Andrew M. Stein

www.trinitymetrics.com

Research Overview

I develop mathematical models of biological systems based on clinical and preclinical data in order to enhance our understanding of diseases and support decision-making in the pharmaceutical industry. My expertise is in oncology and immunology, with experience in leukemia, solid tumors, chimeric antigen receptor T-cells, bispecific target engagers, and target mediated drug disposition for biologic drugs.

Education

- **Ph. D.** University of Michigan, Applied Mathematics, 2007.
- **S. M.** MIT, Mechanical Engineering, 2002.
- **S. B.** MIT, Mechanical Engineering, 2000.

Experience

Novartis – Cambridge, MA, 2009-Present
Senior Director 2022-Present; Director 2019-2021; Associate Director 2015-2018; Expert Modeler 2014; Senior Modeler 2011-2013; Visiting Scientist 2009-2010

PROJECTS

- **Phase 1 Trial Design 2021-Present:** Supported Phase 1 trial design and analysis for translational oncology assets.
- **T Cell Engagers, 2020-Present:** Support dose justification and trial design strategies for bispecific and trispecific target engagers in immunology and oncology indications.
- **Checkpoint inhibitors, 2017-2019:** Supported clinical development of anti-LAG3, anti-TIM-3, and anti-PD-L1 checkpoint inhibitors.
- **Kymriah, 2014-2020:** Developed cellular-kinetic model to support the first regulatory submission for Chimeric Antigen Receptor T-cell (CAR-T) therapy. This model was used by the FDA and received the ASCPT PSP Award in 2020. Assessed dose-exposure-response relationship and the impact of comedication on CART expansion, safety, and efficacy.
- **Odomzo, 2011-2012:** Supported dose selection using popPK and PKPD modeling for both pediatric and adult populations.
- **Afinitor, 2010-2012:** Developed longitudinal models to characterize dose-response relationship for predicting Phase III trial outcomes. Applications include dose justification of 10 mg everolimus over 5 mg in metastatic renal cell carcinoma patients and demonstration that new lesion appearance is more important than target lesion growth for predicting overall survival.
- **Gleevec and Tasigna, 2009-2012:** Developed PD and PKPD models for Chronic Myeloid Leukemia, which suggests that Gleevec and Tasigna therapy induce a reduction in leukemic stem cells.

WORKSTREAMS

- **Synthetic PMX Data Generation:** https://iamstein.github.io/synpmx. Builds synthetic pharmacometric datasets from actual datasets to enable AI-assisted workflows
- **See-Value App for visual inference, 2020-2022:** www.see-value.org. Researchers often find signals in data even when the data is simulated from a null distribution. We developed an app to help researchers better understand their data by using the permutation test to generate a lineup containing both the true data and null plots and then asking teams to try and pick the true data out of the lineup.
- **Uncertainty checklist, 2019-2020:** When using mechanistic (QSP) models to guide decisions, it is critical that uncertainty of the model predictions is taken into account. We have developed an Uncertainty Checklist for scoping projects and facilitating collaboration between the QSP and Pharmacometrics groups. This work was presented to the FDA Systems Pharmacology group in February 2020
- **Pharmacometrics communications coach 2019-2020:** Developed Presentation Checklist to help with improving the presentation of technical results to project teams. Coached associates to better structure their presentations so that they opened with a clear message that illustrated how their work answered a question or solved a problem that was relevant to the team.
- **Exploratory graphics website (xGx) and R package (xgxr), 2018-Present:** Developed open source tool for helping modelers follow a structured approach to exploring PKPD data before they begin modeling. This tool helps modelers to 1) focus on a key question of interest, 2) save time and resources by improving understanding of data and whether a model is even needed, and 3) serve as a tutorial for those new to using R for exploring PKPD data. xGx is used at multiple Pharma companies and received a 2019 ACoP Quality Award.
- **Novartis academia-industry quantitative hackathon, 2018-2019:** Co-organized two week program where 40-50 grad students and postdocs in the quantitative sciences visited Novartis. Following a three day introduction to drug development and fundamental PKPD concepts, students worked for one week in small interdisciplinary teams on R&D problems that Novartis faced.
- **Biologics workstream, 2014-2020:** Provided guidance and tutorials to modelers supporting biologics; advanced the theory for target mediated drug disposition models with publications on target engagement, the onset of PK nonlinearity and model identifiability. This work provides intuition for how model parameters relate to target engagement, which model parameters are identifiable, and how these models can be used to assess targets and inform dose selection.

