Brian T. Tsuji, PharmD, FCCP, FCCM, FIDSA

CURRICULUM VITAE

1. CONTACT INFORMATION

Professional Address:
301 Farber Hall
Division of Clinical and Translational Therapeutics
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2. EDUCATION

5/2001	**Bachelor of Science in Pharmaceutical Sciences** Eugene Applebaum College of Pharmacy and Health Sciences Wayne State University, Detroit, Michigan
5/2003	**Doctor of Pharmacy** Eugene Applebaum College of Pharmacy and Health Sciences Wayne State University, Detroit, Michigan
7/2005	**Post-Doctoral Fellowship in Infectious Diseases Therapeutics** Detroit Medical Center, Detroit, Michigan Wayne State University, Detroit, Michigan

3. POSITIONS HELD (CURRENT)

7/2018 to Present	**Professor with Tenure**
7/2023 to Present	**Linda Edelman Endowed Chair in Experimental Therapeutics** Division of Clinical and Translational Therapeutics Department of Pharmacy Practice Adjunct Professor of Medicine Jacobs School of Medicine and Biomedical Sciences School of Pharmacy and Pharmaceutical Sciences University at Buffalo, SUNY, Buffalo, New York
7/2018 to Present	**Associate Dean for Clinical and Translational Sciences** School of Pharmacy and Pharmaceutical Sciences University at Buffalo, SUNY, Buffalo, New York

7/2018 to Present **Director of Graduate Studies, Department of Pharmacy Practice**
School of Pharmacy and Pharmaceutical Sciences
CTSI, Jacobs School of Medicine
University at Buffalo, SUNY, Buffalo, New York

9/2018 to Present **Founding Director**
MS in Clinical and Translational Therapeutics (CTT)
School of Pharmacy and Pharmaceutical Sciences
University at Buffalo, SUNY, Buffalo, New York

4/2020 to Present **Founding Director**
UB Center of Infectious Diseases and Next Generation Therapeutics (IDagen)
University at Buffalo, SUNY, Buffalo, New York
CTSI, Jacobs School of Medicine, UB, SUNY, Buffalo, New York

7/2023 to Present **Founding Division Head**
Division of Clinical and Translational Therapeutics
School of Pharmacy and Pharmaceutical Sciences
University at Buffalo, SUNY, Buffalo, New York

5/2015 to Present **Infectious Diseases Pharmacy Consultant**
Without Compensation (WOC) Department of VA Appointment
Department of Pharmacy
Division of Medicine, Infectious Diseases
Veterans' Affairs of Western New York Health Care System
Buffalo, New York

4. POSITIONS HELD (PAST)

5/2003 to 7/2005 **Clinical Pharmacist**
Detroit Receiving Hospital
Detroit Medical Center, Detroit, Michigan

7/2003 to 7/2005 **Research Fellow and Clinical Instructor, Infectious Diseases**
Detroit Medical Center & Eugene Applebaum College of Pharmacy
Wayne State University, Detroit, Michigan

8/2005 to 7/2007 **Clinical Assistant Professor of Pharmacy**
School of Pharmacy and Pharmaceutical Sciences
University at Buffalo, SUNY, Buffalo, New York

8/2006 to 8/2008 **Adjunct Clinical Assistant Professor**
Roswell Park Cancer Institute, Buffalo, New York

8/2008 to 8/2013 **Director**
UB Drug Development Fellowship Programs
School of Pharmacy and Pharmaceutical Sciences
University at Buffalo, SUNY, Buffalo, New York

8/2008 to 6/2013	**Assistant Professor** Department of Pharmacy Practice University at Buffalo, SUNY, Buffalo, New York
7/2013 to 7/2018	**Associate Professor with Tenure** Department of Pharmacy Practice University at Buffalo, SUNY, Buffalo, New York
7/2013 to 8/2018	**Director of Clinical Research** Department of Pharmacy Practice School of Pharmacy and Pharmaceutical Sciences University at Buffalo, SUNY, Buffalo, New York

5. LEADERSHIP AND ADMINSTRATION

University at Buffalo School of Pharmacy and Pharmaceutical Sciences

1. Founding Division Head, Division of Clinical and Translational Therapeutics (CTT), SPPS (2022-)

I conceptualized, recruited world-class faculty, and created a new CTT Division from the ground up focused on addressing the world's most pressing problems in clinical therapeutics. My role was to provide leadership in strategic planning, building teams, resources and relationship management, facilities management, conflict resolution, hiring, and faculty and student mentoring. CTT has emerged as one of the leading departments of clinical pharmacy and clinical pharmacology in all Schools of Pharmacy across the US. The division of CTT is comprised of 8 NIH-funded, clinician scientist faculty members with >50 staff scientists, post-doctoral fellows, administrative staff, and students (PharmD, MS, PhD, and MD), directly supported by the division. Through "Team Science" the CTT division of pharmacists, physicians, students, and scientists achieved unprecedented heights of NIH and federal funding across SUNY. In 2024, the division had 47 publications, 6 of the top 20 NIH grants at UB (Primarily comprised of five large ~$4M R01s, one T35, two D43s, and one Large $11M clinical contract). CTT contributed to >40% of the total NIH expenditures at SPPS and was noted by the university a "top performer" across SUNY.

2. Associate Dean for Clinical and Translational Sciences, SPPS (2018-)
Founding Director MS in Clinical and Translational Therapeutics (2018-)
Director of Graduate Studies (2018-)

As a licensed pharmacist and clinician scientist, my role was to expand and grow the academic enterprise in clinical and translational sciences, increase the School's NIH funding base, and foster partnership across pharmacy and medicine. I was charged with establishing innovative educational programs for PharmD. Across the University and within the School, I led the development of new programs offering novel clinical training, and research opportunities for Students in Clinical and Translational Sciences. I worked closely with the Principal Investigator of the Clinical and Translational Sciences Institute (CTSI, Dr. Murphy) at the Jacobs School of Medicine. During this time, I also represented SPPS graduate PharmD education offerings within this domain. Major milestones include:

(1) Led the university's submission to the New York State Education Department and the State University of New York System for a new M.S. program in "Clinical and Translational Therapeutics" for pharmacists, physicians, and health care professionals.

(2) Co-Principal Investigator of the NIH/NIAID T35 submission entitled "Training the next generation of clinician scientists." Created new interdisciplinary paradigms with Dr. Murphy

(PI of the CTSI) by providing interprofessional (PharmD and MD students) research experiences with NIH-funded faculty.
(3) Increased NIH R01-funded projects in the clinical department by more than 250%.
(4) Pioneered three new micro-credential and digital badge programs including the “Clinical Research Program”, “T35 Research Program”, and “Clinical Scientist Program” for PharmD and MD students.
(5) Coordinated and developed innovative methodologies for recruitment of next-generation translational Pharm.D. students together with the Associate Dean Admissions.
(6) Chaired and organized the 2018 Buffalo Fellow Forum Conference: fostered collaborations with Pharm.D. Fellows and mentors from leading Pharmacy Schools across the US (UNC, U. Florida, U. Houston, UIC, Wayne State University, and U. Michigan).
(7) Led structural changes to the Pharm.D. Clinical Research Program and dual degree programs
(8) Currently leading the development of a NIH T32 future submission to train Pharm.D. post-doctoral fellows.
(9) Currently leading submission to NYS Education Department of a New PhD in Experimental Therapeutics across the Health Sciences Schools by partnering with Industry.
(10) Currently leading the School of Pharmacy’s efforts in the CTSI pilot studies program and fostering large NIH Center grants with the Associate Vice President for Health Sciences.

3. Founding Director, UB Center of Infectious Diseases and Next Generation Therapeutics Research (2020-)
I led the strategic reorganization, relocation, and creation of the newly established UB Center of Infectious Diseases Next Generation Therapeutics (IDagen) by bridging new partnerships with UB, NIH, the pharmaceutical industry, and academic groups around the US and world. As Director, my role was to provide compelling leadership to Pharm.D. and graduate students, staff, and faculty from nine leading infectious diseases research groups (10 R01s) at the UB, Hauptman Woodward, Roswell Park Cancer Center, and CTSI. In addition to setting the vision and overall research strategy, the focus was to provide strong student and junior faculty mentorship. Building strategic relationships with the pharmaceutical industry, medicine, pharmacy, and hospital stakeholders was a key component of this role. This resulted in the development of a **$12.04 million Center Grant NIH/NIAID U19** application as Principal Investigator and a recently submitted **$34.56 million Center Grant NIH/NIAID U19** as PI**.** The most recent U19 submission was comprised of 41 co-investigators across the US and world involving 5 Large R01 like projects, 4 Scientific cores, 1 administrative core which was the largest Center application submitted to NIAID/NIH at UB. A major focus of my efforts as PI was to bridge translational research that could cut across Schools SUNY wide, in this Pharmacy-led NIH Center application. Although both center grants were eventually not funded, reviewers noted new innovations for pharmacists, physicians, and scientists as a novel model for funded research to partner with the Pharmaceutical Industry.

