

CURRICULUM VITAE

Dhaval K. Shah, B.Pharm., M.S., Ph.D.

1. CONTACT INFORMATION

Department of Pharmaceutical Sciences
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2. EDUCATION

- August 2005 – Sept 2010 **Ph.D. in Pharmaceutical Sciences**
University at Buffalo, State University of New York School of
Pharmacy and Pharmaceutical Sciences
Graduate Advisor – Prof. Joseph P. Balthasar
Committee – Prof. William Jusko, Prof. Donald Mager
GPA: 3.93/4.00
Thesis Title: Pharmacokinetic strategy to improve the safety
and efficacy of intraperitoneal chemotherapy
- July 2004 – April 2005 **Ph.D. student**
Department of Pharmaceutical Sciences, North Dakota State
University, ND, USA
Graduate Advisor – Dr. Jagdish Singh
GPA: 4.00/4.00
- July 2002 – December 2003 **M.S. in Pharmaceutics**
Department of Pharmaceutics, National Institute of
Pharmaceutical Education and Research.
Graduate Advisor – Prof. Ramesh Panchagnula
GPA: 9.10/10.0
Thesis Title: The role of dehydration and transepidermal water
loss in skin barrier function
- June 1998 – April 2002 **Bachelor of Pharmacy**
K.B. Institute of Pharmaceutical Education and Research,
Gandhinagar, Gujarat, India
Percentage Score: 70% (3rd rank)

3. EMPLOYMENT HISTORY

- Sept 2024 – Present **Professor of Pharmaceutical Sciences**
School of Pharmacy and Pharmaceutical Sciences
University at Buffalo, State University of New York
- July 2018 – Aug 2024 **Associate Professor of Pharmaceutical Sciences**
School of Pharmacy and Pharmaceutical Sciences
University at Buffalo, State University of New York

Sept 2013 – June 2018	Assistant Professor of Pharmaceutical Sciences School of Pharmacy and Pharmaceutical Sciences University at Buffalo, State University of New York
March 2013 – Sept 2013	Principal Scientist, Pfizer Inc. Translational Research, Systems PK/PD Modeling and Simulation Group
Sept 2010 – March 2013	Senior Scientist, Pfizer Inc. Translational Research, Systems PK/PD Modeling and Simulation Group

4. AWARDS and HONORS

INDIVIDUAL AWARDS

2022	Outstanding Academic Investigator , 2022 World ADC Summit
2021	Top Reviewer by the Journal of Pharmaceutical Sciences.
2020	ISSX 2020 North American New Investigator Award.
2016	UB Exceptional Scholar: 2016 Young Investigator Award.
2014	American Association of Pharmaceutical Scientists (AAPS) Outstanding Manuscript in Modeling and Simulation Award obtained at the 2014 AAPS annual meeting held in San Diego. <u>Manuscript:</u> Shah D.K., Haddish-Berhane N., Betts A. Bench to bedside translation of antibody drug conjugates using a multiscale mechanistic PK/PD model: a case study with brentuximab-vedotin. J Pharmacokinet Pharmacodyn. 2012 Dec;39(6): 643-659.
2013	Individual Performance Award by Pfizer, Inc. for “demonstrating exceptional performance and leader behaviors on a daily basis”. This award was given for making translational PK/PD models of ADCs.
2012	Individual Performance Award by Pfizer, Inc. for “demonstrating exceptional performance and leader behaviors on a daily basis”. This award was given for leading the efforts to improve the culture of our working place.
2012	Publication titled " Bench to bedside translation of antibody drug conjugates using a multiscale mechanistic PK/PD model: a case study with brentuximab- vedotin." recommended for the Faculty of 1000 and covered on the front page of the Journal of Pharmacokinetics and Pharmacodynamics.
2011-Oct	Individual Performance Award by Pfizer, Inc. for “demonstrating exceptional performance and leader behaviors on a daily basis”. This award was given for my contribution towards the development of integrated bioanalytical methods for ADCs.
2011-Aug	Individual Performance Award by Pfizer, Inc. for “demonstrating exceptional performance and leader behaviors on a daily basis”. This award was given for developing and disseminating the translational PBPK model for protein therapeutics.
2010	Winner of the 2010 American Association of Pharmaceutical Scientists (AAPS) Graduate Student Symposium Award in PPDM and

- CPTR** at the 2010 International Pharmaceutical Sciences World Congress and AAPS annual meeting.
Poster: Shah D.K., Balthasar J.P. Treating ovarian cancer using combination of anti-angiogenic therapy and intraperitoneal chemotherapy. Presented at the American Association of Pharmaceutical Scientists (AAPS) annual meeting. New Orleans, LA. November 14, 2010.
- 2010** In recognition of quality of research work and accomplishments as a graduate student, elected to **"Who's Who Among Students in American Universities and Colleges"** by the Graduate School of SUNY, Buffalo.
- 2009** **UB Pharmaceutical Sciences Graduate Scholar Award**, the highest award given to a graduate student by the Department of Pharmaceutical Sciences.
- 2009** **American Association of Pharmaceutical Scientists (AAPS) Outstanding Manuscript** in Modeling and Simulation Award obtained at 2009 AAPS annual meeting held in Los Angeles.
Manuscript: Shah D.K., Shin B.S., Veith J., Tóth K., Bernacki R.J., Balthasar J.P. Use of an anti-vascular endothelial growth factor antibody in a pharmacokinetic strategy to increase the efficacy of intraperitoneal chemotherapy. J Pharmacol Exp Ther. 2009 May; 329(2):580-91.
- 2009** **First prize for the outstanding podium presentation** award at the Pharmaceutics Graduate Student Research Meeting held at the Purdue University.
Title: Shah D.K., Shin B.S., Veith J., Bernacki R.J., Balthasar J.P. A Pharmacokinetic Strategy to Increase the Efficacy of Intraperitoneal Chemotherapy. Presented at PGSRM conference held at Purdue University. West Lafayette, IN. May, 2009.
- 2009** **Best poster** and presentation award at University at Buffalo Sigma Xi Research Day held on the Celebration of Academic Excellence Day.
Poster: Shah D.K., Shin B.S., Veith J., Bernacki R.J., Balthasar J.P. A Pharmacokinetic Strategy to Increase the Efficacy of Intraperitoneal Chemotherapy.
- 2008** Nominated as **student representative to represent the Department of Pharmaceutical Sciences** at the office of University Communications at SUNY Buffalo.
- 2008** Nominated as the **Dean's Student Ambassador** by School of Pharmacy and Pharmaceutical Sciences at the University at Buffalo.
- 2007** **First prize for the poster** presented at Great Lake Symposium held at University of Pittsburgh.
Poster: Shah D.K., Shin B.S., Balthasar J.P. Simulations of the influence of antibody-ligand binding kinetics on the pharmacokinetics of "high-clearance" ligands.
- 2003** **Graduate scholarship** supported by the National Institute of Pharmaceutical Education and Research (NIPE), India.
- 2002** **2nd rank at national level entrance exam** conducted by Pharmaceutical Sciences Department at the National Institute of Pharmaceutical Education and Research (NIPE), India.
- 2002** **All India rank 4 with 99.89 percentile** in the National Graduate Aptitude Test (GATE) held by the Government of India.
- 2002** **3rd rank** in the final year Bachelors of Pharmacy exam held by the Gujarat

University at the KB Institute of Pharmaceutical Education and Research.

1996 Obtained the **National Student Scholarship** on basis of Secondary School Certificate examination.

STUDENT AWARDS

2020 **Presidential Trainee Award and a Top Poster Ribbon from ASCPT:** ASCPT 2020 Annual Meeting. **Hsuan Ping Chang**, for research work titled: *'FDA-labeled dosing of IFX falls short of target trough concentrations for pediatric IBD: a population PBPK modeling approach'*.

2020 **Allan Barnett Fellowship to Shufang Liu**, for the discovery of novel pH dependent antibody and antibody-drug conjugates to treat various kind of cancer.

2019 **Presidential Trainee and 2019 David Goldstein Award from ASCPT:** ASCPT 2019 Annual Meeting. **Antari Khot**, for research work titled: *'Measurement and Quantitative Characterization of Whole-Body Pharmacokinetics of Exogenously Administered T Cells in Mice'*.

2019 **Allan Barnett Fellowship to David Bussing**, for the discovery of novel antibody-drug conjugates to treat childhood eye cancer: retinoblastoma.

2019 **2nd prize:** AAPS Novel Approaches Target Brain Barriers for Effective Delivery of Therapeutics Workshop. Poster presented by **Hsueh Yuan Chang**, titled: *'A Translational Physiologically-Based Pharmacokinetic Model for Antibody Disposition in the Brain'*.

2018 **3rd prize:** SPPS undergraduate research poster presentation day. Poster presented by **Wanying Zhang**, titled: *'Endogenous T cell Redistribution in the Presence of Immuno-Oncology (I-O) Therapies'*.

2018 **3rd prize:** SPPS undergraduate research poster presentation day. Poster presented by **Yingyi Li**, titled: *'Towards Development of the Quantitative Relationship Between Protein Sizes and Tumor Exposure'*.

2017 **1st prize:** SPPS undergraduate research poster presentation day. Poster presented by **Jie Hong**, titled: *'Design and Generation of Humanized Anti- Topotecan Single Chain Variable Fragment (scFv) for Inverse Targeting Strategy'*.

2014 **1st prize:** SPPS undergraduate research poster presentation day. Poster presented by **Shabkhaiz Masih**, titled: *'Optimal Experimental Design for Preclinical Tumor Growth Inhibition Studies'*.

5. PROFESSIONAL MEMBERSHIPS AND ACTIVITIES

MEMBERSHIPS

2018-Present International Society for the Study of Xenobiotics (ISSX)

2015-Present International Society of Pharmacometrics (ISoP)

2018 Controlled Release Society (CRS)

2013-2014 The Obesity Society

2005-Present American Association of Pharmaceutical Scientists (AAPS)

2005-2010 Graduate Student Association – Department of Pharmaceutical Sciences UB, **Chair** (August 2008-July 2009)

2005-2010 American Association of Pharmaceutical Scientists-UB Student Chapter

MEMBER OF EDITORIAL ADVISORY BOARD OR GUEST EDITOR

2023	Guest Editor: the William J. Jusko Dedicated Issue of the Journal of Pharmaceutical Sciences (JPharmSci).
2021-Present	Member of the Executive Editorial Advisory Board: Biopharmaceutics & Drug Disposition
2018-Present	Member of the Executive Editorial Advisory Board: British Journal of Clinical Pharmacology
2017-Present	Member of the Executive Editorial Advisory Board: The American Association of Pharmaceutical Scientists (AAPS) Journal
2016	Guest Editor: The American Association of Pharmaceutical Scientists (AAPS) Journal - Theme issue titled "Systems Pharmacokinetics Models for Antibody-Drug Conjugates".
2015- Present	Member of the Editorial Advisory Board: Journal of Pharmacokinetics and Pharmacodynamics

GRANT REVIEWS

2023	Special Emphasis Panel (SEP), SEP-5: NCI Clinical and Translational Cancer Research (ZCA1 SRB-K O1)
2023	NIH/NCI review for RFA-CA-21-059: The NCI Predoctoral to Postdoctoral Fellow Transition Award (F99/K00)
2023	RFA-NS-21-010: HEAL Initiative Non-addictive Analgesic Therapeutics Development [Small Molecules and Biologics] to Treat Pain (UG3/UH3)
2022	NCI Clinical and Translational 2022/10 ZCA1 TCRB-V (O1) S
2022	NIH/NCI review for RFA-CA-21-059: The NCI Predoctoral to Postdoctoral Fellow Transition Award (F99/K00)
2022	Penn State University Clinical and Translational Science Institute (CTSI) Bridges to Translation RFA VII
2021	NCI Clinical and Translational ZCA1 TCRB-V (O1) S
2021	Israel Science Foundation
2020	NCI Clinical and Translational ZCA1 TCRB-V (O1) S
2020	NIH reviewer for Special Emphasis Panel NIHZRG1 MDCN-M (91) S Neuroscience Special Emphasis Panel
2019	NIGMS ESI MIRA: Bioengineering
2018	Ad hoc reviewer, Cancer Society of New Zealand - 2018 National Research Grant Round.
2016-2017	NIH reviewer for Special Emphasis Panel ZRG1 EMNR-R(56) on Early-Stage Pharmacological Validation of Novel Targets and Accompanying Pre- Therapeutic Leads for Diseases of Interest to the NIDDK.
2015	Ad hoc reviewer, Ontario Centers of Excellence (OCE) and Québec Consortium for Drug Discovery (CQDM) - Life Sciences Program grant applications.

SCIENTIFIC JOURNAL REVIEW

For each journal year(s) of activity along with number of publications reviewed are provided.

Reviews performed as the Associate Professor have * next to them.

- Acta Biomaterialia (2023)*
- American Association of Pharmaceutical Scientists (AAPS) Pharm. Sci. Tech. (2015,2016)
- Advanced Drug Delivery Reviews (ADDR) (2020,2021)*
- Antibodies (2018,2021)*
- Bioanalysis (2016-2022, total 8)*
- Biomedicine and Pharmacotherapy (2022)*
- Biopharmaceutics & Drug Disposition (2021-2022, total 4)*
- Biotechnology Journal (2018)*
- BMJ (2014)
- Bone Marrow Transplant (2018, 2019)*
- Brazilian Journal of Pharmaceutical Sciences (2020)*
- British Journal of Clinical Pharmacology (2016-Now, total >20)*
- British Journal of Pharmacology (2021, 2022)*
- Cancer Chemotherapy and Pharmacology (2013-2021, total 3)*
- Cancer Research (2018, total 2)*
- Cancers (2019)*
- Clinical and Experimental Gastroenterology (2022)*
- Clinical and Translational Science (2015, 2019)*
- Clinical Cancer Research (2020, total 3)*
- Clinical Pharmacokinetics (2016-2017, total 3)
- Clinical Pharmacology & Therapeutics (2020-2023, total 5)*
- CPT: Pharmacometrics & Systems Pharmacology (2015-Now, Total >10)*
- Current Drug Delivery (2020, total 2)*
- Cytometry Part B - Clinical Cytometry (2015)
- Drug Metabolism and Disposition (2014-Now, total 8)*
- Drug Discovery Today (2020)*
- Drug Discovery Today – Technologies (2016)
- eLife (2022)*
- Engineering (2019, 2020)*
- European Journal of Cancer (2021)*
- European Journal of Drug Metabolism and Pharmacokinetics (2015, total 2)
- European Journal of Pharmaceutical Sciences (2015-2022, total 4)*
- Expert Opinion on Biological Therapy (2020)*
- Expert Review of Clinical Pharmacology (2022)*
- Exploration of Targeted Anti-tumor Therapy (2022)*
- Frontiers Pharmacology (2020, 2022)*
- Future Oncology (2017)
- Integrative Biology (2014)
- International Immunopharmacology (2021)*
- International Journal of Cancer and Clinical Research (2016)
- International Journal of Pharmaceutics (2018)*
- Investigational New Drug (2017)
- Journal of Biotechnology (2016)
- Journal of Controlled Release (2019-2022, total 6)*
- Journal of Clinical Medicine (2019)*
- Journal of Material Chemistry B (2019)*
- Journal of Nuclear Medicine (2018)*
- Journal of Pharmacokinetics and Pharmacodynamics (2013-Now, total >20)*
- Journal of Pharmacology and Experimental Therapeutics (2013-Now, total 8)*
- Journal of Pharmacy and Pharmacology (2019)*
- Journal of Physics A Mathematical and Theoretical (2019)*
- Journal of the Royal Society Interface (2021)*
- JOVE (2021)*

- Life (2023)*
- Life Sciences (2020)*
- MAbs (2013-Now, total >15)*
- Materials (2021)*
- Mathematical Biosciences and Engineering (2020)*
- Molecular Therapy - Methods & Clinical Development (2022)*
- Molecules (2016)
- Molecular Cancer Therapeutics (2017-2022, total 7)*
- Nature Communications (2021-2023, total 3)*
- Nature Reviews Clinical Oncology (2020, 2021)*
- NPJ Systems Biology and Applications (2019, 2020)*
- Oncology Letters (2018)*
- Oncology Reports (2017)
- Oncotarget (2017, 2019)*
- Pharmaceutical Research (2017-Now, Total >10)*
- Pharmaceutical Patent Analyst (2016)
- Pharmaceutics (2020-2022, total 6)*
- Pharmacology Research & Perspectives (2019)*
- PLOS Computational Biology (2017-2022, total 7)*
- PLOS ONE (2016, 2023)*
- Protein Engineering, Design, and Selection (2016)
- Regulatory Toxicology and Pharmacology (2018-2022, total 3)*
- Saudi Pharmaceutical Journal (2020)*
- Scandinavian Journal of Immunology (2019)*
- Scientia Pharmaceutica (2015)
- Scientific Reports (2017-2022, total 4)*
- The Journal of Immunology (2021)*
- Therapeutic Advances in Medical Oncology (2020)*
- The AAPS Journal (2013-Now, total >20)*
- Therapeutic Advances in Medical Oncology (2020)*
- Toxicon (2022)*
- Translational Breast Cancer Research (2021)*
- Trends in Pharmacological Sciences (2020)*
- Tumor Biology (2016)
- Vaccines (2022)*
- Xenobiotica (2018)*

ADVISORY COMMITTEES

None

CONFERENCE ADVISOR/MODERATOR

2022	Meeting Organizing Committee: 2023 ISSX Annual Meeting . Boston, MA.
2021	Moderator for Symposium title 'Latest Developments for Assessing the ADME of Biologics' at ISSX 24th North American Meeting . Online. September 2021.
2019	Organizer for ISSX's first ADME workshop on Disposition of Biologics . Merck campus, Boston. December 12-13, 2019.
2018	Moderator at the 2018 Controlled Release Society Mini-Symposia: Antibody-Drug Conjugates. NYC, NY. July 24, 2018.
2015	Moderator at the 2015 Gordon Research Conference on Drug Metabolism. Session titled 'Understanding and Predicting the Metabolism and Pharmacokinetics of Biologics'. Holderness, NH. July 15, 2015.