Institute for Math and its Applications – Minneapolis, MN, 2007-2009
Postdoctoral Fellow

- **Biopolymer Mechanics.** The mechanical properties of biopolymer gels play a critical role in cell motility, tumor invasion, blood clotting, and wound healing. Literature models of biopolymer mechanics often are not quantitatively compared to experimental observations and thus it is challenging to select from competing models. We developed image processing algorithms for extracting the 3d biopolymer network architecture from experimental images and then implemented a finite element mechanical model to describe the biopolymer network mechanics. This allowed for realistic models of collagen networks and the identification of the cross-link stiffness as a critical parameter in describing these networks. Mentors: Victor Bacoras and Hans Othmer

University of Michigan – Ann Arbor, MI, 2003-2007
Graduate Research Assistant - PhD

- **Glioblastoma Invasion.** Standard cancer treatments have limited efficacy in glioblastoma patients, in part due to the invasive nature of the disease. We developed a mathematical model for understanding experimental data from a 3d in vitro assay for glioblastoma invasion. The model allowed for the description of invasion by four key parameters: random motility, directed motility, cell shedding, and cell proliferation, thereby helping investigators to understand the mechanisms by which mutations and chemical inhibitors changed the invasive properties of a tumor spheroid. In addition, we developed a novel image processing algorithm for automatically measuring invasion, allowing for fast, repeatable measurements of invasion. Graduate advisers: Leonard Sander and Trachette Jackson

Novartis – East Hanover, NJ, 2005, 2006
Graduate Intern

- Developed integrative model for predicting efficacy of Gleevec in individual patients.
- Developed murine dose-PD model for the effect of an anti-cancer monoclonal antibody on apoptosis biomarker expression. Mentored by Dean Bottino.

Lear Corporation – Southfield, MI, 2003
Advanced Product Development Intern

- Designed support structure for configurable overhead storage module for cars and trucks. Patent: US20060071496A1
- Designed mechanisms and selected materials for a hyperbolic cup holder.

Freedman & Goldberg CPAs – Farmington Hills, MI, 2002
Statistical Consultant

- Advised accountants on statistical techniques for estimating the total amount that an investment company shortchanged its clients.

Massachusetts Institute of Technology - Cambridge, MA, 2002
Graduate Research Assistant

- Analyzed a differential imaging ultrasound system for detecting breast cancer.
- Identified and quantified trade off between shift invariance and depth resolution in imaging systems. Graduate advisor: George Barbastathis.

Articles (Google Scholar Profile)

1. Schjesvold, F, Spencer, A, Cohen, YC, Ocio, EM, Lopez-Pardo, J, Cafro, AM, Callander, NS, Kaufman, JL, Mohan, M, Wermke, M and Doki, N, Kan R, Milanez-Almeida P, **Stein A**, Trabucco G, Ye S, Kulec K, Sechaud R, Banerjee S, Zhong H, Lai C, Rauch PJ, Raab MS. Final clinical data of a phase 1 dose-escalation study of WVT078, a BCMA×CD3 bispecific antibody, alone and in combination with γ-secretase inhibitor WHG626 in patients with relapsed and/or refractory multiple myeloma. *Cancer*, 132(7), p.e70341, 2026 https://doi.org/10.1002/cncr.70341
2. Khera E, Kim J, **Stein A**, Ratanapanichkich M, Thurber, GM. Mechanistically weighted metric to predict in vivo antibody-receptor occupancy: An analytical approach. *Journal of Pharmacology and Experimental Therapeutics*, 2023. https://doi.org/10.1124/jpet.122.001540
3. Xu S, Zhang N, Rinne ML, Sun H, **Stein AM**, Sabatolimab (MBG453) Model Informed Drug Development for Dose Selection in Patients with Myelodysplastic Syndrome/Acute Myeloid Leukemia and Solid Tumors. *Clin Pharmacol. Ther: Pharmacometrics and Systems Pharmacol.* 2023. https://doi.org/10.1002/psp4.12962
4. Chan JR, Allen R, Boras B, Cabal A, Damian V, Gibbons FD, Gulati A, Hosseini I, Kearns JD, Saito R, Cucurull-Sanchez L, Selimkhanov J, **Stein AM**, Umehara K, Wang G, Wang W, Neves-Zaph S. Current practices for QSP model assessment: an IQ consortium survey. *J Pharmacokin. and Pharmacodyn.* 2022 Aug 11:1-3.
5. **Stein, AM**, Kearns JD, Kim, J, Margolskee, A. (2021). Cheat sheet for model uncertainty assessment. Zenodo. http://doi.org/10.5281/zenodo.4409236 [not peer reviewed]
6. Alaybeyoglu B, Cheng HW, Doshi KA, Makani V, **Stein AM**. Estimating drug potency in the competitive Target Mediated Drug Disposition (TMDD) system when the endogenous ligand is included, *J Pharmacokin. And Pharmacodyn.,* 1-18, 2021.
7. Chaudhury A, Zhu X, Chu L, Goliaei A, June CH, Kearns JD, **Stein AM**. Chimeric Antigen Receptor T-Cell (CART) Therapies: A Review of Cellular Kinetic-Pharmacodynamic Modeling Approaches. *J Clin Pharmacol,* 60 (S1) S147–S159, 2020.
8. Ahmed S, Ellis M, Li H, Pallucchini L, **Stein AM**. Guiding dose selection of monoclonal antibodies using a new parameter (AFTIR) for characterizing ligand binding systems. *J Pharmacokin. And Pharmacodyn.,* 46.3, 297-304 2019.