4. Director of Research and Director of UB Pharmaceutical Industry Fellowships
UB-Novartis, UB-Roche, and UB-Pfizer Fellowships, SPPS (2013 to 2018)
The Director of Research is part of the departmental executive committee in service to the Chair and Dean and is responsible for the development and execution of strategic initiatives to promote and advocate for research and scholarship across the entire Department of Pharmacy Practice. As the Director of Clinical Research I advised the Chair through shaping the vision, providing leadership, implementing policy related to research and scholarship, and mentorship. I also served as the director of fellowships and drove interdisciplinary collaborations with the pharmaceutical industry by serving as the director of the drug development fellowships with up to 6 fellows per year.

Leadership in Professional Organizations and Novel Partnerships

5. President-elect, President, and Past-President of the International Society for Antimicrobial Pharmacology (ISAP) (2016 to 2022)

The ISAP is an interdisciplinary scientific society for the study of pharmacodynamics and pharmacokinetics with membership on every continent. My role as President was to bring members together, foster collaborations, and develop new paradigms across the world involving more than 20 countries by organizing symposia, workshops, educational programs, and research collaborations. As president, I led the ISAP executive committee involving 10 countries by setting the scientific agenda and vision of the organization.

6. Chair, Polymyxin Guideline Consortium involving 6 Organizations – ACCP, ESCMID, IDSA, ISAP, and SCCM (2016 to 2019)

Together with an outstanding group, I was honored to lead the creation of the first clinical guidelines for the polymyxins through team building, driving consensus, and conflict resolution. Noteworthy accomplishments include: (1) building and achieving consensus among an interdisciplinary group 18 experts comprised of pharmacists, microbiologists, physicians, and basic scientists across 8 different countries; organizing the 3rd conference on polymyxins together with ISAP (5/2018); establishing pragmatic clinical recommendations. (2) Promoting stakeholder engagement and buy in, as well as serving as the working group's primary liaison to interface, negotiate, and get approval from six different organizations, including the American College of Clinical Pharmacy (ACCP), European Society of Clinical Microbiology and Infectious Diseases (ESCMID), Infectious Diseases Society of America (IDSA), International Society for Anti-infective Pharmacology (ISAP), Society of Critical Care Medicine (SCCM), to endorse the guidelines.

6. AWARDS AND HONORS

2/2001	**Rho Chi Award National Pharmaceutical Society**
9/2004	**George McCracken Infectious Diseases Fellowship Award** American Society for Microbiology Interscience Conference on Antimicrobial Chemotherapy
6/2007	**Researcher of the Year** American Clinical College of Pharmacy New York State Chapter
1/2009	**Outstanding Service Award, Past President** American College of Clinical Pharmacy New York State Chapter
5/2009	**Outstanding Research Investigator Award** Vice President for Research, University at Buffalo, SUNY
10/2013	**Researcher of the Year Award** American Clinical College of Pharmacy, New York State Chapter
9/2015	**First Place, Oral Presentation** (Justin Lenhard, Fellow) ASM Microbe, ISAP Sub-committee

9/2016	**ICAAC Program Committee Award** American Society for Microbiology and ASM Microbe Program
9/2017	**Fellow.** Infectious Diseases Society of America
9/2018	**Fellow**. American College of Clinical Pharmacy
9/2019	**ASM Microbe Outstanding Abstract Award** American Society for Microbiology and ASM Microbe Program
3/2019	**Fellow**. Society of Critical Care Medicine
2/2020	**Keynote Speaker.** American Association of Colleges of Pharmacy (AACP) Insight 2020 Annual Meeting.
9/2020	**SUNY Chancellor's award for Excellence in Scholarship and Creative Activities**. University at Buffalo, SUNY
10/2021	**American College of Clinical Pharmacy (ACCP) Editor's Award for Pharmacotherapy.** Consensus Guidelines for the Optimal Use of the Polymyxins. ACCP Annual Virtual Meeting.

7. PROFESSIONAL MEMBERSHIPS AND ACTIVITIES

7.1 MEMBERSHIPS AND FELLOW AWARD

2003 to Present	American Society of Microbiology
2003 to Present	Society of Infectious Diseases Pharmacy
2003 to 2006	American Society of Health Systems Pharmacists
2005 to Present	American College of Clinical Pharmacy, Fellow
2005 to 2010	Network of Antimicrobial Resistance in *Staphylococcus aureus*
2005 to Present	New York State Chapter of American College of Clinical Pharmacy
2008 to Present	Infectious Diseases Society of America, Fellow
2013 to Present	Society of Critical Care Medicine, Fellow

7.2 SCIENTIFIC JOURNAL REVIEW ACTIVITIES AND EDITORIAL BOARDS

2003 to Present	Antimicrobial Agents and Chemotherapy
2003 to Present	Diagnostic Microbiology and Infectious Diseases
2003 to Present	Drugs
2003 to Present	Pharmacotherapy
2006 to Present	Expert Opinion of Investigational Drugs
2007 to Present	Expert Opinion of New Drugs
2008 to Present	European Journal of Clinical Microbiology and Infection
2008 to Present	Journal of Antimicrobial Chemotherapy
2008 to Present	American Association of Pharmaceutical Scientists Journal
2008 to Present	Clinical Infectious Diseases
2008 to Present	Journal of Infectious Diseases
2009 to Present	Clinical Microbiology and Infection
2011 to Present	Journal of Pharmacokinetics and Pharmacodynamics
2011 to Present	mBIO

2011 to Present	mSphere
2016 to Present	Lancet Infectious Diseases
2016 to Present	Nature Communications
2016 to Present	Annals of Pharmacology and Pharmaceutics, Editorial Board
2016 to Present	Infectious Diseases Diagnosis and Therapy, Editorial Board
2016 to Present	Critical Care Self-Assessment Program, (CCSAP), Infection Critical Care, American College of Clinical Pharmacy (ACCP), Editorial Board

7.3 EXTRAMURAL GRANT REVIEWER

2015 to Present	**Voting Member, Gram-negative Study Section** Antimicrobial Resistance Leadership Group (ARLG), Duke Clinical Research Institute, is funded by the National Institutes of Allergy and Infectious Diseases, National Institutes of Health (UM1 AI10468).
1/2015	**Ad Hoc Reviewer**, Immunity and Infection Board, Medical Research Council, United Kingdom (RCUK)
8/2016	**Reviewer, Special Emphasis Panel,** ZAI1 ZL-M-J2, Program Project, P01, National Institute of Allergy and Infectious Diseases, NIH
8/2016	**Ad Hoc Reviewer**, DFG, German Research Foundation, Germany
2016	**Ad Hoc Reviewer**, US Medical Research and Material Command (MRMC) Military Infectious Disease (MID) panel, Broad Agency Announcement for Extramural Research, Department of Defense, US
2017, 2019	**Reviewer**, Clinical Research and Field Studies of Infectious Diseases Study Section, ZRG1 IDM-R, National Institute of Allergy and Infectious Diseases, NIH
11/2017	**Reviewer, Special Emphasis Panel,** ZRG1 IDM-W, Topics in Antimicrobial Resistance, Drug Discovery and Clinical Field Studies, National Institute of Allergy and Infectious Diseases, NIH
5/2018 to 2022	**Reviewer, Special Emphasis Panel,** ZRG1 IDM, Topics in Antimicrobial Resistance, Drug Discovery and Clinical Field Studies, National Institute of Allergy and Infectious Diseases, NIH
2019 to 2023	**Temporary Member**, Drug Discovery and Resistance (DDR) Study Section, ZRG1 IDM-R, National Institute of Allergy and Infectious Diseases, NIH
4/2020	**Reviewer**, RM18-009: NIH Transformative Research Awards (R01) Review, National Institute of Allergy and Infectious Diseases, NIH
1/2022	**Reviewer**, Small Business Innovation Research Program. SBIR Phase I. National Science Foundation (NSF).
2023 to Present	**Temporary Member**, Advancing Therapeutics, Study Section, National Institute of Allergy and Infectious Diseases, NIH

