, Accepted for poster presentation at the Annual Meeting of the American Association of Pharmaceutical Scientists, October, 2003
14) Garnett C, Liesenfeld KH, Tillmann C, Troconiz I, Schaefer HG, Stangier J, **Lee H**. Clinical Trial Simulation of the Dose-Response Relationship of a Direct Thrombin Inhibitor, dabigatran etexilate (BIBR1048), in Hip Replacement Patients, At the 12th Annual Meeting of Population Approach Group in Europe, June 12-13, 2003, Verona, Italy
15) **Lee H**, Tannenbaum S, Peck C. A novel method for deriving baseline disease event hazard rates using average incidence rates and ratio indices, *Poster presentation at 2002 AAPS Annual Meeting, Toronto, Canada*
16) Tannenbaum S, Holford NHG, Mould D, **Lee H**, Peck CC. A Novel Method of Combining Both Continous and Discrete Categorical Covariates in a Single Joint Function for Generation of Realistic Virtual Patients in a Clinical Trial Simulation*, Poster and podium presentation at 2002 AAPS Annual Meeting, Toronto, Canada*
17) **Lee H**, HC Kimko, M Rogge, D Wang, I Nestorov, CC Peck. Population pharmacokinetic (PK) and pharmacodynamic (PD) modeling of etanercept using logistic regression analysis, *At the 102nd Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, 2002 Atlanta, Georgia, USA*
18) **Lee H**, HC Kimko, M Rogge, D Wang, I Nestorov, C Peck. 50 mg once weekly subcutaneous regimen of etanercept will yield an overlapping steady state time-concentration profile with 25 mg twice weekly dosing, *At the 102nd Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, 2002 Atlanta, Georgia, USA*
19) **Lee H**, C. Kimko, J. Li, IJ Jang, C Peck. Population pharmacokinetic and pharmacodynamic modeling of an antihypertensive agent using 24-hour ambulatory blood pressure monitoring measurements, *Poster and podium presentation at 2001 AAPS Annual Meeting, Denver, Colorado, USA*
20) Cross J, **HK Lee**, JS Nelson, CV Grudzinskas, CC Peck. One in five marketed drugs undergoes a dosage change: 1980 – 1999, *At the 101st Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, 2001, Orlando, Florida, USA*
21) **Lee HK**, MJ Kang, KH Lim et al., 1-Year Experience of Introducing Clinical Quality Assurance Unit into Local Pharmaceutical Company, 1999, *At the 8th Annual Meeting of The Korean Society for Clinical Pharmacology and Therapeutics, Seoul, Korea*
22) **Lee HK**, SJ Cho, KH Lim et al., Factors Affecting Compliance of Pregnant Women Prescribed Iron-Containing Supplements, 1999, *At the 8th Annual Meeting of The Korean Society for Clinical Pharmacology and Therapeutics, Seoul, Korea*
23) **Lee HK**, A Prospective Cohort Study on the Serum Total Cholesterol Level and Five-year Mortality from Cardiovascular Disease and All Causes in 14,287 Korean Men, 1998, *At the Annual Meeting of the Korean Academy of Family Medicine, Seoul, Korea*
24) **Lee HK**, KM Park, KW Lim et al., Change of Job and Perspectives of Korean Pharmaceutical Industry's Clinical Research People Before and After GCP Implementation, 1998, *At the 7th Annual Meeting of The Korean Society for Clinical Pharmacology and Therapeutics, Seoul, Korea*

