

CURRICULUM VITAE

SHEN CHENG, PH.D.

Assistant Professor in Pharmacometrics
Department of Experimental and Clinical Pharmacology
College of Pharmacy
University of Minnesota

Email: cheng423@umn.edu

Mobile: +1 734-846-0741

Address: 717 Delaware St Rm464 Minneapolis MN 55414

Github: <https://github.com/chengshen1992>

Website: <https://chengshen1992.github.io/>

Summary

In my current role as an Assistant Professor in Pharmacometrics, I leverage knowledge and experience in pharmacometric and statistical modeling to:

- Investigate, identify and quantify the source of variability (i.e., genetics, environment, etc) in dose-exposure-response relationship of therapeutics.
- Develop innovative biomarkers (e.g., microbiome communities, disease status, etc) and optimize drug properties (e.g., dosing regimens, administration routes, etc) for the improved therapeutic effectiveness in special populations (e.g., pediatrics, patients with obesity, etc).
- Inform future study design to evaluate drug safety and efficacy for the efficient drug development.

My research training and experience is in the intersection of pharmacometrics and biostatistics. My expertise lies in the implementations of quantitative pharmacological modeling approach (e.g., pharmacokinetic/pharmacodynamic (PK/PD), disease progression, exposure-response (ER), etc) to inform precise dosing of medicines (i.e., Model-Informed Precision Dosing, MIPD) and to facilitate efficient drug development (i.e., Model-Informed Drug Development, MIDD). Additionally, my research interest involves evaluating and developing innovative methodologies for more efficient pharmacometric analyses. With my graduate training background spanning from pharmacology to quantitative sciences, my journey reflects a deep commitment to understanding and optimizing drug therapy through sophisticated modeling techniques. The successful implementation of my research will move us one step forward towards the realization of precision medicine.

Experience

Assistant Professor - Department of Experimental and Clinical Pharmacology, University of Minnesota College of Pharmacy, Twin Cities, MN Feb. 2024 - Present

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- 40% Conduct pharmacometric (PMx) research
 - 40% Teaching and advising graduate students
 - 20% Professional services (e.g., develop and maintain PMx computational facility)

Research Scientist I - Metrum Research Group, Tariffville, CT Jul. 2022 - Feb. 2024

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- 80% scientific consultation with clients in pharmaceutical industry
 - 20% involved in internal research and training

Research Associate II - Metrum Research Group, Tariffville, CT Jan. 2022 - Jul. 2022

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- 50% scientific consultation with clients in pharmaceutical industry
 - 50% involved in internal research and training

Education

Ph.D. in Experimental and Clinical Pharmacology (minor in Biostatistics) - University of Minnesota, Twin Cities, MN Aug. 2017 - Dec. 2021

- Thesis: Understanding the Impact of Pharmacogenetic Differences in Drug-drug Interactions (DDIs): a Model-based Approach to Predict Differences in Drug Exposure centrality.

M.S. in Pharmacology - University of Michigan, Ann Arbor, MI Sep. 2015 - May. 2017

- Thesis: Preparation and characterization of the complexes of cytochrome P450 2B4 and its redox partners in Amphipol A8-35.

B.S. in Biological Sciences - Soochow University, Suzhou, China Sep. 2010 - Jun. 2014

- Undergraduate researcher in toxicology.

Internships

Pharmacometric Intern - Novartis, Boston, MA Jun. 2021 - Aug. 2021

- Translational PK-PD modeling of CAR-T cell therapies.

Biomolecule PK-PD Intern - Eli-Lilly and Company, Indianapolis, IN Jun. 2020 - Aug. 2020

- Retrospective analysis on CL and V of mAbs in various animals species to identify allometric scaling exponents.