2024 to Present	**Temporary Member**, Infectious Disease Drug Development and Molecular Pharmacology, Study Section, National Institute of Allergy and Infectious Diseases, NIH

8. PROFESSIONAL ORGANIZATIONAL SERVICE: LEADERSHIP

8.1 NATIONAL

9/2009 to 9/2011	**Chair,** Microbial Initiative Collaborative (MIC)**,** New York State
1/2010 to 12/2010	**Member, Awards Committee** Society of Infectious Diseases Pharmacists and Pharmacology
4/2014 to 9/2016	**Treasurer** International Society of Anti-Infective Pharmacology (ISAP)
9/2013 and 9/2015	**Member, Organizing Committee** 1st and 2nd Conference on Polymyxins, Prato Italy
8/2015 to 2018	**Co-Chair and Co-organizer,** 3rd Polymyxin Conference, Madrid, Spain
5/2019	**Chair and Organizer** Fellow Forum Conference for Pharm.D. Post-docs Fellows Collaborations with organized together with UNC, U. Florida, U. Houston, UIC, Wayne State University, and U. Michigan Buffalo, NY
9/2016 to 2019	**Co-Chair** Polymyxin Guidelines Working Group endorsed by American College of Clinical Pharmacy (ACCP), Infectious Diseases Society of America (IDSA), European Society of Clinical Microbiology and Infectious Disease (ESCMID), International Society for Anti-infective pharmacology (ISAP), and Society of Critical Care Medicine (SCCM)
9/2016 to 9/2020	**President Elect and President** International Society of Anti-Infective Pharmacology (ISAP)
9/2020 to Present	**Past-President** International Society of Anti-Infective Pharmacology (ISAP)

8.2 STATE

1/2007 to 1/2008	**President** New York State Chapter, American Clinical College of Pharmacy and Pharmacology
1/2008 to 1/2009	**Past President** New York State Chapter, American Clinical College of Pharmacy and Pharmacology

8.3 LOCAL

9/2006 to 5/2007	**Member, Organizing Committee** Annual Pharmacy Symposium, Roswell Park Cancer Institute

9. UNIVERSITY SERVICE

9.1 UNIVERSITY

4/2010 to 9/2010	**Member, Scientific Review for Biomedical Research for UB IRB** Office for Vice President for Research
7/2015 to Present	**Reviewer, Pilot Studies Program** UB Clinical and Translational Institute (CTSI)
2018 to 2021	**Scientific Leadership Committee, Drug Development Core** UB Clinical and Translational Institute (CTSI)
2022 to Present	**Chair, Microcredential and Digital Badge Programs** **T35 Clinical Scientist Program for MD and Pharm.D. Students** **Clinician Scientist Program for MD and Pharm.D. Students** UB Clinical and Translational Institute (CTSI) Jacobs School of Medicine and Biomedical Sciences School of Pharmacy and Pharmaceutical Sciences

9.2 SCHOOL OF PHARMACY

9/2005 to Present	**Admissions Reviewer and Interviewer** School of Pharmacy and Pharmaceutical Sciences
8/2008 to 8/2013	**Chair, Drug Development Fellowship Steering Committee** School of Pharmacy and Pharmaceutical Sciences
1/2015 to 1/2017	**Equipment Matching Program Committee** School of Pharmacy and Pharmaceutical Sciences
1/2015 to Present	**Research Committee and Research Sub-committee responsible for Strategic Plan Development** School of Pharmacy and Pharmaceutical Sciences

9.3 DEPARTMENT OF PHARMACY PRACTICE

2015 to Present	**Chair, Clinical Research Program for Pharm.D. Students** Digital Badge and Microcredential program
2011, 2013, 2015, 2020, 2022	**Chair of Faculty Search Committees:** (1) Critical Care, (2) Oncology, (3) Infectious Diseases, (4) Translational Sciences (5) Chair of the Department of Pharmaceutical Sciences.

9/2011 to Present	**Chair**, Clinical Research Committee for Pharm.D. Students
9/2013 to 9/2014	**Co-Chair,** Departmental Seminar Series
9/2016 to 9/2018	**Chair,** Grant Writing Seminar Series
9/2015 to 9/2018	**Member**, Faculty Development Workshop
9/2014 to Present	**Member**, Department Executive Committee
9/2014 to Present	**Member**, Promotions Committee

10. COURSES TAUGHT

10.1 PROFESSIONAL PHARMD PROGRAM – UB SPPS

Pharmacotherapeutics II (PHM 603, 4 Credits)
Infectious Diseases
Spring Semester, 3/2006 to Present
Lecturer; 8 Contact Hours

Advanced Pharmacotherapeutics (PHM 795 4 Credits)
3/2007 to Present
Lecturer, 4 Contact Hours

Pharmacotherapeutics II (PHM 511, 4 Credits)
Oncology
Spring Semester, 3/2007, 1 Contact Hour
Past Coordinator in 2010

Clinical Research Methods (PHM 551, 3 Credits)
Clinical Research
Fall Semester, 2 Contact Hours
3/2007 to Present

Clinical Research Methods II (PHM 552, 1 Credits)
Clinical Research
Spring Semester
2/2008 to Present
Coordinator and Lecturer, 16 Contact Hours

Pharmacy Projects (PHM 609, 1 Credit)
4/2006 to Present
Spring Semester, Lecturer, 1 contact Hour

Freshman Discover Series (UE141, 2 Credits)
Translational Pharmacogenomics: Linking Genetics Research to Drug Development
2/2007 to 2/2010
Spring Semester, Lecturer, 1 Contact Hour

10.2 RESEARCH SUPERVISION AS PRECEPTOR – ADVANCED PRACTICE PHARMACY EXPERIENCE (APPE, PHM 831, 6 CREDITS): PHARM.D. STUDENTS IN CLINICAL RESEARCH PROGRAM (PROTOCOL DEVELOPMENT, DEFENSE AND TWO x 6 WEEK CLERKSHIP ROTATIONS=12 WEEKS TOTAL PER STUDENT

Milad Elchibani, Pharm.D. Research Track Student
2007 to 2008
Research Project: Activity of Vancomycin against *hemB* mutants of *Staphylococcus aureus*
Role: Major Advisor
Current Position: Pharmacist, CVS

Marina Wu, Pharm.D. Research Track Student
2008 to 2009
Research Project: Comparative Pharmacodynamics of Daptomycin versus Vancomycin against *hemB* mutants of *Staphylococcus epidermidis*
Notable accomplishments from the rotation: Primary Author. Antimicrob Agents Chemother. 2009 Sep;53(9):3992-5
Role: Major Advisor
Current Position: Pharmacist, Rite-aid

Liliana Yohonn, Pharm.D. Research Track Student
2009 to 2010
Research Project: Population Pharmacokinetics and Pharmacodynamics of Colistin
Notable accomplishments from the rotation: First Author, Poster Presentation American Society of Microbiology, Annual Meeting, 2009. Third Author, Antimicrob Agents Chemother. 2009 Sep;53(9):3992-5.
Role: Major Advisor
Current Position, Pharmacist, Rochester Drug Supply

Gauri Rao, Pharm.D. Research Track Student
2010 to 2011
Research Project: Colistin Pharmacokinetics and Pharmacodynamics against *Pseudomonas aeruginosa* Simulating Concentrations from Patients with Kidney or Liver Disease
Notable accomplishments from the rotation: First Author: Poster Presentation 50th American Society of Microbiology Meeting, 2011. First Author: Antimicrob Agents Chemother. 2014;58(3):1381-8.
Role: Major Advisor
Current Position: Assistant Professor, University of North Carolina, School of Pharmacy

Dung Ngo, Pharm.D. Research Track Student
2010 to 2011
Research Project: Population Vancomycin Pharmacodynamics using Dynamic Models
Notable accomplishments from the rotation: Second Author, BMC Infect Dis. 2011 Oct 25;11:287. Second last author. Antimicrob Agents Chemother. 2011 Apr;55(4):1819-20
Role: Major Advisor
Current Position: Clinical Pharmacology Head, Bioceuticals Ltd.