- 2014** Moderator and speaker: **PK of ADCs and Improving Performance** sessions, at the **PEGS Conference** organized by Cambridge HealthTech Institute, Boston, MA. May 5-6, 2014.
- 2013** Advisory board member, session chair, and speaker: 2013 **PK/PD of Novel Biological Construct conference** organized by Cambridge HealthTech Institute, Boston, MA. November 11-12, 2013.
- 2013** Advisory board member: **Bioanalytical Method & Modeling Integration Summit** organized by EXL Pharma, Baltimore, MD. September 16–18, 2013.
- 2012** Advisory board member, session chair, and speaker: The **3rd Pharmacokinetics & Pharmacodynamics conference** organized by GTC Bio, Philadelphia, PA. October 24-26, 2012.
- 2012** Moderator and speaker: Breakout session on PK/PD Models for ADCs at the **PK/PD of Novel Constructs Conference** organized by Cambridge HealthTech Institute, Boston, MA. October 10-12, 2012.
- 2011-2013** **Chair: Global PK/PD Network at Pfizer Inc.** Groton, CT.

6. UNIVERSITY SERVICE

Department of Pharmaceutical Sciences, University at Buffalo, SUNY

- 2023** **Member** – Faculty search committee for Drug Discovery, Development and Evaluation Hub
- 2022** **Member** – Faculty search committee for the chair of the Department of Pharmaceutical Sciences
- 2022-Now** **Faculty Advisor** – Student Chapter: Industry Pharmacists Organization
- 2020-Now** **Faculty Advisor** – Student Chapter: American Association of Pharmaceutical Scientists
- 2020** **Chair** – Faculty search committee for Empire Innovation Professor in Protein Engineering
- 2019** **Chair** – Committee on Evaluation of BS in Pharm. Sci. program
- 2018-2021** **Member** – Admissions Committee, Department of Pharmaceutical Sciences
- 2015** **Chair** - Gerhard Levy Distinguished Lectureship.
- 2014-2015** **Chair** - Pharmaceutical Sciences Seminar. Detailed program is available on the following link: <https://buffalo.box.com/s/mae9g0uytckl4z9ikvydsnlapyqpa2gz>
- 2014** **Chair** - David Chu Lecture.

School of Pharmacy and Pharmaceutical Sciences, University at Buffalo, SUNY

- 2022-Now** **Member**: Curriculum Committee for the School of Pharmacy and Pharmaceutical Sciences
- 2020-Now** **Faculty Advisor** – Student Chapter: Industry Pharmacists Organization.

2022	Member – Search committee for the assistant to the Vice Dean of Academic Affairs.
2022	Member: Curriculum Structure Working Group
2018-2022	Member: Academic Affairs Committee for the School of Pharmacy and Pharmaceutical Sciences
2015-2020	Member: School of Pharmacy and Pharmaceutical Sciences Standing Committee for Research.
2016-2022	Member: School of Pharmacy and Pharmaceutical Sciences Student Advisement Committee.
2016-2018	Member: School of Pharmacy and Pharmaceutical Sciences Teacher of the Year Committee.
2017-2018	Pharmacy Practice Faculty Search and Recruitment Committee

University at Buffalo, State University of New York, Buffalo, NY

2021	Member: SUNY led “smart” bio-manufacturing hub.
2020-Now	Member: Grievance Committee , University at Buffalo.
2016-2019	Member: Honors College Research Award Committee, University at Buffalo.
2016-2019	Faculty mentor for annual UB Interprofessional Education (IP E) forums.
2014-Now	Faculty mentor for CLIMB-UP Program.

7. COURSES TAUGHT

Course Coordinator and/or Chief Lecturer

Basic Pharmaceutical Principles in Drug Development (graduate, required) (PHC 500, 2 Credits, 2-hr lecture) Fall Semesters (even years)

Course Coordinator and sole lecturer: 2020-Present

Provided 13 2-hr lectures and coordinated mid-term and final exams.

“Drug candidate selection and attrition”

“Lipinski’s Rule of 5”

“Biopharmaceutical Classification System & FDA Guidance on BA/BE Study Waiver”

“Biopharmaceutics Drug Disposition Classification System (BDDCS)”

“Solubility principles and solubilization”

“History of Dissolution and F2 statistics”

“IVIVC-FDA guidance and application”

“Intestinal Permeability & Absorption”

“Extended Clearance Classification System (ECCS)”

“Chemical Kinetics and Drug Stability”

“Prodrugs”

“Non-Invasive Systemic Drug Delivery”

“BA/BE-Bioavailability and Bioequivalence”

Introduction to Pharmacokinetics and Biopharmaceutics-II (PharmD/BS, required)
(PHC 412/532, 3 Credits, 1-hr lecture) Spring Semesters
Course Coordinator, Lecturer, and Exam Coordinator: 2013-Present

Provided 14 1-hr lectures:

“PK Variability 4: Hepatic Disease”
“PK Variability 5: Renal Disease”
“PK/PD Variability Optimization & Apps”
“Drug Drug Interaction 1 - Enzyme inhibitors”
“Drug Drug Interaction 2 - Enzyme Inducers”
“Drug Drug Interaction 3 - Transporter interactions”
“Drug Drug Interaction 4 -Protein binding interactions”
“Phenytoin – 1”
“Phenytoin – 2”
“Phenytoin Case Study”
“Carbamazepine / Valproic Acid”
“Ethanol PK”
“PK/PD of Anti-Cancer Agents-1”
“PK/PD of Anti-Cancer Agents-2”

Pharmacokinetics and Pharmacodynamics of Protein Therapeutics (graduate, elective) (PHC 611, 2 Credits, 2-hr lecture) Spring Semesters (even years)
Course Coordinator and sole lecturer: 2016-2018

Provided 14 2-hr lectures and coordinated the final exam.

“Introduction-1: Protein therapeutics - classification, mAb and derivatives, next generation”
“Introduction-2: Protein therapeutics - classification, mAb and derivatives, next generation”
“ADME: Protein therapeutics”
“Transporters/Receptors for Proteins and Peptides”
“Factors Affecting Protein PK/PD-1: TMDD, Immunogenicity, DDI”
“Factors Affecting Protein PK/PD-2: TMDD, Immunogenicity, DDI”
“Bioanalytical Techniques for PK/PD of Protein Therapeutics”
“Limitations of NCA & Mammillary Compartmental Modeling”
“Whole Body PBPK Models for Protein Therapeutics-1”
“Whole Body PBPK Models for Protein Therapeutics-2”
“Tissue Specific PBPK Models for Protein Therapeutics”
“Advanced Systems Models for Protein Therapeutics”
“Allometric Scaling and FIH Dose Selection”
“Clinical Dosing of Protein Therapeutics”

Pharmaceutical Chemistry: The Chemical Basis of Drug Action (PharmD/BS, required)
(PHC 401/501, 3 Credits, 1.5-hr lecture) Fall Semesters
Course Coordinator: 2017

Course contributor (7 lectures): 2016

Provided 7 1.5-hr lectures and coordinated second exam.

“Protein Chemistry”
“Drug Interactions-I”
“Drug Interactions-II”
“Drug Interactions-III”
“Stereochemistry-I”
“Stereochemistry-II”
“Stereochemistry-III”

Pharmaceutics Seminar, Department of Pharmaceutical Sciences (graduate/BS, elective)
(PHC 413/613, 1 Credit, 1.5-hr seminar) Fall Semesters
Course Coordinator: 2014
Coordinated 16 1.5-hr seminars.

Pharmaceutics Seminar, Department of Pharmaceutical Sciences (graduate/BS, elective)
(PHC 414/614, 1 Credit, 1.5-hr seminar) Spring Semesters
Course Coordinator: 2015
Coordinated 17 1.5-hr seminars.

Lecturer

Apothecarial Adventures (BS, required)
(PHC 250, 3 Credits, 3-hr lecture) Fall Semesters
Lecturer: 2013-2015
Provided 3-hr lecture on “Treatment of Cancer_Does One Size Fit All”

Introduction to Research (BS, required)
(PHC 332, 1 Credit, 1-hr lecture) Spring Semesters
Lecturer: 2014-2016
Provided 1-hr lecture on “Drug Discovery-Development & Translational Research in Pharmaceutical Industry”

Faculty Research Seminar (graduate/BS, required)
(PHC 488/588, 1 Credit, 1-hr lecture) Fall Semesters
Lecturer: 2013-Present
Provided 0.5-hr lecture on “Introduction and Opportunities for Research at Shah Lab”

Drug Delivery: Principles and Applications (graduate, required)
(PHC 508, 2 Credits, 2-hr lecture) Fall Semesters (odd years)
Lecturer: 2013-Present
Provided 1-hr lecture and 1-hr homework discussion on “Targeted Drug Delivery Using Antibody-Ligand Based Approaches”

Pharmaceutical Analysis (graduate, required)
(PHC 510, 3 Credits, 2-hr lecture) Spring Semesters
Lecturer: 2016-Present
Provided 2-hr lecture on “Labeled Immunoassays”

Protein Pharmaceuticals (graduate, required)
(PHC 539, 2 Credits, 2-hr lecture) Fall Semesters
Lecturer: 2015-Present
Provided seven 2-hr lecture on the following topics.

“Protein Structure II: mAb and derivatives, next generation”
“Pharmacokinetics I: ADME and Principles of Protein PK”
“Pharmacokinetics II Transporters/Receptors for Proteins and Peptides”
“Pharmacokinetics III: PBPK Models for Protein therapeutics”
“Pharmacokinetics IV: Advanced systems models for protein therapeutics”
“Pharmacokinetics V: Allometric Scaling FIH dosing”
“Immunogenicity II: Impact of immunogenicity on PK”

Advanced Pharmacokinetics (graduate, elective)
(PHC 608, 3 Credits, 2-hr lecture) Spring Semesters (even years)
Lecturer: 2016-Present
Provided 1-hr lecture and 1-hr homework discussion on “PBPK Models for Protein Therapeutics”

Advanced Pharmacodynamics (graduate, elective)

(PHC 609, 3 Credits, 2-hr lecture) Spring Semesters (odd years)

Lecturer: 2015-Present

Provided 1-hr lecture and 1-hr homework discussion on “Modeling Drug Effects on Solid Tumors”

Drug Metabolism and Disposition (graduate, required)

(PHC 630, 3 Credits, 2-hr lecture) Spring Semesters (even years)

Lecturer: 2014, 2016

Provided 2-hr lecture on “Protein Metabolism: From Pharmaceutical Perspective”

Teaching Assistant

2008 PHC-533: Applied Clinical Pharmacokinetics (Instructor: Dr. Jerome Schentag)

2007 PHC-311: Pharmaceutical Calculations (Instructor: Dr. Murali Ramanathan).

2007 PHC-516: Clinical Research Methods (Instructor: Dr. Jerome Schentag)

2006 PHC-607: Intermediate Pharmacokinetics (Instructor: Dr. Joseph P. Balthasar).

8. RESEARCH SUPERVISION

POST-DOCTORAL FELLOWS

So far I have mentored 9 post-doctoral fellows, from which 1 is still with me, some have gone to become a member of pharmaceutical industry and some have become faculty members in academic institutions.

Sharad Sharma, Ph.D. December 2014 – October 2016. Currently at MacroGenics Inc. Project: Development of novel Antibody-Drug Conjugates and understanding the determinants for PK/PD of these molecules.

Contributed to publication # 30, 38, 62, 64, 65, 67.

Chunxia Qiao, Ph.D. October 2015 – August 2017. Currently at Beijing Institute of Pharmacology and Toxicology

Project: Discovery of novel protein therapeutics using antibody engineering.

Contributed to publication # 51, Poster # 1,2,3,6,7, and will be part of 2 pending patents.

Ray Guo, Ph.D. June 2016 – June 2019. Currently in biotech industry in China.

Project-1: Evaluating the combination of mAb and ADC to overcome the binding-site-barrier Project-2: Development of phage display library for the discovery of novel monoclonal antibodies.

Contributed to publication # 3, 16, 22, 37, 39, 41, 50, 51.

Di Wu, Ph.D. July 2016 – Dec 2019. Currently an independent contractor.

Project: Development of pediatric PBPK model for monoclonal antibodies and other protein therapeutics.

Contributed to publication # 27.

Ashwni Verma, Ph.D. June 2017 – June 2022. Currently in biotech industry in India.

Project: Investigation of various immune-oncology therapeutics and combination regimens thereof.

Contributed to publication # 3, 19, 22, 23, 29, 37, 39, 50.

Divyesh Shastri, Ph.D. June 2018 – June 2019. Currently a professor at the K.B. Institute of Pharmaceutical Education and Research, India.

Project: Development of novel sustained release formulations to modulate the pharmacokinetics of protein therapeutics.

Contributed to publication # 9.

Ekram Chowdhury, Ph.D. Aug 2020 – October 2022. Currently in the clinical pharmacology department at Abbvie.

Project: Development of a quantitative systems pharmacology model to understand brain disposition of AAV9 and monoclonal antibodies delivered via the viral vector.

Contributed to publication # 6, 13, 34, and 2 more papers in preparation.

Manuj Ahuja, Ph.D. Jan 2021 – December 2022. Currently in the clinical pharmacology department at BMS.

Project: Development of in vitro systems to facilitate the discovery of novel CNS targeted biologics.

Contributed to 2 publications in preparation.

Cheng Wang, Ph.D. Fall 2022 – Present

Project: Development of quantitative systems toxicology models for antibody-drug conjugates.

Ph.D. STUDENTS

So far, I have mentored 13 PhD students, from which 6 are still with me, and the rest have went on to become scientists in pharmaceutical industry.

Amanpreet Singh, October 2013 – October 2018

Current Position: Associate Director, Quantitative and Clinical Pharmacology, Takeda.

Project: Understanding and mathematically characterizing the disposition of Antibody-Drug Conjugates (ADCs).

Contributed publication # 37, 39, 49, 50, 58, 61, 62, 63, 68, book chapter # 6, and poster # 14.

Lyndsey Meyer, February 2014 – April 2019

Current Position: Researcher at Pfizer.

Project: Development of novel anti-obesity treatment using oxidative phosphorylation uncouplers.