9. **Stein AM**, Grupp SA, Levine JE, Laetsch TW, Pulsipher MA, Boyer, MW, August KJ, Levine BL,, Tomassian L, Shah S, Leung M, Huang PH, Joliet S, Awasthi R, Mueller KT, Wood PA, June CH. Tisagenlecleucel Model-Based Cellular Kinetic Analysis of Chimeric Antigen Receptor T Cells, *Clin Pharmacol. Ther: Pharmacometrics and Systems Pharmacol.* 8.5, 285, 2019.
10. Mueller KT, Waldron ER, Grupp SA, Levine JE, Laetsch TW, Pulsipher MA, Boyer MW, August K, Hamilton J, Awasthi R, **Stein AM**, Sickert D, Chakraborty A, Levine BL, June CH, Tomassian L, Shah S, Leung M, Taran T, Wood PA, Maude SL. Clinical Pharmacology of Tisagenlecleucel in B-Cell Acute Lymphoblastic Leukemia. *Clinical Cancer Research,* 24, 6175, 2018.
11. **Stein AM**, Peletier LA. Characterizing the onset concentration for nonlinear pharmacokinetics of biologics with membrane-bound targets. *Clin. Pharmacol. Ther: Pharmacometrics and Systems Pharmacol,* 7, 670, 2018.
12. **Stein AM**, Looby M. Benchmarking QSP models against simple models: A path to improved comprehension and predictive performance. *Clin. Pharmacol. Ther: Pharmacometrics and Systems Pharmacol,* 7.8, 487, 2018.
13. **Stein AM**, Ramakrishna R. AFIR: A dimensionless potency metric for characterizing the activity of monoclonal antibodies. *Clin. Pharmacol. Ther: Pharmacometrics and Systems Pharmacol,* 6, 258-266, 2017.
14. **Stein AM**. Practical unidentifiability of receptor density in target mediated drug disposition (TMDD) models can lead to over-interpretation of the data. Biorxiv, doi 10.1101/123240, 2017. [first biorxiv pharmacometrics #phmx paper, not peer reviewed]
15. Goel V, Hurh E, **Stein AM**, Nedelman J, Chiparus O, Huang P, Zhou J, Boral A, Gogov S, Sellami D, Population pharmacokinetics of sonidegib (LDE225), an oral inhibitor of the hedgehog signaling pathway, in healthy subjects and in patients with advanced solid tumors. *Cancer Chemotherapy and Pharmacology,* 77, 745-755, 2016.
16. Venkatakrishnan K, Friberg LE, Ouellet D, Mettetal JT, **Stein AM**, Troconiz IF, Bruno R, Mehrotra N, Gobburu J, Mould DR. Optimizing oncology therapeutics through quantitative translational and clinical pharmacology: Challenges and opportunities. *Clin. Pharm. Ther.* 97, 37-54, 2015
17. **Stein AM**, Martinelli G, Hughes TP, Müller M, Beppu L, Gottardi E, Branford S, Soverini S, Hochhaus A, Kim DW, Saglio G, Woodman RC, Radich JP. Integration of BCR-ABL dynamical profiles using a mathematical model for prediction of progression free survival in imatinib-resistant or -intolerant chronic myeloid leukemia patients in chronic phase treated with nilotinib. *BMC Cancer* 13, 173, 2013.