Workshops

Write Winning NIH Grant Proposals - Clinical and Translational Science Institute at the University of Minnesota, Twin Cities, MN 2025

(R)TTE analysis: MIDD applications, concept, methodology and NONMEM hands-on, Pharmetheus - Pharmetheus at American Conference of Pharmacometrics (ACOP) 15, Phoenix, AZ 2024

Efficient reproducible Bayesian population PK modeling with NONMEM and Stan/Torsten - Metrum Research Group at American Conference of Pharmacometrics (ACOP) 15, Phoenix, AZ 2024

Pharmacokinetics and pharmacodynamics of protein therapeutics-principles and pharmacometric approaches - The College of Pharmacy, University of Tennessee Health Science Center (UTHSC), Virtual 2024

An introduction to probabilistic decisions support in drug development - Pharmetheus at American Conference of Pharmacometrics (ACOP) 14, National Harbor, MD 2023

Intermediate and Advanced NONMEM and PDx-Pop Workshop - NONMEM and PDx-Pop development team, ICON Clinical Research LLC, Virtual 2020

Introductory NONMEM and PDx-Pop Workshop - NONMEM and PDx-Pop development team, ICON Clinical Research LLC, Virtual 2020

Bayesian Statistics: From Concept to Data Analysis - University of California, Santa Cruz, Coursera, Online course 2020

Machine Learning - Stanford University, Coursera, Online course 2019

Introduction to bayesian pharmacometric data analysis with NONMEM - Metrum Research Group at American Conference of Pharmacometrics (ACOP) 10, Orlando, FL 2019

Pharmacometric statistics workshop - Taca training, Dublin, Ireland	2019
Simcyp UMN 2-day workshop - College of Pharmacy at University of Minnesota, Minneapolis, MN	2018
Advanced R Workshop in mrgsolve - College of Pharmacy at University of Minnesota, Minneapolis, MN	2017

Tutorials

Model-Based Meta-Analysis: towards more precisely predicted clinical scenarios - Tutorial at American Conference of Pharmacometrics (ACOP) 15, Phoenix, AZ	2024
Pharmacometrics Spring School: Modeling using MonolixSuite - Lixoft (Simulation-sPlus), Virtual	2021
An open-source Pharmacometrician's workflow in R: from exploration (xGx) to model building (nlmixr) and diagnostics (ggPMX) - American Conference of Pharmacometrics (ACOP) 11 Trainee Tutorial, Virtual	2020
Pumas DDMoRe Bootcamp - Pumas development team, Pumas-AI Inc, Virtual	2020
Quantitative Systems Pharmacology in Translational Drug Development - American Conference of Pharmacometrics (ACOP) 10 Trainee Tutorial, Orlando, FL	2019
Minnesota Pharmacometrics Summer Workshop (MPSW) - College of Pharmacy at University of Minnesota, Minneapolis, MN	2019

Skills

- Pharmacometric skills
 - Nonlinear mixed-effect modeling using NONMEM (GUI: bbr-bbi, FinchStudio, Pirana and PDx-Pop), Monolix, Phoenix NLME, STAN and SAAM 2.
 - Concepts and implementations of pharmacometric simulations: deterministic simulations, stochastic simulations, and simulations with parameter uncertainty.
 - Proficient in pharmacometric toolbox, including MetrumRG expo and PsN.
 - Concepts and implementations of pharmacometric modeling using various algorithms (e.g., maximum likelihood estimations, EM-based algorithm and Bayesian approach).
 - Physiological-based PK (PBPK) modeling concepts and skills with Simcyp and mrgsolve.
 - PK non-compartmental analysis (NCA).

- Statistical and programming skills
 - Data wrangling, function writing, data set management, data visualization and statistical analysis and modeling using R (baseR, tidyverse, data.table, etc).
 - R package version control (renv and pkgR) and R package development.
 - Familiarize with IDE, such as Rstudio and VScode.
 - Proficient in using version control tools Github and Subversion.
 - Experience working with high-performance cluster (HPC) using command line tools and SLURM for job submission and scheduling.
 - Familiarize with Python and Julia.
 - Biological data analysis using software such as *GraphPad Prism* and *Sigmaplot*.

- Scientific communication skills
 - Scientific writing and presentation using Latex, Quarto, Rmarkdown and MS office.
 - Experience working as a scientific consultant in pharmaceutical industry.