Contributed to publication # 20, 30, 46, and poster # 5, 8, 10, 12, 13.

Antari Khot, June 2014 – Jan 2020

Current Position: Clinical Pharmacology, Takeda.

Project: Development of systems pharmacokinetics (PK) models for novel protein therapeutics.

Contributed to publication # 48, 52, 57, 63, 67, and poster # 6, 7, 16, 18, 24.

Zhe Li, September 2015 – October 2020

Current Position: Senior Clinical Pharmacokineticist, Abbvie.

Project: Development of a platform physiologically-based pharmacokinetic (PBPK) model for protein therapeutics.

Contributed to publication # 18, 23, 29, 30, 31, 38, 41, 44, 53, 60, 65, and poster # 6, 7.

David Bussing, January 2016 – October 2021

Current Position: Pharmaceutical Scientist, Eli Lilly

Project: Understanding and mathematically characterizing the ocular disposition of protein therapeutics.

Contributed to publication # 3, 23, 30, 35, 38, and poster # 4, 21.

Hsueh Yuan Chang, August 2016 – January 2021

Current Position: Senior Scientist, Boehringer Ingelheim

Project: Development of brain physiologically-based pharmacokinetic (PBPK) model for protein therapeutics.

Contributed to publication # 13, 16, 23, 33, 34, 41, 42, 54, poster # 15.

Juliany Marrero Vega, August 2017 – January 2019 (Withdrawn from the program)

Current Position: Quality Assurance Manager at Care/of

Project: Understanding the disposition of different size protein therapeutics in rat brain.

Shufang Liu, August 2018 – Present

Project: Development of Acid-Switch ADC and PBPK model for antibodies with different physicochemical properties.

So far, contributed to publication # 1, 5, 14, 22, and book chapter # 1.

Shengjia Wu, August 2019 – Present

Project: Development of novel biologics for glioblastoma.

So far, contributed to publication # 6, 11, 13, 15, 16, 33, 34, 42, and book chapter # 3.

Hsueh Ping Chang, August 2019 – Present

Project: Understanding whole-body disposition of ADCs.

So far, contributed to publication # 2, 18, 21, 23, 25, 26, 27, 29, 31, 36, 41, and book chapter 4.

Mokshada Kumar, August 2020 – Present

Project: Development of yeast display libraries to discovery novel monoclonal antibodies against immuno-oncology targets.

So far, contributed to publication # 5, 28.

Sanika Naware, August 2021 – Present

Project: Quantitative evaluation of the disposition of biologics in the eye.

Hsien Wei Huang, August 2022 – Present

Project: Investigation of the role of FcRn in the brain PK of antibodies.

So far, contributed to publication # 34.

M.S. STUDENTS

So far, I have mentored 36 MS students, of which 14 are still with me. While some MS students manage to publish their work, many assist grad students and post-docs as an early learning experience to get the skills and knowledge needed for their next career goal.

Zhe Li, October 2013 - September 2015. Currently pursuing PhD at UB

Project: Influence of molecular size on tissue distribution and clearance of antibody fragments.

Shabkhaiz Masih, August 2014 - September 2016. Currently at Genentech Inc.

Project: Understanding the elimination mechanism for ADCs with Higher DAR.

Sharif Soleman, August 2014 - September 2015. Transfer to another lab.

Project: Understanding and mathematically characterizing the effect of tumor size on tumor PK of anticancer drugs.

Hsueh Yuan Chang, October 2014 - September 2016. Currently pursuing PhD at UB

Project: Understanding and mathematically characterizing the brain disposition of mAbs.

Keith Dolcy, October 2016 - May 2017. Currently at Walgreens (San Francisco)

Project: Estimation of Solid Tumor Doubling Times from Progression-Free Survival Plots using a Novel Statistical Approach.

Morgan Rudick, October 2015 – Fall 2017. Currently at ImmunoGen, Inc. (Boston)

Project: Development of novel Antibody-Drug Conjugates (ADCs) for the treatment of retinoblastoma.

Srividya Myneni, November 2015 – Fall 2017 Currently a Scientific Researcher at Genentech Inc. (San Francisco)
Project: Discovery and development of novel antibody for targeting glioblastoma, brain, and adipocytes.

Farah Al Qaraghuli, August 2016 – Feb 2020
Project: Endogenous T-Cell Redistribution in the Presence of Immuno-Oncology Treatments.

Kasey Morrow, January 2017 – May 2018 (Withdrawn from the program)
Project: Evaluation of novel protein therapeutics for the treatment of Staphylococcal Enterotoxin B (SEB) exposure.

Hsuan Ping Chang, August 2017 – Fall 2019
Project: Understanding the whole body PK of ADCs and development of PBPK model for ADCs.

Shengjia Wu, August 2017 – Fall 2019
Project: Development of novel PDCs/ADCs for the treatment of glioblastoma.

David Beaman, August 2017 – May 2018 Currently at Regeneron Pharmaceuticals (Withdrawn from the program)
Project: Understanding whole body PK and PK-PD of fragment-drug conjugates (FDCs).

Wanying Zhang, January 2018 – Feb 2020
Project: Endogenous T-Cell Redistribution in the Presence of Immuno-Oncology Treatments.

Yagnavalkya Devarakonda, June 2018 – May 2020
Project: Discovery of novel protein therapeutics for amyotrophic lateral sclerosis (ALS, Lou Gehrig's disease).

Xiaoying Yu, Fall 2018 – January 2021
Project: Understanding whole-body PK of CAR-T cells

Yingyi Li, Fall 2018 – January 2021
Project: Development of FDCs and evaluation of their PK/PD

Pooja Rajadhyaksha, Fall 2018 – September 2020
Project: Evaluation of phosphorylation uncouplers as anti-obesity agents.

Mokshada Kumar, Spring 2019 – August 2020
Project: Development of EGFR targeted acid-switch ADCs.

Yuelin Li, Fall 2018 – September 2020
Project: Development of CAR-T for glioblastoma.

Sanika Naware, Fall 2019 – Fall 2021
Project: Development of translational PBPK model for ocular disposition of protein therapeutics.

Anthony Jerez, Fall 2019 – Fall 2022
Project: Development of lateral flow immunoassays.

Yao Heng Huang, Fall 2019 – Present
Project: Humanization of anti-RAGE mAb.

Yuen Kiu Cheung, Fall 2020 – Present

Project: Development of PBPK models for ADCs.

Hsien Wei Huang, Fall 2019 – Fall 2022

Project: Investigation of T-cell disposition in the brain.

Anne Nguyen, January 2021 – Present

Project: Application of yeast display technology to discovery novel antibodies for the treatment of IgA vasculitis.

Aneesh Rajwade, December 2021 – Present

Project: Development of novel therapies using AAV-based gene delivery.

Alka Yadav, December 2021 – Present

Project: Comprehensive Quantitative Analysis of Clinical PK Data Generated using MABs.

Leeha Mahmood, September 2022 – Present

Project: Development of POC applications for monoclonal antibodies.

Sirisha Presingu, September 2022 – Present

Project: Development of PBPK model for ADCs.

Sravani Lanke, September 2022 – Present

Project: Evaluation of the effect of ontogeny on clinical PK of antibodies.

Shweta Jogi, September 2022 – Present

Project: Evaluation of the lung PK of protein therapeutics.

Shrusti Tiwari, September 2022 – Present

Project: Development of LNPs for gene delivery.

Aditi Panchal, September 2022 – Present

Project: Investigation of the brain PK of protein therapeutics.

Lav Patel, September 2022 – Present

Project: Development of display technologies for the discovery of novel antibodies.

Sree Oiji, September 2022 – Present

Project: Understanding the role of pharmacogenomics in PK/PD of biologics.

Lalasa Vavilthota, September 2022 – Present

Project: Development of antibody/gene based therapy for epilepsy.

Pharm.D. STUDENTS

Keith Dolcy, Fall 2015- Fall 2016

Project: Treating obesity using gene delivery.

Eunbyeol (Natalia) Goh, Spring 2015- Fall 2015

Project: In vitro cytotoxicity screening for novel anticancer drugs.

Parul Mital, Fall 2015- Summer 2016

Project: In vitro cytotoxicity screening for novel anticancer drugs.

Ebne Rafi, Fall 2016- Fall 2017

Project: Understanding the PK of vancomycin in cystic fibrosis pediatric patients.

Kateryna Zarudna, Spring 2017- Fall 2017

Project: Development of vc-Doxorubicin liker for making novel ADCs.

Melissa Dhanraj, Summer 2017 – Fall 2017

Project: Evaluation of CRISPR/Cas9 for the development of anti-obesity therapeutics

Quoc Van Anh Pham, Summer 2017 – Fall 2017

Project: Evaluation of oxidative phosphorylation uncouplers as anti-obesity therapeutics.

Nicholas Cashman, Fall 2017 – Fall 2019

Project: Investigation of the prevalence of immunogenicity against protein therapeutics.

Lydia Deinhart, Fall 2017 – Fall 2019

Project: Evaluation of saliva as a surrogate for systemic concentrations of protein therapeutics.

Navaldeep Singh, Spring 2019 – Fall 2020

Project: Development of test strips for detection of immunogenicity against protein therapeutics.

Se Jin Kim, Fall 2017 – Fall 2021

Project: Potential of CRISPR/Cas-9 as pharmaceutical and therapeutic modality.

Navya Desireddy, Fall 2022 – Present

Project: Comprehensive summarization of most frequently used medicines for pediatric population.

B.S. STUDENTS

Yun Jeong Jang, Fall 2013 – Spring 2014

Project: In vitro cytotoxicity of trastuzumab

Yong Hee Lee, Fall 2013 – Spring 2014

Project: Differentiation of 3T3-L1 adipocytes

Shabkhaiz Masih, Fall 2013 – Spring 2014

Project: Optimal Experimental Design for Preclinical Tumor Growth Inhibition Studies

Samuel Kim, Fall 2014 – Spring 2015

Project: In vitro cytotoxicity screening for novel anticancer drugs

Phillip Tran, Fall 2015

Project: Development of novel anti-obesity treatment using oxidative phosphorylation uncouplers.

Jie Hong, Fall 2015 – May 2017

Project: Development of humanized 8C2 scFv for inverse-targeting strategy to improve the IP chemotherapy of ovarian cancer.

Wanying Zhang, Fall 2016 – Fall 2017

Project: Analysis of brain microdialysis samples using ELISA

Mahmud Bhuiyan, Spring 2017 – May 2018

Project: Development of peptide-drug conjugate for treating glioblastoma

Hasan Kumar Bhandari, Summer 2017- May 2018

Project: In vitro and in vivo evaluation of T-cell Engaging Bi-Specific Antibodies.

Xiaoying Yu, Fall 2016 – Fall 2018

Project: In vitro evaluation of Azonafide ADCs

Yingyi Li, Fall 2016 – Fall 2018

Project: Development of Fab and F(ab)₂ fragments of monoclonal antibodies

Sara Armstrong, Fall 2017 – May 2018

Project: Understanding brain disposition of monoclonal antibodies using microdialysis.

Mairead Heavey, Fall 2017 – Spring 2019

Project: Evaluation of anti-SEB sweeping antibody as a therapy against MRSA induced sepsis.

Pooja Rajadhyaksha, Fall 2017 – Fall 2018

Project: Evaluation of phosphorylation uncouplers as anti-obesity agents.

Anthony Keung, Fall 2017 – Fall 2018

Project: Development of peptide-drug conjugates for treating glioblastoma.

Yuelin Li, Fall 2017 – Fall 2018

Project: Investigation of endogenous T-Cell redistribution in the presence of immuno-oncology treatments.

Yao Heng Huang, Spring 2019 – Spring 2020

Project: Development of acid-switch ADCs.

Anthony Jerez, Spring 2019 – Spring 2020

Project: Development of test strips for detection of immunogenicity against protein therapeutics.

Anne Nguyen, Spring 2020 – Fall 2020

Project: Development of QSPKR relationships for protein therapeutics.

Harley Le, Fall 2021 – Present

Project: Investigation of novel routes of administration for ADCs.

Sara Hahn, Fall 2021 – Present

Project: Development of novel therapies for congenital pediatric disorders.

Navya Desireddy, Fall 2021 – Fall 2022

Project: Comprehensive summarization of most frequently used medicines for pediatric population.

Bao Ly, Fall 2021 – Present

Project: In vivo evaluation of novel ADCs to treat retinoblastoma.

Minority and Other Students via CLIMB-UP Program

Alyssa Gbewonyoa, Summer 2014

Project: Towards Treating Obesity with Targeted Delivery of Protonophores.

Benita Okeke, Summer 2015

Project: Effects of drug loading on ADC pharmacokinetics.

Zoe Vaughn, Summer 2016- Spring 2018

Project: Development of novel linker for ADCs.

Caitlin Deubell, Summer 2017

Project: Development of flow cytometry based analytical method to quantify bi-specific T-cell engaging (BiTE) molecules in mouse plasma.

Rose Durnell, Summer 2018

Project: Evaluation of ocular PK of protein therapeutics.

Abigail Buckley, Summer 2019

Project: Development of peptide-drug conjugates to treat glioblastoma.

Destiny Osborne, Summer 2021

Project: Development of novel ADCs to treat retinoblastoma.

Bradley Balk, Summer 2021

Project: Discovery of novel antibodies using yeast-display technology.

Maygha Chowdhury, Summer 2022

Project: Discovery of novel natural product derived chemicals to treat cancer.

Visiting Students**Alexandra Van Hall, Fall 2015 - Spring 2016**

Project: Synthesis of novel linker-payload combination for ADCs.

Yu (Zoe) Tang, Fall 2015 – Spring 2016

Project: Population PK/PD modeling of ADC.

Maxwell Scott, Summer 2017

Project: In vitro evaluation of Oncolinx ADCs.

Gloria Wong, Spring 2017 – Fall 2018

Project: In vivo tumor growth inhibition studies with ADCs and monoclonal antibodies.

Soham Shah, Summer 2022 - Present

Project: Discovery of novel natural product derived chemicals to treat cancer.

Sanjida Riea, Summer 2022 – Present

Project: Investigation of the brain PK of protein therapeutics.

Thesis Advisory Committee Member**Patrick Glassman, PhD Committee Member, 2013-2016**

Dissertation title: PBPK models of mAb.

Veena Thomas, PhD Committee Member, 2014-2018

Dissertation title: Investigation of Interindividual variability in Monoclonal Antibody Pharmacokinetics.

Andrew Kroetsch, PhD Committee Member, 2015-2019

Dissertation title: Optimized Engineering Platform for Generation of a pH Sensitive Antibody.

Ryan Polli, PhD Committee Member, 2016-2019

Dissertation title: Development and Assessment of “Catch-and-Release” Immunoconjugates as Anti-Cancer Constructs.

Van Anh Nguyen, PhD Committee Member, 2016-2019

Dissertation title: investigation of anti-CD20 therapy outcomes and combination strategies in chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

Alexandria Trujillo, PhD Committee Member, 2016-2019

Dissertation title: Generation and Optimization of Hammerhead Ribozymes as Mutation- Independent Gene Therapeutics for Autosomal Dominant Retinitis Pigmentosa due to Mutations in the Rhodopsin Gene.

Brandon M. Bordeau, PhD Committee Member, 2017-2020

Dissertation title: Overcoming Tumor Barriers to Monoclonal Antibody Distribution and Efficacy.

Upendra Chitgupi, PhD Committee Member, 2017-2019

Dissertation title: Porphyrin Based Materials for Active Targeting and Phototherapy.

Sihang Liu, PhD Committee Member, 2017-2022

Dissertation title: Intracrine Androgen Metabolism in Prostate Cancer.

Yi Ting (Kayla) Lien, MS Committee Member, 2015-2016

Dissertation title: Evaluation of a catenary PBPK model for predicting monoclonal antibody disposition in the brain.

Zeng Jin, MS Committee Member, 2018-2019

Dissertation title: Directed Evolution of Hammerhead Ribozyme Kinetic Facilitator Targeting 266 and 725 Site in Rhodopsin mRNA.

Ping Chen, MS Committee Member, 2018-2022

Dissertation title: Development of novel strategies to improve the therapeutic index of ADCs.