25) **Lee HK**, KW Lim, KM Park et al., Change and Development of Korean Pharmaceutical Industry on Clinical Trial Practice Before and After GCP Implementation, 1998, *At the 7th Annual Meeting of The Korean Society for Clinical Pharmacology and Therapeutics, Seoul, Korea*
26) **Lee HK**, CJ Kim, SG Shin, JS Chang. Industrial Perspectives on Clinical Trial Practice: 3 Year's Experience and Change After GCP Implementation in Korea, 1998, *At the DIA Asian Pacific Meeting, Taipei, Taiwan*
27) Park BJ, CJ Kim, HK Kim, BW Moon, HL Moon, SG Shin, **HK Lee**, JH Yang, JH Woo, MS Lee. Survey on Clinical Investigator's Practice of Clinical Drug Trials in Korea. 1997. *At the 4th Annual Meeting of The Korean Society for Clinical Pharmacology and Therapeutics, Seoul, Korea*
28) Park BJ, CJ Kim, HK Kim, BW Moon, HL Moon, SG Shin, **HK Lee**, JH Yang, JH Woo, MS Lee. Survey on Clinical Investigator's Perspective of Clinical Drug Trials in Korea. 1996. *At the 5th Workshop sponsored by The Korean Society for Clinical Pharmacology and Therapeutics, Seoul, Korea*
29) **Lee HK**, Kim CJ, MK Kim, SY Kim. Knowledge, Attitude, and Practice of Clinical Trial Monitors in Korea, 1995, *At the 4th Annual Meeting of The Korean Society for Clinical Pharmacology and Therapeutics, Seoul, Korea*
30) Ahn YO, BK Park, JK Lee, JY No, MS Lee, DH Kim, MH Shin, JM Bae, **HK Lee**. Korean Cancer Research Survey: Cohort Construction, 1994. *At the Federation Meeting of Korean Basic Medical Scientists*, Jun 3-4, 1994*, Seoul, Korea*
31) Kim SW, JK Chung, MC Lee, CS Koh, **HK Lee**, KY Yoo, JS Kim. The normal range of serum CEA level and its determinants among Koreans. A*t the 33rd Annual Meeting of The Korean Society of Nuclear Medicine*, May 27-28, 1994, Seoul, Korea
32) Kim SW, JK Chung, MC Lee, BY Cho, CS Koh, **HK Lee**, KY Yoo, JS Kim. Determination of the normal range of serum TSH level among Koreans. *At the 33rd Annual Meeting of The Korean Society of Nuclear Medicine*, May 27-28, 1994, Seoul, Korea
33) **Lee HK**, YO Ahn. The use of a model including both alcoholic beverage type effects and beverage preferences effects for the investigation of the relationship between alcohol consumption and smoking habits. *At the 15th Annual Meeting of The Korean Academy of Family Medicine*, Oct 30-31, 1993, Seoul, Korea
34) Shin MH, DH Kim, JM Bae, **HK Lee**, MS Lee, TS Park, YO Ahn. The correlation between coffee drinking and blood pressure and serum total cholesterol level among healthy middle aged men. *At the 45th Annual Scientific Meeting of The Korean Society for Preventive Medicine*, Oct 28-30, 1993*,* Seoul, Korea
35) **Lee HK**, YO Ahn, TS Park. Effects of life style and diets on total health care expenditures. *At the 45th Annual Scientific Meeting of The Korean Society for Preventive Medicine*, Oct 28-30, 1993*,* Seoul, Korea

PUBLICATIONS IN OTHER JOURNALS:

1) **Lee HK**. Pharmaceutical Industry's Perspectives on Clinical Trial Regulation Reform in Korea. *Pharmaceutical Industry Information,* 1999;1:17-23
2) **Lee HK**. Data Management in Clinical Trials. *New Drug News*, 1999;7(7):3-12
3) **Lee HK**. Manual of Clinical Investigation, IRB Procedure, and Current Status of Clinical Trials in Korea. The Korean Society for Clinical Trial, C & R, Seoul, Korea, 1998
4) **Lee HK**. Designing Clinical Trials. *New Drug News*, 1997; 5(3): 3-13

RESEARCH AND CREATIVE ACTIVITIES:

CLINICAL STUDIES (AS PI since 2012)

