INDIAN INSTITUTE OF TECHNOLOGY DELHI
DEPARTMENT OF BIOCHEMICAL ENGINEERING & BIOTECHNOLOGY

2018-19 Seminar Series

Friday, 30th November, 2018

Dr. Satyaprakash Nayak
Pharmacometrician - Global Clinical Pharmacology
Pfizer Inc., Cambridge, MA

Title: Mechanism Based Mathematical Modeling and its Applications in Drug Development

Modeling and simulation is increasingly playing an important in clinical drug development. A recent statement by FDA lays emphasis on the application of computer models to develop and evaluate devices and drugs to advance novel therapeutics more efficiently through the different stages of clinical trials. Traditional pharmacokinetic (PK) and pharmacodynamic (PD) modeling has been used to answer clinical questions regarding a specific drug's behavior in the body and its pharmacological effect. However, mechanistic modeling of biological networks is now increasingly being applied to further our understanding of diseases to answer questions such as target selection, biomarker behavior, combination therapies and safety/efficacy in special populations such as pediatric or geriatric subjects. In this talk, I will provide examples of application of mechanistic modeling to aid drug development in two different therapeutic areas, i.e., modeling the human blood coagulation network to advance therapeutic development in hematological disorders and modeling of immune system for inflammatory bowel diseases.

All are welcome

Seminar will be held in DBEB Seminar room at Block I, Room 223 at 4 pm
For additional information, contact Seminar coordinator Dr. Preeti Srivastava at preeti@dbeb.iitd.ac.in or Dr. D. Sundar at sundar@dbeb.iitd.ac.in

SATYAPRAKASH NAYAK

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EDUCATION

PhD, Chemical and Biomolecular Engineering Aug 2005 - Jan 2010
Cornell University, Ithaca, NY
Thesis title - *A Study Of Cell Growth, Division And Programmed Differentiation By Simulation And Experiments* (link)

MS, Chemical and Biomolecular Engineering Aug 2005 - May 2008
Cornell University, Ithaca, NY

BTech, Chemical Biomolecular Engineering Aug 2000 - May 2004
Indian Institute of Technology, Roorkee India
• Ranked 3^{rd} in the graduating class of Chemical Engineering, 2004 (CGPA - 8.85/10.00)
• Was among the ∼20 students who were able to change their engineering branch based on first year's performance.

SKILLS

- **Computational Skills:** Expertise in mathematical modeling, computer simulation and analysis of biological systems ranging from intra-cellular level to physiological level in multiple areas of biology, e.g., cancer signaling systems, hematology, immunology and vaccine biology.
  Tools and Languages - Expertise in `MATLAB/Octave`, `R`, `C/C++`, `Python`, `NONMEM`

  Open Source Contribution - I am the author and maintainer of `R` package `sundialr` which provides an interface to the renowned `SUNDIALS` ODE solving `C` library in `R`. (link)

- **Numerical Skills:** Expertise in global optimization methods, parameter optimization in ODE systems, monte-carlo sensitivity analysis of biological networks and novel analysis of models of signaling pathways of importance in human health. In addition, I also have deep expertise in non-linear mixed effects (NLME) modeling of clinical pharmacokinetic and pharmacodynamic data.

- **Biological Data Science:** In depth knowledge of current biological knowledge and clinical development in the areas of oncology (breast and prostate cancer, leukemia), immunology, vaccine development, skin biology and health, rare diseases such as Hemophilia, Intra-cerebral Hemorrhage and Inflammatory Bowel Diseases (Crohn's Disease and Ulcerative Colitis) and experience in working with teams in early (pre-clinical) as well as late (clinical) stages of drug development.

- **Experimental Biology Skills:** Adept in handling and experimentation in Human Cancel Cell lines (e.g., HL-60, NB4). Experienced in sterile technologies and cell-culture, SDS-PAGE Analysis, Multi-parametric Cytometric Analysis, co-immunoprecipitation and RT-PCR.

MENTORSHIP EXPERIENCE

- Co-mentored 2 post-doctoral scholars at Pfizer in large-scale modeling of human diseases, e.g., disorders of the blood coagulation and Inflammatory Bowel Diseases . Both the post-docs presented their results at numerous prestigious conferences, and the post-doctoral experience resulted in 4 high-quality publications (2 published, 2 submitted) in a total span of 4.5 years. I continue to mentor young scientists, who want to pursue a technical track in industrial research career in the field of modeling and simulation in the pharmaceutical industry.