Shiham Huo, MS Committee Member, 2018-2021

Dissertation title: Spatial proteomics of brain tissue by ultrahigh-resolution LC-MS and 3D-printing assisted micro sampling.

Mason McComb, PhD Committee Member, 2018-2021

Dissertation title: Development of Generalized Population Modeling, A Novel Pharmacometrics Paradigm.

Nicole Jarvi, PhD Committee Member, 2020-Present

Dissertation title: Prediction and Mitigation of Immunogenic Response toward Subcutaneously Administered Therapeutic Proteins.

Jie Pu, PhD Committee Member, 2020-Present

Dissertation title: Novel LC-MS based strategies for sensitive, accurate and multiplexed quantification of biotherapeutics and biomarkers.

Kirk Hofman, PhD Committee Member, 2021-Present

Dissertation title: Reversal of Immunogenicity Toward Viral Vector Based Gene Therapy Platforms using a novel Nanoparticle Oral preTreatment Strategy (NOTS).

Qingqing Shen, PhD Committee Member, 2022-Present

Dissertation title: FAIMS-based “antibody-free quantification” methods.

Autumn M. Spyhalsky, Phrmd/MS Committee Member, 2021-2023

Dissertation title: Dynamics of Urinary Biomarkers to Detect Acute Kidney Injury in Critically Ill Children Receiving Vancomycin.

Caroline Bosmajian, PhD Committee Member, 2023-Present

Dissertation title: Development of QSP model for SiRNA based therapies.

Kiarra Furey, MS Committee Member, 2023-Present

Dissertation title: Targeted Drug Therapy of Retinoblastoma.

Mentoring at Pfizer Inc.

2011-2013 **Ileana Ionita:** Principal Scientist in the field of PK/PD and M&S.

2013 **Brian Rago:** Associate Scientist in the field of PK/PD of ADCs.

9. GRANT SUPPORT

Note: The grants from the Center for Protein Therapeutics are supported by external funding and involve peer-review process for funding mechanism.

ACTIVE SUPPORT

- 1) **NIH, R01CA275967** (National Institute of Cancer)
Role: Co-Principal Investigator (contact PI: Balthasar)
Title: Pharmacokinetic / Pharmacodynamic Optimization of ADC Therapy for Acute Myeloid Leukemia.
February 2023 – January 2028, \$2,137,191 (total) \$229,740 (direct to DKS)
- 2) **NIH, 1R01CA246785-01A1** (National Institute of Cancer)
Role: Co-Principal Investigator (contact PI: Balthasar)
Title: Pharmacokinetic strategies to increase monoclonal antibody uptake, distribution, and efficacy for treatment of solid tumors.
June 2020 – May 2025, \$1,814,481 (total) \$228,750 (direct to DKS)
- 3) **NIH, 1R01CA CA256928** (National Institute of Cancer)
Role: Co-Investigator (PI: Balthasar)
Title: Enhancement of ADC selectivity by inverse targeting: Mechanistic studies and optimization.
June, 2021 – May 2026, \$1,817,098 (total) \$228,750 (direct to DKS)
- 4) **AstraZeneca Post-Doc Fellowship** (AstraZeneca)
Role: Principal Investigator
Title: Development of quantitative systems toxicology models for antibody-drug conjugates.
June, 2022 – May 2025, \$300,000 (total)
- 5) **NIH, R21 AI138195-011** (National Institute of Allergy and Infectious Diseases)
Role: Co-Investigator (PI: Sheldon Park, Department of Biomedical Engineering, University at Buffalo)
Title: Modulation of antigen pharmacokinetics with pH dependent antibody.
Jan, 2018 – Dec 2022, \$425,383 (total)
- 6) **Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Comprehensive Quantitative Analysis of Clinical PK Data Generated using Antibody-Based Therapeutics.
August 1, 2022 – July 31 2023, \$100,000 (total)
- 7) **Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Evaluation and Mitigation of the Effect of Shed Antigen on ADC PK/PD.
August 1, 2022 – July 31 2023, \$100,000 (total)
- 8) **Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Strategies to Improve the Dose Potency of Antibody-Drug Conjugates (ADCs).

August 1, 2022 – July 31 2023, \$100,000 (total)

- 9) **Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Development of Dose-Exposure/Response Relationship for AAV Mediated Delivery of Antibody Genes.
August 1, 2022 – July 31 2023, \$100,000 (total)
- 10) **Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Investigation of the role of FcRn in Brain Disposition of mAb using hFcRn Expressing Mice and Large-Pore Microdialysis System.
August 1, 2022 – July 31 2023, \$50,000 (total)
- 11) **Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Effect of FcRn Binding and Acute Lung Injury on Pulmonary PK of Antibodies.
August 1, 2022 – July 31 2023, \$50,000 (total)
- 12) **MPRINT (Maternal and Pediatrics Precision in Therapeutics Hub) P30 Grant**
Role: Co-Investigator
Title: The Indiana University-Ohio State University Maternal and Pediatric Precision in Therapeutics Data, Model, Knowledge, and Research Coordination Center (IU-OSU MPRINT DMKRCC).
Sept, 2021 – Aug 2026, \$250,000 (direct to DKS)

COMPLETED

- 13) **AstraZeneca Research Agreement**
Role: Principal Investigator
Title: Investigation of AAV mediated delivery of mAb gene in the brain.
July 1, 2020 – October 31 2022, \$375,000 (total)
- 14) **NIH, 1R01GM114179-01 (National Institute of General Medical Sciences)**
Role: Principal Investigator
Title: Translational Systems Pharmacokinetic Models of Novel Anticancer Biologics.
May, 2015 – March 2022, \$1,500,000 (total)
- 15) **Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Quantitative Evaluation of Monoclonal Antibody Transport Across Blood-CSF Barrier Using Rat and Human In Vitro Models.
August 1, 2021 – July 31 2022, \$100,000 (total)
- 16) **Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: To Investigate the Role of FcRn in Brain Disposition of MAbs using hFcRn Expressing Mice and Large-Pore Microdialysis System.
August 1, 2021 – July 31 2022, \$100,000 (total)
- 17) **Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Evaluation of Strategies to Enhance Ocular Exposure of Systemically Administered Antibodies in Rabbits.
August 1, 2021 – July 31 2022, \$100,000 (total)

- 18) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: PBPK Model for Characterizing Whole-Body Disposition of Different AAV Serotypes and their Transgene Product.
August 1, 2021 – July 31 2022, \$100,000 (total)
- 19) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: PK/PD Evaluation of ADCs Administered via Nonconventional Routes.
August 1, 2021 – July 31 2022, \$50,000 (total)
- 20) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Comprehensive Quantitative Analysis of Clinical PK Data Generated using MAbs.
August 1, 2021 – July 31 2022, \$50,000 (total)
- 21) EVQLV (UB-CAT)**
Role: Principal Investigator
Title: Artificial Intelligence Based Discovery of Novel Nanobodies to Treat COVID-19.
August 1, 2021 – July 31 2022, \$100,000 (total)
- 22) Manhattan Biosolutions (UB-CAT)**
Role: Principal Investigator
Title: Development of novel CD5 targeted treatments.
January, 2022 – July 31 2022, \$25,000 (total)
- 23) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Quantitative Evaluation of AAV9 Mediated Brain Delivery of Protein Therapeutics.
August 1, 2020 – July 31 2021, \$100,000 (total)
- 24) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Expansion of Platform PBPK Model to Characterize TMDD of Antibody in the Brain.
August 1, 2020 – July 31 2021, \$100,000 (total)
- 25) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Translational PBPK Model for Pulmonary Disposition of Protein Therapeutics.
August 1, 2020 – July 31 2021, \$100,000 (total)
- 26) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Pharmacokinetics-Pharmacodynamics (PK-PD) of Enhanced Effector Function (EEF) ADC.
August 1, 2020 – July 31 2021, \$100,000 (total)
- 27) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Targeting TfR to Improve Ocular Exposure of Protein Therapeutics.
August 1, 2020 – July 31 2021, \$50,000 (total)

- 28) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Evaluation of Brain Pharmacokinetics of Protein Therapeutics after Local Administration
 August 1, 2019 – July 31 2020, \$100,000 (total)
- 29) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Effect of Charge Variation on the Disposition of Monoclonal Antibodies
 August 1, 2019 – July 31 2020, \$100,000 (total)
- 30) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Evaluation of pH Dependent Antigen Binding and Geldanamycin Co-administration as Novel Strategies for Enhanced Intracellular Delivery of Antibody-Drug Conjugates (ADCs)
 August 1, 2018 – July 31 2020, \$100,000 (total)
- 31) Oncolinx Post-Doctoral Fellowship**
Role: Principal Investigator
Title: Investigation of various immune-oncology therapeutics and combination regimens thereof.
 July 1, 2017 – June 30 2019, \$174,300 (total)
- 32) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Clinical Validation of Antibody PBPK Model Using 89Zr Labelled Imaging Studies
 August 1, 2018 – July 31 2019, \$100,000 (total)
- 33) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Brain Pharmacokinetics of Different Size Antibody Fragments
 August 1, 2018 – July 31 2019, \$100,000 (total)
- 34) Childhood Eye Cancer Trust**
Role: Co-Investigator (PI: Gail Seigel, Department of Communicative Disorders and Sciences, University at Buffalo)
Title: Targeted Antibody-Drug Conjugates for Retinoblastoma.
 September 1, 2017 – August 31 2018, £25,000 (total)
- 35) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Development of the Quantitative Relationship between Protein Size and Tumor Exposure
 August 1, 2017 – July 31 2018, \$100,000 (total)
- 36) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Endogenous T-Cell Redistribution in the Presence of Immuno-Oncology Treatments
 August 1, 2017 – July 31 2018, \$100,000 (total)
- 37) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: PK of Anti-TfR Antibody Affinity Variants in Rat Brain Using Microdialysis
 August 1, 2017 – July 31 2018, \$100,000 (total)

- 38)Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Effect of CD3 Affinity and Plasma Half-Life on Tumor PK and Efficacy of T-cell Redirecting Bispecific Antibody
August 1, 2016 – July 31 2017, \$100,000 (total)
- 39)Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Understanding Brain Disposition of Antibodies and Development of Brain PBPK Model
August 1, 2016 – July 31 2017, \$100,000 (total)
- 40)Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Overcoming the Binding-Site-Barrier for ADCs by Co-administration of Antibody
August 1, 2016 – July 31 2017, \$100,000 (total)
- 41)Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Validation of Quantitative Relationship between Receptor Expression and ADC Exposure in Cancer Cells and Tumor
August 1, 2015 – July 31 2016, \$100,000 (total)
- 42)Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Quantifying Immune Checkpoint Inhibitor Induced Tumor Infiltration of TIL
August 1, 2015 – July 31 2016, \$62,000 (total)
- 43)Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Preclinical Evaluation of Immune Checkpoint Inhibitor and Bi-specific T-cell Engaging Molecule Combination
August 1, 2015 – July 31 2016, \$100,000 (total)
- 44)Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Development of a Translational and Truly Physiologically Based PK (PBPK) Model of Brain for Antibodies
August 1, 2015 – July 31 2016, \$100,000 (total)
- 45)Roche Pharmaceuticals**
Role: Principal investigator
Title: Platform PBPK Model for Biologics
July 1, 2014 – June 30 2017, \$272,840 (total)
- 46)Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Understanding and Characterizing the Bystander Effect for Antibody-Drug Conjugates
August 1, 2014 – July 31 2015, \$100,000 (total)
- 47)Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Development of Translational PBPK Model for ADCs
August 1, 2014 – July 31 2015, \$100,000 (total)

48) Center for Protein Therapeutics, University at Buffalo
Role: Principal Investigator
Title: Elimination Mechanism for Antibody-Drug Conjugates (ADCs) with Higher DAR
August 1, 2014 – July 31 2015, \$62,000 (total)

SUBMITTED but NON-FUNDED

- 1) NIH, R01GM146097 (NIGMS)**
Role: Co-PI (Contact PI: Majeti)
Title: Polyesters with controlled topologies for probing transcytosis at the gut-blood barrier.
April, 2023 – March 2027, \$1,874,128 (total) \$292,587 (direct to DKS)
- 2) NIH, U19 (NINDS)**
Role: Co-PI (Contact PI: Leong)
Title: Novel protein therapeutics for coronavirus.
Sept, 2020 – Aug 2022, \$14,754,189 (total) (direct to UB: 1,093,251)
- 3) AstraZeneca Post-Doc Fellowship**
Role: Principal-Investigator
Title: Development of QSP Model for AAV mediated delivery of proteins in the brain.
January, 2023 – December 2024, Budget – TBD
- 4) NIH, R21 (NIAID)**
Role: Co-Investigator (PI: Park)
Title: Novel protein therapeutics for coronavirus.
Sept, 2020 – Aug 2022, \$429,227 (total) \$100,000 (direct to DKS)
- 5) NIH, R21 (NIAID)**
Role: Co-Principal Investigator (PI: Tumey)
Title: Targeted modulation of endosomal processing as a strategy to mitigate viral fusion.
Aug, 2020 – Jul 2022, \$446,000 (total) TBD (direct to DKS)
- 6) NIH, 1 R35 GM136368-01 (National Institute of General Medical Sciences)**
Role: Principal Investigator
Title: Translational Systems Pharmacokinetic Models for Protein Therapeutics.
May, 2020 – March 2025, \$3,456,927.00 (total)
- 7) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Effect of Albumin Binding on the Disposition and Efficacy of Peptide-ABD Fusion Proteins.
August 1, 2019 – July 31 2020, \$100,000 (total)
- 8) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Evaluation of Systemic Administration of Small Protein Therapeutics as a Viable Treatment Option for Ocular Disorders.
August 1, 2019 – July 31 2020, \$100,000 (total)
- 9) NIH, R21 (NEI)**
Role: Principal Investigator
Title: Translational PBPK Model for Protein Therapeutic Disposition in the Eye.
September 1, 2019 – August 31 2021, \$436,393 (total)

- 10) Clinical and Translational Science Award-Translational Pilot Studies Grant, University at Buffalo**
Role: Co-Principal Investigator (contact)
Title: Optimization of conditioning therapy for CAR-T cells.
October, 2017 – September 2017, \$20,000 (direct to DKS)
- 11) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: The Effect of Target Expression on the Efficacy of Bi-Specific T-cell Engaging Molecule.
August 1, 2017 – July 31 2018, \$100,000 (total)
- 12) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Regional Pharmacokinetics of Antibody Derivatives in Rat Brain.
August 1, 2017 – July 31 2018, \$100,000 (total)
- 13) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Two-Pore PBPK Model with A Priori Determined Parameters for Predicting the Disposition of Different Size Antibody Derivatives in Mice.
August 1, 2017 – July 31 2018, \$100,000 (total)
- 14) Center for Protein Therapeutics, University at Buffalo**
Role: Co-Principal Investigator
Title: Evaluation of Sweeping Antibody as the Next Generation Immunotoxicotherapy Agent using Staphylococcal Enterotoxin B (SEB) as the Target.
August 1, 2017 – July 31 2018, \$100,000 (total)
- 15) NSF, 15-1 1605287**
Role: Co-Principal Investigator
Title: Optimized engineering platform for pH switch antibody.
Aug, 2016 – July 2019, \$425,709 (direct)
- 16) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Optimization of ICI Co-administration to Overcome the Resistance to T-cell Redirecting Molecule by Cancer Cells.
August 1, 2016 – July 31 2017, \$100,000 (total)
- 17) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
Title: Antibody-Drug Conjugate and Immune Checkpoint Inhibitor Combination.
August 1, 2016 – July 31 2017, \$100,000 (total)
- 18) NIH, R01 CA208441-01 (National Institute of Cancer, Developmental Therapeutics Study Section)**
Role: Principal Investigator
Title: Preclinical evaluation of a novel antibody-drug conjugate developed to treat retinoblastoma.
July, 2016 – June 2021, \$1,250,000 (direct)
- 19) University at Buffalo- Bristol-Myers Squibb Partnership Grant**
Role: Principal Investigator
Title: Preclinical Evaluation of Immune Checkpoint Inhibitor and Antibody-Drug Conjugate Combination.
June, 2016 – May 2017, \$50,000 (direct)

20) Alex's Lemonade Stand Foundation

Role: Principal Investigator

Title: Preclinical Evaluation of a Novel Antibody-Drug Conjugate Developed to Treat Retinoblastoma.

