


Curriculum Vitae

Name	Donghoon Shin	
Current Position & Affiliation	Vice President, Medical Team, Samsung Bioepis	
Country	Korea	

Educational Background

Time	Institution	Major	Degree
2016.03-2018.08	Sungkyunkwan University	MBA	MBA
2009.03-2014.02	Seoul National University	Clinical Pharmacology	Ph.D
2004.03-2008.02	Seoul National University	Medicine	M.D.
2001.03-2003.02	Seoul National University	Organic Chemistry	M.S.
1994.03-2001.02	Seoul National University	Chemistry	B.S.

Professional Experience

- Dec 2020-Present: Vice President, Medical and Lifecycle Safety Team, Samsung Bioepis
 - Lead of Medical Team
- Feb 2020-Dec 2020: Vice President, Medical Affairs Group, Medical Team, Samsung Bioepis
 - Medical Affairs group management
- Feb 2018-Jan 2020: Vice President, Clinical Development Group, Medical Team, Samsung Bioepis
 - Clinical development group management
 - Supervision for clinical development planning

- Mar 2017-Feb 2018: Group Lead, Clinical Development Group, Medical Team, Samsung Bioepis
 - Clinical development group management
 - Supervision for clinical development planning
- Mar 2013-Feb 2017: Director, Medical Team, Samsung Bioepis
 - Clinical development planning, Clinical trial design
 - Medical monitoring, study result reporting and publication of trial results
 - Provide medical opinion on regulatory communication and marketing
- Mar 2009-Feb 2013: Resident trainee, Dep. of Clinical Pharmacology, Seoul Nat' Univ. hospital
 - Execution of early and late trials in Clinical trial unit including medical monitoring
 - Clinical development consulting and clinical pharmacology analysis
 - Drug monitoring and clinical pharmacology consulting for patients
- 2008-2009, Intern physician, Seoul Nat' Univ. Hospital
 - General physician

Professional Organizations

- Feb 2008: Medical License (Korea)
- Feb 2013: Clinical Pharmacology Certificate

Main Scientific Publications

- Efficacy and Safety of a Proposed Ranibizumab Biosimilar Product vs a Reference Ranibizumab Product for Patients With Neovascular Age-Related Macular Degeneration: A Randomized Clinical Trial
JAMA Ophthalmology. 2021; 139(1): 68-76: 68-76
Woo SJ, Veith M, Hamouz J, Ernest J, Zalewski D, Studnicka J, Vajas A, Papp A, Gabor V, Luu J, Matuskova V, Yoon YH, Pregun T, Kim T, **Shin D**, Bressler NM
- A phase I, randomized, single-dose pharmacokinetic study comparing sb8 (bevacizumab biosimilar) with reference bevacizumab in healthy volunteers
Cancer Chemother Pharmacol. 2020; 86: 567–575
Shin D, Lee Y, Choi J, Lee D, Park M, Petkova M

- A phase III, randomized, double-blind, multicenter study to compare the efficacy, safety, pharmacokinetics, and immunogenicity between SB8 (proposed bevacizumab biosimilar) and reference bevacizumab in patients with metastatic or recurrent nonsquamous non-small cell lung cancer
Lung Cancer. 2020; 146: 12-18
Reck M, Luft A, Bondarenko I, Shevnia S, Trukhin D, Kovalenko NV, Vacharadze K, Andrea F, Hontsa A, Choi J, **Shin D**
- Comparison of the Pharmacokinetics, Safety, and Tolerability of the Autoinjector (AI) and Pre-Filled Syringe (PFS) of SB4 in Healthy Subjects
Drug Des Devel Ther. 2020; 14: 43–50.
Shin D, Kim Y, Go A, Velinova M
- Comparative pharmacokinetics of an adalimumab biosimilar SB5 administered via autoinjector or prefilled syringe in healthy subjects.
Drug Des Devel Ther. 2018; 12: 3799–3805.
Shin D, Lee Y, Jeong D, Ellis-Pegler R
- A randomized phase 1 pharmacokinetic equivalence study comparing SB5 with reference adalimumab in healthy volunteers.
Arthritis and Rheumatology. 2017; 42(6): 672-678
Shin D, Lee Y, Kim H, Körnicke T, Fuhr R.
- A Randomized Phase I Pharmacokinetic Study Comparing Biosimilar Candidate SB3 and Trastuzumab in Healthy Male Subjects
Clinical Therapeutics. 2016; 38(7): 1665-1673
Pivot X, Curtit E, Lee YJ, Golor G, Gauliard A, **Shin D**, Kim Y, Kim H, Fuhr R
- Population pharmacokinetic analysis to recommend the optimal dose of udenafil in patients with mild and moderate hepatic impairment.
Br J Clin Pharmacol. 2016; 82(2): 389-398.
Kim A, Lee J, **Shin D**, Jung YJ, Bahng MY, Cho JY, Jang IJ.
- A randomized phase 1 pharmacokinetic study comparing SB4 and etanercept reference product (Enbrel®) in healthy subjects.
Br J Clin Pharmacol. 2016; 82(1): 64-73.
Lee YJ, **Shin D**, Kim Y, Kang J, Gauliard A, Fuhr R.

