# **BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.** 

NAME: Vidmantas Petraitis, M.D.

#### eRA COMMONS USER NAME (credential, e.g., agency login): VPETRAITIS

POSITION TITLE: Mgr Associate Member, Center for Discovery and Innovation, Hackensack Meridian Health

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Kaunas University of Medicine, The Faculty of Medicine, Kaunas, Lithuania	MD	05/1986	Medicine
Surgery-Traumatology Intern, Kaunas First Clinical Hospital, Kaunas, Lithuania		05/1986	Traumatology
Traumatology Development Course, Vilnius University Clinic of Trauma, Vilnius, Lithuania		02/1992	Traumatology
Research Fellow, National Cancer Institute (NCI), Bethesda, MD		05/1998	Infectious Diseases
Senior Research Fellow, National Cancer Institute (NCI), Bethesda, MD		05//2001	Infectious Diseases

#### A. Personal Statement

As of May 1, 2023, I joined the Center for Discovery and Innovation (CDI), part of Hackensack University Medical Center in Nutley, NJ, as Principal Investigator and Pharmacology Core Lead. From 2024 I am Associate Professor of the Hackensack Meridian School of Medicine, Nutley NJ. Over the past two year, I have led translational pharmacology efforts under the CETR and MAVDA grants, with a primary focus on pharmacokinetics/pharmacodynamics (PK/PD) of antimicrobial agents.

With over 28 years of hands-on laboratory experience and more than 100 peer-reviewed publications, my research has consistently focused on optimizing the therapeutic use of antimicrobial agents—both approved and investigational. My expertise lies in evaluating drug penetration at infection sites and designing optimized, human-simulated dosing regimens through rigorous PK/PD modeling. A hallmark of my work is the development of predictive in vitro and in vivo preclinical platforms that replicate key aspects of infectious disease pathophysiology, host immune responses, and antimicrobial pharmacology.

Throughout my career, I have developed, refined, and employed over 25 rabbit infection models to evaluate antimicrobial efficacy and resistance suppression. These models have been instrumental in determining humanized dosing strategies and PK/PD targets, which directly inform clinical trial design and shape treatment guidelines for immunocompromised patient populations.

Our laboratory also brings extensive experience in project administration, milestone tracking, and contractual compliance across multiple federal and industry-sponsored research initiatives. We have collaborated closely with a range of biopharmaceutical companies—including Allergan, Amplyx, Cubist, Leadiant, The Medicines Company, Merck, Novartis, Scynexis, Shionogi, Tetraphase, Viosera, and the FDA—to support preclinical development of antimicrobial agents.

These collaborations have directly contributed to the advancement and clinical approval of key antibacterial therapies, including novobiocin/rifampin, trimethoprim/sulfamethoxazole, ceftazidime, ceftazidime/avibactam, and ceftolozane/tazobactam.

Citations that highlight my experience, qualifications, and interactions with other investigators:

- a. Petraitis V, Petraitiene R, Kavaliauskas P, Naing E, Garcia A, Georgiades BN, Echols R, Bonomo RA, Yamano Y, Satlin MJ, Walsh TJ. Efficacy of cefiderocol in experimental *Stenotrophomonas maltophilia* pneumonia in persistently neutropenic rabbits. Antimicrob Agents Chemother. 2022 Oct 18;66(10):e0061822. doi: 10.1128/aac.00618-22. PMID: 36154614.
- b. Smith NM, Boissonneault KR, Chen L, Petraitis V, Petraitiene R, Tao X, Zhou J, Lang Y, Kavaliauskas P, Bulman ZP, Holden PN, Cha R, Bulitta JB, Kreiswirth BN, Walsh TJ, Tsuji BT. Mechanistic insights to combating NDM- and CTX-M-coproducing *Klebsiella pneumoniae* by targeting cell wall synthesis and outer membrane integrity. Antimicrob Agents Chemother. 2022 Aug 4:e0052722. doi: 10.1128/aac.00527-22. Online ahead of print. PMID: 35924913
- c. **Petraitis V**, Petraitiene R, Kavaliauskas P, Naing E, Garcia A, Sutherland C, Kau AY, Goldner N, Bulow C, Nicolau DP, Walsh TJ. Pharmacokinetics, tissue distribution, and efficacy of VIO-001 (Meropenem/Piperacillin/Tazobactam) for treatment of methicillin-resistant *Staphylococcus aureus* bacteremia in immunocompetent rabbits with chronic indwelling vascular catheters. Antimicrob Agents Chemother. 2021 Oct 18;65(11):e0116821. doi: 10.1128/AAC.01168-21. PMID: 34460301.
- d. Petraitis V, Petraitiene R, Naing E, Aung T, Thi WP, Kavaliauskas P, Maung BBW, Michel AO, Ricart Arbona RJ, DeRyke AC, Culshaw DL, Nicolau DP, Satlin MJ, Walsh TJ. Ceftolozane-Tazobactam in the treatment of experimental *Pseudomonas aeruginosa* pneumonia in persistently neutropenic rabbits: Impact on strains with genetically defined mechanisms of resistance. Antimicrob Agents Chemother. 2019 Aug 23;63(9). pii: e00344-19. doi: 10.1128/AAC.00344-19. PMID: 31235620.