May, 2016 – April 2020, \$799,065 (direct)

21) IMPACT (Innovative Micro-Programs Accelerating Collaboration in Themes) Grant, University at Buffalo

Role: Co-Principal Investigator

Title: Generalized platform for engineering pH switch antibody for therapeutic applications.

April, 2016 – March 2017, \$30,000 (direct)

22) AAPS Foundation New Investigator Grant

Role: Principal Investigator

Title: Novel Targeted Therapy for the Treatment of Retinoblastoma.

March, 2016 – February 2017, \$100,000 (direct)

23) Simcyp Grant and Partnership Scheme Application

Role: Principal Investigator

Title: Development of a Simcyp Guided PBPK Model for ADCs in Tumor Bearing Mice.

December, 2015 – November 2017, £100,000 (total)

24) Center for Protein Therapeutics, University at Buffalo

Role: Principal Investigator

Title: Understanding and Quantitatively Characterizing the Disposition of Biologics in Eye.

August 1, 2015 – July 31 2016, \$100,000 (total)

25) School of Pharmacy and Pharmaceutical Sciences Seed Funding, University at Buffalo

Role: Co-Principal Investigator

Title: Employing pH-dependent antigen binding to improve the efficiency of anti-Staphylococcal Enterotoxin B (SEB) antibody.

January, 2015 – December 2015, \$10,000 (direct)

26) PhRMA Foundation-Translational Medicine and Therapeutics Research Starter Grant

Role: Principal Investigator

Title: Evaluation of Tumor Size as an Important Determinant for the Clinical Translation of ADCs.

January, 2015 – December 2015, \$100,000 (direct)

27) Simcyp Grant and Partnership Scheme Application

Role: Principal Investigator

Title: Simcyp Guided PBPK Model for Ocular Disposition of Protein Therapeutics.

December, 2014 – November 2016, £100,000 (total)

28) Fight-for-Sight Foundation

Role: Co-Principal Investigator (PI: Seigel)

Title: A Novel Therapeutic Approach to Retinoblastoma Using Epithelial Cell Adhesion Molecule (EpCAM) Targeted Antibody-Drug Conjugate.

November, 2014 – October 2015, \$22,500 (direct) \$10,000 (direct to DKS)

29) IMPACT (Innovative Micro-Programs Accelerating Collaboration in Themes) Grant, University at Buffalo

Role: Co-Principal Investigator (PI: Seigel)

Title: A Novel Therapeutic Approach to Retinoblastoma Using Epithelial Cell Adhesion Molecule (EpCAM) Targeted Antibody-Drug Conjugate.

November, 2014 – October 2015, \$30,000 (direct) \$10,000 (direct to DKS)

- 30) NIH, R01 CA190712-01** (National Institute of Cancer, Developmental Therapeutics Study Section)
Role: Principal Investigator
 Title: Multi-Scale Computational Model for the Development of Antibody Drug Conjugates.
 Sept, 2014 – Aug 2019, \$1,250,000 (direct)
- 31) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
 Title: Effect of Tumor Size on the Exposure and Efficacy of Antibody-Drug Conjugates (ADCs).
 August 1, 2014 – July 31 2015, \$100,000 (total)
- 32) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
 Title: Physiologically Based Pharmacokinetic (PBPK) Model for T-Cell Engaging Bi- Specific Molecules.
 August 1, 2014 – July 31 2015, \$100,000 (total)
- 33) Center for Protein Therapeutics, University at Buffalo**
Role: Principal Investigator
 Title: Absolute Quantitation of Anti-Therapeutic Antibody in Preclinical Species. August 1, 2014 – July 31 2015, \$100,000 (total)
- 34) Clinical and Translational Science Award-Translational Pilot Studies Grant, University at Buffalo**
Role: Co-Principal Investigator (PI: Lin)
 Title: Development of Ubiquitin-Drug Conjugates as Targeted Cancer Therapy.
 April, 2014 – March 2015, \$50,000 (direct) \$15,000 (direct to DKS)
- 35) Obesity Society- Early-Career Research Grant**
Role: Principal Investigator
 Title: Development of Antibody-Drug Conjugates for the Peripheral Ablation of Adipocytes.
 March, 2014 – February 2015, \$25,000 (direct)
- 36) Simcyp Grant and Partnership Scheme**
Application Role: Principal Investigator
 Title: Developing Simcyp Guided PBPK Model to Predict Antibody PK in Pediatric Patients.
 December, 2013 – November 2015, £100,000 (total)

10. PUBLICATIONS (h-index: 27, i10-index: 49).

Total 54 Articles Published since last promotion.

PEER REVIEWED PUBLISHED MANUSCRIPTS

*** Denotes senior/lead authorship**

1. Shufang Liu, **Shah D.K.***. *Physiologically-Based Pharmacokinetic Modeling to Characterize the Effect of Molecular Charge on Whole-Body Disposition of Monoclonal Antibodies*. **The AAPS Journal**. **2023**. **Articles in Press**.
2. Chang HP, Le HK, **Shah D.K.***. *Pharmacokinetics and Pharmacodynamics of Antibody-Drug Conjugates Administered via Subcutaneous and Intratumoral Routes*. **Pharmaceutics** 15 (4), 1132.

3. Bussing D, Li Y, Guo L, Verma A, Sullivan JM, **Shah D.K.***. *Pharmacokinetics of Monoclonal Antibody and Antibody Fragments in the Mouse Eye Following Intravitreal Administration*. **Journal of Pharmaceutical Sciences**. 2023 Apr 14: S0022-3549 (23) 00152-1.
4. Kavya Teja P, Ly BQ, **Shah D.K.**, Chauthe SK. *Isolation, Characterization of Undescribed Alkaloids, and Semisynthetic Modifications of Cytotoxic Pyranoacridone Alkaloids from Glycosmis pentaphylla*. **ACS Omega**. 2023 Mar 13;8(12):11201-11212.
5. Kumar M, Kulkarni P, Liu S, Chemuturi N, **Shah D.K.***. *Nanoparticle biodistribution coefficients: A quantitative approach for understanding the tissue distribution of nanoparticles*. **Adv Drug Deliv Rev**. 2023 Mar;194:114708.
6. Chandran J, Chowdhury EA, Perkinton M, Jamier T, Sutton D, Wu S, Dobson C, **Shah D.K.**, Chessell I, Meno-Tetang GML. *Assessment of AAV9 distribution and transduction in rats after administration through Intrastratal, Intracisterna magna and Lumbar Intrathecal routes*. **Gene Ther**. 2023 Feb;30(1-2):132-141.
7. **Shah D.K.** et al. *Thanks to our Reviewers of 2022!*. **J Pharmacokinet Pharmacodyn** 50, 75 (2023).
8. Quinney SK, Bies RR, Grannis SJ, Bartlett CW, Mendonca E, Rogerson CM, Backes CH, **Shah D.K.**, Tillman EM, Costantine MM, Aruldas BW, Allam R, Grant A, Abbasi MY, Kandasamy M, Zang Y, Wang L, Shendre A, Li L. *The MPRINT Hub Data, Model, Knowledge and Research Coordination Center: Bridging the gap in maternal-pediatric therapeutics research through data integration and pharmacometrics*. **Pharmacotherapy**. 2023 Jan 10. doi: 10.1002/phar.2765. Online ahead of print.
9. Rajadhyaksha PM, Shastri DH, **Shah D.K.***. *Pharmacokinetic Evaluation of Thermosensitive Sustained Release Formulations Developed for Subcutaneous Delivery of Protein Therapeutics*. **Journal of Pharmaceutical Sciences**. 2023 Mar;112(3):868-876.
10. Jagdale P, Sepp A, **Shah D.K.***. *Physiologically-Based Pharmacokinetic Model for Pulmonary Disposition of Protein Therapeutics in Humans*. **J Pharmacokinet Pharmacodyn**. 2022 Dec;49(6):607-624.
11. Wu S, Le Priault F, Phipps CJ, Mezler M, **Shah D.K.***. *PBPK model for antibody disposition in mouse brain: validation using large-pore microdialysis data*. **J Pharmacokinet Pharmacodyn**. 2022 Dec;49(6):579-592.
12. Stüber CJ, Rechberger KF, Miladinović SM, Pöschinger T, Zimmermann T, Villenave R, Eigenmann MJ, Kraft TE, **Shah DK**, Kettenberger H, Richter WF. *Impact of charge patches on tumor disposition and biodistribution of therapeutic antibodies*. **AAPS Open**. Volume 8, Article number: 3 (2022).
13. Chang HY, Wu S, Chowdhury EA, **Shah D.K.***. *Towards a translational physiologically-based pharmacokinetic (PBPK) model for receptor-mediated transcytosis of anti-transferrin receptor monoclonal antibodies in the central nervous system*. **J Pharmacokinet Pharmacodyn**. 2022 Jun;49(3):337-362.
14. S Liu and **Shah D.K.***. *Mathematical Models to Characterize the Absorption, Distribution, Metabolism, and Excretion of Protein Therapeutics*. **Drug Metab Dispos**. 2022 Jun;50(6):867-878. doi: 10.1124/dmd.121.000460.
15. Patsatzis DG, Wu S, **Shah DK**, Goussis DA. *Algorithmic multiscale analysis for the FcRn mediated regulation of antibody PK in human*. **Scientific Reports**. 2022 Apr 13;12(1):6208. doi: 10.1038/s41598-022-09846-x.

16. Chang HY, Wu S, Guo L, Y Li, **Shah D.K.***. *Effect of the Size of Protein Therapeutics on Brain Pharmacokinetics Following Systematic Administration*. **The AAPS journal** 2022 May 2;24(3):62. doi: 10.1208/s12248-022-00701-5.
17. Omar AM, Khayat MT, Ahmed F, Muhammad YA, Malebari AM, Ibrahim SM, Khan MI, **Shah DK**, Childers WE, El-Araby ME. *SAR Probing of KX2-391 Provided Analogues With Juxtaposed Activity Profile Against Major Oncogenic Kinases*. **Front Oncol**. 2022 May 20;12:879457. doi: 10.3389/fonc.2022.879457. eCollection 2022.
18. Chang HP, Li Z, **Shah D.K.***. *Development of a Physiologically-Based Pharmacokinetic Model for Whole-Body Disposition of MMAE Containing Antibody-Drug Conjugate in Mice*. **Pharm Res**. 2022 Jan;39(1):1-24. doi: 10.1007/s11095-021-03162-1.
19. Li M, Ong CY, Langouët-Astrié CJ, Tan L, Verma A, Yang Y, Zhang X, **Shah DK**, Schmidt EP, Xu D. *Heparan sulfate-dependent RAGE oligomerization is indispensable for pathophysiological functions of RAGE*. **Elife**. 2022 Feb 9;11. doi: 10.7554/eLife.71403.
20. Meyer LF, Rajadhyaksha PM, **Shah D.K.***. *Physiologically-based pharmacokinetic model for 2,4-dinitrophenol*. **J Pharmacokinet Pharmacodyn**. 2022 Jan 28;. doi: 10.1007/s10928-022-09806-y.
21. Chang HP, Cheung YK, **Shah D.K.***. *Whole-Body Pharmacokinetics and Physiologically Based Pharmacokinetic Model for Monomethyl Auristatin E (MMAE)*. **J Clin Med**. 2021 Mar 23;10(6).
22. Liu S, Verma A, Kettenberger H, Richter WF, **Shah D.K.***. *Effect of variable domain charge on in vitro and in vivo disposition of monoclonal antibodies*. **MAbs**. 2021 Jan-Dec;13(1):1993769. doi: 10.1080/19420862.2021.1993769. PMID: 34711143.
23. Bussing D, Li Z, Li Y, Chang HP, Chang HY, Guo L, Verma A, **Shah D.K.***. *Pharmacokinetics of Monoclonal Antibody and Antibody Fragments in the Mouse Eye Following Systemic Administration*. **AAPS J**. 2021 Nov 8;23(6):116. doi: 10.1208/s12248-021-00647-0. PMID: 34750690.
24. Huisman MC, Menke-van der Houven van Oordt CW, Zijlstra JM, Hoekstra OS, Boellaard R, van Dongen GAMS, **Shah DK**, Jauw YWS. *Potential and pitfalls of 89Zr-immuno-PET to assess target status: 89Zr-trastuzumab as an example*. **EJNMMI Res**. 2021 Aug 21;11(1):74. doi: 10.1186/s13550-021-00813-7. PMID: 34417917.
25. McCombs JR, Chang HP, **Shah DK**, Owen SC. *Antibody-drug conjugate and free geldanamycin combination therapy enhances anti-cancer efficacy*. **Int J Pharm**. 2021 Dec 15;610:121272. doi: 10.1016/j.ijpharm.2021.121272. Epub 2021 Nov 8. PMID: 34763035.
26. Chang HP, Shakhnovich V, Frymoyer A, Funk RS, Becker ML, Park KT, **Shah D.K.***. *A population physiologically-based pharmacokinetic model to characterize antibody disposition in pediatrics and evaluation of the model using infliximab*. **Br J Clin Pharmacol**. 2021 Jun 29. doi: 10.1111/bcp.14963. Online ahead of print.
27. Chang HP, Kim SJ, Wu D, Shah K, **Shah D.K.***. *Age-Related Changes in Pediatric Physiology: Quantitative Analysis of Organ Weights and Blood Flows*. **The AAPS Journal** 2021 March. 23 (3), 1-15.
28. Zou D, Arora M, Ganugula R, Kumar M, Scott EM, **Shah DK**, and Kumar MNVR. *Nanoparticles that do not compete with endogenous ligands—Molecular characterization in vitro, acute safety in canine, and interspecies pharmacokinetics*

modeling to humans. **Journal of Controlled Release** 2021 April. 332, 64-73.

29. Li Z, Yu X, Li Y, Verma A, Chang HP, **Shah D.K.***. A Two-Pore Physiologically Based Pharmacokinetic Model to Predict Subcutaneously Administered Different-Size Antibody/Antibody Fragments. **The AAPS Journal** 2021 May. 23 (3), 1-13.
30. Bussing D, Sharma S, Li Z, Meyer LF, **Shah D.K.***. Quantitative Evaluation of the Effect of Antigen Expression Level on Antibody–Drug Conjugate Exposure in Solid Tumor. **The AAPS Journal** 2021 April. 23 (3), 1-11.
31. Li Z, Li Y, Chang HP, Yu X, **Shah D.K.***. Two-pore physiologically based pharmacokinetic model validation using whole-body biodistribution of trastuzumab and different-size fragments in mice. **Journal of Pharmacokinetics and Pharmacodynamics**. 2021 October. doi: 10.1007/s10928-021-09772-x. Online ahead of print.
32. Huisman M.C, Houven van Oordt C., Zijlstra J.M., Hoekstra O.S., Boellaard R., Van Dongen G, **Shah D.K.**, Jauw Y.W. Potential and pitfalls of 89Zr-immuno-PET to assess target status: 89Zr-trastuzumab as an example. **EJNMMI Research** volume 11, Article number: 74 (2021).
33. Chang HY, Wu S, Li Y, Zhang W, Burrell M, Webster CI, and **Shah D.K.***. Brain pharmacokinetics of anti-transferrin receptor antibody affinity variants in rats determined using microdialysis. **mAbs**. Jan 2021. Accepted (In Press).
34. Chowdhury EA, Meno-Tetang G, Chang HY, Wu S, Huang HW, Jamier T, Chandran J, and **Shah D.K.***. Current progress and limitations of AAV mediated delivery of protein therapeutic genes and the importance of developing quantitative pharmacokinetic/pharmacodynamic (PK/PD) models. **Advanced Drug Delivery Reviews**. Jan 2021. Published Online.
35. Bussing D and **Shah D.K.***. Development of a Physiologically-Based Pharmacokinetic Model for Ocular Disposition of Monoclonal Antibodies in Rabbits. **J Pharmacokinet Pharmacodyn**. Aug 2020.
36. Chang HP, Kim SJ, **Shah D.K.***. Whole-Body Pharmacokinetics of Antibody in Mice Determined using Enzyme-Linked Immunosorbent Assay and Derivation of Tissue Interstitial Concentrations. **J Pharm Sci**, 2020 Jun 2:S0022-3549(20)30301-4. doi: 10.1016/j.xphs.2020.05.025. Online ahead of print. PMID: 32502472
37. Singh AP, Seigel GM, Guo L, Verma A, Wong GG, Cheng HP, **Shah D.K.***. Evolution of the Systems Pharmacokinetics-Pharmacodynamics Model for Antibody-Drug Conjugates to Characterize Tumor Heterogeneity and In Vivo Bystander Effect. **J Pharmacol Exp Ther**. 2020 Jul;374(1):184-199. doi: 10.1124/jpet.119.262287. Epub 2020 Apr 9. PMID: 32273304
38. Sharma S., Li Z., Bussing D., **Shah D.K.***. Evaluation of Quantitative Relationship Between Target Expression and ADC Exposure Inside Cancer Cells. **Drug Metab Dispos**, 2020 Feb 21. pii: dmd.119.089276. doi 10.1124/dmd.119.089276.
39. Singh AP, Guo L, Verma A, Wong GG, Thurber GM, **Shah D.K.***. Antibody Coadministration as a Strategy to Overcome Binding-Site Barrier for ADCs: a Quantitative Investigation. **AAPS J**. 2020 Jan 14;22(2):28. doi: 10.1208/s12248-019-0387-x.
40. Seigel GM*, **Shah DK**, Mendoza P, Szalai E, Grossniklaus H, Song Y, Shan J. In situ analysis of Her2 DNA and RNA in retinoblastoma and adjacent retina. **Oncoscience**. 2019 Aug 23;6(7-8):357-366. doi: 10.18632/oncoscience.489. eCollection 2019 Jul.