18. **Stein AM,** Belmunt J, Escudier B, Kim D, Stergiopoulos SG, Mietlowski W, Motzer RJ. Survival prediction in everolimus-treated patients with metastatic renal cell carcinoma incorporating tumor burden response in the RECORD-1 trial. *Eur. Urol.* 64, 994, 2013
19. **Stein, AM**, DeWoskin D, Higley M, Lemoi K, Owens B, Rahman A, Rotstein H, Rumschitzki D, Swaminathan S, Tanzy M, Varfolomiyev O, Witelski T, Zubekov V, Dynamic models of metastatic tumor growth. Final Report of the 27th Annual Workshop on Mathematical Problems in Industry, New Jersey Institute of Technology. 2012. [not peer reviewed]
20. **Stein AM**, Wang WA, Carter A, Chiparus O, Hollaender N, Kim H, Motzer R, Sarr C. A pharmacodynamic model to describe the dose-response relationship for everolimus in the RECORD-1 phase III trial: tumor size as a biomarker for clinical efficacy in metastatic renal cell carcinoma. *BMC Cancer* 12, 311, 2012.
21. **Stein AM**, Bottino, DB, Modur V, Branford S, Kaeda J, Goldman JM, Hughes TP, Radich JP, Hochhaus A. BCR-ABL transcript dynamics support the hypothesis that leukemic stem cells are reduced during imatinib treatment. *Clinical Cancer Research* 17 (21) 1-10, 2011.
22. **Stein AM**, Vader DA, Weitz DA, Sander LM. The micromechanics of collagen-I gels. *Complexity,* 16, 22-28, 2011.
23. Sander EA, **Stein AM**, Swickrath M, Barocas VB. Out of many, one: modeling schemes for biopolymer and biofibril networks. *Trends in Computational Nanomechanics: Transcending Space and Time.* Springer, Heidelberg, 2009.
24. Vader D, Muenster S, Jawerth L, **Stein AM**, Fabry B, Weitz D. Large amplitude oscillatory shear in collagen rheology shows early strain stiffening. *Journal of Biomechanics*, 41, S318-S318, 2008.
25. **Stein AM**, Vader DA, Jawerth LJ, Weitz DA, Sander LM. An algorithm for extracting the network geometry of three-dimensional collagen gels. *J. Microscopy,* 232 (3) 463-475, 2008.
26. Nowicki MO, Dmitrieva N, **Stein AM,** Cutter JL, Godlewski J, Saeki Y, Nita M, Berens ME, Sander LM, Newton HB, Chiocca EA, Lawler S. Lithium inhibits invasion of glioma cells; possible involvement of glycogen synthase kinase-3. *Neuro-Oncol*, 10(5):690–9, 2008.
27. **Stein AM,** Nowicki MO, Demuth T, Berens ME, Lawler SE, Chiocca EA, Sandel, LM. Estimating the cell