Curtis Johnston, Pharm.D. Research Track Student
2011 to 2012
Research Project: Impact of Bacterial Density on Vancomycin Pharmacodynamics against Community-Associated Methicillin-Resistant *Staphylococcus aureus*

Notable accomplishments from rotation: First Author, Poster Presentation, American College of Clinical Pharmacy Annual Meeting, 2011.
Role: Major Advisor
Current Position: Principal Scientist, Metrum Research Group

Iris Wang, Pharm.D. Research Track Student
2012 to 2013
Research Project: Pharmacokinetic Profiling of Ceftaroline against *Staphylococcus aureus*
Notable accomplishments from rotation: Co-Investigator. Investigator Initiated Grant from Forrest Laboratories.
Role: Major Advisor
Current Position: Director, Medical Science Liaison, Precision Medicine, Novartis

Christine Trezza, Pharm.D. Research Track Student
2012 to 2013
Research Project: Monte Carlo Simulations of Novel daptomycin and rifampicin combinations against *E. faecalis*
Notable accomplishments from the rotation: First Author. Poster Presentation, American College of Clinical Pharmacy Annual Meeting, 2012
Role: Major Advisor
Current Position: Director, Head of Medical Governance, Global Medical Affairs, ViiV Healthcare

Justin Lenhard, Pharm.D. Research Track Student
2013 to 2014
Research Project: Vancomycin Small Colony Variants
Role: Major Advisor
Current Position: Assistant Professor, California Northstate School of Pharmacy

Michael Bear, Pharm.D. Research Track Student
2013 to 2014
Research Project: Triple Combinations for Polymyxins
Role: Major Advisor
Current Position: Assistant Professor, Massachusetts College of Pharmacy and Pharmaceutical Sciences

Amy Suen, Pharm.D. Research Track Student
2013 to 2014
Research Project: Ceftaroline Combinations with Daptomycin
Role: Major Advisor
Current Position: Senior Clinical Scientist, CSL Behring

Zachery Bulman, Pharm.D. Research Track Student
2014 to 2015
Research Project: Quorum Sensing Inhibitors in Combination with Polymyxin B
Role: Major Advisor
Current Position: Assistant Professor, University of Illinois Chicago (UIC), Pharmacy

Iffat Shafiq, Pharm.D. Research Track Student
2014 to 2015
Research Project: PK/PD Driven novel Combinations to suppress resistance amplification

Role: Major Advisor
Current Position: Clinical Pharmacist, Fidelis Care

Sarah Spitznogle, Pharm.D. Research Track Student
2016 to Present
Research Project: Delineating the role of virulence, resistance in killing in A. baumannii
Role: Major Advisor
Current Position: PGY2 Infectious Diseases Resident, MD Anderson Cancer Center

Arthur Chan, Pharm.D. Student
2016 to Present
Research Project: polymyxin vs. mobile colistin resistance (MCR-1)
Role: Major Advisor
Current Position: Research Pharmacist, VAMC WNY

Nicholas M. Smith, Pharm.D. Student
2016 to 2020
Research Project: Target attainment of polymyxin and meropenem combinations
Role: Major Advisor
Current Position: Assistant Professor, School of Pharmacy and Pharmaceutical Sciences, University at Buffalo.

10.3 RESEARCH SUPERVISION – M.S. Students

MS in Pharmacometrics, Department of Pharmaceutical Sciences, UB
MS in Translational Pharmacology, Roswell Park Cancer Institute, RPCI
MS of Science in Clinical and Translational Therapeutics, UB

Sonya Kokil
M.S. in Translational Pharmacology, Roswell Park Cancer Institute
MIR 520 (4 Credits)
2008 to 2009
Research Project: Impact of accessory gene regulator mutation on Vancomycin Dynamics
Role: Primary Mentor
Current Position: Senior Manager, Eli Lilly and Co.

Samira Merali, Pharm.D.
M.S. Program in Pharmaceutical Sciences
PHC 616 (5 Credits)
2009 to 2012
Research Project: Vancomycin combination therapy against *Staphylococcus* aureus: Developing Novel Dosing Strategies
Role: Co-Mentor (with Dr. Alan Forrest and Dr. Donald Major)
Current position: Associate Director, Clinical Pharmacology and Pharmacometrics, Brisol-Myer Squibb

Nicholas M. Smith, Pharm.D./M.S./Ph.D. Candidate
M.S. Program in Pharmaceutical Sciences
PHC 616 (5 Credits)
2015 to Present
Research Project: Pharmacometrics of Polymyxin Dosing Strategies: Toward Optimal Target

Attainment in Patients
Role: Primary Mentor (with Dr. Donald Major)
Current Position: Assistant Professor, School of Pharmacy and Pharmaceutical Sciences, University at Buffalo.

Tyler Bedard, Pharm.D./M.S. Candidate
M.S. Program in Pharmaceutical Sciences
PHC 616 (5 Credits)
2017 to Present
Research Project: Pharmacometrics of Combination Dosing Strategies
Role: Primary Mentor (with Dr. Donald Major)
Current Position: Pharmacy Resident, Yale New Haven Medical Center

Jack Klem, Pharm.D./M.S. Candidate
M.S. Program in Clinical and Translational Therapeutics
2021 to Present
Research Project: Pharmacometrics of Beta-lactam Dosing Strategies: Optimal Combinations
Role: Primary Mentor

10.4 RESEARCH SUPERVISION – DOCTOR OF PHILOSOPHY, SCHOOL OF PHARMACY AND PHARMACEUTICAL SCINCES AND SCHOOL OF MEDICINE AND BIOMEDICAL SCIENCES

Neang Ly
Ph.D Program in Pharmaceutical Sciences
PHC 615, PHC 616 (5 Credit)
2008 to 2013
Research Project: Development of mechanism-based PK/PD models to optimize dosing for polymyxin antibiotics. Impact of quorum sensing in *P. aeruginosa* on antimicrobial pharmacodynamics.
Role: Primary Mentor (Co-mentors with Dr. Donald Major and Dr. Alan Forrest)
Current Position: Senior Scientist, Medimmune, San Francisco, CA

Greg Canfield
M.D./Ph.D in Microbiology and Immunology, Biomedical Medical Sciences, Jacobs School of Medicine and Biomedical Sciences
2008 to 2013
Research Project: Evolution in fast forward: role of DNA mismatch repair mutators in Accelerating Staphylococcus aureus Pathoadaptation
Role: Outside Reader
Current Position: Internal Medicine, Scripps, La Jolla, CA

Miao Xhao, Ph.D. Candidate, Fudan University Shanghai, China
Institute of Antibiotics, Huashan Hospital, Fudan University, Shanghai, China;
2015 to 2019
Research Project: Population Pharmacokinetics of Colistin in Chinese Health Volunteers
Role: Secondary Advisor
Current Position: Scientific Reviewer, Food and Drug Administration

Shunxin Lin
Ph.D Program in Pharmaceutical Sciences
2013 to Present
Research Project: Development of antibodies for the treatment of *A. baumannii* infection
Role: Committee Member (Primary mentor Dr. Joseph Balthsar)

Christian Arheads
Ph.D in Microbiology and Immunology, Biomedical Medical Sciences, Jacobs School of Medicine and Biomedical Sciences
2005 to 2019
Research Project: Nontypeable Haemophilus influenza genomes reveal vaccine antigen genetic diversity and a novel host cell invasion
Role: Outside Reader

Nicholas M. Smith, Pharm.D./M.S./Ph.D Candidate
Ph.D. Candidate Program in Pharmaceutical Sciences
PHC 615, PHC 616 (5 Credit)
Research Project: Pharmacometrics of Polymyxin Dosing Strategies: Toward Optimal Target Attainment in Patients
Role: Primary Mentor (Co-mentors with Dr. Donald Major and Dr. Robert Bies)
Current Position: Assistant Professor, School of Pharmacy and Pharmaceutical Sciences, University at Buffalo.