41. Li Z, Li Y, Chang HP, Chang HY, Guo L, **Shah D.K.***. *Effect of Size on Solid Tumor Disposition of Protein Therapeutics*. **Drug Metabolism and Disposition**, 2019 Aug 6. pii: dmd.119.087809. doi: 10.1124/dmd.119.087809. [Epub ahead of print] . 119.087809.
42. Chang HY, Wu S, Meno-Tetang G, **Shah D.K.***. *A translational platform PBPK model for antibody disposition in the brain*. **J Pharmacokinet Pharmacodyn**. 2019 Aug;46(4):319-338. doi: 10.1007/s10928-019-09641-8. Epub 2019 May 21.
43. Betts A, Haddish-Berhane N, **Shah D.K.**, van der Graaf PH, Barletta F, King L, Clark T, Kamperschroer C, Root A, Hooper A, Chen X. *Correction to: A Translational Quantitative Systems Pharmacology Model for CD3 Bispecific Molecules: Application to Quantify T Cell-Mediated Tumor Cell Killing by P-Cadherin LP DART®*. **AAPS J**. 2019 Jun 4;21(4):73. doi: 10.1208/s12248-019-0348-4. PubMed PMID: 31165304; PubMed Central PMCID: PMC6828401.
44. Li Z and **Shah D.K.***. *Two-pore physiologically based pharmacokinetic model with de novo derived parameters for predicting plasma PK of different size protein therapeutics.* **J Pharmacokinet Pharmacodyn**. 2019 Jun;46(3):305-318. doi: 10.1007/s10928-019-09639-2. Epub 2019 Apr 26.
45. **Betts A.***, Haddish-Berhane N, Shah DK, van der Graaf PH, Barletta F, King L, Clark T, Kamperschroer C, Root A, Hooper A, Chen X. *A Translational Quantitative Systems Pharmacology Model for CD3 Bispecific Molecules: Application to Quantify T Cell-Mediated Tumor Cell Killing by P-Cadherin LP DART®*. **AAPS J**. 2019 May 22;21(4):66. doi: 10.1208/s12248-019-0332-z.
46. Meyer LF and **Shah D.K.***. *Development and validation of an LC-MS/MS method for tyrphostin A9*. **J Pharm Anal**. 2019 Jun;9(3):163-169. doi: 10.1016/j.jpha.2019.03.003. Epub 2019 Mar 8.
47. Kay K, Dolcy K, Bies R, **Shah D.K.***. *Estimation of Solid Tumor Doubling Times from Progression-Free Survival Plots Using a Novel Statistical Approach*. **AAPS J**. 2019 Feb 8;21(2):27. doi: 10.1208/s12248-019-0302-5.
48. Khot A, Matsueda S, Thomas VA, Koya RC, **Shah D.K.***. *Measurement and Quantitative Characterization of Whole-Body Pharmacokinetics of Exogenously Administered T Cells in Mice*. **J Pharmacol Exp Ther**. 2019 Mar;368(3):503-513. doi: 10.1124/jpet.118.252858. Epub 2019 Jan 8.
49. Singh AP and **Shah D.K.***. *A "Dual" Cell-Level Systems PK-PD Model to Characterize the Bystander Effect of ADC*. **J Pharm Sci**. 2019 Jul;108(7):2465-2475. doi: 10.1016/j.xphs.2019.01.034. Epub 2019 Feb 18.
50. Singh AP, Guo L, Verma A, Wong GG, **Shah D.K.***. *A Cell-Level Systems PK-PD Model to Characterize In Vivo Efficacy of ADCs*. **Pharmaceutics**. 2019 Feb 25;11(2). pii: E98. doi: 10.3390/pharmaceutics11020098.
51. Kroetsch A, Qiao C, Heavey M, Guo L, **Shah D.K.*** and **Park S***. *Engineered pH-dependent recycling antibodies enhance elimination of Staphylococcal enterotoxin B superantigen in mice*. **MAbs**. 2019 Feb/Mar;11(2):411-421. doi: 10.1080/19420862.2018.1545510. Epub 2018 Dec 11.
52. Schropp J*, Khot A, **Shah D.K.*** Koch G*. *Target-Mediated Drug Disposition Model for Bispecific Antibodies: Properties, Approximation and Optimal Dosing Strategy*. **CPT Pharmacometrics Syst Pharmacol**. 2018 Nov. doi: 10.1002/psp4.12369.
53. B Bumbaca B, Li Z, **Shah D.K.***. *Pharmacokinetics of Protein and Peptide Conjugates*. **Drug Metabolism and Pharmacokinetics**. 2018 Nov.

54. Chang HY, Morrow K, Bonacquisti E, Zhang WY, **Shah D.K.***. *Antibody pharmacokinetics in rat brain determined using microdialysis*. **mAbs**. 2018 Aug 14. 10 (6), 843-853.
55. **Shah D.K.***, Loganzo F., Haddish-Berhane N., Musto S., Wald H.S., Barletta F., Lucas J., Clark T., Hansel S., Betts A.*. *Establishing in vitro-in vivo correlation for antibody drug conjugate efficacy: a PK/PD modeling approach*. **J Pharmacokinet Pharmacodyn**. 2018 Apr;45(2):339-349. doi: 10.1007/s10928-018-9577-x. [Epub ahead of print].
56. Kay K., **Shah D.K.**, Rohan L., Bies R.*. *Development of a Translational Physiologically-based pharmacokinetic model of vaginally administered dapivirine ring and film formulations*. **Br J Clin Pharmacol**. 2018 May. doi: 10.1111/bcp.13625. [Epub ahead of print].
57. Khot A., Tibbitts J., Rock D., **Shah D.K.***. *Development of a Translational Physiologically Based Pharmacokinetic Model for Antibody-Drug Conjugates: A Case Study with T-DM1*. **AAPS J**. 2017 Aug 14. doi: 10.1208/s12248-017-0131-3. [Epub ahead of print].
58. Singh A.P. and **Shah D.K.***. *Measurement and Mathematical Characterization of Cell-Level Pharmacokinetics of Antibody-Drug Conjugates: A Case Study with Trastuzumab-vc-MMAE*. **Drug Metab Dispos**. 2017 Aug 18. doi: 10.1124/dmd.117.076414. [Epub ahead of print].
59. Bloomingdale P., Housand C., Apgar J., Millard B., Mager D.E., Burke J.M, and **Shah D.K.***. *Quantitative Systems Toxicology*. **Current Opinion in Toxicology**. 2017 Jul; 4: 79-87.
60. Li Z., Krippendorff B., **Shah D.K.***. *Influence of molecular size on the clearance of antibody fragments*. **Pharmaceutical Research**. 2017 July 5. doi: 10.1007/s11095-017-2219-y. [Epub ahead of print].].
61. Singh A.P. and **Shah D.K.***. *Application of a PK-PD Modeling and Simulation-Based Strategy for Clinical Translation of Antibody-Drug Conjugates: a Case Study with Trastuzumab Emtansine (T-DM1)*. **AAPS J**. 2017 Jul;19(4):1054-1070.
62. Singh A.P., Sharma S., **Shah D.K.***. *Quantitative characterization of in vitro bystander effect of antibody-drug conjugates*. **J Pharmacokinet Pharmacodyn**. 2016 Dec;43(6):567-582.
63. Singh A.P., Mass K.F., Betts A.M., Wittrup K.D., Kulkarni C., King L.E., Khot A., and **Shah D.K.***. *Evolution of Antibody-Drug Conjugate Tumor Disposition Model to Predict Preclinical Tumor Pharmacokinetics of Trastuzumab-Emtansine (T-DM1)*. **AAPS J**. 2016 Jul;18(4):861-75.
64. Seigel G.M., Sharma S., Hackam A.S., **Shah D.K.***. *HER2/ERBB2 immunoreactivity in human retinoblastoma*. **Tumour Biol**. 2016 May;37(5):6135-42.
65. Li Z., Krippendorff B.F., Sharma S., Walz A.C., Lavé T. and **Shah D.K.***. *Influence of molecular size on tissue distribution of antibody fragments*. **MAbs**. 2016;8(1):113-9.
66. **Shah D.K.***. *Pharmacokinetic and pharmacodynamic considerations for the next generation protein therapeutics*. **J Pharmacokinet Pharmacodyn**. 2015 Oct;42(5):553-71.
67. Khot A., Sharma S., and **Shah D.K.***. *Integration of bioanalytical measurements using PK-PD modeling and simulation: implications for antibody-drug conjugate development*. **Bioanalysis**. 2015; 7(13), 1633-1648.

68. Singh A.P., Shin Y.G., and **Shah D.K.***. *Application of Pharmacokinetic-Pharmacodynamic Modeling and Simulation for Antibody-Drug Conjugate Development*. **Pharmaceutical Research**. 2015 Nov;32(11):3508-25.
69. Leal M., Sapra P., Hurvitz S., Senter P., Wahl A., Schutten M., **Shah D.K.**, Haddish-Berhane N, Kabbarah O. *Antibody–drug conjugates: an emerging modality for the treatment of cancer*. **Annals of the New York Academy of Sciences**. 2014 Aug; 1321: 41–54.
70. **Shah D.K.***, King LE, Han X, Wentland JA, Zhang Y, Lucas J, Haddish-Berhane N, Betts A, and Leal M. *A Priori Prediction of Tumor Payload Concentrations: Preclinical Case Study with an Auristatin Based Anti-5T4 Antibody Drug Conjugate*. **AAPS J**. 2014 May;16(3):452-63.
71. **Shah D.K.**, Balthasar J.P. *PK/TD modeling for prediction of the effects of 8C2, an anti-topotecan mAb, on topotecan-induced toxicity in mice*. **Int J Pharm**. 2014 Apr 25;465(1-2):228-38.
72. **Shah D.K.**, Balthasar J.P. *Predicting the effect of anti-topotecan antibody on plasma and tissue disposition of topotecan*. **J Pharmacokinet Pharmacodyn**. 2014 Feb;41(1):55-69.
73. Klinguer-Hamour C., Strop P., **Shah D.K.**, Ducry L., Xu A., Beck A. Meeting Report: World Antibody-Drug Conjugate Summit, October 15–16, 2013, San Francisco, CA. **MAbs**. 2014 Jan-Feb; 6:0-11.
74. Haddish-Berhane N., **Shah D.K.**, Betts A. *On translation of antibody drug conjugates efficacy from mouse experimental tumors to the clinic: a PK/PD approach*. **J Pharmacokinet Pharmacodyn**. 2013 Oct; 40(5):557-571.
75. **Shah D.K.***, Barletta F., Betts A., Hansel S. *Key Bioanalytical Measurements for Antibody Drug Conjugate Development: PK/PD Modelers' Perspective*. Editorial-**Bioanalysis**. 2013 May; 5(9):989–992.
76. **Shah D.K.***, Betts A. *Antibody Biodistribution Coefficient (ABC): Inferring Tissue Concentrations of Monoclonal Antibodies Based on the Plasma Concentrations in Several Preclinical Species and Human*. **MAbs**. 2013 Mar-Apr; 5(2):297-305.
77. **Shah D.K.***, Haddish-Berhane N., Betts A. *Bench to bedside translation of antibody drug conjugates using a multiscale mechanistic PK/PD model: a case study with brentuximab-vedotin*. **J Pharmacokinet Pharmacodyn**. 2012 Dec; 39(6):643-59.
78. **Shah D.K.***, Betts A. *Towards a platform PBPK model to characterize the plasma and tissue disposition of monoclonal antibodies in preclinical species and human*. **J Pharmacokinet Pharmacodyn**. 2012 Feb; 39(1):67-86.
7.
79. Parekh J.M., **Shah D.K.**, Shrivastav P.S. *Development of an SPE-LC-MS/MS method for simultaneous quantification of bosentan and its active metabolite hydroxybosentan in human plasma to support a bioequivalence study*. **Journal of Pharmaceutical and Biomedical Analysis**. 2012 Nov; 70:462-70.
80. **Shah D.K.**, Veith J., Bernacki R.J., Balthasar J.P. *Evaluation of combined bevacizumab and intraperitoneal carboplatin or paclitaxel therapy in a mouse model of ovarian cancer*. **Cancer Chemother Pharmacol**. 2011 Oct; 68(4):951-8.
81. **Shah D.K.**, Balthasar J.P. *Physiologically based pharmacokinetic model for topotecan in mice*. **J Pharmacokinet Pharmacodyn**. 2011 Feb; 38(1):121-42.
82. **Shah D.K.**, Shin B.S., Veith J., Tóth K., Bernacki R.J., Balthasar J.P. *Use of an anti-vascular endothelial growth factor antibody in a pharmacokinetic strategy to increase the*

efficacy of intraperitoneal chemotherapy. **J Pharmacol Exp Ther.** 2009 May; 329(2):580-91.

83. **Shah D.K.**, Khandavilli S., Panchagnula R. *Alteration of skin hydration and its barrier function by vehicle and permeation enhancers: a study using TGA, FTIR, TEWL and drug permeation as markers.* **Methods Find Exp Clin Pharmacol.** 2008 Sep; 30(7):499-512.

