Resume & Curriculum Vitae

SANDEEP DUTTA, *Ph.D.*

Vice President, Global Clinical Development, AMGEN
Global Head, Clinical Pharmacology, Modeling & Simulations, Digital Medicine, and Clinical Device Investigations
Contact: sdutta02@amgen.com

EXECUTIVE SUMMARY

EDUCATION

Degree	Discipline	University
Ph.D.	PKPD	State University of New York, Buffalo, New York, USA
B.S.	Pharmacy	Jadavpur University, Calcutta, INDIA

PUBLICATIONS/PRESENTATIONS

- 18 granted patents and >200 filed patent families
- >100 articles in peer-reviewed journals & >200 abstracts in national/international meetings
- Invited presentations in (inter)national meetings: ASCPT, AAPS, ASPET, KSP (Korea), IPC (India)
- Workshop/Symposium Chair and organizer, Focus Group Chair: ACoP, ASCPT
- Member of Industry/Academia/Regulatory Working Groups: *PhRMA Model Informed Drug Development (MIDD)*, *PhRMA PISC Compound Properties Working Group*, *Coalition Against Major Diseases (CAMD) Working Group*, *The DILI-sim Initiative and DILIsym® Software*, and *PhRMA Biomarkers Evidentiary Standards Working Group*.

SELECTED AWARDS AND HONORS

2022: Distinguished Alumni, Dept of Pharmaceutical Sciences, University at Buffalo
2019: R&D Leader of the Year, Amgen
2017-26: Adjunct Faculty, Pharmaceutics and Translational Therapeutics, University of Iowa
2015-16: *Senior Research Fellow*, Volwiler Society, AbbVie
2002-21: *Editorial Board Member* (present/past) & reviewer for multiple journals

SCIENTIFIC/CLINICAL/TRANSLATIONAL

- More than two decades of drug development and translational sciences experience in small and large molecule, nucleic acid and cell based therapies across >15 different modalities and drug-device combinations.
- As Clinical Pharmacology Modeling and Simulation (CPMS) functional head was responsible for driving and overseeing CPMS contributions for >25 world-wide BLA/NDA filings & approvals of NBE/NCEs
- ***Key past contributions as an individual contributor and functional TA head:***
  - Translational Sciences: Expertise in development and execution of strategies for:
    - Clinical, biomarker, genetic and bioinformatic/quantitative translation of in vitro/ preclinical Discovery and FIH/Phase 1b data to inform Phase 2a/POC human studies
    - Experience in adaptive design clinical trials (Bayesian, drop-arm, enrichment); defining rules & execution of blinded Phase 2/3 exposure-response analyses for decision-making
    - Leading bioinformatic/statistical scientists mining of large external databases (public, consortia) of genetic, genomic, epigenetic and microbiome data to inform clinical trials and back translate to Discovery
  - Clinical PKPD/Pharmacology: Strategic & tactical execution of clinical pharm programs for 10 (s)NDA/MAA/JNDA filings; >200 Phase 1/translational and >50 Phase 2-4 trials
  - Quantitative Pharmacology: Technical and strategic expertise in using quantitative methods for answering key questions that drive translational and drug development decisions
    - Selection of doses & study durations for Phase 2a/b studies based on exposure-response (efficacy & safety) analyses for numerous programs in pain, neuroscience, HCV, renal

  - Extensive experience in use of model based meta-analyses for integrating preclinical, clinical trial, & published data to define drug target/clinical product profile & support decision-making
  - Quantitative determination of optimal regimen and dose to drive critical decision to shorten duration of first interferon-free HCV treatment from 48 to 12 weeks for the 3D combination (Viekira Pak/Technivie and Mavyret), and in multiple approvals of Depakote family of products
- QSP, PBPK & Biopharmaceutics: BiTEs for immuno-oncology, mechanistic HCV viral load, liver fibrosis, receptor dynamics and neuro-degenerative diseases/pain, drug-drug interactions, drug absorption & IVIVC models

PROFESSIONAL EXPERIENCE

- More than two decades of experience in multiple scientific and managerial positions; currently lead departments responsible for clinical pharmacology and pharmacometrics of Amgen clinical candidates (oncology/hematology, inflammation, cardiovascular, neuroscience, nephrology, bone & biosimilars), Digital Medicine, and Clinical Device Investigations
- Serve on company governance committees as technical authority on dose selection/clinical trial design, contribute to portfolio decisions, lead organizational invention and company-wide initiatives on innovation: MIDD, Novel-Novel Combination Development Strategies, PhRMA Time & Cost Initiative to lower cost of drug development for diseases with high unmet need, Innovative Approaches Initiative for clinical trials; and build external alliances with academia and industry peers
- Re-engineered and setup efficient outsourcing models for Phase 1 clinical studies, reporting and pharmacometric analyses, which resulted increased bandwidth and significantly decreased timelines
- Re-built Modeling & Simulation group to widen the scope beyond traditional mixed effects and categorical analyses to expand talent pool for QSP, PBPK, meta analysis and broad data analytics (AI/ML) capabilities
- As past leader of Clinical Pharmacogenetics, Pharmacogenomics and Bioinformatics Department, created the vision & strategy and executed the tactical plan for expanding the group >5-fold with diverse expertise in genetics, biostatistics and bioinformatics; created the bioinformatics group; increased capital & operating budget and laboratory footprint by 3-fold
- Strong track record of accomplishment building and integrating departments into effective, value-added members of the larger R&D organization, creating high performing teams, facilitating professional development of direct reports in matrixed environment, liaising with executive management to identify and retain talent with demonstrated ability to match personnel with experience
  - Developed highly competent clinical pharmacology/PKPD and pharmacometrics leaders and groups; extensive experience mentoring and training many scientists and leaders within clinical pharmacology and pharmacometrics
  - Deep technical expertise has resulted in assuming leadership responsibilities for introducing, championing, training and implementing many novel quantitative approaches and software platforms within AbbVie and Amgen
  - Extensive experience building cloud-based pharmacometrics infrastructure
- Quantitative Clinical/Systems Pharmacology/Pharmacometrics corporate leadership role with significant impact on use of innovative trial designs in multiple clinical programs. Cross-functional leadership of data sciences and analytics (machine learning, artificial intelligence) and digital health initiatives.