- Provided mentorship and guidance to ∼ 5 undergraduate students in during graduate school, a few of them have co-authored papers with me. Provided mentorship to 4 students from prestigious universities e.g., Harvard University, MIT, Yale and NCSU to complete projects at Pfizer which provided crucial inputs in decision making.

AWARDS & ACHIEVEMENTS

- Awarded the McMullen Fellowship from Cornell University for support in PhD.
- Awarded Merit Scholarship by IIT Roorkee for excellence in academic performance. (Top 5% students were awarded the scholarship)
- Ranked in the top 1% of students competing in the entrance examination for IIT Roorkee (Ranked 960 out of 100,000 applicants)
- Model developed by me was awarded the 'Model of the month' recognition by 'Biomodels.net' an online repository maintained by the European Bioinformatics Institute (PDF)
- Selected by the journal PSP:CPT to do a podcast on the Blood Coagulation model publication (link)
- Awarded the UpJohn Award for excellent performance at Pfizer for multiple years for excellence in data science and modeling.
- Was invited by Harvard Medical School to present on my modeling and provide the students with an industry perspective on application of modeling and simulation to further drug development. (Invitation email)
- Was invited by INRIA (Paris, France) to participate in the evaluation of projects by INRIA project-teams as an external expert from the industry. (Invitation email)

PROFESSIONAL EXPERIENCE

• Pharmacometrician - Global Clinical Pharmacology
Pfizer Inc., Cambridge, MA Jan 2013- Present
Major Projects

· **Modeling:** Developed and published a mechanistic model of the human blood coagulation network. The model is currently being used to support a variety of programs in the hematology area at Pfizer for diseases such as Hemophilia A and B and Intra-cerebral Hemorrhage (ICH). The results from the model have been used to help progress clinical development of 3 different drugs at Pfizer. The model was further being developed by a Post-Doctoral researcher using the original code written by me.

· **Data Science:** Analyzed clinical data (Pharmacokinetic and Pharmcodynamic) from Phase 2 studies of programs in Inflammatory Bowel Disease area - Crohn's Disease and Ulcerative Colitis. The results of my analysis were used for decision making to move the clinical development forward. Also, the analysis is being used to estimate the dose and design of the Phase 3 trial in one of the diseases.

· **Student Mentorship** Co-mentored two Post-doctoral scholars in developing and expanding mechanistic models of diseases in hematology (blood coagulation) and immunology (Inflammatory Bowel Diseases). Acted as their technical mentor and provided guidance in model formulation, literature and internal data collection, parameter optimization and finally application in clinical development programs. These efforts have led to numerous poster presentations at prestigious meetings (e.g., Gordon conference, American Society of Hematology (ASH), International Society of Thrombosis and Hemostasis (ISTH)) and have led to 4 manuscripts (2 published, 2 submitted).

• Scientist - Systems Biologist
The Procter & Gamble Company (P&G), Cincinnati, OH June 2010 - Jan 2013
Major Projects

· **Modeling:** Developed mechanistic (intra-cellular to physiological level) models to understand fundamental epidermal biology related to skin inflammation/irritation (acute and chronic), barrier disruption and lipid metabolism pathways. Integrated internal models with an external model from industry leader in *in silico* simulations.

· **Development of Modeling Capability:** Developed a framework to rapidly construct models from literature and in-house biological knowledge, performed integration of models with SBML framework and analyzed the networks using tools from open-source C/C++ and SBML libraries.

· **Experimental Design:** Led a cross-functional team of experienced biologists to incorporate proprietary biological knowledge in the model, provided key inputs in designing new experiments to test model hypothesis in an in vitro system and use experimental results to train and improve the model.