Andy Tse, Pharm.D./M.S./Ph.D. Candidate
M.S. and Ph.D. Program in Pharmaceutical Sciences
PHC 616 (5 Credits)
2018 to Present
Research Project: Therapeutic Individualization to combat emerging resistance
Role: Primary Mentor (Co-mentors with Dr. Donald Major and Dr. Robert Bies)

Yang Liu, Ph.D. Candidate
Ph.D. Program in Pharmaceutical Sciences
PHC 615, PHC 616 (5 Credit)
2022 to Present
Research Project: PK/PD/PG Approaches to Combat Diseases: Novel Immunodynamics
Role: Primary Mentor (Co-mentors with Dr. Nicholas Smith and Dr. Jason Sprowl)

Horan Gao, Ph.D. Candidate
Ph.D. Program in Pharmaceutical Sciences
PHC 615, PHC 616 (5 Credit)
2022 to Present
Research Project: PBPK Modeling of Bacteriophages to Combat ‘Superbugs’
Role: Secondary Mentor (Mentors with Dr. Nicholas Smith and Dr. Jason Sprowl)

10.5 RESEARCH SUPERVISION – DOCTOR OF MEDICINE

Devea De, M.D. Candidate (M1 7/2019)
M.D. Candidate Program in Jacobs School of Medicine
T35 Clinician Scientist Program Research Fellowship
Research Project: Interplay between virulence and antibiotic resistance
Role: Primary Mentor

Erika Zheng, M.D. Candidate (M1 7/2023)
M.D. Candidate Program in Jacobs School of Medicine
T35 Clinician Scientist Program Research Fellowship
Research Project: Aztreonam induced persistence of resistant Klebsiella pneumoniae Role: Primary Mentor

Albert Chen, M.D. Candidate (M1 7/2027)
M.D. Candidate Program in Jacobs School of Medicine
T35 Clinician Scientist Program Research Fellowship
Research Project: Phenotypic Control of the Outer Membrane for Therapeutic Gain
Role: Primary Mentor

10.6 RESEARCH SUPERVISION - POST-DOCTORAL FELLOWS

Date	Name	Current Position
2006 to 2008	Sarah McCabe, Pharm.D. Post-Doctoral Fellow University of Buffalo Novartis Pharmaceuticals Role: Mentor Project: Beta-lactamase Inhibitor Target Attainment for Prevent Resistance in *P. aeruginosa*	Clinical Associate Professor University of Rhode Island Kingston, RI
2006 to 2008	Jenny Yang, Pharm.D. Post-Doctoral Fellow University of Buffalo Novartis Pharmaceuticals Role: Mentor Project: Colistin PK/PD: Impact of Bacterial Density on Translation	Director Clinical Research Gilead Sciences Foster City, CA
2006 to 2008	Yoriko Harigaya, Pharm.D. Post-Doctoral Fellow University of Buffalo Glaxo Smith Kline Role: Mentor Project: Simulating Vancomycin ELF concentrations using pharmacokinetic modeling to evaluate resistance suppression in *S. aureus*	Senior Scientific Reviewer OCP, CDER Division of Clinical Pharmacology 4 Food and Drug Administration Silver Springs, MD
2007 to 2009	Damir Begic Post-Doctoral Fellow University at Buffalo/Novartis Fellow Role: Mentor Project: Daptomycin Pharmacodynamics against S. aureus SCVs	Director Solid Tumors Division Celgene San Francisco, CA
2009 to 2012	Samira Merali, Pharm.D. Post-Doctoral Fellow University of Buffalo Novartis Pharmaceuticals Role: Co-Mentor Research Project: Developing Novel Dosing Strategies for Vancomycin combination therapy against *Staphylococcus aureus*: A Pharmacometric	Senior Director Novartis Institutes for BioMedical Research Novartis Pharmaceuticals East Hanover, NJ

Approach. Colistin Population Pharmacokinetics in 202 Critically Ill Patients.

2010 to 2012	Ridhi Parasrampuria, Ph.D. Post-Doctoral Fellow University of Buffalo Novartis Pharmaceuticals Role: Mentor	Senior Scientist CSL (Pharmaceutical Company) King of Prussia, PA
	Project: Comparative Pharmacodynamics against SCV *S. aureus* integrating population pharmacokinetics of vancomycin	
2010 to 2011	Hongmei Xu, Ph.D. Post-Doctoral Fellow University of Buffalo Pfizer Alliance (PI: Jusko) Role: Co-Mentor	Vice President, Quantitative Pharmacology Bicycle Therapeutics Boston, MA
	Project: Polymyxin B PK/PD: Towards Optimal Therapy in Patients	
2011 to 2013	Gauri Rao, Pharm.D. Post-Doctoral Fellow University of Buffalo Roche Pharmaceuticals Role: Mentor	Associate Professor and Director Previously at UNC Now at University of Southern California School of Pharmacy and Pharmaceutical Sciences
	Project: PK/PD for Colistin and Polymyxin B: Optimizing Polymyxin Antibiotics	
2011 to 2013	Rachel Soon, Pharm.D. Post-Doctoral Fellow University of Buffalo Novartis Pharmaceuticals Role: Mentor	Senior Clinical Scientist Novartis Institutes for BioMedical Research Novartis Pharmaceuticals East Hanover, NJ
	Project: Optimizing PKPD Beta-lactam/Beta-lactamase inhibitor combinations. Explaining pharmacodynamic variability beyond MIC.	
2014 to 2016	Justin Lenhard, Pharm.D. Post-Doctoral Fellow University of Buffalo Role: Mentor	Chair, Assistant Dean, and Associate Professor California Northstate University Sacramento, CA
	Project: Resistance Suppression in *A. baumannii*	
2015 to 2017	Zackery Bulman, Pharm.D. Post-Doctoral Fellow University of Buffalo Role: Mentor	Associate Professor University of Illinois Chicago
	Project: Strategies to combat MCR-1 and NDM-5	
2019 to Present	Jan Kaur, PhD Post-Doctoral Fellow University of Buffalo Role: Mentor	Current Position

Project: Overcoming Plasmic Mediated Resistance targeting GNR

2025 to Present	Solomon Hailu, PhD Post-Doctoral Fellow University of Buffalo Role: Mentor Project: Natural Product Synthesis for New Compound Development	Current Position

11. GRANTS

11.1 ACTIVE GRANTS

1. **NIH/NIAID R01 AI65997**
   7/01/2022 – 7/01/2027
   Therapeutic Strategies to combat Hypermutable Pseudomonas aeruginosa
   Role: Principal Investigator
   Direct costs for all years: $2,389,844
   Total Cost $3,802,274
   The major goals of this project are to study the relationship between the development of innovative strategies involving non-natural nucleosides and antimicrobial combinations to combat bacterial persistence and resistance in resistant *P. aeruginosa*.

2. **NIH/NIAID 1R01AI148661**
   7/1/2020 – 6/30/2026
   Exploitation of Multiple Hetero-resistance for Effective Antibiotic Combination Therapy
   Role: Co-Investigator
   PI: David S. Weiss (Prime: Emory University)
   Direct costs for all years: $2,331,922
   Total costs: $3,655,433

   The major goals of this project are to study the relationship between the resistant subpopulations in multiple heteroresistant isolates. This research has the potential to provide clinicians with a rational and predictable method with which to prescribe effective antibiotic combinations for patients.

3. **NIH/NIAID R01 AI48560**
   12/20/2019 – 11/31/2025 (NCE)
   Novel Strategies for Antibiotic Combinations against Gram-negative Superbugs
   Role: Principal Investigator (UB Prime)
   MPI: Juergen Bulitta, University of Florida
   Direct costs for all years: $2,495,939
   Total costs: $3,956,939

   The major goals of this project are to investigate novel combination strategies for treatment of infections caused by carbapenem-resistant enterobacteriaceae and the mechanism(s) by which resistance develops to improve the care of patients.

4. **NIH/NIAID T35 AI089693**
   7/01/2022 – 7/01/2027
   Training the Next Generation of Clinician Scientists

Role: Co-Investigator
PI: Timothy Murphy
Submitted: 10/5/2021

The major goals of this training grant are to expand interdisciplinary and mentored research training with NIH funded faculty to develop future MD and PharmD scientists. Innovations include involving pharmacy students to respond to a national priority to remedy the paucity of well-trained pharmacist clinician-scientists.

11.2 PENDING GRANTS

5. **Bill and Melinda Gates Foundation: Global Grand Challenge**
1/1/2026 – 1/1/2029
Consortium to Combat Urgent Infectious Diseases, High Priority Threats to Save Lives
Role: Principal Investigator
Direct costs for all years: $7,544,321
Total costs: $8,675,969

The major goal of this project is to create an innovative hub of interdisciplinary scientists to develop a novel small molecule capable of maximal resistance suppression against high priority bacterial threats.