Sandeep Dutta Curriculum Vitae (cont.)

Professional Positions

Jan 2022 – present	Vice President, Global Clinical Development, Amgen Global Head, Clinical Pharmacology, Modeling & Simulations Head, Digital Medicine, Clinical Development Head, Clinical Device Investigations, Clinical Development
April 2021 – Dec2021	Executive Director, Global Clinical Development, Amgen Global Head, Clinical Pharmacology, Modeling & Simulations Head, Digital Medicine, Clinical Development Head, Clinical Device Investigations, Clinical Development
Jan 2020 – April 2021	Executive Director, Translational Medicine, Amgen Global Head, Clinical Pharmacology, Modeling & Simulations and Interim Global Head, Preclinical Pharmacokinetics and Drug Metabolism
Oct 2016 – Dec 2019	Executive Director, Medical Sciences, Amgen Global Head, Clinical Pharmacology, Modeling & Simulations
Nov 2015 – Oct 2016	Senior Director, *Senior Research Fellow* Clinical Pharmacology & Pharmacometrics and Head, Pharmacogenomics/Bioinformatics Dept, AbbVie
Apr 2012 – Nov 2015	Senior Director, *Research Fellow* Clinical Pharmacology & Pharmacometrics and Head, Pharmacogenomics/Bioinformatics Dept, AbbVie
Jan 2011 – Apr 2012	Senior Director, *Research Fellow* Clinical PKPD Neuroscience, Pain & Antiviral, Abbott
Apr 2007 – Jan 2011	Director, Neuroscience, Pain & Antiviral *Research Fellow* Dept. of Clinical Pharmacokinetics & Pharmacodynamics, Abbott
Apr 2007 – Nov 2009	Director, Neuroscience, Pain & Antiviral *Associate Research Fellow* Dept. of Clinical Pharmacokinetics & Pharmacodynamics, Abbott

Aug 2004 – Apr 2007	Associate Director, Neuroscience & Pain *Associate Research Fellow* Dept. of Clinical Pharmacokinetics, Abbott
Oct 2003 – Aug 2004	Section Manager, Neuroscience & Pain *Associate Research Fellow* Dept. of Clinical Pharmacokinetics, Abbott
Feb 2002 – Sep 2003	Group Leader, Neuroscience & Pain Research Investigator Pharmacokineticist Dept. of Clinical Pharmacokinetics, Abbott
Mar 2000 – Jan 2002	Project Leader, Neuroscience & Pain Senior Research Pharmacokineticist Dept. of Clinical Pharmacokinetics, Abbott
Oct 1997 – Feb 2000	Research Pharmacokineticist Dept. of Clinical Pharmacokinetics and Toxicokinetics, Abbott
Aug 1992 - Oct 1997	Graduate Research and Teaching Assistant Dept. of Pharmaceutics, State University of New York, Buffalo

Research Experience

Professional Research: October 1997 – present
Clinical pharmacology and PKPD of therapies in oncology, hematology, inflammation, cardiovascular, nephrology, bone, antivirals (hepatitis-C), pain, neuroscience (migraine, Alzheimer's disease [symptomatic and disease-modifying], multiple sclerosis, Parkinson's disease, peripheral supra-nuclear palsy [PSP], neuropathic and nociceptive pain, epilepsy, bipolar, schizophrenia, cognitive deficits in schizophrenia and other psycho-affective and cognitive disorders, ADHD), immune modulators (pain, anti-inflammatory, antifibrotic [NASH, NAFLD], auto-immune), COX2 inhibitors (anti-inflammatory/ pain), benign prostatic hyperplasia agents (urology) and endothelin antagonists (oncology/cardiovascular), secondary hyperparathyroidism in chronic kidney disease (renal)
Pharmacogenetics/Pharmacogenomics/Bioinformatics of all AbbVie drugs in development and marketed products