PUBLISHED BOOK CHAPTERS

1. Liu S., **Shah D.K.*** *Development and Application of a Single Cell-Level PK-PD Model for ADC.* in **Methods In Pharmacology and Toxicology: Quantitative Analysis of Cellular Drug Transport, Disposition, and Delivery** edited by Gus R. Rosania and Greg M. Thurber. Springer. 08 June 2021
2. E Lange, HY Chang, **Shah D.K.** *Approaches towards prediction of CNS PK and PD.* In: de Lange, E.C., Hammarlund-Udenaes, M., Thorne, R.G. (eds) **Drug Delivery to the Brain.** AAPS Advances in the Pharmaceutical Sciences Series, vol 33. Springer, Cham. https://doi.org/10.1007/978-3-030-88773-5_12. 25 May 2022
3. Wu S., **Shah D.K.*** *Determination of ADC Cytotoxicity in Immortalized Human Cell Lines.* in **Methods Molecular Biology: Antibody-Drug Conjugates** edited by L. Nathan Tumey. Springer. Aug 27 2021.
4. Chang HP., **Shah D.K.*** *Determination of ADC Concentration by Ligand-Binding Assays.* in **Methods Molecular Biology: Antibody-Drug Conjugates** edited by L. Nathan Tumey. Springer. 24 October 2019.
5. Molly Z., Wang S., Yan F., Agrawal S., **Shah D.K.*** *Application of Novel PKPD modeling Approaches for Immune-Oncology Drugs.* in **Development of Antibody-Based Therapeutics: Translational Considerations and Challenges (2nd Edition)** edited by Tabrizi M.A., Bornstein G.G., Klakamp S.L. Springer. 2018
6. Singh A. and **Shah D.K..** *PK/PD Modeling to Inform Decision Making for ADCs.* in **Innovations for Next-Generation Antibody-Drug Conjugates** edited Damelin M. Springer. May 29, 2018.
7. **Shah D.K.*** **Chapter 8: Pharmacokinetics and Pharmacology of ADCs**, 121-137. in **Optimizing Antibody-Drug Conjugates for Targeted Delivery of Therapeutics** edited by Sewald N (2016). ISBN: 978-1-910419-35-9
8. Shin BS, **Shah D.K.**, Balthasar JP. **Chapter 34: Pharmacodynamics**, 1133-67. in **Preclinical Development Handbook: ADME and Biopharmaceutical Properties** edited by Gad SC (2008). ISBN: 978-0-470-24847-8

INVITED BOOK CHAPTERS UNDER REVIEW

9. Sharma S., Li Z., Masih S., **Shah D.K.*** *PK and PK-PD Modeling of Antibody-Drug Conjugates.* in **Quantitative and Translational PK/PD of Antibody Based Therapeutics** edited by Chimalakonda A., Kamath A., Narayanan R. Springer.
10. Chang HP., Kumar M., **Shah D.K.*** *PK/PD M&S of Antibody-Drug Conjugates.* in **Antibody-Drug Conjugates** edited by Ashutosh Kulkarni and Hovik Gukasyan. Springer.

PATENTS

1. Method for treating stomach cancer
Moustafa E El-Araby, Abdelsattar M Omar, Maan T Khayat, **Dhaval Shah**, Martin K Safo, Azizah M Malebari, Farid Ahmed
US Patent 11,325,885
May 10, 2022
2. Method for treating a patient having a colon cancer
Moustafa E El-Araby, Abdelsattar M Omar, Maan T Khayat, **Dhaval Shah**, Martin K Safo, Azizah M Malebari, Farid Ahmed
US Patent 11,312,680
April 26, 2022
3. Method for making anti-cancer compounds
Moustafa E El-Araby, Abdelsattar M Omar, Maan T Khayat, **Dhaval Shah**, Martin K Safo, Azizah M Malebari, Farid Ahmed
US Patent 11,214,537
January 4, 2022
4. Pharmaceutical composition for treating cancer
Moustafa E El-Araby, Abdelsattar M Omar, Maan T Khayat, **Dhaval Shah**, Martin K Safo, Azizah M Malebari, Farid Ahmed
US Patent 11,142,493
October 12, 2021
5. Method for treating a patient having cancer
Moustafa E El-Araby, Abdelsattar M Omar, Maan T Khayat, **Dhaval Shah**, Martin K Safo, Azizah M Malebari, Farid Ahmed
US Patent 11,136,288
October 5, 2021
6. Cytotoxic compounds, pharmaceutical compositions thereof, and methods of treating cancer
Moustafa E El-Araby, Abdelsattar M Omar, Maan T Khayat, **Dhaval Shah**, Martin K Safo, Azizah M Malebari, Farid Ahmed
US Patent 10,988,439
April 27, 2021
7. Amide group-containing compounds and use for cancer treatment
Moustafa E El-Araby, Abdelsattar M Omar, Maan T Khayat, **Dhaval Shah**, Martin K Safo, Azizah M Malebari, Farid Ahmed
US Patent 10,844,007
November 24, 2020

11. POSTER PRESENTATIONS

Note: This is not a comprehensive list. I have not included many University at Buffalo poster presentations. We have an undergraduate research symposium annually in the School of Pharmacy and Pharmaceutical Sciences plus the UB Celebration of Excellence, and poster presentations annually for the CLIMB-UP/iSEED programs. I have 1-2 students present at each of these poster presentations and give podium presentations as well.

Local

1. Hong J., Qiao C., **Shah D.K.*** *Design and Generation of Humanized Anti-Topotecan*

- Single Chain Variable Fragment (scFv) for Inverse Targeting Strategy*. Presented at the School of Pharmacy and Pharmaceutical Sciences Poster Day, University at Buffalo, April 27, 2017.
2. Hong J., Qiao C., **Shah D.K.*** *Design and Generation of Humanized Anti-Topotecan Single Chain Variable Fragment (scFv) for Inverse Targeting Strategy*. Presented at the Celebration of Student Academic Excellence, University at Buffalo, April 7, 2017.
 3. Hong J., Qiao C., **Shah D.K.*** *Design and Generation of Humanized Anti-Topotecan Single Chain Variable Fragment (scFv) for Inverse Targeting Strategy*. Presented at the SUNY Undergraduate Research Conference Research Fair at SUNY Fredonia, April 22, 2017.
 4. Vaughn Z., Hall A.V., Bussing D., **Shah D.K.*** *The Creation of an Antibody Drug Conjugate, Trastuzumab-VC-Dox*. Presented at the GEM GRAD lab conference Binghamton University, Binghamton, NY October 14, 2016.
 5. Meyer L.F., Tran P., Shah D.K.* *Reducing Lipid Content of Adipocytes Using Oxidative Phosphorylation Uncouplers*. Presented at the Women in STEM Summit, University at Buffalo, April 2016.
 6. Hong J., Khot A., Rudick M., Li Z., Qiao C., **Shah D.K.*** *Developing a Platform for Monoclonal Antibodies Expression and Production*. Presented at the 2016 Women in STEM Summit, University at Buffalo, April 13, 2016.
 7. Hong J., Khot A., Rudick M., Li Z., Qiao C., **Shah D.K.*** *Developing a Platform for Monoclonal Antibodies Expression and Production*. Presented at the Celebration of Student Academic Excellence, University at Buffalo, April 7, 2016.
 8. Kim S., Meyer L.F., **Shah D.K.*** *Determining the Pharmacodynamic Properties of Oxidative Phosphorylation Uncouplers*. Presented at the School of Pharmacy and Pharmaceutical Sciences Poster Day, University at Buffalo, April 2015.
 9. Okeke B., Masih S., **Shah D.K.*** *Effects of Drug Loading on Antibody Pharmacokinetics*. Presented at the CLIMB-UP poster session at The State University of New York, Buffalo, 2015.
 10. Gbewonyo A., Meyer L.F., **Shah D.K.*** *Towards Treating Obesity by Uncoupling Mitochondria using 2,4-Dinitrophenol*. Presented at the UB Summer Research Symposium, Clinical and Translation Research Center, University at Buffalo, August 2014.
 11. Singh A.P., Masih S., **Shah D.K.*** *Optimization of Experimental design for Preclinical Tumor Growth Inhibition Studies* Presented at the 2014 Buffalo Pharmaceutics Symposium, University at Buffalo, August 2014.
 12. Meyer L.F., **Shah D.K.*** *Towards the Treatment of Obesity with Targeted Protonophores*. Presented at the 2014 Buffalo Pharmaceutics Symposium, University at Buffalo, August 2014.
 13. Gbewonyo A., Meyer L.F., **Shah D.K.*** *Towards Treating Obesity with Targeted Delivery of Protonophores*. Presented at the CLIMB-UP poster session at The State University of New York, Buffalo, 2014.
 14. Masih S., Singh A., **Shah D.K.*** *Optimal Experimental Design for Preclinical Tumor Growth Inhibition Studies*. SUNY Buffalo SoPPS poster day 2014.

National

15. Chang HY., **Shah D.K.*** *A Translational Physiologically-Based Pharmacokinetic Model for Antibody Disposition in the Brain*. Presented at AAPS Novel Approaches Target Brain Barriers for Effective Delivery of Therapeutics Workshop, May 2019.
16. Khot A., **Shah D.K.*** *Measurement and Quantitative Characterization of Whole-Body Pharmacokinetics of Exogenously Administered T Cells in Mice*. Presented at the ASCPT 2019 Annual Meeting, March 2019.
17. Li Z., **Shah D.K.*** *A platform physiologically based pharmacokinetic (PBPK) model for different-size protein therapeutics*. Presented at the 9th ACoP Conference, October 2018.
18. Khot A., **Shah D.K.*** *Development of a Translational Physiologically Based Pharmacokinetic Model for Antibody-Drug Conjugates: A Case Study with T-DM1*. Presented at the Northeast American Association of Pharmaceutical Scientists (AAPS) Student Chapter Conference, GlaxoSmithKline Research and Development site, June 2017.
19. Meyer L.F., **Shah D.K.*** *Potential of Oxidative Phosphorylation Uncouplers as Anti-Obesity Agents*. Presented at the Northeast American Association of Pharmaceutical Scientists (AAPS) Student Chapter Conference, GlaxoSmithKline Research and Development site, June 2017.
20. Singh A.P., **Shah D.K.*** *A PK-PD Modeling and Simulation Based Strategy for Clinical Translation of Antibody-Drug Conjugates: A case study with T-DM1*. Presented at Rosa Impact Webinar Series, April 19, 2017.
21. Vaughn Z., Hall A.V., Bussing D., **Shah D.K.*** *The Creation of an Antibody Drug Conjugate, Trastuzumab-VC-Dox*. Presented at the ERN conference, Washington, D.C. March 2-4, 2017.
22. Singh A.P., Sharma S., **Shah D.K.*** *Understanding and Characterizing Bystander Effect of Antibody-Drug Conjugates*. Presented at American Conference on Pharmacometrics (ACoP), October 2016, Bellevue, WA.
23. Vaughn Z., Hall A.V., **Shah D.K.*** *Synthesis of a Novel Linker, MC-val-cit-PAB-PNP, for Payload of ADC*. Presented at the McNair's Undergraduate Research Conference Niagara Falls, NY July 21-23, 2016.
24. Khot A., **Shah D.K.*** *Development of a Translational Physiologically Based Pharmacokinetic Model for Antibody-Drug Conjugates: A Case Study with T-DM1*. Presented at the American Association of Pharmaceutical Scientists - National Biotech Conference, May 2016.
25. **Shah D.K.*** and Betts A.M. *Kinetic In-Vitro Cell Killing Experiment for Antibody Drug Conjugates: Validation of the Mechanism and Cellular Biomarkers*. American Association of Pharmaceutical Scientists (AAPS) National Biotech Conference (NBC) 2013.
26. **Shah D.K.***, Haddish-Berhane N, Betts A.M. *Development of a mechanistic mathematical model to simultaneously characterize the effect of ADCs on cell viability, cell cycle phases and cellular level biomarkers*. American Association of Pharmaceutical Scientists (AAPS) National Biotech Conference (NBC) 2013.
27. **Shah D.K.***, Betts A.M., Fate G. *Evolving PBPK Modeling to Predict the PK and Appropriate Doses of Monoclonal Antibodies for Pediatric Patients*. American Association of Pharmaceutical Scientists (AAPS) National Biotech Conference (NBC) 2013.
28. **Shah D.K.*** and Betts A.M. *Inferring Tissue Concentrations of Monoclonal Antibodies*

Based on the Plasma Concentrations Using Antibody Biodistribution Coefficient (ABC).
American Association of Pharmaceutical Scientists (AAPS) National Biotech Conference (NBC) 2013.

29. **Shah D.K.***, Haddish-Berhane N., Leal M., DiJoseph J., Sapra P., Gerber H.P. and Betts A.M. *A Mechanistic Model of ADC Disposition and Tumor Penetration*. Presented at Systems Pharmacology Global Summit. 2012.
30. Haddish-Berhane N., Betts A.M., **Shah D.K.**, DiJoseph J., Leal M., Gerber H.P. and Sapra P. *Optimization and Use of PK/PD Modeling of Xenograft Tumor response as a Translational Strategy To Predict Efficacious Clinical Doses of Antibody Drug Conjugates*. Presented at World ADC Summit 2011.
31. **Shah D.K.***, Betts A.M., Maurer T.S. *A platform PBPK model to characterize the plasma and tissue disposition of monoclonal antibodies in preclinical species and human*. Presented at National Biotech Conference (NBC) annual meeting 2011.
32. **Shah D.K.**, Shin B.S., Veith J., Bernacki R.J., Balthasar J.P. *Treating Ovarian Cancer Using a Combination of Antiangiogenic Therapy and Intraperitoneal Chemotherapy*. Presented at American Association of Pharmaceutical Scientists (AAPS) annual meeting 2010.
33. **Shah D.K.**, Shin B.S., Veith J., Bernacki R.J., Balthasar J.P. *A Pharmacokinetic Strategy to Increase the Efficacy of Intraperitoneal Chemotherapy*. Presented at University at Buffalo Sigma Xi Research Day held on the Celebration of Academic Excellence Day 2009.
34. **Shah D.K.**, Shin B.S., Veith J., Bernacki R.J., Balthasar J.P. *A Pharmacokinetic Strategy to Increase the Efficacy of Intraperitoneal Chemotherapy*. Presented at American Association of Pharmaceutical Scientists (AAPS) annual meeting 2008.
35. **Shah D.K.**, Shin B.S., Veith J., Bernacki R.J., Balthasar J.P. *Improving Therapeutic Benefits of Intraperitoneal Chemotherapy by Co-administration of Anti-angiogenic Therapy*. Presented at American Association of Pharmaceutical Scientists (AAPS) annual meeting 2008.
36. **Shah D.K.**, Shin B.S., Balthasar J.P. *Simulations of the influence of antibody-ligand binding kinetics on the pharmacokinetics of "high-clearance" ligands*. Presented at the Great Lake Symposium held at University of Pittsburg in 2007
37. **Shah D.K.**, Shin B.S., Balthasar J.P. *Simulations of the influence of antibody-ligand binding kinetics on the pharmacokinetics of "high-clearance" ligands*. Presented at the American Association of Pharmaceutical Scientists (AAPS) annual meeting 2007.

12. INVITED TALKS and PRESENTATIONS

International

1. **Shah D.K.***. *Towards Development of a Platform PBPK Model for AAV Mediated Delivery of MAb genes*. Joint meeting between the Drug Metabolism Discussion Group (DMDG), Group of Metabolism and Pharmacokinetics (GMP) and the Swedish Academy of Pharmaceutical Sciences (SPS). **Amsterdam, Netherlands**. Oct 2022.
2. **Shah D.K.***. *Novel Biologics and Application of PK-PD Modelling and Simulation for their Development*. **National Institute of Pharmaceutical Education and Research, Ahmedabad, India**. Feb 2021.
3. **Shah D.K.***. *PK/PD Modeling and Simulation for Clinical Development of ADCs: Application and Challenges*. Presentation at Peking University. **Beijing, China**. Oct

2020.

4. **Shah D.K.*.** *PK/PD Based Strategies to Improve the Therapeutic Index of ADCs.* Presentation at World ADC London. **London, UK.** May 2019.
5. **Shah D.K.*.** *Systems Pharmacokinetic Modeling of ADCs.* Presentation at 22nd North American ISSX Meeting. **Montréal, Canada.** July 15-19, 2018.
6. **Shah D.K.*.** *Quantitative Characterization of the Bystander Effect of ADCs.* Presentation at the 7th World ADC Summit. **Berlin, Germany.** February 20-22, 2017.
7. **Shah D.K.*.** *Bench-to-bedside translation of ADCs using PKPD M&S.* Presentation at the 2nd World Conference on Pharmacometrics (WCOP). **Brisbane, Australia.** August 23, 2016.
8. **Shah D.K.*.** *Model-based Drug Development of Protein Therapeutics.* Presentation at the 11th International International Society for the Study of Xenobiotics (ISSX) Meeting. **Busan, Korea.** June 12-16, 2016.
9. **Shah D.K.*.** *Model Based Development of Antibody Drug Conjugates.* Presentation at the Clinical & Pharmaceutical Solutions through Analysis Conference 2014. **Shanghai, China.** April 16, 2014.
10. **Shah D.K.*.** *Quantitative PKPD Approaches to Guide the Discovery and Development of ADCs.* Presentation at the Samsung Medical Center. **Seoul, South Korea.** April 15, 2014.
11. **Shah D.K.*.** *Quantitative PKPD Approaches to Guide the Discovery and Development of ADCs.* Presentation at the Green Cross Pharmaceuticals. **Seoul, South Korea.** April 14, 2014.