- A Randomized, Phase I Pharmacokinetic Study Comparing SB2 and Infliximab Reference Product (Remicade®) in Healthy Subjects.
BioDrugs. 2015;29(6):381-388.
Shin D, Kim Y, Kim YS, Körnicke T, Fuhr R.
- Pharmacokinetics, pharmacodynamics, and tolerability of LC350189, a novel xanthine oxidase inhibitor, in healthy subjects
Drug Des Devel Ther. 2015;9:5033-5049.
Yoon S, **Shin D**, Lee H, Jang IJ, Yu KS.
- Successful Empirical Antifungal Therapy of Intravenous Itraconazole with Pharmacokinetic Evidence in Pediatric Cancer Patients Undergoing Hematopoietic Stem Cell Transplantation.
Clin Drug Investig. 2015; 35(7): 437-446.
Kim H, **Shin D**, Kang HJ, Yu KS, Lee JW, Kim SJ, Kim MS, Song ES, Jang MK, Park JD, Jand IJ, Park KD, Shin EY, Ahn HS. (**co-first author**)
- Effect of renal function on the pharmacokinetics of fimasartan: a single-dose, open-label, Phase I study.
Drug Des Devel Ther. 2014 Oct 6;8:1723-31.
Kim S, Lee J, **Shin D**, Lim KS, Kim YS, Jang IJ, Yu KS.
- Trough concentration over 12.1 mg/L is a major risk factor of vancomycin-related nephrotoxicity in patients with therapeutic drug monitoring.
Ther Drug Monit. 2014 Oct;36(5):606-11.
Han HK, An H, Shin KH, **Shin D**, Lee SH, Kim JH, Cho SH, Kang HR, Jang IJ, Yu KS, Lim KS.
- Investigation of bioequivalence of a new fixed-dose combination of acarbose and metformin with the corresponding loose combination as well as the drug-drug interaction potential between both drugs in healthy adult male subjects.
J Clin Pharm Ther. 2014 Aug;39(4):424-31.
Kim S, Jang IJ, **Shin D**, Shin DS, Yoon S, Lim KS, Yu KS, Li J, Zhang H, Liu Y, Brendel E, Blode H, Wang Y.
- Predictive performance of gentamicin dosing nomograms.
Drug Des Devel Ther. 2014 Aug 16;8:1097-106.
Lee J, Yoon S, **Shin D**, Han H, An H, Lee J, Lim KS, Yu KS, Lee H.

- Pharmacodynamics, pharmacokinetics, and tolerability of intravenous or subcutaneous GC1113, a novel erythropoiesis-stimulating agent.
Clin Drug Investig. 2014 Jun;34(6):373-82.
Han H, Lee J, **Shin D**, Shin KH, Jeon H, Lim KS, Yoon SH, Shin SG, Jang IJ, Cho JY, Yu KS.
- Aspirin decreases systemic exposure to clopidogrel through modulation of P-glycoprotein but does not alter its antithrombotic activity.
Clin Pharmacol Ther. 2014 Jun;95(6):608-16.
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. (**co-first author**)
- Pharmacokinetic study of single and multiple oral administrations of 2 mg dienogest in healthy Korean women.
Contraception. 2013 Jun;87(6):750-5.
Shin D, Lee S, Lim KS, Park JS, Shin SG, Jang IJ, Yu KS.
- Assessment of the pharmacokinetics of co-administered metformin and lobeglitazone, a thiazolidinedione antihyperglycemic agent, in healthy subjects.
Curr Med Res Opin. 2012 Jul;28(7):1213-20.
Shin D, Kim TE, Yoon SH, Cho JY, Shin SG, Jang IJ, Yu KS.
- Assessment of the analgesic effect of remifentanyl using three pain models in healthy Korean volunteers: a randomized, controlled study.
Basic Clin Pharmacol Toxicol. 2012 Jun;110(6):518-23.
Kim TE, Kim KP, **Shin D**, Chung YJ, Price J, Mistry P, Jang IJ, Yu KS.
- Single-dose pharmacokinetics of garenoxacin in healthy Korean volunteers
J Korean Soc Clin Pharmacol Ther. 2010 Jun;18(1):43-52.
Shin D, Hong JW, Yi SJ, Kim TE, Jang IJ, Shin SG, Yu KS.