Awards and Honors

2022: Distinguished Alumni, Department of Pharmaceutical Sciences, University at Buffalo
2019: R&D Leader of the Year, Amgen
2017-26: Adjunct Faculty, Pharmaceutics and Translational Therapeutics, University of Iowa
2016: *President's Award* Novel Bioequivalence of Duopa Next Gen Formulation, AbbVie
2015: *Chairman's Award* Viekira Pak Clin. Pharmacology DDI Strategy, AbbVie
2015: *Volwiler Outstanding Research Team Award* Modeling & Simulation Team, AbbVie
2015: *Senior Research Fellow*, Volwiler Society, AbbVie
2014: *President's Award* HCV Clinical Pharmacology DDI Strategy, AbbVie
2012: *President's Award* Defining Dose & Duration of HCV Combination Therapy, Abbott
2011: *President's Award* Vicodin CR 5/325 Reformulation, Abbott
2009: *Research Fellow*, Volwiler Society, Abbott
2008: *Life Cycle Management Award* Depakote Pediatric Exclusivity, Abbott
2008: *President's Award* Vicodin CR NDA, Abbott
2008: *Spot Award* for Depakote Pediatric Exclusivity, Abbott
2010-17: *Editorial Board Member,* International Scholarly Research Notices: Pharmaceutics
2007-16: *Editorial Board Member,* The Open Pharmacology Journal
2005-18: *Editorial Board Member,* Current Clinical Pharmacology
2004: *President's Award* for Depakote Pediatric Written Request, Abbott
2003: *Associate Research Fellow*, Volwiler Society, Abbott
2002: *Certificate of Appreciation*, Depacon Rapid Infusion Approval, Abbott
1998: *Team Service Achievement Award*, Dexmedetomidine NDA, Abbott
1992-7: *Graduate Student Assistantship*, State University of New York at Buffalo.
1992: *Prof. Anupam Sengupta Memorial Award in Medicinal Chemistry*, Bachelor of Pharmacy, Jadavpur University, Calcutta, India.
1992: *Rank Holder* (2nd position) in Bachelor of Pharmacy, Jadavpur University, Calcutta, India.

PhD Thesis Committee

2022-25: Nan Wu, Pharmaceutics and Translational Therapeutics, University of Iowa

Patents

Granted

1. Qiu Yihong, Bollinger J Daniel, ***Dutta Sandeep***, Cheskin Howard S, Engh Kevin R and Poska Richard P. ***Controlled Release Formulation of Divalproex Sodium.*** US Patent No.

6,511,678; January 28, 2003; (United States Patent Application 20010020039 and United States Patent Application 20020031549).

2. Qiu Yihong, Bollinger J Daniel, Cheskin Howard S, ***Dutta Sandeep***, Engh Kevin R and Poska Richard P. ***Controlled Release Formulation of Divalproex Sodium.*** US Patent No. 6,528,090; March 4, 2003; (United States Patent Application 20010005512).

3. Qiu Yihong, Bollinger J Daniel, Cheskin Howard S, ***Dutta Sandeep***, Engh Kevin R and Poska Richard P. ***Controlled Release Formulation of Divalproex Sodium.*** US Patent No. 6,713,086; March 30, 2004; (United States Patent Application 20030118656).

4. Qiu Yihong, Bollinger J Daniel, ***Dutta Sandeep***, Cheskin Howard S, Engh Kevin R and Poska Richard P. ***Controlled Release Formulation of Divalproex Sodium.*** US Patent No. 6,720,004; April 13, 2004; (United States Patent Application 20030104057).

5. Bain Earle E, Abi-Saab Walid M, ***Dutta Sandeep***, Garimella Tushar S, Awni Walid M, Saltarelli Mario D. ***Treatment of Attention-Deficit/Hyperactivity Disorder.*** US Patent No. 8,222,278; July 17, 2012 (US Patent Application 20100144795, Serial Number 475440; June 10, 2010) and ***Sofinicline (ABT-894) for Attention-Deficit/Hyperactivity Disorder***. EP2303272, April 6, 2011, also published as WO2009149003, US2010144795, TW201002719, MX2010013237, JP2011522051, CN 102056608, CA 2725470.

6. Powell John, Casson Duncan, Maginn Mark, Liu Wei, ***Dutta Sandeep***, Best Andrea, Hall Jerry A. ***Antibodies Against Nerve Growth Factor (NGF) with Enhanced In Vivo Stability***. US Patent No. 8,435,523; May 7, 2013.

7. Bernstein Barry M, Menon Rajeev M, Khatri Amit, Mensing, Sven, ***Dutta Sandeep***, Cohen Daniel E, Podsadecki Thomas J, Brun Scott C, Awni Walid M, Dumas Emily O, Klein Cheri E. ***Methods for Treating HCV***. (12-week ABT-450/r ± ABT-333 ± ABT-267 at least 2DAA GT1 interferon-free therapies) US Patent No. 8,466,159; June 18, 2013.

8. Bernstein Barry M, Menon Rajeev M, Khatri Amit, Mensing, Sven, ***Dutta Sandeep***, Cohen Daniel E, Podsadecki Thomas J, Brun Scott C, Awni Walid M, Dumas Emily O, Klein Cheri E. ***Methods for Treating HCV***. (12-week ABT-450/r ± ABT-333 ± ABT-267 at least 2DAA GT1 interferon- and ribavirin-free therapies) US Patent No. 8,492,386; July 23, 2013.

9. Bernstein Barry M, Menon Rajeev M, Khatri Amit, Mensing, Sven, ***Dutta Sandeep***, Cohen Daniel E, Brun Scott C, Awni Walid M, Dumas Emily O, Klein Cheri E, Podsadecki Thomas J. ***Methods for Treating HCV***. (8-week ABT-450/r ± ABT-333 ± ABT-267 at least 2DAA GT1 interferon-free therapies) US Patent No. 8,680,106; March 25, 2014.

10. Bernstein Barry M, Menon Rajeev M, Khatri Amit, Mensing, Sven, ***Dutta Sandeep***, Cohen Daniel E, Brun Scott C, Awni Walid M, Dumas Emily O, Klein Cheri E, Podsadecki Thomas J. ***Methods for Treating HCV***. (8-week ABT-450/r ± ABT-333 ± ABT-267 at least 2DAA GT1 interferon- and ribavirin-free therapies) US Patent No. 8,685,984; April 1, 2014.