Honors and Awards

- 2021 Award Winner, Trainee Communication Challenge, American Conference of Pharmacometrics (ACoP)
- Doctoral Dissertation Fellowship, University of Minnesota
- Honorable Mention, Rho Chi Research Day, University of Minnesota College of Pharmacy
- Fellowship, Experimental & Clinical Pharmacology Department, University of Minnesota College of Pharmacy
- Recruitment Fellowship, Experimental & Clinical Pharmacology Department, University of Minnesota
- Outstanding Graduate, Soochow University, Medical College, Suzhou, China
- Technology Innovation Scholarship, Soochow University, Suzhou, China
- College Merited Student Scholarship, Soochow University, Suzhou, China
- 3rd place, Undergraduate Science & Technology Contests, Jiangsu Province, China

Professional Services

- Journal reviewer
 - ACS Omega
 - Advances in Pharmacological and Pharmaceutical Sciences
 - Antibiotics
 - Biomedicine and Pharmacotherapy
 - Clinical and Experimental Pharmacology and Physiology
 - Clinical Pharmacology and Therapeutics
 - CPT: Pharmacometrics and System Pharmacology
 - Current Issues in Molecular Biology
 - Drug Metabolism and Disposition
 - European Journal of Drug Metabolism and Pharmacokinetics
 - International Journal of Molecular Sciences
 - Journal of Clinical Pharmacology
 - Journal of Pharmacology and Experimental Therapeutics
 - Journal of Pharmacokinetics and Pharmacodynamics
 - Mathematics
 - Polymers
 - Toxics
- Abstract reviewer
 - American Conference of Pharmacometrics (ACoP) 14
 - American Society of Clinical Pharmacology and Therapeutics (ASCPT) 2024 Annual Meeting
- Proposal reviewer
 - American Society of Clinical Pharmacology and Therapeutics (ASCPT) 2024 Annual Meeting
- Professional societies
 - Trainee lunch mentor, American Conference of Pharmacometrics (ACoP) 15 (Nov. 2024)
 - Member of International Society of Pharmacometrics (ISoP) (Sept. 2019 - present)
 - Member of American Society of Clinical Pharmacology and Therapeutics (ASCPT) (Sept. 2020 - present)
 - Member of American College of Clinical Pharmacology (ACCP) (Sept. 2021 - present)
 - Member of American College of Clinical Pharmacology (ACCP) Early-stage Professionals (ESP) Committee (Sept. 2024 - present).

- Member of International Society of Pharmacometrics (ISoP) student committee communication group (Aug. 2019 - Dec. 2021).

Teaching

- Course director
 - ECP8506 Clinical Trial Simulations (2024 - present) University of Minnesota
- Lecture contributor
 - ECP8440 Modeling Biologics (2020) University of Minnesota: Implementation of target-mediated drug disposition (TMDD) model
- Teaching assistantship
 - PHAR6786 Acute Patient Care Pharmacotherapy (2019-2020) University of Minnesota
 - PHAR6732 Medicinal Chemistry and Pharmacology of Cardiovascular Agents (2019) University of Minnesota
 - PHAR6756 Kidney, Fluid and Electrocytes (2017-2018) University of Minnesota
 - PHAR7401 and PHAR7433 Advanced Pharmacy Practice Experience (2017-2018) University of Minnesota

Grant Support

Evaluate and develop methodologies to incorporate high-dimensional covariates in pharmacometric analysis - Office of Discovery and Translation (ODAT), Clinical and Translational Science Institute (CTSI), University of Minnesota