Active or recently completed government funded projects I would like to highlight:

1 U19 AI1714010(Perlin, Rice co-PI)05/17/22- 05/16/27NIH-NIAIDMetropolitan AntiViral Drug Accelerator (MAVDA)Role: Pharmacology Core Leader

1 U19 AI142731-01 (Perlin PI) 05/17/22- 05/16/27 NIH-NIAID

Center to develop therapeutic countermeasures to high-threat bacterial agents (CETR) Role: Pharmacology Core Leader

### B. Positions, Scientific Appointments, and honors

#### **Positions and Scientific Appointments**

- 2024 present Associate Professor of the Hackensack Meridian School of Medicine, Nutley NJ, USA
- 2023 present Director of Pharmacology, Mgr Associate Member, Center for Discovery and Innovation (CDI) from the Hackensack University Medical Center (HUMC), Nutley NJ, USA
- 2017 2025 Assistant Professor of Research in Medicine, Transplant-Oncology Infectious Diseases Program, Division of Infectious Diseases, Department of Medicine, Weill Cornell Medical Center of Cornell University, New York, NY
- 2010 2017 Senior Research Associate in Medicine, Transplant-Oncology Infectious Diseases Program, Division of Infectious Diseases, Department of Medicine, Weill Cornell Medical Center of Cornell University, New York, NY
- 2009 2010 Consultant, Ordway Research Institute, Inc., Bacterial and Fungal Emerging Infections and Pharmacodynamics Laboratory, Albany, NY

2005 – 2009	Scientist I, LASP, SAIC-Frederick, Inc., Frederick, MD, Immunocompromised Host Section, Pediatric Oncology Branch, NCI, Bethesda, MD
2004 – 2005	Senior Research Associate, Laboratory Animal Science Program, Science Applications International Corporation (SAIC), SAIC-Frederick, Inc., Frederick, MD, Infectious Disease Section, Pediatric Branch, NCI, Bethesda, MD
2001 – 2004	Research Associate, Biomedical Personnel Service Inc. (BPSI), Severna Park, MD; and Special Volunteer, Infectious Disease Section, Pediatric Branch, NCI, Bethesda, MD
1995 – 2000	Cancer Research and Treatment Award Fellow, Pediatric Branch, NCI, Bethesda, MD
1987 – 1994	Surgeon, Prienai District Central Hospital, Prienai, Lithuania

# **Other Experience and Professional Memberships:**

2004 – present	European Society of Clinical Microbiology and Infectious Diseases	Member
1998 – present	American Society for Microbiology	Member
1994 – present	Lithuanian Physicians' Association	Member
1986 – present	Lithuanian Traumatologist's Association	Member

# Honors:

2021 – Present Ambassador from American Society of Microbiology to Lithuania
2004 Special Category Award for Language Interpreter, NIH Clinical Research Center, Volunteer Office
2014 Outstanding Poster Award, "Pharmacokinetics and Efficacy of Isavuconazole for Treatment of Experimental Invasive Pulmonary Aspergillosis", 6<sup>th</sup> Advances Against Aspergillosis, Conference, Madrid, Spain