1. A phase 1/2a, Randomized, Double-blind, Dose Escalation Study to Assess the Safety, Tolerability, Efficacy, and Pharmacokinetics Following Single and Multiple Doses of KH001 solution in Dentin Hypersensitivity Patients
2. A mass balance study to investigate the absorption, metabolism, excretion of LCB01-0371 after a single oral LCB01-0371 dose with a [14C]LCB01-0371-microtracer dose in healthy male subjects
3. A First-in-Human, Double-blind, Randomized, Placebo-controlled, Single Ascending Dose Study to Assess Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of GLH8NDE in Healthy Korean and Caucasian Subjects
4. A First-in-Human, Double-blind, Randomized, Placebo-controlled, Single Ascending Dose Study to Assess Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of HM15136 in Healthy Subjects
5. A microtracing study using accelerator mass spectrometry to determine the absolute bioavailability, intravenous pharmacokinetics, and mass balance of GX-I7 in healthy volunteers
6. A microtracing study using accelerator mass spectrometry to determine the absolute bioavailability and intravenous pharmacokinetics of YH4808 in healthy volunteers
7. A microtracing human mass balance study using accelerator mass spectrometry to determine the absorption,

metabolism, and excretion of KD101 in healthy volunteers
8. A microtracing study using accelerator mass spectrometry to determine the absolute bioavailability, intravenous pharmacokinetics, and mass balance of YH12852 in healthy volunteers
9. A randomized, double-blind, placebo-controlled single dose ascending phase I study to determine the safety, tolerability, pharmacokinetic, and pharmacodynamic profiles of HL2351, a recombinant hybrid human Fc-IL1Ra, in healthy volunteers
10. A pharmacogenomics-pharmacometabolomic-pharmacokinetic study to develop multiomics biomarkers to predict drug response in patients with psoriasis
11. A randomized, double-blind, single- and repeated-dose phase I study to determine the safety, tolerability and, pharmacokinetic profiles of apremilast in healthy volunteers
12. A randomized, double-blind, placebo-controlled single dose ascending phase I study to determine the safety, tolerability, pharmacokinetic, and pharmacodynamic profiles of GX-I7, a recombinant hybrid human Fc-IL7, in healthy volunteers
13. A randomized, double-blind, placebo-controlled multiple ascending dose phase I study to determine the safety, tolerability, pharmacokinetic, and pharmacodynamic profiles of URC102, a human uric acid transporter inhibitor, in healthy volunteers
14. A randomized, double-blind, placebo-controlled repeated dose phase II study to determine the safety, tolerability, pharmacokinetic, and pharmacodynamic profiles of URC102, a human uric acid transporter inhibitor, in patients with gout
15. A randomized, open-label, placebo-controlled, parallel, single- and repeated-dose phase /IIa study to determine the safety, tolerability, pharmacokinetic, and pharmacodynamic profiles of YH12852 in healthy volunteers and patients with constipation
16. A randomized, double-blind, placebo-controlled single ascending dose phase I study to determine the safety, tolerability, pharmacokinetic, and pharmacodynamic profiles of KD101, an anti-obesity drug under development, in healthy volunteers
17. A randomized, double-blind, placebo-controlled multiple ascending dose phase I study to determine the safety, tolerability, pharmacokinetic, and pharmacodynamic profiles of KD101, an anti-obesity drug under development, in patients with overweight or obesity
18. A randomized, double-blind, two-way, two-treatment, cross-over study to compare the safety, tolerability, and profiles of Tacrobell (tacrolimus in tablet) versus Prograf (tacrolimus in capsule) in healthy volunteers
19. A randomized, double-blind, two-way, two-treatment, cross-over study to compare the safety, tolerability, and profiles of Tacrobell (generic tacrolimus) versus Prograf (reference tacrolimus) in healthy volunteers
20. A randomized, double-blind, placebo-controlled, parallel, two-week, phase IIa study to determine the pharmacokinetic-pharmacodynamic relationship of coadministered fimasartan and hydrochlorothizied in patients with mild to moderate hypertension
21. An open-label phase I study to determine the safety, tolerability, pharmacokinetic, and immunogenicity profiles of GC1118, an EFGR antagonist, in patients with advanced solid tumor (PI for clinical pharmacology)
22. An open-label phase II study to determine the safety, tolerability, pharmacokinetic, and immunogenicity profiles of GC1118, an EFGR antagonist, in patients with advanced solid tumor (PI for clinical pharmacology)
23. A molecular imaging phase I study using positron emission tomography to determine the distribution of [18F]DHP-107 in patients with advanced solid tumor