2024-2025

- Role: PI
- Amount: \$ 50,000

Publications

1. **Cheng S.**, Al-Kofahi M., Leeder S., Brown J. Population Pharmacokinetic Analysis of Atomoxetine and its Metabolites in Children and Adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD). *Clinical Pharmacology and Therapeutics*, 2024. DOI: 10.1002/cpt.3155.
2. **Cheng S.**, Flora D.R., Rettie A.E., Brundage R.C., Tracy T.S. A physiological-based pharmacokinetic model embedded with a target mediated drug disposition mechanism can characterize single dose warfarin pharmacokinetic profiles in subjects with various CYP2C9 genotypes under different co-treatments. *Drug Metabolism and Disposition*, 2023. DOI: 10.1124/dmd.122.001048
3. Sahasrabudhe S.A., **Cheng S.**, Al-Kofahi M., Jarnes J.R., Weinreb N.J., Kartha R.V. PBPK Model Development, Validation and Application for Prediction of Eliglustat Drug-Drug Interactions. *Clinical Pharmacology and Therapeutics*, 2023. DOI: 10.1002/cpt.2738.
4. **Cheng S.**, Flora D.R., Rettie A.E., Brundage R.C., Tracy T.S. Pharmacokinetic Modeling of Warfarin I-Model-based Analysis of Warfarin Enantiomers with a Target Mediated Drug Disposition Model Reveals CYP2C9 Genotype-dependent Drug-drug Interactions of S-Warfarin. *Drug Metabolism and Disposition*, 2022. DOI: 10.1124/dmd.122.000876
5. **Cheng S.**, Flora D.R., Rettie A.E., Brundage R.C., Tracy T.S. Pharmacokinetic Modeling of Warfarin II-Model-based Analysis of Warfarin Metabolites following Warfarin Administered either Alone or Together with Fluconazole or Rifampin. *Drug Metabolism and Disposition*, 2022. DOI: 10.1124/dmd.122.000877
6. **Cheng S.** Understanding the impact of pharmacogenetic differences in drug-drug interactions (DDIS): A model-based approach to predict differences in drug exposure. *University of Minnesota ProQuest Dissertations Publishing; [Order No. 28870041]*. 2021
7. Jaber M. M., **Cheng S.**, Brundage R.C. Evaluation of Bias in Weighted Residual Calculations When Handling BLQ Data Using Beals M3 Method. *CPT: Pharmacometrics & Systems Pharmacology*, 2021. DOI: 10.1002/psp4.12616

8. **Cheng S.**, Bo Z., Hollenberg P.F., Osawa Y., and Zhang H. Amphipol-facilitated Elucidation of the Functional Tetrameric Complex of Full-length Cytochrome P450 CYP2B4 and NADPH-Cytochrome-P450 Oxidoreductase. *J Biol Chem*, 2021. DOI: 10.1016/j.jbc.2021.100645
9. **Cheng S.**, Nethi S.K. Al-Kofahi M., Prabha S. Pharmacokinetic-Pharmacodynamic (PK-PD) Modeling of Tumor Targeted Drug Delivery using Nano-engineered Mesenchymal Stem Cells (Nano-MSCs). *Pharmaceutics*, 2021. DOI: 10.3390/pharmaceutics13010092
10. **Cheng S.**, Nethi, S. K., Rathi, S., Layek, B., Prabha, S. Engineered Mesenchymal Stem Cells for Targeting Solid Tumors: Therapeutic Potential beyond Regenerative Therapy. *J Pharmacol Exp Ther*, 2019. DOI: 10.1124/jpet.119.259796
11. Zhang, H., Yokom, A. L., **Cheng S.**, Su, M., Hollenberg, P. F., Southworth, D. R., Osawa, Y. The full-length cytochrome P450 enzyme CYP102A1 dimerizes at its reductase domains and has flexible heme domains for efficient catalysis. *J Biol Chem*, 2018. DOI: 10.1074/jbc.ra117.000600
12. Su J., Li B., **Cheng S.**, Zhu Z., Sang X., Gui S., Xie Y., Sun Q., Cheng Z., Cheng J., Hu R., Shen W., Xia Q., Zhao P., Hong F. Phoxim-induced damages of Bombyx mori larval midgut and titanium dioxide nanoparticles protective role under phoxim-induced toxicity. *Environ Toxicol*, 2014. DOI: 10.1002/tox.21866
13. Sheng L., Wang L., Sang X., Zhao X., Hong J., **Cheng S.**, Yu X., Liu D., Xu B., Hu R., Sun Q., Cheng J., Cheng Z., Gui S., Hong F. Nano-sized titanium dioxide-induced splenic toxicity: a biological pathway explored using microarray technology. *J Hazard Mater*, 2014. DOI: 10.1016/j.jhazmat.2014.06.005

Manuscripts Submitted

1. Clinical Pharmacokinetics and Pharmacodynamics of Empagliflozin in Pediatric Patients with Type 2 Diabetes Mellitus.
2. Population Pharmacokinetics, Pharmacodynamics and Exposure-Response modelling of Garadacimab in Healthy Volunteers and Patients with Hereditary Angioedema