11. Bernstein Barry M, Menon Rajeev M, Khatri Amit, Mensing, Sven, ***Dutta Sandeep***, Cohen Daniel E, Brun Scott C, Awni Walid M, Dumas Emily O, Klein Cheri E, Podsadecki Thomas J. ***Methods for Treating HCV***. (8-week PSI-7977 & any NS5A at least 2DAA GT1 interferon- and ribavirin-free therapies) US Patent No. 8,809,265; August 19, 2014.

12. Bernstein Barry M, Menon Rajeev M, Khatri Amit, Mensing, Sven, ***Dutta Sandeep***, Cohen Daniel E, Brun Scott C, Awni Walid M, Dumas Emily O, Klein Cheri E, Podsadecki Thomas J. ***Methods for Treating HCV***. (12-week ABT-450/r+ABT-267 at least 2DAA GT1 interferon-free therapies) US Patent No. 8,853,176; October 7, 2014.

13. Bernstein Barry M, Menon Rajeev M, Khatri Amit, Mensing, Sven, ***Dutta Sandeep***, Cohen Daniel E, Brun Scott C, Awni Walid M, Dumas Emily O, Klein Cheri E, Podsadecki Thomas J. ***Methods for Treating HCV***. (8 – 12-week PSI-7977 ± ABT-450/r ± ABT-267 at least 2DAA GT1 interferon-free therapies) US Patent No. 8,969,357; March 3, 2015.

14. Bernstein Barry M, Menon Rajeev M, Khatri Amit, Mensing, Sven, ***Dutta Sandeep***, Cohen Daniel E, Brun Scott C, Awni Walid M, Dumas Emily O, Klein Cheri E, Podsadecki Thomas J. ***Methods for Treating HCV***. (8 – 12-week PSI-7977 ± ABT-450/r ± ABT-267 at least 2DAA GT1 interferon- and ribavirin-free therapies) US Patent No. 8,993,578; March 31, 2015.

15. Powell John, Casson Duncan, Maginn Mark, Liu Wei, Dutta Sandeep, Best Andrea, Hall Jerry A. Antibodies Against Nerve Growth Factor (NGF) with Enhanced In Vivo Stability. US Patent No. 9,447,181; September 20, 2016.

16. Awni Walid M, Bernstein Barry M, Brun Scott C, Cohen Daniel E, Dumas Emily O, ***Dutta Sandeep***, Khatri Amit, Klein Cheri E, Menon Rajeev M, Mensing Sven, Podsadecki Thomas J. ***Methods for Treating HCV***. (8 – 12-week PSI-7977 ± ABT-450/r ± ABT-267 at least 2DAA GT1 interferon- and ribavirin-free therapies) US Patent No. 9,452,194; September 27, 2016.

17. Awni Walid M, Bernstein Barry M, Brun Scott C, Campbell Andrew L, ***Dutta Sandeep***, Lin Chih-Wei, Menon Rajeev M, Podsadecki Thomas J, Wang, Tianli, Mensing Sven. ***Methods for Treating HCV***. (8 – 12-week 2nd generation [glecaprevir and pibrentasvir] at least 2DAA GT1-3 interferon- and ribavirin-free therapies) US Patent No. 10,286,029; May 14, 2019.

18. Awni Walid M, Bernstein Barry M, Brun Scott C, Campbell Andrew L, ***Dutta Sandeep***, Lin Chih-Wei, Menon Rajeev M, Mensing Sven, Podsadecki Thomas J, Wang Tianli,. ***Methods for Treating HCV***. (8 – 12-week 2nd generation [glecaprevir and pibrentasvir] at least 2DAA GT1-3 interferon- and ribavirin-free therapies) US Patent No. 10,286,029; Nov 01, 2022.

Applications Filed (selected, >200 filed)

19. Rosenberg Joerg, Woehrle Gerd H, Kessler Thomas Y, Breitenbach Joerg, Durak Salih, Richter Friedrich W, Liu Wei, ***Dutta Sandeep***. ***Formulations of Nonopioid and Confined Opioid Analgesics.*** US Patent Application 20090022798, Serial Number **780625**, January 22, 2009; also published as TW 200904431.

20. Rosenberg Joerg, Woehrle Gerd H, Kessler Thomas Y, Breitenbach Joerg, Durak Salih, Richter Friedrich W, ***Dutta Sandeep*** , Liu Wei. ***Formulations of Nonopioid and Confined Opioid Analgesics.*** EP2182928, May 12, 2010; also published as WO2009014534, MX2010000803, JP2010534204, CN101917977, CA2690829, IL 202680.

21. Roth Wolfgang, Burst Alexander, Zietsch Martina, Liu Wei, ***Dutta Sandeep***. ***Abuse Resistant Melt Extruded Formulation having Reduced Alcohol Interaction***. US Patent Application 20100172989, Serial Number 631010, July 8, 2010; and WO2011068723, June 9, 2011.

22. Rosenberg Joerg, Woehrle Gerd H, Kessler Thomas Y, Breitenbach Joerg, Durak Salih, Richter Friedrich W, Liu Wei, ***Dutta Sandeep***. ***Formulations of Nonopioid and Confined Opioid Analgesics***. US Patent Application 20110229526, Serial Number 984373, September 22, 2011.