density and invasive radius of 3d glioblastoma tumor spheroids grown in vitro. *Applied Optics*, 46(22):5110–5118, 2007.

28. **Stein AM**, Demuth T, Mobley DA, Berens ME, Sander LM. A mathematical model of glioblastoma tumor spheroid invasion in a three-dimensional in vitro experiment. *Biophys. J.*, 92:356–365 2007.
29. **Stein AM**, Vader DA, Weitz DA, Sander LM. Stochastic models of glioblastoma invasion In: Mathematical Modeling of Biological Systems. Vol. I, edited by Deutsch, A. et. al., Birkhauser, Boston, 2006.
30. Khain E, Sander LM, **Stein, AM.** A model for glioma growth. *Complexity.* 11, 53-57, 2005
31. **Stein AM,** Barbastathis G. Axial imaging necessitates loss of lateral shift invariance, *Applied Optics: Information Processing.* 41 6055-6061, 2002

Conference Posters and Talks

1. Stein AM, Pogodaev A, Enabling AI-Assisted Workflows Using Synthetic Data, ACoP, 2026
2. Khera E, Mukherjee L, Ferguson A, Van De Vyver A, Lee M, Polli R, **Stein A**, Ye S, Gaudet S, Schlender, JF. Reverse translational modeling for early benchmarking of clinically active doses from in vitro cell killing and T-cell activation data for BCMAxCD3 T-cell engagers, AAPS National Biotech Conf, 2025.
3. Kim J, **Stein A**, Sy S, Grosch K, PK model development guidance for biologics and case study on crizanlizumab PK, ACoP, 2023
4. Zhu X, **Stein A**., Pearson D, Price A, Sohoni A, Barton N, Bradshaw L, Pinzon-Ortiz M, Bu D, Engels B, Novel Benchmark Scaling Method for First-in-Human Dose of CAR-T Therapies. *ASGCT* meeting, in Molecular Therapy, 30, 4, 524-524, 2022.
5. Engels B, Zhu X, Yang J, Price A, Sohoni A, **Stein AM**, Parent L, Greene M, Niederst M, Whalen J, Orlando EJ, Treanor LM, Brogdon JL. Preservation of T-Cell Stemness with a Novel Expansionless CAR-T Manufacturing Process, Which Reduces Manufacturing Time to Less Than Two Days, Drives Enhanced CAR-T Cell Efficacy. Blood, 138, Seppl 1 (*ASH* 2021)
6. Chaudhury A, **Stein A**, Grupp S, Levine J, Pulsipher M, Myers GD, Waldron E, Zhu X, McBlane F, Awasthi R, Waller E. Conversion of Cellular Kinetic Data for Chimeric Antigen Receptor T-cell Therapy (CAR-T) into Interpretable Units. *AACR* 2021
7. Wei AH, Esteve Ji, Porkka K, Knapper S, Vey N, Scholl S, Garcia-Manero G, Wermk M, Janssen J, Traer E, Loo S, Narayan R, Tovar N, Kontro M, Ottmann O, Xu S, Liao S, **Stein AM**, Khanshan F, Naidu P, Zhang N, Mohammed A, Rinne ML, Sun H, Brunner AM, Borate U. Dose Selection and Dose-Response Analysis in Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML): Population Pharmacokinetics (PK) Modeling and Evaluation of Clinical Efficacy/Safety By Dose. 2020. (*ASH* poster)
8. Diehl H, **Stein AM**, Roy Chowdhury N, Shiffman M, Gelman A, Broderick T, The “See”-Value App: Visual Decision Making for Drug Development. *Data Science, Statistics, and Visualization (DSSV)* online conference, 2020 (poster)
9. Margolskee A, Khanshan F, **Stein AM,** Ho, Y-Y, Looby M. Exploratory graphics (xGx): promoting the purposeful exploration of PKPD data. PAGE 2019 (oral presentation, by Alison Margolskee); R in Pharma (oral presentation); *ACoP* 2019 (oral presentation, by Fariba Khanshan - winner of ACoP poster quality award)
10. Kim J, Khanshan F, Ho, Y-Y, **Stein AM**. Utilizing receptor occupancy and tumor penetration for the phase 2 dose selection of monoclonal antibodies targeting solid tumors. *J PKPD,* 45, S49-S49, 2018 (ACoP poster).
11. Tsitkov S, Biliouris K, Pigeolet E, Ramakrishna, R, Ho, Y-Y and **Stein, AM**, Evaluating model evaluation: shall we trust a model whose parameter estimation yields low RSEs and/or successful output messages? *J PKPD*, 45, S67-S67, 2018 (*ACoP* poster).
12. Ahmed S, Ellis M, Li H, Pallucchini L, **Stein AM**. Guiding dose selection of monoclonal antibodies using a new parameter (AFTIR) for characterizing ligand binding systems. *PAGE* 2018 (poster)
13. **Stein AM,** Grupp SA, Levine JE, Laetsch TW, Pulsipher MA, Boyer, MW, August KJ, Levine BL, June CH, Tomassian L, Shah S, Leung M, Huang PH, Joliet S, Awasthi R, Mueller KT, Wood PA, Maude SL, CTL019 Model-Based Cellular Kinetic Analysis of Chimeric Antigen Receptor (CAR) T Cells to Characterize the Impact of Tocilizumab on Expansion and to Identify Correlates of Cytokine Release Syndrome Severity, *ASH* 2017 (poster)
14. Biliouris K, Pigeolet E, Lowe PJ, Ramakrishna R, **Stein AM**, Predicting the free target levels based on total drug and total target levels for monoclonal antibodies, *ACoP* 2017 (poster)