GOVERNMENT RESEARCH GRANTS

SUCCESS 2019-2021
Role: PI ($1,500,000, 3 years)
Grantor: Ministry of Trade, Industry and Energy

A dimensionality reduction model to increase the efficiency and accuracy of clinical trial feasibility assessment using electronic medical records 2019-2021
Role: PI ($250,000, 3 years)
Grantor: National Research Foundation, Korea

AI-based Clinical Trial Resource Information System (ACTRiS) 2018
Role: PI ($600,000, 1 year)

Grantor: Ministry of Health and Welfare, Korea

Microtracing by AMS for Biologics 2017 - 2018
Role: PI ($1,000,000)
Grantor: Ministry of Health and Welfare, Korea

Policy to facilitate integrating electronic medical records with other public health records 2017
Role: PI ($20,000)
Grantor: Korea National Enterprise for Clinical Trials (KoNECT)

Use of microdosing studies in drug development (policy project) 2016 - 2017
Role: PI ($40,000)
Grantor: KIRAMS

TICKET (Microdosing study) 2015 - 2017
Role: PI ($500,000)
Grantor: Ministry of Health and Welfare, Korea

A microtracing study using accelerator mass spectrometry to determine the absolute bioavailability, intravenous pharmacokinetics, and mass balance of YH12852 in healthy volunteers 2014
Role: PI ($20,000)
Grantor: Seoul National University Hospital (New Faculty Settlement Grant)

Bioimgaging in Drug Development 2014 – 2019
Role: Co-PI of the Drug Regulatory Core (PI: Sang-Eun Kim)
Grantor: Ministry of Health and Welfare, Korea

Hanmi Clinical Pharmacology Fellowship Grant 11/1/2013-2/28/2015
Role: PI ($200,000 fellowship training award)
Grantor: Hanmi Pharmaceutical Inc., Seoul, Korea

Global Center of Excellence Grant 11/1/2013-3/31/2017
Role: Co-I ($9,000,000, 10%)
Grantor: The Ministry of Health and Welfare, Korea

Drug Development for Bio-terrorism Preparedness 2014-2015
Role: Co-I ($40,000, 10%, PI: Prof. Jong-Gu Lee, SNU)
Grantor: The Ministry of Food and Drug Safety, Korea

CDC PrEP Pharmacometric Analysis 9/1/2009 - 2011
Funding Organization: CDC (Pharmacometric subcontractor, $10,000 award, PI: Craig Hendrix, John Hopkins University Hospital)
Role: Pharmacometric subcontractor, 5% effort
The proposed work will develop a mechanistic population pharmacokinetic model for intracellular tenofovir concentrations in patients with active AIDS.

Funding Organization: NIH HD-03-001 (Total award: $1,418,617, no salary support)
PI: John N. van den Anker, MD, PhD, CNMC
Role: Co-I, Project D. “Development of a Population Pharmacokinetic/Pharmacodynamic Model for Rational Dosing of Morphine in Preterm Neonates, 5% effort

The NIGMS Clinical Pharmacology Training Grant, Renewal 1/31/05-02/28/05
Funding Organization: NIH (Total award: $1,000,000 for 5 years, no salary support)
PI: M. Zasloff, Georgetown University
Role: Fellowship Supervisor, 5% effort

P30 CA82103 Cancer Center Support Grant 8/5/99- 5/31/12
Funding Organization: NIH/NCI (Total Award: $3,793,733, PI: McCormick, F., FY09, 9 month award, $45,000)
The Cancer Center Support Grant provides support for administration and infrastructure for the UCSF Comprehensive Cancer Center. I am the co-Director for the Pharmacokinetics and Pharmacodynamics core. This grant supports 10% of my salary.