11.3 COMPLETED GRANTS

6. **NIH/NIAID R01 AI111990**
4/01/2014 – 3/01/2020
Novel Strategies for Polymyxin Combinations against Gram-negative Superbugs
Role: Principal Investigator (UB Prime)
MPI: Jian Li, Monash University
Direct costs for all years: $3,253,578.
Total Cost $4,448,044 (*Largest R01 at the University at Buffalo during funding period)

The major goals of this project are to investigate novel polymyxin combination strategies for treatment of infections caused by Gram-negative ‘superbugs’ and the mechanism(s) by which the synergy of the combinations occurs using PK/PD approaches. This application will develop a highly innovative interdisciplinary approach to address the global health challenge of antimicrobial resistance and directly improve the care of patients infected with these untreatable pathogens.

7. **NIH/NIAID R01 AI019641**
09/01/2013 – 8/31/2019
Dynamics of nasopharyngeal colonization in otitis media
Role: Co-Investigator
Principal Investigator: Timothy F. Murphy, MD, Director, CTSI
Direct costs for all years: $2,209,428
Total costs for all years: $3,583,237

The goal of the proposed research is to elucidate dynamics nasopharyngeal of colonization of otopathogens for the development of novel approaches for treatment and prevention of otitis media. My role in this application is to develop new strategies to combat antimicrobial resistance against otopathogens. With nearly 1 billion of new cases

of otitis media each year, by elucidating the interrelationships between antibiotic exposure and development of resistance, this application seeks to address the public health problem of antimicrobial resistance around the globe.

8. **Achaogen Inc.**
   09/01/2017 – 9/1/2018
   PK/PD of C-SCAPE against Carbapenem Resistant Enterobacteriaceae
   Role: Principal Investigator
   Direct costs for all years: $149,807
   Total costs for all years: $188,757

9. **NIH/NIAID UM1 AI10468. Antimicrobial Resistance Leadership Group (ARLG).**
   12/01/2017 – 11/30/2018
   Efficacy and Safety of Ceftazidime-Avibactam in Combination with Aztreonam
   Role: Principal Investigator of UB Subcontract (Co-Investigator)
   Direct costs for all years: $332,980
   Total costs for all years: $527,773

   The major goals of this project are to conduct in vitro models to guide dose selection in Phase I clinical trials. This application focuses on developing new treatment strategies for agents which lack individual activity against Gram-negative pathogens. Co-development together with the Concept Acceleration Program at National Institutes of Health, the Food and Drug Administration and the pharmaceutical industry (Allergan Inc. and Pfizer Inc.).

10. **NIH/NIAID R01 PA-11-260**
    ACTG Supplement in HIV/AIDS
    Multimodal Nanoparticle Formulations for Targeted Drug Delivery in Tuberculosis
    2/1/2013 – 12/31/2014
    Direct Costs for all years: $100,000
    Role: Co-Investigator (PI: Morse, GD)

    The major goals of this project are to investigate multimodal nanoparticle therapy in human monocyte derived macrophages infected with Mycobacterium bovis (BCG) and characterize the intracellular pharmacokinetics and pharmacodynamics (PK/PD).

11. **Forest Laboratories**
    Pharmacokinetics and Pharmacodynamics of Ceftaroline against High Density *S. aureus*
    2/1/2013 – 1/31/2017
    Role: Principal Investigator
    Direct costs: $98,500

12. **Merck & Co.**
    Pharmacokinetic-Pharmacodynamic Evaluation of Novel Cephalosporin and Beta-Lactamase Combination CXA-201 against difficult to treat Gram Negatives.
    07/01/2011-07/01/2017
    Role: Principal Investigator
    Direct costs: $187,500

13. **F. Hoffmann-La-Roche Ltd.**
    07/01/2011-07/01/2015
    Post-Doctoral Fellowship Award

Role: Principal Investigator (Co-PI Forrest)
Direct costs: $100,000

14. **NIH/NIAID R01 A1079330**
    07/01/2008 – 06/30/2012
    Targeting MDR Hetero-resistant Gram-negatives: PK/PD for Rational Combinations
    University at Buffalo (Sub-contract)
    Role: Principal Investigator of UB subcontract (PI: Nation RL, Monash University)
    Direct costs of UB subcontract for project period: $412,803
    Direct costs for UB subaward and Monash University for project period: $2,302,445

15. **Foundation for Healthy Living**
    Upstate New York Consortium for Health Care Research and Quality (UNYCHRQ)
    From CTSA award to University of Rochester, NIH 1 UL 1 RR024160-01
    02/01/2008 – 6/30/2012
    Epidemiology of Vancomycin Resistance in *Staphylococcus* in Upstate New York
    Role: Principal Investigator
    Direct costs for all years: $48,225

16. **Interdisciplinary Research Fund (IRDF), University at Buffalo, VP for Research**
    5/1/2006 – 5/1/2007
    Optimizing Antibiotic Dosing in *Staphylococcus aureus* Bloodstream Infection
    Role: Principal Investigator
    Direct costs for all years: $44,000

17. **Gustavo's and Louise Pfeiffer Research Foundation**
    07/01/2006 – 07/01/2008
    Novel Approaches to Combat Multidrug Resistant Superbug Infections
    Role: Principal Investigator
    Direct costs for all years: $48,050

18. **Affinium Pharmaceuticals**
    07/01/2006-07/01/2008
    Utility of Pharmacokinetic and Pharmacodynamic Strategies to Optimize the Activity of a New Bacteriol Enoyl Reductase Inhibitor
    Role: Principal Investigator
    Direct costs for all years: $44,100

19. **Joseph F. Dasta Critical Care Research Grant, Society of Critical Care Medicine**
    09/01/2006-09/01/2008
    Pharmacokinetics and pharmacodynamics of colistin and colistin methanesulfonate in the presence of severe liver and renal disease compared to normal adults.
    Role: Co-Investigator (Hass CE, PI)
    Direct costs for all years: $28,160

20. **Cubist Pharmaceuticals Inc.**
    07/01/2007 – 07/01/2009
    Utilizing Pharmacodynamic Approaches to Combat the Development of Resistance in Bacterial Small Colony Variants
    Role: Principal Investigator
    Direct costs for all years: $38,999

21. **Oishei Foundation**
    07/01/2007 – 07/01/2010
    A Population-based Study of Staphylococcus aureus Bacteremia in Western New York
    Role: Co-Investigator (Lesse AJ, PI)
    Direct costs for all years: $500,000

22. **Center for Protein Therapeutics (CPT), University at Buffalo**
    9/01/2008-12/01/2009
    PK/PD/PG Models for the Dynamics of Bacterial Responses to Peptide Antibiotics
    Role: Co-Principal Investigator (Co-PI: Bulitta JB)
    Direct costs for all years: $82,000

23. **Pfizer Pharmaceuticals**
    5/01/2008-9/01/2010
    Profiling the Evolution of Antimicrobial Resistance in Bacterial Subpopulations
    Role: Principal Investigator
    Direct costs for all years: $38,134

24. **Cubist Pharmaceuticals**
    5/01/2008-9/01/2010
    Novel Regimens to Optimize Antimicrobial Dosing against *S. aureus*
    Role: Principal Investigator
    Direct costs for all years: $59, 415

25. **Pfizer Pharmaceuticals**
    12/01/2009-12/01/2010
    Impact of Linezolid on the Accessory Gene Regulator (*agr*) System of *S. aureus* by Profiling Pharmacodynamics and RNAIII
    Role: Principal Investigator
    Direct costs for all years: $77,000

26. **Pfizer Pharmaceuticals**
    02/01/2008 – 02/01/2011
    Optimizing Linezolid Dosing to Prevent Emergence of Resistance in *Staphylococcus*
    Role: Principal Investigator
    Direct costs for all years: $321,293

27. **American Foundation for Pharmaceutical Education, Pre-Doctoral Fellowship**
    09/01/2011-09/01/2012
    Mechanistic modeling to maximize killing and prevent resistance
    Pre-Doctoral Fellowship Award
    Role: Principal Investigator
    Direct costs for all years: $12,000

11.4 NIH/NIAID CENTER GRANTS SUBMITTED - NOT FUNDED

28. **U19 NIH/NIAID AI157742**
Center Grant Combating Antibiotic-Resistant Bacteria (CARB) Interdisciplinary Research Units (U19)
Novel Adjuvant-Antibiotic Strategies to Combat Gram-negative Urgent Threats
3/1/2021 to 2/28/2026
Role: Principal Investigator

This U19 center grant included 7 individual grants combined in one application involving 3 'R01-structured' Projects, 4 Cores involving 7 principal investigators/project leads and 20 key personnel. As overall Principal Investigator, I lead this outstanding NIH-funded group to create a novel interdisciplinary center as the first center NIAID grant of its kind at UB focusing on antimicrobial pharmacology.