15. Mietlowski WL, **Stein AM**, Bao W, Waltzman R, Wood PA, Prognostic value of waterfall plots with the addition of nontarget lesion data. *J Clin Oncol* Abs#11082 2013 (*ASCO* Poster)
16. **Stein AM**, Sharma M, Bruno R, Proposals for How Oncology Pharmacometricians Can Collaborate to Make Tumor Dynamics Models for Trial Design a Standard Part of Drug Development. *ACoP* 2013 (oral presentation)
17. Mietlowski WL, Bao W, Wood PA, Williams DE, El-Hashimy M, Sarr C, **Stein AM**, Shi M, Weber W, Habr D, Porro MG. Clinical importance of including new and nontarget lesion assessment of disease progression to predict overall survival: Implications for randomized phase II study design. *J Clin Oncol* Abs#2543 2012 (ASCO poster)
18. Reddy PL, Choppa P, Moradian MM, Potter NT, Quigley MM, Watt CD, Holger A, Hoefling A, Manning BM, Mignault AA, Ossa DF, **Stein AM**, Wang S, Yang F, Wetzler M. Performance Variability of BCR-ABL Monitoring Tests: Impact of PCR Platform Standardization on Health Care Systems. *J. Mol. Diag., 2011* (Am. Molec. Pathol. poster)
19. **Stein, AM**, Carter A, Hollaender N, Motzer R, Sarr C. Quantifying the effect of everolimus on both tumor growth and new metastases in metastatic renal cell carcinoma (RCC): A dynamic tumor model of the RECORD-1 phase III trial. *J Clin Oncol* Abs#4602 2011. (ASCO poster)
20. Kim, D**, Stein AM**, Wang WA, Carter A, Chiparus O, Hollaender N, Kim H, Motzer R, Sarr C. A pharmacodynamic model to describe the dose-response relationship for everolimus in the RECORD-1 phase III trial: tumor size as a biomarker for clinical efficacy in metastatic renal cell carcinoma. *Eur. Assoc. Urology* Abs#1568, 2011. (*EAU* extended poster presentation)
21. **Stein AM**, Shou Y, Bottino D, Chia YL, Woodman RC, Martinelli G, Hughes TP, Müller M, Beppu L, Gottardi E, Branford S, Soverini S, Goh H, Hochhaus A, Kim DW, Saglio G, Radich JP. Rapid initial decline in Bcr-Abl levels is associated with superior responses in imatinib-resistant or -intolerant chronic myeloid leukemia patients in chronic phase treated with nilotinib. *Eur. Hem. Assoc.* Abs #0139, 2010 (*EHA* poster)
22. Saglio S, Hughes T, Kim DW, Hanfstein B, Gottardi E, Branford S, Goh H, Beppu L, Soverini S, Shou Y, **Stein AM**, Woodman R, Kantarjian H, Radich J, Hochhaus A, Martinelli G, Response to nilotinib in patients with imatinib-resistant or -intolerant chronic myeloid leukemia in chronic phase (CML-CP) with different BCR-ABL transcript types, *Haematologica*, 95 suppl. 2: 342, Abs#0819, 2010 (*EHA* poster)
23. Kim D, Saglio G, Martinelli G, Shou Y, **Stein AM**, Woodman RC, Kantarjian H, Hughes TP, Radich JP, Hochhaus A. Bcr-Abl transcript analysis of patients with imatinib-resistant or -intolerant chronic myeloid leukemia in chronic phase treated with nilotinib. *J Clin Oncol* 28 (7s) Abs #6567 2010. (*ASCO* poster)
24. **Stein AM**, Kalebic T, Bottino D. Bcr-abl kinetics suggest self-renewing leukemic cells are reduced during imatinib treatment. *Blood.* 114 (22) 209, Abs #506, 2009. (*ASH* oral presentation)
25. Bottino D, Chia Y, **Stein AM**, Georgieva A, Yu J, Kahn J, Helmlinger G, Kalebic T. Inference of imatinib (IM) effects on leukemic stem cell (SC) compartment via mathematical modeling of IRIS treatment response data. *J Clin Oncol*. 27 (15s) Abs #7056, 2009. (*ASCO* poster)

Patents

- 17104983 - Chimeric antigen receptors and uses thereof
- 20210147547 - Dosage regimens for anti-PD-L1 antibodies and uses thereof
- 20200223924 - Dosage regimens of anti-TIM-3 antibodies and uses thereof
- 20200172617 - Dosage regimens of anti-LAG-3 antibodies and uses thereof
- 7052068 - Configurable overhead console for cars and trucks.