UCSF CTSI. 2006 - 2008
Funding Organization: NIH
Role: Faculty Manager, The Regulatory Knowledge Support (25% effort, 25% salary support)

A Systematic Policy Analysis to Identify Key Strategies for Implementing Good Review Practices into the Korea Food and Drug Administration 7/1/05-6/30/06
Funding Organization: MSD International Grant (Total Award: $41,708 for 1 year, 8.5% salary support)
Role: PI, 8.5% effort
The proposed work will systematically seek the most effective ways to modernize the regulatory review processes of the Korea Food and Drug Administration (KFDA) with a focus on the implementation of Good Review Practices (GRP) as the review standards.

5 U10 HD47905-02 (PI: Steve Caritis, MD) 7/1/04-4/30/08
Magee-Womens Health Corp. (Total Award: $60,125, 10% salary support)
Pregnancy and Drug Metabolizing Enzymes and Transporters (Drug Use Project)
Role: Co-I, 10% effort
The major goal of this project is to establish centers to investigate Obstetric-Fetal Pharmacology including pregnancy and drug metabolizing enzymes and transporters.

Molecular and Cellular Determinants of Disease Heterogeneity in COPD 12/01/06-11/31/11
Funding Organization: NIH (RFA-HL-05-008, Total award: $3,572,893 for 5 years, 10% salary support)
PI: Frank Sciurba, MD, University of Pittsburgh
Role: Co-Investigator, Pharmacometrics
The University of Pittsburgh SCORR in COPD builds upon our long tradition of research in Chronic Obstructive Pulmonary Disease to propose a four projects proposal which extends our previous work and our strong collaboration with the University of British Columbia.

<u>PAST CONTRACT (Incomplete)</u>

Evaluation of the Safety and Pharmacokinetics of Ascending Dose Levels of 2 methoxyestradiol Suspension for Injection in Healthy Male Volunteers 10/1/05– 9/30/06
Funding Organization: PR Pharmaceuticals (Total Award: $288,000 for 1 year, 24% salary support)
Role: PI

The Washington Obstetric Pharmacology Research Unit (WOPRU) 7/1/04-6/30/09
Funding Organization: NIH HD-03-017 (Total award: $2,803,000, 5% salary support)
PI: Menachem Miodovnik, MD, Georgetown University
Role: Co-PI for Clinical Pharmacology and Pharmacometric Core, 5% effort
(After moving to University of Pittsburgh, there has been no salary support from this grant since March, 2005)

Drug Dosage Study 6/1/99-12/31/00
Funding Organization: Drug Information Association (Total support: $20,000)
Role: Co-investigator (PI: J. Cross)

<u>Prior Industrial Grant Supports</u>
Population Pharmacokinetic-Pharmacodynamic Analysis and Simulation of Posidur in Postoperative Patients, 2007 - 2008
Sponsor: Durect

Population pharmacokinetic-pharmacodynamic modeling and simulation analysis of Zenvia, 2007
Sponsor: Avanir Pharmaceuticals

Population Pharmacokinetic Analysis and Simulation of Golimumab in Patients with Active Rheumatoid Arthritis, 2007
Sponsor: Centocor

Population Pharmacokinetic Analysis and Simulation of Golimumab in Patients with Active Ankylosing Spondylitis, 2007
Sponsor: Centocor

Population Pharmacokinetic Analysis and Simulation of Golimumab in Patients with Active Psoriatic Arthritis, 2007
Sponsor: Centocor

Population pharmacokinetic-pharmacodynamic modeling and simulation of the T2 formulation of etanercept in patients with rheumatoid arthritis 10/1/04-1/31/05
Sponsor: Amgen, Thousand Oaks, California (Total award: $150,000)
Role: PI and Project Leader

Population pharmacokinetic modeling of Advicor 10/1/04-12/31/04
Sponsor: Kos Pharmaceuticals Inc., Miami, Florida (Total award: $ 58,000)