23. Bernstein Barry M, ***Dutta Sandeep***, Liu Wei, Podsadecki Thomas J, Campbell Andrew L, Menon Rajeev M, Lin Chih-Wei, Wang Tianli, Awni Walid M. ***Methods for Treating HCV***. (2nd Generation interferon- and ribavirin-free therapies) US Patent Application 61/783,376, March 14, 2013.

24. Bernstein Barry M, ***Dutta Sandeep***, Liu Wei, Podsadecki Thomas J, Campbell Andrew L, Menon Rajeev M, Lin Chih-Wei, Wang Tianli, Awni Walid M. ***Methods for Treating HCV***. (2nd Generation interferon-free therapies) US Patent Application 61/783,437, March 14, 2013.

25. Walid M. Awni, Prajakta Badri, Daniel E. Cohen, ***Dutta Sandeep***, Amit Khatri, Rajeev M. Menon, Thomas Podsadecki, Akshanth Polepally, Roger Trinh, Tianli Wang, Jiuhong Zha. ***Dose Adjustment***. (1st Generation HCV) US Patent Application US 14/606,369 (Publication# US20150209403 A1 & WO2015116594A1, Jan 27, 2015.

26. ***Dutta Sandeep***, Kosloski Matthew, Liu Wei. ***Dose Adjustment***. (2nd Generation HCV[glecaprevir and pibrentasvir] cadmic DDIs) US Patent Application US 14/606,369 (Publication# US20180085330 A1) March 29, 2018.

Invited Presentations

Nov 25, 2004 "Use of *In Vitro In Vivo* Correlation in Formulation Development and Biowaiver Applications" at the 34th Annual Meeting of the Korean Society for Pharmaceutics, November 25-26, 2004, Seoul, Korea. Abstract published in *Korean Society for Pharmaceutics Annual Meeting-The role of pharmaceutical scientists in post-genomic era*, 63-68, 2004.

Dec 4, 2004 "Drug Development, Clinical Trials and Regulatory Affairs - Opportunity for Strategic Guidance from JUOPAA"at the 56th Indian Pharmaceutical Congress, December 3-5, 2004, Kolkata, India. Abstract published in *Indian Pharmaceutical Congress Annual Meeting-Pharmacists in Healthcare System*, xxxix-xi, 2004.

Dec 17, 2004 "Present Trends in Drug Development" and "Pharmacokinetics & Pharmacodynamics in Drug Development" in the Department of Chemical Technology, University of Calcutta

Jul 29, 2006 "Role of IVIVC and BCS Classification in Generic Drug Development" at the *2nd International Workshop*-"Complying with Regulatory and Sponsor's Requirements in New and Generic Drug Development" by Transworld Institute of Professional Development & Training and Indian Pharmaceutical Association – Industrial Pharmacy Division, July 28-29, 2006, Hyderabad, India.

Nov 15, 2007 "Integration of Preclinical PK/PD to Clinical Studies" in session titled "PK/PD Modeling and Simulation in Drug Discovery" at the *American Association of Pharmaceutical Scientists Annual Meeting and Exposition*, November 11-15, 2007, San Diego, California.

Sep 15, 2011 "Exposure-Response Modeling and Clinical Trial Simulations to Predict Phase 2/3 Study Clinical Endpoints Using Data from Early Clinical Trials" in session titled "Modeling from Bench to Human" at the *Land O'Lakes Conference*, September 12-16, 2011, Devil's Head Resort and Conference Center, Merrimac, Wisconsin.

Jan 31, 2014 "Modeling and Simulations in Drug Development" in the Department of Mathematical Sciences, Northern Illinois University.

Oct 28, 2015 "Nonlinear Mixed Effects Models with Applications in Pharmacokinetic/ Pharmacodynamic (PK/PD) Modeling" American Statistical Association Webinar. Presented jointly with Prof. Bala Hosmane, Northern Illinois University.

May 10, 2016 "Model Based Drug Development" in the Department of Pharmaceutical Sciences and Experimental Therapeutics / Division of Pharmaceutics and Translational Therapeutic, University of Iowa.

Mar 30, 2018 "Clinical pharmacology approach for dose selection in product development under the animal rule: modeling and simulation application in acute radiation syndrome" ASCPT Orlando, Florida.

Apr 23, 2018 "Surmounting the insurmountable obstacles in drug discovery and development - real world case studies: evolocumab" ASPET, San Diego, California.

May 01, 2018 "Model Informed Drug Development" in the Department of Pharmaceutical Sciences and Experimental Therapeutics / Division of Pharmaceutics and Translational Therapeutic, University of Iowa.

Nov 15, 2019 "PKPD Primer on Biologics Discovery and Development" in the Department of Pharmaceutical Sciences and Experimental Therapeutics / Division of Pharmaceutics and Translational Therapeutic, University of Iowa.

Nov 15, 2019 "Model Informed Drug Development" in the Department of Pharmaceutical Sciences and Experimental Therapeutics / Division of Pharmaceutics and Translational Therapeutic, University of Iowa.

Nov 03, 2020 "Clinical Pharmacology Considerations for Targeted Covalent Inhibitor" in "Targeted Covalent Inhibitors and Protein Degraders: From Discovery and Preclinical Development to Clinical Proof of Concept" at the *American Association of Pharmaceutical Scientists Annual Meeting and Exposition*, November 03, 2020, New Orleans, Louisiana (Virtual).

May 11, 2022 "Applications of MIDD in Clinical Pharmacology". Distinguished Alumni seminar in the Department of Pharmaceutical Sciences, University at Buffalo.