Software and Websites

- TrinityMetrics page of Pharmacometrics Tools and Learning Guides: www.trinitymetrics.com
- Exploratory Graphics (xGx) for Pharmacometrics https://opensource.nibr.com/xgx/
- Exploratory Graphics R package http://www.github.com/Novartis/xgxr

Awards

- 2020: PSP (Pharmacometrics and Systems Pharmacology) award from ASCPT for Tisagenlecleucel Model-Based Cellular Kinetic Analysis of Chimeric Antigen Receptor T Cells
- 2019: ACoP10 Quality Award for Exploratory Graphics (xGx): Promoting the purposeful exploration of PKPD data.

Teaching

- U Minnesota Pharmacometrics Summer School (Minneapolis, MN) One day training course on exploratory graphics (xGx). 2019
- One day of lectures on Introduction to Fundamental PK and PD concepts for quantitative scientists at Novartis Academia-Industry Quantitative Hackathon 2018, 2019
- Calculus I (University of Michigan) 2005
- Engineering Concepts (Boston Academy) 2001

Technical Skills

- Currently use: R, Monolix, nlmixr2
- Previously used: Matlab, NONMEM

Invited Talks

- *ACoP 2021* (Virtual Talk). Advances in mechanism-based cellular kinetic-pharmacodynamic modeling approaches for the development of next generation CAR-T therapies
- *FDA Systems Pharmacology Seminar* 2020. Assessing the uncertainty and predictive accuracy of mechanistic models; with applications in CML and receptor occupancy.
- *ASCPT 2019* (Webinar) Tisagenlecleucel Model-Based Cellular Kinetic Analysis of Chimeric Antigen Receptor–T Cells (with Edward Waldron)
- *ACoP 2019* (Orlando, FL) The cellular kinetics and anti-tumor dynamics of Kymriah
- *ACoP 2017* (Ft Lauderdale, FL) *Two new parameters for characterizing ligand binding systems*
- *Pharmacometrics + Applied Math = Better QSP:* 2017 (Cambridge, MA and ACoP 2017) Identifiability: concepts + software
- *Society for Industrial and Applied Mathematics:* 2016 (Boston, MA) Assessing the Identifiability of Models for Monoclonal Antibody Target Mediated Drug Disposition Using a New Metric of Drug Potency
- *Northeastern University Pharmacology Seminar*, 2015, (Boston, MA) The importance of understanding exposure in clinical drug development,
- *Joint Workshop in Math and Industry,* 2014, (Seoul, South Korea). A mathematical career in the pharmaceutical industry.
- *Institute for Math and its Applications - Careers in Mathematics*, 2014 (Minneapolis, MN)
- *Pharmaceutical Users Software Exchange (PhUSE)*, 2013 (Cambridge, MA). Using longitudinal solid tumor data to improve drug development decisions.
- *American Conference on Pharmacometrics (ACoP),* 2013 (Ft. Lauderdale, FL). Proposals for how oncology pharmacometricians can collaborate to make tumor dynamics models for trial design a standard part of drug development
- *PKPD summit,* 2013 (Boston, MA). Using longitudinal solid tumor data to better characterize dose-response in oncology clinical trials.
- *Institute for Math and its Applications / Minnesota Center for Industrial Mathematics Seminar (IMA/MCIM), 2013.* (Minneapolis, MN) Applying mathematical models for solid tumor growth in the pharmaceutical industry.
- *Math Biosciences Institute Young Researchers Workshop,* 2012 (Columbus, OH) Applying mathematical models for solid tumor growth in the pharmaceutical industry.
- *Mathematical Problems in Industry Workshop (MPI) ,*2011 (Newark, NJ). Dynamics models of metastatic tumor growth.