Population pharmacokinetic-pharmacodynamic modeling of TACI-Fc5 in patients with rheumatoid arthritis
Sponsor: Serono/Zymogenetics, Geneva/Seattle (Total support: $90,000) 1/1/04 -6/30/04
Role: PI

Clinical trial simulation project I of BIBR 1048 1/1/04-6/30/04
Sponsor: Boehringer Ingelheim Pharma KG, Germany (Total award: $81,000)
Role: PI

Population pharmacokinetic modeling and simulation of talampanel in patients with epilepsy
Sponsor: Ivax, Miami, Florida (Total award: $57,000) 6/1/03-12/31/03
Role: Project leader and supervisor

Population pharmacokinetic modeling and simulation of etanercept in patients with juvenile rheumatoid arthritis
Sponsor: Amgen, San Francisco, California (Total support: $70,000) 7/1/03-8/31/03
Role: PI

Clinical trial simulation project of S18886 1/1/02-6/30/03
Institut de Recherches Internationales SERVIER, France (Total support : $410,000)
Role: Co-investigator and project supervisor (PI: S. Tannenbaum, PhD)

Clinical trial simulation project II of BIBR 1048 6/1/01-6/30/03
Boehringer Ingelheim Pharma KG, Germany (Total support: $150,000)
Role: Co-investigator and project supervisor (PI: C. Garnette, PharmD)

Population pharmacokinetic-pharmacodynamic modeling and clinical trial simulation of etanercept
Sponsor: Immunex Corp. Inc., Seattle, Washington (Total support: $90,000) 3/1/01-12/31/01
Role: PI

Population pharmacokinetic-pharmacodynamic modeling of lercanidipine 2/1/00-12/31/00
Sponsor: Recordati, Italy (Total support: $90,000)
Role: PI

Washington D.C. Collaborative Pediatric Pharmacology Research Unit Network 1/1/04-02/28/05

DRUG DEVELOPMENT CONSULTING PROJECTS (INCOMPLETE):