Manuscripts in Preparation

1. Pulsatile Delivery of Subcutaneous Hydrocortisone in Children with Congenital Adrenal Hyperplasia: A Proof-of-Concept Study.
2. Intranasal naloxone during recurrent exercise in patients with type-1 diabetes mellitus: Evaluation of the clinical predictors on pharmacokinetics and exposure-response.
3. Impact of Gut Microbiome Communities on Enterohepatic Recirculation of Mycophenolate and Dose Simulations.
4. A Model-based Analysis of the CYP2C9 Genotype Effects on the Fluconazole Inhibition of Flurbiprofen, Ketoprofen and Tolbutamide.
5. A Model-based Analysis of Preclinical to Clinical Scaling of Chimeric Antigen Receptor (CAR) T-Cell Therapy.

Contributed and Invited Talks

1. Model-Based Approaches to Elucidate the Impact of CYP2D6 Activity on Atomoxetine Exposures in Children and Adolescents with ADHD. *ASCPT Network & Community Experience 2024 PGx community: Recent Developments in Pharmacogenomics Research and Access to Care for Children and Adolescents*. 2024 (virtual)
2. Application of a target-mediated drug disposition (TMDD) model for warfarin. *Certara UMN webinar*. 2020 (virtual)

Conference Proceedings

1. Mohamed, M.E., **Cheng S.**, Staley, C; Holtan, S.G., Jacobson, P.A. Factors influencing pharmacokinetics of tacrolimus in hematopoietic stem cell transplantation; The integration of microbiome and pharmacogenomics. Association for Clinical and Translational Science (ACTS) 2025, Washington, DC (Accepted).