Workshop/Symposium Chair

Apr 2, 2011 "Non-linear Mixed Effects Modeling in R" at the *American Conference on Pharmacometrics (ACoP),* April 3-6, 2011, San Diego, California.

Mar 12, 2016 "Clinical and Translational Pharmacology of Emerging Modalities of Therapeutics: RNA and Gene Therapies" at the *American Society for Clinical Pharmacology (ASCPT),* March 8-12, 2016, San Diego, California.

Oct 23, 2016 "Quantitative Applications in Biopharmaceutics: Development and Use of Quantitative Mechanistic Modeling and In Vitro In Vivo Correlations for Formulation Screening and Selection, and Setting Clinically Relevant Dissolution Specifications" at the *American Conference on Pharmacometrics (ACoP),* October 23-26, 2016, Bellevue, Washington.

Sep 18, 2017 "Safety Assessment in Phase 1 Healthy Volunteer Trials" Webinar Chair for the *American Society for Clinical Pharmacology (ASCPT) Early Development & Drug Safety (EDDS) Community ,* September 18, 2017.

Feb 1, 2018 "Clinical MIDD in Oncology" session at the *FDA-ISoP Public Workshop: Model Informed Drug Development (MIDD) for Oncology Products,* February 1, 2018, FDA White Oak, Maryland.

Mar 14, 2019 "Poster Walk III: Physiologically-Based Pharmacokinetics" at the *American Society for Clinical Pharmacology (ASCPT),* March 13-16, 2019, Washington, DC.

Industry/Academia/Regulatory Working Groups

2006-11 Member and contributor of the ***PhRMA PISC Compound Properties Working Group*** responsible for evaluating current methods for the modeling and simulation of compound properties across industry and academia as it relates to prediction of human pharmacokinetics from *in vitro* and *in situ* compound properties and animal pharmacokinetics.

2008-11 Member and contributor of the ***Coalition Against Major Diseases (CAMD) Working Group on Disease Progression Modeling for Alzheimer's and Parkinson's diseases.*** CAMD, led by the Critical Path Institute, is a coalition of major pharmaceutical companies, the Food and Drug Administration (FDA), the National Institute for Aging (NIA), and patient advocacy groups

2014-16 Member and contributor of the ***The DILI-sim Initiative and DILIsym® Software.*** The DILI-sim Initiative is a pre-competitive partnership between The Hamner Institute (academia) and a diverse set of stakeholders (Pharma Industry, FDA) to develop a computational model that will predict whether new drug candidates will cause drug-induced liver injury (DILI) in patients.

2015-16 Member and contributor of the ***PhRMA Biomarkers Evidentiary Standards Working Group.***

2017-19 Chair (2018-19) and Vice Chair (2017-18), ***ASCPT Early Development & Drug Safety (EDDS) Community.***

2018-21 Member and contributor of the ***PhRMA Model Informed Drug Development Working Group.***

Journal Referee:

Epilepsia
Journal of Clinical Pharmacy and Therapeutics
Journal of Clinical Pharmacology
Journal of Pharmaceutical Sciences
Clinical Pharmacokinetics and Therapeutics
Pharmacological Research, Italian Society of Pharmacology
Expert Opinion on Pharmacotherapy (UK)
The AAPS Journal
Biopharmaceutics and Drug Disposition
Journal of Pharmaceutical and Biomedical Analysis
Journal of Pharmacy and Pharmacology
Current Clinical Pharmacology
ISRN Pharmaceutics
The Open Pharmacology Journal
AIChE Journal
Human Psychopharmacology: Clinical and Experimental
British Journal of Clinical Pharmacology
Journal of Pharmacokinetics and Pharmacodynamics
The AAPS Journal
International Journal of Pharmaceutics
Xenobiotica
Clinical Pharmacokinetics
Nature Reviews

Regulatory (FDA/EMA/PMDA/Health Canada) Interactions:

Face-to-Face Meetings:

FDA

Jan 3, 2001: Depakote ER
May 3, 2001: Depakote ER
Mar 4, 2002: Depakote
Jun 12, 2003: Vicodin CR Pre-IND Meeting
Dec 5, 2003: Hydromorphone-PCA Pre-IND Meeting
Sep 2, 2004: Depakote Pediatric Written Request
Sep 9, 2004: Vicodin CR Pre-Phase 2 Meeting
Mar 16, 2005: Vicodin CR End-of-Phase 2 Meeting
Oct 24, 2007: Vicodin CR Pre-NDA Meeting
Nov 5, 2009: Vicodin 10/650 End-of-Phase 2 Meeting
Nov 18, 2010: ABT-110 anti-NGF Antibody End-of-Phase 2a Meeting
Mar 8, 2011: Vicodin 10/650 Type A Meeting
Sep 14, 2011: HCV 1st Generation Interferon-free DAA Combination Program
Oct 1, 2012: EOP2 HCV 1st Generation Interferon-free DAA Combination Program
Nov 13, 2012: ABT-110 anti-NGF Antibody Type C Meeting
July 22, 2013: HCV 1st Generation Interferon-free Broad GT1 DAA Combination Program
Jan 28, 2014: HCV 1st Generation DAA Combination Program Pre-NDA
Aug 18, 2015: Duopa 2nd Generation Type C Meeting