- *U. Conn Undergraduate Math Seminar* October, 2010 (Storrs, CT). Mathematical models for CML and their potential impact on managing patient care.
- *Nagoya CML Seminar,* August, 2010. (Nagoya, Japan). BCR-ABL kinetics and implications for CML stem cell reduction during imatinib or nilotinib therapy.
- *M.D. Anderson Cancer Center* (Houston, TX) January, 2007. Models for glioblastoma invasion.
- *U. Michigan/Michigan State Mathematical Biology Day,* December, 2006. Models for glioblastoma invasion.
- *Complex Systems Academic Workshop* (Ann Arbor, MI) October, 2005. Cellular autonoma models for glioblastoma invasion.

Other professional activities

ISoP New England - Coordinated regional ISoP New England events from 2014-2017

Novartis Academia-Industry Quantitative Hackathon - Initiated and co-organized quantitative hackathons with 40-50 grad students and postdocs over two weeks, to teach them about challenges in Pharma and provide them with real problems to work on in diverse teams. 2018-2019.

Workshops and Conferences (attended at least three times)

- *American Conference on Pharmacometrics (ACoP),* 2009, 2013, 2015, 2016, 2017, 2019, 2021, 2023, 2024, 2026
- *Novartis Academia-Industry Quantitative Hackathon* (Cambridge, MA), 2018-2021
- *Society for Industrial and Applied Math (SIAM) Life Sciences,* 2006, 2012, 2016,

Workshops and Conferences (other)

- *Population Approach Group in Europe (PAGE*, Montreux, Switzerland), June 2018
- *Math-to-Industry Bootcamp* (Minneapolis, MN) July 2017
- *IMA and NIMS Joint Workshop on Math in Industry* (Daejeon, South Korea), October 2014
- *American Association for Cancer Research (AACR)* (Boston, MA) October 2013
- *American Statistical Association Biopharmaceuticals joint FDA Workshop* (Wash. DC) September 2013
- *Pharmaceuticals Users Software Exchange (PhUSE)* (Cambridge, MA) June 2013
- *PKPD Summit* (Boston, MA), March 2013
- *MBI Workshop for Young Researchers in Math Bio.* (Columbus, OH) August 2012
- *Mathematical Problems in Industry* (Newark, NJ) June 2011
- *American Society of Clinical Oncology* (Chicago, IL) June 2011
- *American Society of Hematology* (Orlando, FL) December 2010
- *Rakesh Jain Tumor Biology Course* (Cambridge, MA) September 2010
- *Nagoya CML Seminar* (Nagoya, Japan) August 2010
- *American Society of Clinical Oncology* (Chicago, IL) June 2010
- *American Society of Hematology* (New Orleans, LA) December 2009
- *MBI - Multiscale Methods in Biology* (Columbus, OH) November 2008
- *MBI - Cell and Tissue Movement* (Columbus, OH) September 2008
- *ECMTB* (Edinburgh, UK), July, 2008
- *Microrheology Workshop* (Los Angeles, CA) January 2008
- *Biomedical Engineering Society Fall Meeting* (Los Angeles, CA), October 2007
- *IMA – Molecular and Cellular Biology* (Minneapolis, MN), 2007-2008
- *Society for Mathematical Biology* (San Jose, CA), August 2007
- *Summer Bioengineering Conference* (Keystone, CO), June 2007
- *MCTP/ICAM Biomechanics Workshop* (Ann Arbor, MI), June 2007
- *MBI - Workshop for Young Researchers in Math Bio.* (Columbus, OH), March 2007
- *SIAM Life Sciences / SMB* (Raleigh, NC). August 2006
- *IPAM Angiogen. Neovasc. and Morphogen.* (Los Angeles, CA), May 2006
- *AMS Regional Meeting* (South Bend, IN), April, 2006
- *Cancer Symposium* (Ann Arbor, MI), November, 2005
- *ECMTB* (Dresden, Germany), July, 2005

- *Dynamics of Cancer: Modeling and Experiment* (Ann Arbor, MI), May, 2005
- *Society for Mathematical Biology* (Ann Arbor, MI), July, 2004
- *SIAM Annual Meeting/Life Sciences* (Portland, OR), July, 2004
- *Complex Systems Summer School* (Santa Fe, NM), June, 2002
- *ICIS* (Albuquerque, NM), Nov., 2001
- *NIPS* (Boulder, CO), Dec., 2000