PUBLICATIONS

1. **Satyaprakash Nayak**, S Salim, D Luan, M Zai and Jeffrey Varner, A test of highly optimized tolerance reveals fragile cell-cycle mechanisms are molecular targets in clinical cancer trials, PLoS ONE, 3(4); 2008, e2016. (PDF)

2. **Satyaprakash Nayak**, M Shen, J Varner and Andrew Yen, Arsenic Trioxide (ATO) cooperates with All Trans Retinoic Acid (ATRA) to enhance MAPK activation and differentiation in Human Myeloblastic Leukemia (HL-60) cells, Leukemia and Lymphoma, 51(9); 2009, 1 - 14. (PDF)

3. **Satyaprakash Nayak**, J Siddiqui and Jeffrey Varner, Modeling and Analysis of an Ensemble of Eukaryotic Translation Initiation Models, IET Systems Biology, 5(1); 2011, 2 - 14. (PDF)

4. R Tasseff, **Satyaprakash Nayak**, S Song, Jeffrey Varner, A Computational Model of Signaling Networks in Prostate Cancer Cells, PLoS ONE, 5(1), 2008, e8864. (PDF)

5. R Tasseff, **Satyaprakash Nayak**, S Song, Jeffrey Varner, Modeling and Analysis of the Differentiation Program of a model Adult Hematopoetic Stem Cell line HL-60, Integrative Biology, 3(5); 2011, 578 - 591. (PDF)

6. J Lequieu, A Chakrabarti, **Satyaprakash Nayak** and Jeffrey Varner, Computational Modeling and Analysis of Insulin Induced Eukaryotic Translation Initiation, PLoS Comp. Biol., 7(11); 2011, e1002263. (PDF)

7. T Hickling, X Chen, P Vicini and **Satyaprakash Nayak**, A review of quantitative modeling of B cell response to Antigenic Challenge, Journal of Pharmacokinetics and Pharmacodynamics, 41 (5), 2014, 445 - 459 *(Invited Review)* (PDF)

8. **Satyaprakash Nayak**, D Lee, S Patel-Hett, D Pittman, P Vicini, S Martin, A Heatherington, F Hua, Using a systems pharmacology model of blood coagulation network to predict the effects of various therapies on biomarkers, Clinical Pharmacology and Therapeutics: Pharmacometrics and Systems Pharmacology, 4, 396 - 405 (2015) (PDF)

9. D Lee, **Satyaprakash Nayak**, S Martin, A Heatherington, P Vicini, F Hua, A quantitative systems pharmacology model of blood coagulation describes in vivo biomarker changes in Non-Bleeding Subjects, Journal of Thrombosis and Hemostasis, 14 (12); 2016, 2430-2445 (PDF)

10. WJ Sandborn,..., **Satyaprakash Nayak**,..., Geert R D'Haens, Phase II evaluation of anti-MAdCAM antibody PF-00547659 in the treatment of Crohn's disease: report of the OPERA study, Gut, 2017, DOI: 10.1136/ gutjnl-2016-313457 (PDF)

11. MH Zahraee , ... **Satyaprakash Nayak**, ..., K Hung, Anti-MAdCAM Antibody Increases β7+ T Cells and CCR9 Gene Expression in the Peripheral Blood of Patients With Crohn's Disease, Journal of Crohn's and Colitis, 2018, 12(5), 77 -86 (PDF)

12. KV Rogers, I Bhattacharya, SW Martin, **Satyaprakash Nayak**, Know your variability: challenges in mechanistic modeling of inflammatory response in inflammatory bowel disease (IBD), Clinical and Translational Science, 1(11), 2018, 4-7. *(Senior Author)* (PDF)

13. **Satyaprakash Nayak** *et. al.*, Getting Innovative Therapies Faster to Patients at the Right Dose: Impact of Quantitative Pharmacology Towards First Registration and Expanding Therapeutic Use, Clinical Pharmacology and Therapeutics, 103(3); 2018, 378-383. (PDF)

14. R Schoemaker, **Satyaprakash Nayak**, LO Harnisch, M Karlsson, Modeling and simulation of the modified Rankin Scale and National Institute of Health Stroke Scale neurological endpoints in intracerebral hemorrhage. *(submitted, Clinical Pharmacology and Therapeutics)*

15. KV Rogers, SW Martin, I Bhattacharya, RSP Singh, **Satyaprakash Nayak**, A Dynamic Quantitative Systems Pharmacology Model of Inflammatory Bowel Disease: Part 1 - Model Framework *(submitted, Clinical Pharmacology and Therapeutics - draft available upon request) (Senior Author)*