1. Population pharmacokinetic and pharmacodynamic modeling of lercanidipine using 24-hour ambulatory blood pressure monitoring measurements. Recordati, Italy, 2000
2. Data analysis plan: in vivo drug interaction study of BusPar, BMS, USA, 2000
3. Review of study protocols and reports: in vivo drug interaction studies of pioglitazone, Takeda America, USA, 2000
4. Development strategy for new formulation of cordarone, Wyeth-Ayerst, Philadelphia, Pennsylvania, USA, 2001
5. Population pharmacokinetic-pharmacodynamic modeling of Enbrel in Patients with Active Rheumatoid Arthritis. Immunex, Seattle, Washington, 2001
6. Concentration simulations and investigation of 50 mg once weekly subcutaneous dose of Enbrel in Patients with Active Rheumatoid Arthritis. Immunex, Seattle, Washington, 2001
7. Review of IND Deficiency Document submitted to FDA, AQUAVAN™, Guilford Pharmaceuticals, Baltimore, Maryland, 2002
8. Consulting drug development strategy and clinical development program, Orally inhaled Amphotericin B (prevention of Asperogillosis in immune compromised host), Inhale Therapeutic Systems, San Carlos, California, 2002
9. Designing phase I/II study of PEG-paclitaxel and consulting drug development strategy, Enzon Inc., Piscataway, New Jersey, 2002
10. Review of data analysis phase III study and regulatory submission strategy for oral heparin, Emisphere Technologies Inc., New York, 2002
11. Certican Advisory Board Meeting (NDA Submission of Certican), Novartis Pharma AG, Paris, France, 2002
12. Iressa Advisory Board Meeting, Clinical Pharmacology Section Review for NDA Submission, AstraZeneca, New York City, USA, 2002
13. Relpax Bioequivalence Advisory Board Meeting, Pfizer, New York City, USA, 2002
14. Scientific Advisory Board service, IVAX, Miami, USA, 2002
15. Consulting on Synthroid Bioequivalence study and simulation, Abbott Laboratories, USA, 2002
16. Clinical Trial Simulation Project. S18886 --- Secondary prevention of major vascular events in patients with an ischemic event and at risk of atherothrombosis. Institut de Recherches Internationales SERVIER, France, 2002
17. Clinical Trial Simulation Project. BIBR 1048 in prevention of deep vein thrombosis, Boehringer Ingelheim Pharma KG, Germany, 2002
18. Consulting on TA-20 development project, Trimeris, USA, 2002
19. Review of Phase I study protocol, TPI, Chiron Pharma, 2003
20. Review of Clinical Pharmacology section in Alvimorpan NDA, Adolor Corp., 2003
21. Drafting the Request for Proposal for modeling and simulation of epoetin and darbepoetin in patients with chemotherapy related anemia, NCI, 2003
22. Population pharmacokinetic modeling and simulation of concentrations of etanercept in patients with Juvenile Rheumatoid Arthritis, Amgen, USA, 2003
23. Population pharmacokinetic modeling of talampanel in patients with epilepsy, Ivax, Miami, USA, 2003
24. Review of and consulting on the End-of-Phase-IIa Meeting with FDA for talampanel, IVAX, Miami, USA, 2003
25. Scientific Advisory Board service, Bayer, Germany, 2003
26. Review of and consulting on the clinical drug development program, Recombinant AAT, Arriva Pharmaceuticals, Inc., Alameda, CA, USA 2003
27. Full review of the clinical pharmacology section of the NDA for Alvimopan, targeted at reducing symptoms and signs of patients with postoperative ileus, Adolor Corporation, Exton, PA, USA, 2004
28. Full review of clinical drug development program. Ascend Pharmaceutical Inc., Fairfax, VA, USA, 2004
29. Population pharmacokinetic-pharmacodynamic modeling and clinical trials simulations of TACI-Fc5 for the treatment of patients with rheumatoid arthritis, Serono, Geneva, Switzerland, ZymoGenetics, Seattle, WA, USA, 2004
30. Population pharmacokinetic-pharmacodynamic modeling and clinical trials simulations of the T2 formulation of etanercept in patients with rheumatoid arthritis, Amgen, Thousand Oaks, California, USA, 2004
31. Clinical pharmacology review on bridging data of etoricoxib in Korean population, MSD Korea, Seoul, Korea, 2004
32. Regulatory strategy consulting on data exclusivity issue of sibutramine hydrochloride (Reductil®) in Korea, Abbott Korea Ltd., Seoul, Korea, 2004
33. Population pharmacokinetic-pharmacodynamic modeling and simulation of Zenvia, Avanir Pharmaceuticals, 2007
34. Population pharmacokinetic modeling and simulation of golimumab in patients with rheumatoid arthritis for US FDA, Centocor, 2007
35. Population pharmacokinetic modeling and simulation of golimumab in patients with ankylosing spondylitis for US FDA, Centocor, 2007
36. Population pharmacokinetic modeling and simulation of golimumab in patients with psoriatic arthritis for US FDA, Centocor, 2007

37. Population pharmacokinetic-pharmacodynamic modeling and simulation of Posidur for US FDA, Durect Pharmaceuticals, 2007-2008
38. Population pharmacokinetic pharmacodynamic analysis of fimasartan, Boryung Pharmaceutical Corp., Korea, 2009
39. FDA pre-IND meeting project, fimasartan, Boryung Pharmaceutical Corp., Korea, 2011
40. Ethnic sensitivity analysis for fimasartan, Boryung Pharmaceutical Corp., Korea, 2014 (in association with an IND submission in Brazil)
41. Ethnic sensitivity analysis, Hanmi, Korea, 2015
42. Population pharmacokinetic-pharmacodynamic analysis of CWP232291 in patients with CML, Choong-Awe Pharma, Korea, 2016-2017
43. Population pharmacokinetic analysis of GC1118 in patients with advanced solid tumor, Green Cross, Korea, 2016-2017
44. Population pharmacokinetic-pharmacodynamic analysis of hyFc growth hormone in children with growth hormone deficiency, Genexine, Korea, 2017