EMA/European Agencies

Jun 10, 2011: EMA, HCV 1st Generation Interferon-free DAA Combination Program
Mar 02, 2012: EMA, HCV 1st Generation Interferon-free DAA Combination Program
Dec 13, 2012: MHRA, Pediatric Investigation Plan (PIP) HCV 1st Generation Interferon-free DAA Combination Program
Sep 09, 2013: EMA, HCV 2nd Generation Interferon-free DAA Combination Program
Sep 04, 2015: EMA, HCV 2nd Generation End-of-Phase 2 Scientific Advice

PMDA

Apr 04, 2012: HCV 1st Generation Interferon-free DAA Combination Program

Health Canada

Feb 26, 2014: HCV 1st Generation DAA Combination Program Pre-NDS

Teleconferences:

FDA

Nov 30, 2000: Depacon population pharmacokinetic analyses
Apr 27, 2001: Depacon labeling
Oct 18, 2001: Depakote ER – IVIVC application for “Biowaiver” for lower strength tablet

May 1, 2002: Depakote ER – Setting dissolution specifications using IVIVC
Sep 25, 2002: Depakote Pediatric Written Request
Dec 12, 2002: Depakote ER label negotiations
Dec 16, 2002: Depakote ER label negotiations
Dec 17, 2002: Depakote ER label negotiations
Mar 11, 2003: Depakote Migraine Prophylaxis Study for Pediatric Written Request
Apr 14, 2003: Depakote Epilepsy Study for Pediatric Written Request
Jun 10, 2003: Dilaudid OROS Pre-Phase II Meeting
Aug 13, 2003: Depakote ER label negotiations for Pediatric Indications
Sep 11, 2003: Depakote Pediatric Written Request-Longterm Safety
Sep 7, 2005: ABT-894 Pre-IND/Multiple-dose Study Design
Nov 14, 2006: Vicodin CR Abuse Liability Study
Jan 15, 2008: ABT-116 FIH Study
May 27, 2010: Depakote ER Bipolar NDA Post Approval Commitment
Feb 15, 2011: ABT-639 Pre-IND
Nov 5, 2012: EOP2 HCV Combination Program
Feb 15, 2013: EMA, Pediatric Investigation Plan (PIP) HCV 1st Generation Interferon-free DAA Combination Program
Jun 30, 2014: EOP1 HCV 2nd Generation Combination Program
February 22, 2016: Break-Through Designation HCV 2nd Generation Combination Program & HCV 1st Generation GT4
August 26, 2019: AMG 510 KRAS Inhibitor NSCLC & Colon Cancer Phase 2 Dose Selection
November 10, 2020: Sotorasib (AMG 510) KRAS Inhibitor Pre-NDA
February 26, 2021: Sotorasib (AMG 510) KRAS Inhibitor Dose Comparison Study
March 11, 2021: Sotorasib (AMG 510) KRAS Inhibitor Mid-Cycle Review
April 21, 2021: Sotorasib (AMG 510) KRAS Inhibitor Late-Cycle Review

Health Canada
Oct 24, 2013: Ribavirin Pre-Submission

EMA/European Agencies
July 13, 2015: EMA, Pediatric Investigation Plan (PIP) - HCV 2nd Generation Interferon-free DAA Combination Program

Professional Memberships

American Society for Clinical Pharmacology and Therapeutics 1999-2023.
American Society of Pharmacometrics 2011-2023.
American Association of Pharmaceutical Scientists: 1995-2008, 2012.

Presentations

Posters/Podium Abstracts:

1. ***Dutta S***, Matsumoto Y, Ebling WF: Assessing sigmoid Emax model parameter estimatability with a monte carlo jacknife method. Second International Symposium on *Measurement and Kinetics of In Vivo Drug Effects,* 14-16 April 1994, Noordwijkerhout, The Netherlands. Abstract published in *Measurement and Kinetics of In Vivo Drug Effects: Advances in Simultaneous Pharmacokinetic/Pharmacodynamic Modelling,* 102-3, 1994.

2. ***Dutta S***, Matsumoto Y, Ebling WF: Role of intralipid in the pharmacokinetics and pharmacodynamics of propofol in rats. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, November 6-11, 1995, Miami, Florida. Abstract published in *Pharmaceutical Research,* 12 (9): S401, 1995.

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4. ***Dutta S,*** Ebling WF: Safety of phenol anesthetic is enhanced by emulsion formulation. *Pharmacokinetics/Pharmacodynamics in the Developing System and Impact on Risk Assessment*, April 21-23, 1996, Little Rock, Arkansas. Abstract published in *Journal of Toxicology and Environmental Health,* 49: 355, 1996.

5. ***Dutta S***, Ebling WF: Parameter estimatability of additive biphasic effect models [*Podium Presentation*]. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, October 27-31, 1996, Seattle, Washington. Abstract published in *Pharmaceutical Research,* 13 (9): S474, 1996.

6. ***Dutta S,*** Ebling WF: Potency and safety of propofol is enhanced by emulsion formulation. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, October 27-31, 1996, Seattle, Washington. Abstract published in *Pharmaceutical Research,* 13 (9): S461, 1996.

7. ***Dutta S***, Ebling WF: Steady state propofol brain:plasma partition coefficient and the effect site equilibration paradox[*Podium Presentation*]. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, November 2-6, 1997, Boston, Massachusetts. Abstract published in *Pharmaceutical Research,* 14 (11): S621, 1997.

8. ***Dutta S***, Ebling WF: Influence of intravenous formulation on tissue uptake, pharmacokinetics, pharmacodynamics and kinetics of pharmacologic effect of propofol [*Podium Presentation*]. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, November 2-6, 1997, Boston, Massachusetts. Abstract published in *Pharmaceutical Research,* 14 (11): S623, 1997.