16. KV Rogers, SW Martin, I Bhattacharya, RSP Singh, **Satyaprakash Nayak**, A Dynamic Quantitative Systems Pharmacology Model of Inflammatory Bowel Disease: Part 2 - Application to Current Therapies in

Crohn's Disease *(submitted, Clinical Pharmacology and Therapeutics - draft available upon request) (Senior Author)*

17. **Satyaprakash Nayak**, Mathematical modeling of the Immune System Biology *(invited article from Mathematical Biosciences - in preparation)*

CONFERENCE PRESENTATIONS

1. V Akcelik, L Lee, **Satyaprakash Nayak**, K Ko and J Varner, Multiscale Simulation of Breast Cancer Tumorigensis Using Single Cell Models and Kinetic Monte Carlo, American Institute of Chemical Engineers (AIChE), Annual Meeting, November 2006, San Francisco, CA. (PDF)
2. **Satyaprakash Nayak**, S Salim and J Varner, Predicted points of cell-cycle fragility are consistent with known malfunctions in solid and hematological cancers, American Chemical Society (ACS), Annual Meeting, August 2007, Boston, MA. (PDF)
3. **Satyaprakash Nayak**, J Siddiqui and J Varner, Deregulation of CAP dependent translation can play a role in malignant transformation of eukaryotes, American Chemical Society (ACS), Annual Meeting, August 2007, Boston, MA. (PDF)
4. **Satyaprakash Nayak**, M Zai, D Luan and J Varner, Identification Of Therapeutic Targets For Solid And Hematological Cancers Using Mathematical Modeling And Sensitivity Analysis Of The Cell-Cycle And Ubiquitin Proteasome System (UPS), American Institute of Chemical Engineers (AIChE), Annual Meeting, November 2007, Salt Lake City, UT. (PDF)
5. R Tasseff, J Varner, **Satyaprakash Nayak**, T Mansell and D Luan, Identification of Fragile Mechanisms in the Human Complement Cascade Is Sensitive to the Choice of Numerical Method for the Solution of the Sensitivity Equations, American Institute of Chemical Engineers (AIChE), Annual Meeting, November 2007, Salt Lake City, UT. (PDF)
6. **Satyaprakash Nayak**, J Siddiqui and J Varner, Deregulation Of Cap-Mediated Initiation Plays A Role In The Malignant Transformation Of Cells, American Institute of Chemical Engineers (AIChE), Annual Meeting, November 2007, Salt Lake City, UT. (PDF)
7. **Satyaprakash Nayak**, J Siddiqui and J Varner, Modeling and analysis of eukaryotic translation initiation reveals the fragility of PI3K/Akt/mTOR sub-system, American Chemical Society (ACS), Annual Meeting, August 2008, Philadelphia, PA. (PDF)
8. R Tasseff, **Satyaprakash Nayak**, P Kaushik, N Rizvi, S Salim and J Varner, Formulation and Analysis of An Ultrascale Protein Interaction Network Involved In the Androgen Response of Prostate Cancer Epithelial Cells , American Institute of Chemical Engineers (AIChE), Annual Meeting, November 2008, Philadelphia, PA. (PDF)
9. R Tasseff, **Satyaprakash Nayak**, D Kudela, J Siddiqui, A Yen and J Varner, Mathematical Modeling and Analysis of the Role of the BLR1 Protein and MAPK Activation In the Growth-Arrest and Differentiation Program of a Model Adult Stem-Cell, American Institute of Chemical Engineers (AIChE), Annual Meeting, November 2008, Philadelphia, PA. (PDF)
10. **Satyaprakash Nayak**, M Shen, J Varner and A Yen, Arsenic Trioxide Combined with All-Trans Retinoic Acid (ATRA) leads to Enhanced MAPK Activity and Differentiation in HL-60 cells, Cornell Engineering Research Conference (CERC), Cornell University, April 2009, Ithaca, NY.(Confirmation email)
11. M Shen, S Song, A Yen, **Satyaprakash Nayak**, R Tasseff, J Varner, Modeling and analysis of proliferation and differentiation program of a model adult stem cell, Americal Chemical Society (ACS), - BIOT (Division of Biochemical Technology), Annual Meeting, March 2010, Salt Lake City, UT. (PDF)
12. R Tasseff, **Satyaprakash Nayak**, J Varner, Analysis of the molecular networks in androgen dependent and independent prostate cancer, Americal Chemical Society (ACS), - BIOT (Division of Biochemical Technology), Annual Meeting, March 2010, Salt Lake City, UT. (PDF)