# C. Contributions to Science

- 1. During my early career as a researcher, my primary focus was on efficacy and pharmacokinetics/pharmacodynamics of antifungal agents. During that time, I conducted *in vivo* studies, analyzed data, and prepared publications of new antifungal echinocandins anidulafungin, caspofungin, and micafungin against multiple fungal pathogens. Data from PK/PD and efficacy studies presented in selected publications laid the foundation for Phase II and III clinical studies that resulted in FDA approval for all three echinocandins. In addition, under my direct supervision to improve outcomes of difficult fungal diseases in immunocompromised patients, we have conducted pre-clinical studies of combinations of approved or investigational antifungal agents. These results provided a scientific basis for rational selection of combination therapies that in turn can save lives.
  - a. Petraitis V, Petraitiene R, Groll AH, Roussillon K, Hemmings M, Lyman CA, Sein T, Bacher J, Bekersky I, Walsh TJ. Comparative antifungal activity and plasma pharmacokinetics of micafungin (FK463) against disseminated candidiasis and invasive pulmonary aspergillosis in persistently neutropenic rabbits. Antimicrobial Agents and Chemotherapy, 2002 Jun; 46(6):1857-1869. PMID: 12019101.
  - b. Petraitiene R, Petraitis V, Groll AH, Sein T, Schaufele RL, Francesconi A, Bacher J, Avila NA, Walsh TJ. Antifungal efficacy of caspofungin (MK-0991) in experimental pulmonary aspergillosis in persistently neutropenic rabbits: pharmacokinetics, drug disposition and relationship to galactomannan antigenemia. Antimicrobial Agents and Chemotherapy, 2002 Jan; 46(1):12-23. PMID: 11751105.

- c. **Petraitis V**, Petraitiene R, Groll AH, Sein T, Schaufele RL, Lyman CA, Francesconi A, Bacher J, Piscitelli SC, Walsh TJ. Dosage-dependent antifungal efficacy of V-echinocandin (LY303366) against experimental fluconazole-resistant oropharyngeal and esophageal candidiasis. Antimicrobial Agents and Chemotherapy, 2001 Feb; 45(2): 471-479. PMID: 11158743.
- d. Petraitis V, Petraitiene R, Groll AH, Bell A, Callender DP, Sein T, Schaufele RL, McMillian CL, Bacher J, Walsh TJ. Antifungal efficacy, safety, and single-dose pharmacokinetics of LY 303366, a novel echinocandin B, in experimental pulmonary aspergillosis in persistently neutropenic rabbits. Antimicrobial Agents and Chemotherapy, 1998 Nov; 42(11): 2898-2905. PMID: 9797223.
- 2. Over the past decade, our research focus has expanded to include the investigation of new antibacterial agents targeting multidrug-resistant organisms. We recently completed the successful development of the first rabbit models of ventilator-associated bacterial pneumonia produced by carbapenem-resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii* under the US Food and Drug Administration Broad Agency Announcement Agreement FDABAA-20-00123N. Through collaborative efforts with fellow researchers, we've undertaken preclinical studies on several novel antimicrobial compounds. Personally, I have played a direct role in the design, execution, and reporting of pharmacokinetic/pharmacodynamic (PK/PD) studies. For instance, I spearheaded studies evaluating the efficacy of ceftolozane-tazobactam in treating experimental *Pseudomonas aeruginosa* pneumonia in persistently neutropenic rabbits. Additionally, I led extensive investigations into the pharmacokinetics and comprehensive analysis of the tissue distribution of eravacycline and minocycline in rabbits, among other endeavors. Furthermore, our research included an extensive investigation of drug penetration and optimization of dosing regimens, with a particular emphasis on understanding penetration into the central nervous system of various antimicrobial agents.
  - Petraitis V, Petraitiene R, Kavaliauskas P, Naing E, Garcia A, Zigmantaite V, Grigaleviciute R, Kucinskas A, Pockevicius A, Stakauskas R, Walsh TJ. Development of rabbit models of ventilator-associated bacterial pneumonia produced by carbapenem-resistant *Pseudomonas aeruginosa*. Antimicrob Agents Chemother. 2024 Apr 30:e0020524. doi: 10.1128/aac.00205-24. Epub ahead of print. PMID: 38687014.
  - b. Petraitiene R, Petraitis V, Kavaliauskas P, Maung BBW, Khan F, Naing E, Aung T, Zigmantaite V, Grigaleviciute R, Kucinskas A, Stakauskas R, Georgiades BN, Mazur CA, Hayden JA, Satlin MJ, Walsh TJ. Pharmacokinetics and efficacy of ceftazidime-avibactam in the treatment of experimental pneumonia caused by *Klebsiella pneumoniae* carbapenemase-producing *K. pneumoniae* in persistently neutropenic rabbits. Antimicrob Agents Chemother. 2020 Mar 24;64(4):e02157-19. doi: 10.1128/AAC.02157-19. Print 2020 Mar 24. PMID: 32015048.
  - c. **Petraitis V**, Petraitiene R, Maung BBW, Khan F, Alisauskaite I, Olesky M, Newman J, Mutlib, Niu X, Satlin MJ, Singh RS, Derendorf H, Walsh TJ. Pharmacokinetics and comprehensive analysis of the tissue distribution of eravacycline in rabbits. Antimicrob Agents Chemother. 2018 Aug 27;62(9). pii: e00275-18. doi: 10.1128/AAC.00275-18. PMID: 29941646.
  - d. Petraitis V, Petraitiene R, Valdez JM, Pyrgos V, Lizak MJ, Klaunberg BA, Kalasauskas D, Basevicius A, Bacher JD, Benjamin DK Jr, Hope WW, Walsh TJ. Amphotericin B penetrates into the central nervous system through focal disruption of the blood-brain-barrier in experimental hematogenous *Candida* meningoencephalitis. Antimicrob Agents Chemother. 2019 Oct 7;63(12):e01626-19. doi: 10.1128/AAC.01626-19. PMID: 31591128.
- 3. Over recent years, my lab has spearheaded the formation of a consortium dedicated to advancing the development of small molecules, with a particular focus on antimicrobial and anticancer agents. This collaborative effort has enabled us to establish a dynamic platform for groundbreaking research and innovation. Through our combined expertise and resources, we have successfully identified and propelled several promising candidates through various stages of development, with the ultimate goal of achieving clinical impact. Our commitment to understanding the intricacies of disease pathways is driven by our aim to develop targeted therapies that are both effective and precise. By fostering a culture of collaboration and innovation, our consortium is at the forefront of small molecule development, making significant strides in the