2. Suriyapakorn B., **Cheng S.**, Rosenthal E., Cloyd J., Kapur J., Silbergleit R., Chamberlain J., Zehtabchi S., Bleck T., Quigg M., Coles L. A Model-based Approach to Evaluate Pharmacokinetic Sampling Strategies for Ketamine in the Ketamine Add-on Therapy for Established Status Epilepticus Treatment Trial (KESETT). American Epilepsy Society (AES) Annual Meeting 2024, Los Angeles, LA (Accepted).
3. Saqr A., Al-Kofahi M., **Cheng S.**, Staley C., Jacobson P.A. Incorporating High Dimensional Gut Microbiome Data into Population Pharmacokinetic Modeling of Mycophenolate Mofetil. American Conference of Pharmacometrics (ACOP) 15 2024, Phoenix, AZ.
4. Khatri A., Cobbina E., **Cheng S.**, Abutarif M., Garimella T. Population Pharmacokinetics of Trastuzumab Deruxtecan (T-DXd) in Subjects with HER2-mutant and HER2-overexpressing Non-Small Cell Lung Cancer (NSCLC). American Society of Clinical Oncology (ASCO) 2024, Chicago, IL.
5. Glassman F., Sharma A., **Cheng S.**, Johnston C., DeMiguelLillo B., Lawo J., Jacobs I., Polhamus D., Nandy P. Population Pharmacokinetic / Pharmacodynamic Analysis of Garadacimab, in Patients with Hereditary Angioedema. American Academy of Allergy Asthma & Immunology (AAAAI) 2024, Washington, DC.
6. **Cheng S.**, Green S., Marinelli R., Baron K.T. *smpar*: an R Package for Parameter Uncertainty Simulations in Pharmacometric Modeling. American Conference of Pharmacometrics (ACOP) 14 2023, National Harbor, MD.
7. **Cheng S.**, Lennie J., Reilly B., Kawakatsu S., Kay K., Wang X., Johnston C., Tartakovsky I., Nock V. Population Pharmacokinetic (PK) and Exposure-Response (ER) Analysis of Empagliflozin in Pediatric Patients with Type 2 Diabetes Mellitus (T2DM). American Conference of Pharmacometrics (ACOP) 14 2023, National Harbor, MD.
8. Reilly B., Kawakatsu S., Baron K.T., **Cheng S.**, Lennie J., Kay K., Johnston C., Wang X., Tartakovsky I., Nock V. Population Pharmacokinetic (PK) and Exposure-Response (ER) Analysis of Linagliptin in Pediatric Patients with Type 2 Diabetes Mellitus (T2DM). American Conference of Pharmacometrics (ACOP) 14 2023, National Harbor, MD.
9. AlKofahi M., **Cheng S.**, Leeder S., Brown J. Population pharmacokinetics of atomoxetine and its metabolites in children and adolescents with attention-deficit/hyperactivity disorder (ADHD). American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting 2022, Virtual.
10. **Cheng S.**, Flora D.R., Tracy T. S., Rettie A.E., Brundage R.C. A physiological-based pharmacokinetic (PBPK) model embedded with a target mediated drug disposition (TMDD) mechanism can characterize S-warfarin pharmacokinetic (PK) profiles in subjects with various CYP2C9 genotypes under different co-treatments. American Conference of Pharmacometrics (ACOP) 12 2021, Virtual.
11. **Cheng S.**, Jaber M. M., Flora D.R., Tracy T. S., Rettie A.E., Brundage R.C. Model-based analysis of the CYP2C9 genotype impact on the fluconazole inhibition of the commonly prescribed drugs flurbiprofen, ketoprofen, and tolbutamide. American College of Clinical Pharmacology (ACCP) Annual Meeting 2021, Virtual.
12. **Cheng S.**, Flora D.R., Tracy T. S., Rettie A.E., Brundage R.C. Population based pharmacokinetic analysis of the S-Warfarin metabolites following warfarin administered alone and together with fluconazole and rifampin. University of Minnesota College of Pharmacy Annual Research Day 2021, Virtual.
13. **Cheng S.**, Flora D.R., Tracy T. S., Rettie A.E., Brundage R.C. Genotype-dependent changes in warfarin clearance upon co-administration of an inhibitor (fluconazole) and an inducer (rifampin): A model-based analysis. American Conference of Pharmacometrics (ACOP) 11 2020, Virtual.
14. **Cheng S.**, Tracy T. S., Brundage R.C. Evaluation of the impact of CYP2C9 genetic polymorphism on S-warfarin drug-drug interactions using a pharmacometric approach. University of Minnesota College of Pharmacy Annual Research Day 2020, Minneapolis, MN.
15. **Cheng S.**, Layek B., Al-Kofahi M., Brundage R. C., Prabha S. Elucidating the disposition of nano-engineered mesenchymal stem cells using pharmacokinetic modeling. 9th Annual Masonic Cancer Center (MCC) Cancer Research Symposium 2019, Minneapolis, MN.
16. **Cheng S.**, Layek B., Al-Kofahi M., Brundage R. C., Prabha S. Development of pharmacokinetic model for chemotherapeutics delivered by nano-engineered mesenchymal stem cells. University of Minnesota College of Pharmacy Annual Research Day 2019, Minneapolis, MN.
17. **Cheng S.**, Layek B., Al-Kofahi M., Brundage R. C., Prabha S. Elucidating the disposition of nano-engineered mesenchymal stem cells using pharmacokinetic modeling. American Conference of Pharmacometrics (ACOP) 10 2019, Orlando, FL.

18. Nethi S.K., Sehgal D., **Cheng S.**, Panyam J. and Prabha S. Synthetic antigen receptor mesenchymal stem cells (SAR-MSCs) targeting perlecan for drug delivery to ovarian cancer. American Association for Cancer Research (AACR) Annual Meeting 2019, Atlanta, GA.
19. **Cheng S.**, Yokom A. L., Hollenberg P. F., Southworth D. R., Osawa Y., Zhang H. Preparation and characterization of the complex of cytochrome P450 2B4 and cytochrome P450 oxidoreductase incorporated into Amphipol A8-35. 12th Great Lake Drug Metabolism and Disposition Group (GLDMDG) Annual Meeting 2017, Kalamazoo, MI.

Mentoring Activities

- Graduate mentorship
 - Diqin Yan, M.S., Graduate student in Experimental and Clinical Pharmacology Program, University of Minnesota (2024-present).
- Fellowship mentorship
 - Moataz Mohamed, M.S., Graduate trainee in Translational Research Development Program (TRDP), Clinical and Translational Science Institute (CTSI), University of Minnesota (2024-present).