13. R Tasseff, **Satyaprakash Nayak**, S O Song, A Yen and Jeffrey D. Varner, Modeling and Analysis of the Retinoic Acid Induced Proliferation and Differentiation Program of HL-60, American Institute of Chemical Engineers (AIChE), Annual Meeting, November 2010, Salt Lake City, UT. (PDF)

14. A Chakrabarti, J Lequieu, **Satyaprakash Nayak** and J Varner, Modeling Insulin-mediated growth factor signaling and its role in Diabetes, Biomedical Engineering Society Annual Meeting, Annual Meeting (BMES), October 2010, Austin, TX. (PDF - See page 59)

15. R Tasseff, **Satyaprakash Nayak**, A Yen and J Varner, Modeling and Analysis of the Retinoic Acid Induced Proliferation and Differentiation Program of HL-60, 3rd International Conference on Biomolecular Engineering (ICBE), January 2011, San Francisco, CA. (PDF)

16. A Chakrabarti, J Lequieu, **Satyaprakash Nayak** and J Varner, Model of Insulin-Mediated Eukaryotic Translation Initiation Identifies Distinct Functional Sub-Modules Highlighting the Key Role of IRS1 and mTORC1, 3rd International Conference on Biomolecular Engineering, January 2011, San Francisco, CA. (PDF)

17. **Satyaprakash Nayak**, M Peterson, D Chen, Systems Pharmacology in the open space of drug discovery and development at Pfizer, Applications of Systems Biology Approaches in Drug Discovery and Development by Thompson Reuters and Novartis, June 25, 2015, Cambridge MA. *(Invited presentation)* (Program Agenda)

18. **Satyaprakash Nayak**, D Lee, S Patel-Hett, D Pittman, P Vicini, A Heatherington, S Martin and F Hua, A systems biology model of the coagulation network in bleeding state reveals differences in behaviors of biomarkers in response to perturbations, The International Conference on Systems Biology of Human Diseases (SBHD 2014), Boston MA (PDF - see page 128)

19. D Lee, **Satyaprakash Nayak**, S Martin, A Heatherington, P Vicini and F Hua, A systems biology model for the coagulation network in non-bleeding state describes baseline activity of clotting, The International Conference on Systems Biology of Human Diseases (SBHD 2014), Boston MA (PDF - see page 136)

20. H Zhou, Z Liu and **Satyaprakash Nayak**, Utilizing Pharmacometric Modeling in Pharmacogenetic Association Tests to Increase Study Power, American Society of Human Genetics Annual meeting, October 2014, San Diego CA (PDF - see page 99)

21. D Lee, **Satyaprakash Nayak**, S Martin, A Heatherington, P Vicini and F Hua, A systems biology model for the coagulation network in non-bleeding state describes baseline activity of clotting, Gordon Research Conference on Hemostasis, July 27-August 1, 2014, Waterville Valley NH

22. D Lee, **Satyaprakash Nayak**, D Pittman, S Arkin, S Martin, A Heatherington, P Vicini, F Hua, A systems biology model for the coagulation network in non-bleeding state describes baseline activity of coagulation, 56th ASH (American Society of Hematology) Annual Meeting and Exposition, December 6-9, 2014, San Francisco, CA. (PDF)

23. **Satyaprakash Nayak**, D Lee, S Patel-Hett, D Pittman, P Vicini, A Heatherington, S Martin and F Hua, A systems biology model of the coagulation network in bleeding state reveals differences in behaviors of biomarkers in response to perturbations, Quantitative Systems Pharmacology Congress, QSP-Congress 2015, January 27-29, Boston MA