Impact Score of 43. Submitted 5/7/2019. Not funded. Total Costs for 5 years: $12,064,558

29. **U19 NIH/NIAID AI 189191**
Centers of Excellence for Translational Research (CETR) (U19)
Innovating Gram-Negative Therapeutics (IGNITE)
9/1/2025 to 8/31/2030
Role: Overall Principal Investigator

This U19 center grant included 10 individual grants combined in one application involving 4 'R01-structured' Projects, 5 Cores (administrative, IND-enabling, vertebrate animal, genomics, and pharmacology) involving 10 project principal investigators/project leads, 41 co-investigators from leading universities and biopharma across the US. The IGNITE CETR was comprised of a highly interdisciplinary team of world-class investigators together with leaders from Biopharma to develop novel therapeutics against Gram-negatives through 'Team Science'.

Not funded. Submitted May 6, 2024. Total Costs for 5 years: $34,623,584.
Overall Impact Scores from Reviewers:
Reviewer #1:Significance:1, Investigator(s):3, Innovation:2, Approach:5, Environment:4.
Reviewer #2:Significance:3, Investigator(s):1, Innovation:4, Approach:3, Environment:2.
Reviewer #3:Significance:3, Investigator(s):2, Innovation:3, Approach:3, Environment:1.
Reviewer #4:Significance:1, Investigator(s):1, Innovation:4, Approach:4, Environment:1.
Reviewer #5:Significance:1, Investigator(s):1, Innovation:2, Approach:2, Environment:1.

12. PUBLICATIONS

12.1 PEER-REVIEWED MANUSCRIPTS (n=107):

1. **Tsuji BT, Rybak MJ.** 2005. Short-course gentamicin in combination with daptomycin or vancomycin against Staphylococcus aureus in an in vitro pharmacodynamic model with simulated endocardial vegetations. Antimicrobial agents and chemotherapy **49:**2735-2745.

2. **Smith PF, Tsuji B, Booker BM, Forrest A, Bajic S, Kelchlin P, Bhavnani SM, Jones RN, Ambrose PG.** 2006. Pharmacodynamics of cefprozil against

Haemophilus influenzae in an in vitro pharmacodynamic model. Diagnostic microbiology and infectious disease **56:**379-386.

3. **Tsuji BT, Rybak MJ.** 2006. Etest synergy testing of clinical isolates of Staphylococcus aureus demonstrating heterogeneous resistance to vancomycin. Diagnostic microbiology and infectious disease **54:**73-77.

4. **LaPlante KL, Rybak MJ, Tsuji B, Lodise TP, Kaatz GW.** 2007. Fluoroquinolone resistance in Streptococcus pneumoniae: area under the concentration-time curve/MIC ratio and resistance development with gatifloxacin, gemifloxacin, levofloxacin, and moxifloxacin. Antimicrobial agents and chemotherapy **51:**1315-1320.

5. **Narita M, Tsuji BT, Yu VL.** 2007. Linezolid-associated peripheral and optic neuropathy, lactic acidosis, and serotonin syndrome. Pharmacotherapy **27:**1189-1197.

6. **Rose WE, Rybak MJ, Tsuji BT, Kaatz GW, Sakoulas G.** 2007. Correlation of vancomycin and daptomycin susceptibility in Staphylococcus aureus in reference to accessory gene regulator (agr) polymorphism and function. The Journal of antimicrobial chemotherapy **59:**1190-1193.

7. **Tsuji BT, Rybak MJ, Cheung CM, Amjad M, Kaatz GW.** 2007. Community- and health care-associated methicillin-resistant Staphylococcus aureus: a comparison of molecular epidemiology and antimicrobial activities of various agents. Diagnostic microbiology and infectious disease **58:**41-47.

8. **Tsuji BT, Rybak MJ, Lau KL, Sakoulas G.** 2007. Evaluation of accessory gene regulator (agr) group and function in the proclivity towards vancomycin intermediate resistance in Staphylococcus aureus. Antimicrobial agents and chemotherapy **51:**1089-1091.

9. **Yang JC, Tsuji BT, Forrest A.** 2007. Optimizing use of quinolones in the critically ill. Seminars in respiratory and critical care medicine **28:**586-595.

10. **Tsuji BT, Leonard SN, Rhomberg PR, Jones RN, Rybak MJ.** 2008. Evaluation of daptomycin, telavancin, teicoplanin, and vancomycin activity in the presence of albumin or serum. Diagnostic microbiology and infectious disease **60:**441-444.

11. **Tsuji BT, von Eiff C, Kelchlin PA, Forrest A, Smith PF.** 2008. Attenuated vancomycin bactericidal activity against Staphylococcus aureus hemB mutants expressing the small-colony-variant phenotype. Antimicrobial agents and chemotherapy **52:**1533-1537.

12. **Tsuji BT, Yang JC, Forrest A, Kelchlin PA, Smith PF.** 2008. In vitro pharmacodynamics of novel rifamycin ABI-0043 against Staphylococcus aureus. The Journal of antimicrobial chemotherapy **62:**156-160.

13. **Begic D, von Eiff C, Tsuji BT.** 2009. Daptomycin pharmacodynamics against Staphylococcus aureus hemB mutants displaying the small colony variant phenotype. The Journal of antimicrobial chemotherapy **63:**977-981.

14. **Bulitta JB, Ly NS, Yang JC, Forrest A, Jusko WJ, Tsuji BT.** 2009. Development and qualification of a pharmacodynamic model for the pronounced inoculum effect of ceftazidime against Pseudomonas aeruginosa. Antimicrobial agents and chemotherapy **53:**46-56.

15. **Harigaya Y, Bulitta JB, Forrest A, Sakoulas G, Lesse AJ, Mylotte JM, Tsuji BT.** 2009. Pharmacodynamics of vancomycin at simulated epithelial lining fluid concentrations against methicillin-resistant Staphylococcus aureus (MRSA): implications for dosing in MRSA pneumonia. Antimicrobial agents and chemotherapy **53:**3894-3901.

16. **Tsuji BT, Harigaya Y, Lesse AJ, Sakoulas G, Mylotte JM.** 2009. Loss of vancomycin bactericidal activity against accessory gene regulator (agr) dysfunctional Staphylococcus aureus under conditions of high bacterial density. Diagnostic microbiology and infectious disease **64:**220-224.

17. **Wu M, von Eiff C, Al Laham N, Tsuji BT.** 2009. Vancomycin and daptomycin pharmacodynamics differ against a site-directed Staphylococcus epidermidis mutant displaying the small-colony-variant phenotype. Antimicrobial agents and chemotherapy **53:**3992-3995.

18. **Bergen PJ, Bulitta JB, Forrest A, Tsuji BT, Li J, Nation RL.** 2010. Pharmacokinetic/pharmacodynamic investigation of colistin against Pseudomonas aeruginosa using an in vitro model. Antimicrobial agents and chemotherapy **54:**3783-3789.

19. **Bulitta JB, Yang JC, Yohonn L, Ly NS, Brown SV, D'Hondt RE, Jusko WJ, Forrest A, Tsuji BT.** 2010. Attenuation of colistin bactericidal activity by high inoculum of Pseudomonas aeruginosa characterized by a new mechanism-based population pharmacodynamic model. Antimicrobial agents and chemotherapy **54:**2051-2062.

20. **Guskey MT, Tsuji BT.** 2010. A comparative review of the lipoglycopeptides: oritavancin, dalbavancin, and telavancin. Pharmacotherapy **30:**80-94.