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11. ***Dutta S,*** Lal R, Karol MD, Cohen T, Ebert T: Dexmedetomidine pharmacokinetics in a human maximum tolerated dose study. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, November 14-18, 1999, New Orleans, Louisiana. Abstract published in *AAPS PharmSci,* 1(4): 494, 1999; available from: *http://www.aapspharmsci.org/.*

12. ***Dutta S,*** Karol MD, Cohen T, Jones RM, Mant T: Dexmedetomidine-propofol pharmacodynamic interaction in healthy volunteers. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, November 14-18, 1999, New Orleans, Louisiana. Abstract published in *AAPS PharmSci,* 1(4): 535, 1999; available from: *http://www.aapspharmsci.org/.*

13. Ryan CW, Janus TJ, Vogelzang NJ, Vokes EE, Kindler HL, ***Dutta S***, Conroy M, Ratain MJ: A Phase I study of men and women with refractory malignancies given daily dosing of an endothelin receptor antagonist. *American Society of Clinical Oncology, Thirty-Sixth Annual Meeting*, May 20-23, 2000, New Orleans, Louisiana. Abstract published in *Proceedings of the Thirty-Sixth Annual Meeting of the American Society of Clinical Oncology* 19: 201a, 2000.

14. Bertz R, Hsu A, Lam W, Williams L, Renz C, Karol MD, ***Dutta S***, Carr R, Zhang Y, Wang Q, Schweitzer S, Foit C, Andre A, Bernstein B, Granneman GR, Sun E: Pharmacokinetic interactions between lopinavir/ritonavir (ABT-378/r) and other non-HIV drugs. *Fifth International Congress on Drug Therapy in HIV Infection*, October 22-26, 2000, Glasgow, United Kingdom. Abstract published in *AIDS* 14 (Suppl 4): S100, 2000.

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dose pharmacokinetics of ABT627, an endothelin-a receptor antagonist. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, October 29 - November 2, 2000, Indianapolis, Indiana. Abstract published in *AAPS PharmSci,* 2 (4), 2000; available from*:* **Error! Hyperlink reference not valid.***www.aapspharmsci.org/*.

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18. ***Dutta S,*** Zhang Y, Granneman R, Verlinden M: Single dose pharmacokinetics of fiduxosin under fasting conditions in healthy elderly male subjects. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, October 21-25, 2001, Denver, Colorado. Abstract published in *AAPS PharmSci,* 3 (4), 2001; available from: *http://www.aapspharmsci.org/*.

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22. ***Dutta S,*** Zhang Y, Selness DS, Lee LL, Ye X, Williams LA, and Sommerville KW: Comparison of the bioavailability of two novel 250 mg Depakote extended-release formulations relative to a 500 mg Depakote extended-release reference formulation in healthy volunteers. *American Epilepsy Society Annual Meeting (AES)*, November 30 - December 5, 2001, Philadelphia, Pennsylvania. Abstract published in *Epilepsia,* 42 (Suppl. 7): 88-89, 2001.

23. ***Dutta S,*** Cloyd JC, Granneman GR, and Sommerville KW: Evaluation of dosing strategies for IV and oral valproic acid (VPA) products in epilepsy using simulations. *American Society of Clinical Pharmacology and Experimental Therapeutics Annual Meeting (ASCPT)*, March 24 - 27, 2002, Atlanta, Georgia. Abstract published in *Clinical Pharmacology and Therapeutics,* 71 (2): P96, 2002.

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26. ***Dutta S,*** Cloyd JC, and Sommerville KW: Exploration, using simulations, of optimal IV valproic acid initiation intervals and maintenance regimens following IV loading in the typical patient in various epilepsy patient populations. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, November 10-14, 2002, Toronto, Canada. Abstract published in *AAPS PharmSci,* 4 (4), 2002; available from: *http://www.aapspharmsci.org/.*

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30. Reed RC, ***Dutta S***: What happens to steady-state plasma valproate concentrations when a patient misses a single daily dose of divalproex sodium extended-release tablets? - Computer simulation and dose replacement recommendation for the clinician. *American Academy of Neurology 55th Annual Meeting (AAN)*, March 29 – April 5, 2003, Honolulu, Hawaii. Abstract published in *Neurology,* 60 [Suppl 1]: A473, 2003.

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32. Cummins T, ***Dutta S***, Sommerville KW, Cloyd JC, Kearns GL: Pharmacokinetics and safety of divalproex ER in the pediatric population. *American Psychiatric Association 156th Annual Meeting (APA)*, May 17-22, 2003, San Francisco, California. Abstract published in *New Research Abstracts, American Psychiatric Association 2003 Annual Meeting*: 150, 2003.

33. ***Dutta S***, Reed RC, Cavanaugh J: Absolute bioavailability and absorption characteristics of divalproex sodium extended-release tablets in healthy volunteers. *American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS)*, October 26-30, 2003, Salt Lake City, Utah. Abstract published in *AAPS PharmSci,* 5 (4), 2003, Abstract W5224; available from: *http://www.aapspharmsci.org/*.

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41. Reed RC, ***Dutta S***: Forgetting to take a daily dose of divalproex sodium extended-release tablets beyond 12 hours: what is a patient to do? *American College of Clinical Pharmacology Annual Meeting (ACCP)*, October 3-5, 2004, Pheonix**,** Arizona. Abstract published in *Journal of Clinical Pharmacology,* 44 (10): 1201, 2004.

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