24. D Lee, **Satyaprakash Nayak**, M Peterson, P Vicini, F Hua, S W Martin, and A C Heatherington, Applications of Quantitative Systems Pharmacology Models to Advance Clinical Trials Development: Case studies in Hematological Disorders and Osteoporosis, Quantitative Systems Pharmacology: Progress Towards Integration into Drug Discovery and Development, New York Academy of Sciences (NYAS), May 26, 2015, New York City, New York. (PDF - see page 5)

25. D Lee, **Satyaprakash Nayak**, S Arkin, S W. Martin, A C Heatherington, P Vicini, F Hua, A Systems Biology Model for the Coagulation Network Describes Biomarker Changes Observed in a Clinical Study with FVIIa Variant, International Society on Thrombosis and Hemostasis, June 20 -25, Montreal 2015. (PDF)

26. **Satyaprakash Nayak**, Development of a Quantitative Systems Pharmacology (QSP) Model of the Blood Coagulation Network and its Application to Clinical Programs, Webinar by Rosa and Company LLC (*Invited*

webinar) (link - See the webinar on Sep 16, 2015)

27. **Satyaprakash Nayak**, Dooyoung Lee, Steven Arkin, Steven W. Martin, Anne C. Heatherington, William S. Denney, Paolo Vicini, and Fei Hua, A Quantitative Systems Pharmacology Model for the Coagulation Network Describes Biomarker Changes Observed in a Clinical Study with FXa Variant and Predicts Age-Associated Biomarker Variations, American Society of Hematology (ASH) Annual Meeting, December 5-8, 2015, Orlando, FL. (PDF)
28. **Satyaprakash Nayak** Speaker at a Roundtable on 'Right-Sizing (Develop, Extend, Reduce) Systems Pharmacology Models' AAPS NBC meeting, 16-18 May, 2016 *Speaker and Panelist, Invited presentation* (Invitation notice)
29. R Schoemaker, **Satyaprakash Nayak**, WS Denney, EN Johsson, MO Karlsson, LO Harnisch, Modelling and simulation of neurological endpoints (modified Rankin Scale [mRS] and National Institute of Health Stroke Scale [NIHSS]) to aid clinical trial design in intracerebral hemorrhage (ICH), PAGE 2016, Lisbon, Portugal, 7 - 10 June, 2016. (link)
30. ISTH Application of Quantitative Systems Pharmacology (QSP) Model of Human Blood Coagulation to Understand the Response of Clinical Biomarkers from a Recent Anti-TFPI Trial in Healthy Subjects, International Society on Thrombosis and Hemostasis, Berlin, Germany, 8 - 13 July, 2017 (PDF)
31. S Koride, **Satyaprakash Nayak**, C Banfield, M Peterson, A Quantitative Systems Pharmaocology Model Describes Changes in Platelets following JAK Modulation, American Society of Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting, March 2017. (PDF)
32. K Rogers, **Satyaprakash Nayak**, A Ahmed, S Martin, Development of a Quantitative Systems Pharmacology Model of Inflammatory Bowel Diseases, American Society of Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting, March 2017. (PDF)
33. K Rogers, **Satyaprakash Nayak**, A Ahmed, S Martin, QSP Model of IBD Provides Insights Into Different Therapeutic Mechanisms, American Society of Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting, March 2018. (PDF)

PEER REVIEW & PROFESSIONAL ACTIVITIES

- Member of the Editorial Board - Mathematical Biosciences (link) (PDF)
- Member of the Editorial Board - Theoretical Biology and Medical Modeling (link)
- Reviewer of a number of journals specializing in mathematical modeling and biological applications
  - Mathematical Biosciences, Journal of Theoretical Biology, Computers in Biology and Medicine
  - BioSystems, BMC Systems Biology, IET Systems Biology
  - Clinical Pharmacology and Therapeutics, Frontiers in Biotechnology and Bioengineering
  - Systems Biology in Reproductive Medicine, European Journal of Pharmaceutical Sciences
- Lead an industry-wide initiative on behalf of the American Society of Clinical Pharmacology and Therapeutics (ASCPT) to collate impactful examples of mathematical modeling in Drug Development to highlight its role in crucial decision-making. (PDF)
- Session organizer and moderator for a Symposium titled - 'Leveraging High-Dimensional Data in Systems Pharmacology Modeling of Diseases', AAPS, San Diego, CA, USA, 2014 (PDF)

REFERENCES

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