

- **Name:** Donghoon Shin
- **Current Position & Affiliation:** Vice President, Medical Team, Samsung Bioepis
- **Country:** Republic of 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 I 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, Jang 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 remifentanil 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.