National

12. **Shah D.K.*.** *Mathematical Models to Characterize the Absorption, Distribution, Metabolism, and Excretion (ADME) of Protein Therapeutics.* ISSX Member Webinar Series. Online. March 2023.
13. **Shah D.K.*.** *Towards Development of a Platform PBPK Model for AAV Mediated Delivery of MAbs Genes.* Pharmaceutical & BioScience Society, International (PBSSI). Online. December 2022.
14. **Shah D.K.*.** *Basic tenets of ADC PK/PD and examples of how M&S can be used to support MIDD of ADCs.* AAPS Bay Area Discussion Group. Online. June 2022.
15. **Shah D.K.*.** *Towards Development of Predictive PBPK Models for Biologics.* Indiana Clinical and Translational Sciences Institute (CTSI), 11th Annual Symposium on Disease and Therapeutic Response Modeling and Simulation. Feb 2022.
16. **Shah D.K.*.** *PK/PD Considerations for the Development of AAV Mediated Gene Delivery.* AAPS Cell and Gene Delivery Section. AAPS Webinar Series. Aug 2021.
17. **Shah D.K.*.** *Towards Development of Translational Systems Pharmacokinetics Models for Protein Therapeutics.* ISSX New Investigator Award Lecture. Online. Feb 2021.
18. **Shah D.K.*.** *Measurement and Quantitative Characterization of Protein Therapeutics Transport Across the BBB and BCSFB.* PEGS. ISSX Webinar Series. Dec 2020.
19. **Shah D.K.*.** *Application of PK/PD M&S for Preclinical-to-Clinical Translation of ADCs.* PEGS. Boston, MA. Sept 2020.

20. **Shah D.K.*.** *Tissue Distribution of Antibodies: Pharmacokinetics/Pharmacodynamics Perspective.* Antibodies as Drugs, Keystone Symposia. Santa Fe, NM. Feb 2020.
21. **Shah D.K.*.** *Quantitative Characterization and Prediction of the Disposition of Biologics.* 1st ISSX workshop on the Disposition of Biologics. Boston, MA. Dec 2019.
22. **Shah D.K.*.** *Systems PKPD models for cancer immunotherapy.* 12th International ISSX Meeting. Portland, OR. July 2019.
23. **Shah D.K.*.** *Development of a Translational PK Model for Characterizing and Predicting Protein Therapeutics Disposition in Brain.* New Orleans, LA. Nov 13, 2018.
24. **Shah D.K.*.** *Role of PK-PD in ADC Development.* Presentation at the **Controlled Release Society Annual Meeting & Exposition.** New York City, NY. July 24, 2018.
25. **Shah D.K.*.** *PK-PD M&S Driven FIH Dose Projection for ADCs.* Presentation at **Boston Pharmaceutical & BioScience Society.** Boston, MA. April 27, 2018.
26. **Shah D.K.*.** *Development of Predictive Systems Pharmacokinetics Models for Novel Biotherapeutics.* Presentation at the first **ISoP** event at Buffalo. Buffalo, NY. April 16, 2018.
27. **Shah D.K.*.** *Towards understanding the disposition of protein therapeutics in the brain using microdialysis.* Presentation at **Amgen Inc.** Boston, MA. January 10, 2018.
28. **Shah D.K.*.** *Development of Predictive QSPK Models for Novel Biotherapeutics.* Presentation at **Boston QSP.** Boston, MA. January 10, 2018.
29. **Shah D.K.*.** *Development of Translational PK Model for Characterizing and Predicting Protein Therapeutics Disposition in Brain.* Presentation at **The National Academies of Sciences, Engineering, and Medicine's** Forum on Neuroscience and Nervous System Disorders. Washington, DC. September 8, 2017.
30. **Shah D.K.*.** *PK/PD Considerations for the Next Generation Protein Therapeutics.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) National Biotech Conference. San Diego, CA. May 2, 2017.
31. **Shah D.K.*.** *Protein Therapeutics: The Next Generation of Medicines.* Presentation at the University of New England, College of Pharmacy. Portland, ME. April 10, 2017.
32. **Shah D.K.*.** *Physiologically Based Pharmacokinetic (PBPK) Modeling of Monoclonal Antibodies (MAbs).* Presentation at the American Association of Pharmaceutical Scientists (AAPS) Educational Webinar Series. April 6, 2017.
33. **Shah D.K.*.** *PBPK Modeling of Monoclonal Antibodies and Antibody-Drug Conjugate.* Presentation at the Boston Pharmaceutical & BioSciences Society (PBSS). Boston, MA. October 2, 2016.
34. **Shah D.K.*.** *Quantitative Characterization of the Bystander Effect of ADCs.* Presentation at the 7th World ADC Summit. San Diego, CA. October 10-13, 2016.
35. **Shah D.K.*.** *Use of Mechanistic Models to Predict the Pharmacokinetics and Pharmacodynamics of Antibody-Drug Conjugates.* Presentation at the 2016 Globalization of Pharmaceuticals Education Network (GPEN) Meeting. Lawrence, KS. November 12, 2016.
36. **Shah D.K.*.** *Platform PBPK Model for Biologics and Its Evolution Towards Pediatric Population.* Presentation at **the St. Jude Children's Research Hospital.** Memphis, TN. June 2, 2016
37. **Shah D.K.*.** *Role of Bioanalysis in Preclinical-to-Clinical Translation of ADCs.*

Presentation at the 2016 Waters ADC Summit. Pleasanton, CA. March 3, 2016.

38. **Shah D.K.*.** *Preclinical-to-Clinical Translation of ADCs Using Mechanistic Modeling.* Presentation at the 2015 American Conference on Pharmacometrics (ACoP-6). Arlington, VA. October 6, 2015.
39. **Shah D.K.*.** *Important Tumor Model Properties for PK/PD Modeling and Simulation Driven Preclinical-to-Clinical Translation.* Presentation at the 2015 Tumor Model Conference. Boston, MA. July 23, 2015.
40. **Shah D.K.*.** *Platform PBPK Model for Biologics and Its Evolution Towards Pediatric Population.* Presentation at the 2015 **Gordon Research Conference** on Drug Metabolism. Holderness, NH. July 15, 2015.
41. **Shah D.K.*.** *PK/PD Considerations for Antibody Drug Conjugates.* Presentation at the 2014 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting. San Diego, CA. November 4, 2014.
42. **Shah D.K.*.** *The Integration of ADC PK and Cellular Biomeasures into Mechanistic PK/PD Models.* Presentation at the 2014 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, San Diego, CA. November 4, 2014.
43. **Shah D.K.*.** *Evolution of the Platform PBPK Model for Monoclonal Antibodies Towards Pediatric Population.* Presentation at the ROSA World-Wide Webinar Series: Impact of Modeling & Simulation in Drug Development. September 24, 2014.
44. **Shah D.K.*.** *Incorporation of ontogeny related changes in mAb PBPK model to assess their influence on the PK of mAbs.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) National Biotechnology Conference 2014. San Diego, CA. May 20, 2014.
45. **Shah D.K.*.** *Prediction of 'Optimal Biological Dose' for Antibody Drug Conjugates.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) National Biotechnology Conference 2014. San Diego, CA. May 20, 2014.
46. **Shah D.K.*.** *Optimizing ADC Development Using PK/PD Modeling and Simulation.* Presentation at the 2014 PEGS Conference. Boston, MA. May 6, 2014.
47. **Shah D.K.*.** *Utilizing PKPD Modeling and Simulation to Guide the Discovery and Development of ADCs.* Presentation at the 2014 PEGS Conference. Boston, MA. May 6, 2014.
48. **Shah D.K.*.** *Key Bioanalytical Measurements for ADC Development: A Customer's Wish List.* Presentation at The 2014 Biopharmaceutical Technology Summit for Antibody-Drug Conjugates by Waters Corporation. Pittsburg, PA. April 9, 2014.
49. **Shah D.K.*.** *Bench to Bedside Translation of Antibody Drug Conjugates.* Presentation at The American Society for Clinical Pharmacology and Therapeutics (**ASCPT**) 2014 annual meeting. Atlanta, GA. March 20, 2014.
50. **Shah D.K.*.** *Bench to Bedside Translation of ADC Efficacy.* Presentation at **The New York Academy of Sciences** 2014 Antibody-Drug Conjugates: An Emerging Modality for the Treatment of Cancer Conference. New York City, NY. January 28, 2014.
51. **Shah D.K.*.** *Employing Quantitative PKPD Approaches for Bench-to-Bedside Translation of ADCs.* Presentation at the 2013 Leaders in Bio Banking Conference. Indianapolis, IN. November 5, 2013.
52. **Shah D.K.*.** *Employing PK/PD modeling and simulation to guide ADC development.* Presentation at the 2013 World ADC Summit. San Francisco, CA. October 15, 2013.

53. **Shah D.K.*.** *Overcoming PK/PD barriers to link drug levels with the biological effects in a tumor.* Presentation at the 2013 Tumor Model Conference. Boston, MA. July 25, 2013.
54. **Shah D.K.*.** *Evolving PBPK Modeling to Predict the PK and Appropriate Doses of Biotherapeutics for Pediatric Patients.* Presentation at the 2013 American Association of Pharmaceutical Scientists (AAPS) National Biotech Conference (NBC) Meeting. San Diego, CA. May 21, 2013.
55. **Shah D.K.*.** *Preclinical to Clinical Translation of Antibody Drug Conjugate (ADC) Efficacy using PK/PD Modeling and Simulation.* Presentation at the 2013 American Association of Pharmaceutical Scientists (AAPS) Webinar Series by CPTR. May 9, 2013.
56. **Shah D.K.*.** *Development and Validation of a Mechanism Based PK/PD Model for Preclinical to Clinical Translation of ADC Efficacy.* Presentation at the 2013 PEGS Inaugural 'PK/PD of Antibody-Derived Molecules: Improving Pre-Clinical Results for Clinical Success' conference. Boston, MA. May 1, 2013.
57. **Shah D.K.*.** *Novel Applications of PBPK Models.* Presentation at the PK/PD summit 2013. Boston, MA. March 21, 2013.
58. **Shah D.K.*.** *Bench to Bedside Translation of Antibody Drug Conjugates Using a Multiscale Mechanistic PK/PD Model: A Case Study with SGN-35.* Presentation at the ROSA's 2012 World-Wide Webinars: Impact of Modeling and Simulation in Drug Development. November 22, 2012.
59. Nahor H.B., **Shah D.K..** *Using Mechanistic Preclinical PK/PD Studies to Inform Dose, Dose Regimen Selection and Beyond: Can we make Preclinical Models more Predictive?* Presentation at the 2012 World ADC Summit. San Francisco, CA. October 25, 2012.
60. **Shah D.K.*.** *Preclinical-to-clinical translation of ADC efficacy using the multi-scaled mechanistic PK/PD model.* Presentation at the 2012 '3rd Pharmacokinetics & Pharmacodynamics Conference' organized by the GTC. Philadelphia, PA. October 23, 2012
61. **Shah D.K.*.** *Development and Validation of the multi-scaled mechanistic PK/PD model for ADCs.* Presentation at the 2012 inaugural 'PK/PD of Novel Constructs Conference' organized by the Cambridge Healthtech Institute. Bethesda, MD. October 12, 2012.
62. **Shah D.K.*.** *A platform PBPK model to characterize the plasma and tissue disposition of mAbs.* Presentation at The 2012 Rozman Symposium organized by The Delaware Valley DRUG METABOLISM DISCUSSION GROUP. Langhorne PA. June 7, 2012.
63. **Shah D.K.*.** *Mechanistic Modeling for Rational Selection of Clinical Doses for Biologics.* Presentation at American Association of Pharmaceutical Scientists (AAPS) annual meeting. Washington, DA. October 27, 2011.
64. **Shah D.K.*.** *Mathematical Modeling of Antibody-Ligand Interaction: What should we measure – unbound antibody, bound antibody, total antibody, or total ligand?* Presented at American Association of Pharmaceutical Scientists (AAPS) National Biotech Conference (NBC) annual meeting 2011. San Francisco, CA. May 17, 2011.
65. **Shah D.K.,** Balthasar J.P. *Treating ovarian cancer using combination of anti-angiogenic therapy and intraperitoneal chemotherapy.* Presented at the American Association of Pharmaceutical Scientists (AAPS) annual meeting. New Orleans, LA. November 14, 2010.
66. **Shah D.K.,** Shin B.S., Veith J., Bernacki R.J., Balthasar J.P. *A Pharmacokinetic Strategy to Increase the Efficacy of Intraperitoneal Chemotherapy.* Presented at PGSRM

conference held at Purdue University. West Lafayette, IN. May, 2009.

Local

67. **Shah D.K.*** Development of Physiologically Based Pharmacokinetic Models for Biologics. Institute for Artificial Intelligence and Data Science (IAD), University at Buffalo, New York. March 28, 2023
68. **Shah D.K.*** Annual 4-day Workshop on Pharmacokinetics and Pharmacodynamics & Systems Pharmacology. Niagara Falls, New York. May 16-18, 2022
69. **Shah D.K.*** Annual 3-day Workshop on mAb Pharmacokinetics and Pharmacodynamics. Niagara Falls, New York. May 23-25, 2021
70. **Shah D.K.*** Annual 4-day Workshop on Pharmacokinetics and Pharmacodynamics & Systems Pharmacology. Niagara Falls, New York. May 17-20, 2021
71. **Shah D.K.*** Annual 3-day Workshop on mAb Pharmacokinetics and Pharmacodynamics. Niagara Falls, New York. May 24-26, 2021
72. **Shah D.K.*** Annual 4-day Workshop on Pharmacokinetics and Pharmacodynamics & Systems Pharmacology. Niagara Falls, New York. May 13-15, 2019
73. **Shah D.K.*** Annual 3-day Workshop on mAb Pharmacokinetics and Pharmacodynamics. Niagara Falls, New York. May 16-18, 2019
74. **Shah D.K.*** Annual 4-day Workshop on Pharmacokinetics and Pharmacodynamics & Systems Pharmacology. Niagara Falls, New York. May 14-16, 2018
75. **Shah D.K.*** Annual 2-day Workshop on mAb Pharmacokinetics and Pharmacodynamics. Niagara Falls, New York. May 17-19, 2018
76. **Shah D.K.*** Annual 4-day Workshop on Pharmacokinetics and Pharmacodynamics & Systems Pharmacology. Niagara Falls, New York. May 8-10, 2017
77. **Shah D.K.*** Annual 2-day Workshop on mAb Pharmacokinetics and Pharmacodynamics. Niagara Falls, New York. May 11-12, 2017
78. **Shah D.K.*** Annual 4-day Workshop on Pharmacokinetics and Pharmacodynamics & Systems Pharmacology. Niagara Falls, New York. May 17-18, 2016
79. **Shah D.K.*** Annual 2-day Workshop on mAb Pharmacokinetics and Pharmacodynamics. Niagara Falls, New York. May 19-20, 2016
80. **Shah D.K.*** Annual 4-day Workshop on Pharmacokinetics and Pharmacodynamics & Systems Pharmacology. Niagara Falls, New York. June 9-11, 2014
81. **Shah D.K.*** Annual 2-day Workshop on mAb Pharmacokinetics and Pharmacodynamics. Niagara Falls, New York. June 5-6, 2014
82. **Shah D.K.,** Shin B.S., Veith J., Tóth K., Bernacki R.J., Balthasar J.P. *Use of an anti-vascular endothelial growth factor antibody in a pharmacokinetic strategy to increase the efficacy of intraperitoneal chemotherapy.* Department of Pharmaceutical Sciences, University at Buffalo. Buffalo, NY. February, 2009.
83. **Shah D.K.,** Balthasar J.P. *Application of anti-angiogenic therapy to improve drug penetration in solid tumors, following regional chemotherapy.* UB/Pfizer monoclonal antibody videoconference. Buffalo, NY. February 2, 2007.
84. **Shah D.K.,** Khandavilli S., Panchagnula R. *The role of dehydration and transepidermal water loss in skin barriers function.* NIPER. **Mohali, India.** December 15, 2003.