21. **Lim LM, Ly N, Anderson D, Yang JC, Macander L, Jarkowski A, 3rd, Forrest A, Bulitta JB, Tsuji BT.** 2010. Resurgence of colistin: a review of resistance, toxicity, pharmacodynamics, and dosing. Pharmacotherapy **30:**1279-1291. (Impact Factor: 2.932)

22. **Bergen PJ, Forrest A, Bulitta JB, Tsuji BT, Sidjabat HE, Paterson DL, Li J, Nation RL.** 2011. Clinically relevant plasma concentrations of colistin in combination with imipenem enhance pharmacodynamic activity against multidrug-resistant Pseudomonas aeruginosa at multiple inocula. Antimicrobial agents and chemotherapy **55:**5134-5142.

23. **Bergen PJ, Tsuji BT, Bulitta JB, Forrest A, Jacob J, Sidjabat HE, Paterson DL, Nation RL, Li J.** 2011. Synergistic killing of multidrug-resistant Pseudomonas aeruginosa at multiple inocula by colistin combined with doripenem in an in vitro pharmacokinetic/pharmacodynamic model. Antimicrobial agents and chemotherapy **55:**5685-5695.

24. **Bulitta JB, Landersdorfer CB, Forrest A, Brown SV, Neely MN, Tsuji BT, Louie A.** 2011. Relevance of pharmacokinetic and pharmacodynamic modeling to clinical care of critically ill patients. Current pharmaceutical biotechnology **12:**2044-2061.

25. **Butterfield JM, Tsuji BT, Brown J, Ashley ED, Hardy D, Brown K, Forrest A, Lodise TP.** 2011. Predictors of agr dysfunction in methicillin-resistant Staphylococcus aureus (MRSA) isolates among patients with MRSA bloodstream infections. Antimicrobial agents and chemotherapy **55:**5433-5437.

26. **Harigaya Y, Ngo D, Lesse AJ, Huang V, Tsuji BT.** 2011. Characterization of heterogeneous vancomycin-intermediate resistance, MIC and accessory gene regulator (agr) dysfunction among clinical bloodstream isolates of staphyloccocus aureus. BMC infectious diseases **11:**287.

27. **Miyazaki M, Takata T, Yoshimura H, Matsunaga A, Ohta D, Ishikura H, Futo M, Hara S, Kamimura H, Tamura K, Ngo D, Tsuji BT.** 2011. Vancomycin bactericidal activity as a predictor of 30-day mortality in patients with methicillin-resistant Staphylococcus aureus bacteremia. Antimicrobial agents and chemotherapy **55:**1819-1820.

28. **Okusanya OO, Tsuji BT, Bulitta JB, Forrest A, Bulik CC, Bhavnani SM, Fernandes P, Ambrose PG.** 2011. Evaluation of the pharmacokinetics-pharmacodynamics of fusidic acid against Staphylococcus aureus and Streptococcus pyogenes using in vitro infection models: implications for dose selection. Diagnostic microbiology and infectious disease **70:**101-111.

29. **Tsuji BT, MacLean RD, Dresser LD, McGavin MJ, Simor AE.** 2011. Impact of accessory gene regulator (agr) dysfunction on vancomycin pharmacodynamics among Canadian community and health-care associated methicillin-resistant Staphylococcus aureus. Annals of clinical microbiology and antimicrobials **10:**20.

30. **Tsuji BT, Okusanya OO, Bulitta JB, Forrest A, Bhavnani SM, Fernandez PB, Ambrose PG.** 2011. Application of pharmacokinetic-pharmacodynamic modeling and the justification of a novel fusidic acid dosing regimen: raising Lazarus from the dead. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America **52 Suppl 7:**S513-519.

31. **Deris ZZ, Yu HH, Davis K, Soon RL, Jacob J, Ku CK, Poudyal A, Bergen PJ, Tsuji BT, Bulitta JB, Forrest A, Paterson DL, Velkov T, Li J, Nation RL.** 2012. The combination of colistin and doripenem is synergistic against Klebsiella pneumoniae at multiple inocula and suppresses colistin resistance in an in vitro pharmacokinetic/pharmacodynamic model. Antimicrobial agents and chemotherapy **56:**5103-5112.

32. **Ly NS, Yang J, Bulitta JB, Tsuji BT.** 2012. Impact of two-component regulatory systems PhoP-PhoQ and PmrA-PmrB on colistin pharmacodynamics in Pseudomonas aeruginosa. Antimicrobial agents and chemotherapy **56:**3453-3456.

33. **Sakoulas G, Bayer AS, Pogliano J, Tsuji BT, Yang SJ, Mishra NN, Nizet V, Yeaman MR, Moise PA.** 2012. Ampicillin enhances daptomycin- and cationic host defense peptide-mediated killing of ampicillin- and vancomycin-resistant Enterococcus faecium. Antimicrobial agents and chemotherapy **56:**838-844.

34. **Stevens V, Lodise TP, Tsuji B, Stringham M, Butterfield J, Dodds Ashley E, Brown K, Forrest A, Brown J.** 2012. The utility of acute physiology and chronic health evaluation II scores for prediction of mortality among intensive care unit (ICU) and non-ICU patients with methicillin-resistant Staphylococcus aureus bacteremia. Infection control and hospital epidemiology **33:**558-564.

35. **Tsuji BT, Brown T, Parasrampuria R, Brazeau DA, Forrest A, Kelchlin PA, Holden PN, Peloquin CA, Hanna D, Bulitta JB.** 2012. Front-loaded linezolid regimens result in increased killing and suppression of the accessory gene regulator system of Staphylococcus aureus. Antimicrobial agents and chemotherapy **56:**3712-3719.

36. **Tsuji BT, Bulitta JB, Brown T, Forrest A, Kelchlin PA, Holden PN, Peloquin CA, Skerlos L, Hanna D.** 2012. Pharmacodynamics of early, high-dose linezolid against vancomycin-resistant enterococci with elevated MICs and pre-existing genetic mutations. The Journal of antimicrobial chemotherapy **67:**2182-2190.

37. **He H, Li JC, Nation RL, Jacob J, Chen G, Lee HJ, Tsuji BT, Thompson PE, Roberts K, Velkov T, Li J.** 2013. Pharmacokinetics of four different brands of colistimethate and formed colistin in rats. The Journal of antimicrobial chemotherapy **68:**2311-2317.

38. **Landersdorfer CB, Ly NS, Xu H, Tsuji BT, Bulitta JB.** 2013. Quantifying subpopulation synergy for antibiotic combinations via mechanism-based modeling and a sequential dosing design. Antimicrobial agents and chemotherapy **57:**2343-2351.

39. **Lee HJ, Bergen PJ, Bulitta JB, Tsuji B, Forrest A, Nation RL, Li J.** 2013. Synergistic activity of colistin and rifampin combination against multidrug-resistant Acinetobacter baumannii in an in vitro pharmacokinetic/pharmacodynamic model. Antimicrobial agents and chemotherapy **57:**3738-3745.

40. **McEvoy CR, Tsuji B, Gao W, Seemann T, Porter JL, Doig K, Ngo D, Howden BP, Stinear TP.** 2013. Decreased vancomycin susceptibility in Staphylococcus aureus caused by IS256 tempering of WalKR expression. Antimicrobial agents and chemotherapy **57:**3240-3249.

41. **Soon RL, Ly NS, Rao G, Wollenberg L, Yang K, Tsuji B, Forrest A.** 2013. Pharmacodynamic variability beyond that explained by MICs. Antimicrobial agents and chemotherapy **57:**1730-1735.

42. **Soon RL, Turner SJ, Forrest A, Tsuji BT, Brown J.** 2013. Pharmacokinetic/pharmacodynamic evaluation of the efficacy and safety of daptomycin against Staphylococcus aureus. International journal of antimicrobial agents **42:**53-58.

43. **Takata T, Miyazaki M, Futo M, Hara S, Shiotsuka S, Kamimura H, Yoshimura H, Matsunaga A, Nishida T, Ishikura H, Ishikawa T, Tamura K, Tsuji BT.** 2013. Presence of both heterogeneous vancomycin-intermediate resistance and beta-lactam antibiotic-induced vancomycin resistance phenotypes is associated with the outcome in methicillin-resistant Staphylococcus aureus bloodstream infection. Scandinavian journal of infectious diseases **45:**203-212.

44. **Tsuji BT, Harigaya Y, Lesse AJ, Forrest A, Ngo D.** 2013. Activity of AFN-1252, a novel FabI inhibitor, against Staphylococcus aureus in an in vitro pharmacodynamic model simulating human pharmacokinetics. Journal of chemotherapy **25:**32-35.

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