fight against infectious diseases and cancer. We remain dedicated to translating our research findings into tangible clinical outcomes, ultimately improving patient care and advancing the field of medicine.

- a. Kavaliauskas P, Acevedo W, Garcia A, Naing E, Grybaite B, Sapijanskaite-Banevic B, Grigaleviciute R, Petraitiene R, Mickevicius V, **Petraitis V**. Exploring the potential of bis(thiazol-5-yl)phenylmethane derivatives as novel candidates against genetically defined multidrug-resistant *Staphylococcus aureus*. PLoS One. 2024 Mar 22;19(3):e0300380. doi: 10.1371/journal.pone.0300380. PMID: 38517855; PMCID: PMC10959338.
- b. Balandis B, Kavaliauskas P, Grybaitė B, Petraitis V, Petraitienė R, Naing E, Garcia A, Grigalevičiūtė R, Mickevičius V. Synthesis of Novel Benzenesulfonamide-Bearing Functionalized Imidazole Derivatives as Novel Candidates Targeting Multidrug-Resistant *Mycobacterium abscessus* Complex. Microorganisms. 2023 Apr 3;11(4):935. doi: 10.3390/microorganisms11040935. PMID: 37110358; PMCID: PMC10145568.
- c. Bertašiūtė M, Kavaliauskas P, Vaickelionienė R, Grybaitė B, Petraitis V, Petraitienė R, Naing E, Garcia A, Šiugždaitė J, Lelešius R, Mickevičius V. Synthesis of 1-(2-Hydroxyphenyl)- and (3,5-Dichloro-2-hydroxyphenyl)-5-oxopyrrolidine-3-carboxylic Acid Derivatives as Promising Scaffolds for the Development of Novel Antimicrobial and Anticancer Agents. Int J Mol Sci. 2023 Apr 27;24(9):7966. doi: 10.3390/ijms24097966. PMID: 37175673; PMCID: PMC10178429.
- d. Kavaliauskas P, Opazo FS, Acevedo W, Petraitiene R, Grybaitė B, Anusevičius K, Mickevičius V, Belyakov S, Petraitis V. Synthesis, biological activity, and molecular modelling studies of naphthoquinone derivatives as promising anticancer candidates targeting COX-2. Pharmaceuticals (Basel). 2022 Apr 27;15(5):541. doi: 10.3390/ph15050541. PMID: 35631366

### Complete list of Published Work in Pubmed:

https://pubmed.ncbi.nlm.nih.gov/?term=petraitis+v