### **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: Ruta Petraitiene

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

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.)

DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
MD	06/1985	Medicine
	06/1986	Obstetrics/Gynecology
	1992	Obstetrics/Gynecology
	1993	Natural Family Planning
	1996	Computer science and English language
	08/1998	Infectious Diseases
	08/2001	Infectious Diseases
	(if applicable)	(if applicable) Date MM/YYYY  MD 06/1985 06/1986 1992 1993 1996 08/1998

## A. Personal Statement

As of April, 2025, I joined the Center for Discovery and Innovation (CDI), part of Hackensack University Medical Center in Nutley, NJ, as a Mgr Associate Member. Previously I served as the Associate Director of the Laboratory Animal Facility and Director of Diagnostic Unit within the Transplantation-Oncology Infectious Diseases Program at Weill Cornell Medicine, where my focus was on rabbit infectious disease efficacy models in translational research. Since 1996, I have been deeply involved in translational research in infectious diseases, particularly in the preclinical evaluation of novel antimicrobial agents.

With over 28 years of hands-on laboratory experience and a portfolio of more than 100 publications, my work revolves around devising innovative strategies for the diagnosis, treatment, and prevention of life-threatening infections in both immunocompromised children and adults. I specialize in developing pharmacodynamically rational methods for administering existing antibacterial agents and in the development of novel compounds.

My expertise lies in the development, execution, and oversight of numerous rabbit infectious disease models. These models serve as invaluable tools for the development of predictive *in vitro* and *in vivo* preclinical systems, which enhance our comprehension of pathophysiology, microbiology, diagnostic markers, and pharmacology. Throughout my research career, I have contributed to the refinement and utilization of more than 25 rabbit infection models. These endeavors have facilitated the establishment of predictive dosing regimens and response monitoring tools, ultimately translating into practical therapeutic applications and clinical trials for antimicrobial therapy in immunocompromised patients.

Our laboratory boasts extensive administrative experience in reporting, goal attainment, milestone achievement, and meeting objectives across various contract mechanisms. We collaborated closely with

esteemed organizations such as Allergan Inc., Amplyx Pharmaceuticals Inc., Astellas Pharma Inc, Basilea Pharmaceutica Ltd., Cubist Pharmaceuticals Inc., Eli Lilly & Co., Gilead Sciences Inc., Leadiant Biosciences Inc., The Medicines Company, Merck & Co. Inc., Novartis Pharmaceuticals Co., Pfizer Inc.), Scynexis Inc., Shionogi Inc., Tetraphase Pharmaceuticals Inc., Vicuron Pharmaceuticals, Viosera Therapeutics, and the FDA. As a result of these collaborations, our team and I have made significant contributions to the development and approval of numerous antifungal agents (echinocandins, such as anidulafungin, caspofungin, micafungin; triazoles. such isavuconazole. posaconazole. ravuconazole. voriconazole. polyenes-Ambisome); other antifungals (fosmanogepix; triterpenoid antifungal lbrexafungerp), and antibacterial agents, including cefiderocol, trimethoprim/sulfamethoxazole, ceftazidime/avibactam, ceftolozane/tazobactam.

With my expertise, skills, dedication, and motivation, I am well-equipped to supervise and coordinate studies. I am deeply enthusiastic about contributing to projects that address critical public health concerns.

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

- 1. Petraitiene R, Petraitis V, Zaw MH, Hussain K, Ricart Arbona RJ, Roilides E, Walsh TJ. Combination of systemic and lock-therapies with micafungin eradicate catheter-based biofilms and infections caused by *Candida albicans* and *Candida parapsilosis* in neutropenic rabbit models. J Fungi (Basel). 2024 Apr 17;10(4):293. doi: 10.3390/jof10040293. PMID: 38667964.
- 2. Petraitiene R, Petraitis V, Maung BBW, Mansbach RS, Hodges MR, Finkelman MA, Shaw KJ, Walsh TJ. Efficacy and pharmacokinetics of fosmanogepix (APX001) in the treatment of *Candida* endophthalmitis and hematogenous meningoencephalitis in nonneutropenic rabbits. Antimicrob Agents Chemother. 2021 Feb 17;65(3):e01795-20. doi: 10.1128/AAC.01795-20. PMID: 33361304.
- 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. PMID: 32015048.
- 4. Petraitiene R, Petraitis V, Bacher JD, Finkelman MA, Walsh TJ. Effects of host response and antifungal therapy on serum and BAL levels of galactomannan and (1→3)-β-D-glucan in experimental invasive pulmonary aspergillosis. Med Mycol. 2015 Aug;53(6):558-68. doi: 10.1093/mmy/myv034. PMID: 26129890.
- Petraitiene R, Petraitis V, Hope WW, Mickiene D, Kelaher AM, Murray HA, Mya-San C, Hughes JE, Cotton MP, Bacher J, Walsh TJ. Cerebrospinal fluid and plasma (1-->3)-beta-D-glucan as surrogate markers for detection and monitoring of therapeutic response in experimental hematogenous *Candida* meningoencephalitis. Antimicrob Agents Chemother. 2008 Nov;52(11):4121-9. doi: 10.1128/AAC.00674-08. PMID: 18779361.

## B. Positions, Scientific Appointments, and Honors

2025 – present	Manager, Associate Member, Center for Discovery and Innovation (CDI) from the Hackensack University Medical Center (HUMC), Nutley NJ		
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		
	Medicine 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, Laboratory Animal Sciences Program (LASP), Science Applications		
	International Corporation, SAIC-Frederick, Inc., Frederick, MD, and Immunocompromised Host Section, Pediatric Oncology Branch, NCI, NIH, Bethesda, MD		

2004 – 2005	Senior Research Associate, Laboratory Animal Science Program (LASP), Science Applications International Corporation, SAIC-Frederick, Inc., Frederick, MD, and, Immunocompromised Host Section, Pediatric Oncology Branch, NCI, NIH, Bethesda, MD
2001 – 2004	Research Associate, Biomedical Personnel Service Inc. (BPSI), Severna Park, MD, and Special Volunteer, Infectious Disease Section, Pediatric Branch, NCI, NIH, Bethesda, MD
1998 – 2001	Senior Research Fellow, Cancer Research Training Awardee, National Cancer Institute, National Institutes of Health, Bethesda, MD
1996 – 1998	Research Fellow, Intramural Research Training Awardee, National Cancer Institute, National Institutes of Health, Bethesda, MD
1995 – 1996 1986 – 1994	National Graduate University, Arlington, VA Obstetrician-Gynecologist, Prienai District Central Hospital, Prienai, Lithuania

# Other Experience and Professional Memberships:

2017 – present	Infectious Diseases Society of America (IDSA) Member
2016 – present	Medical Mycological Society of the Americas) Member
2015 – 2019	Medical Mycology Society of New York (MMSNY)
Meml	per
2015 – present	European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Member
1998 – present	American Society of Microbiology (ASM)  Member
1993 – 1994	National Association of Natural Family Planning Teachers
Member	
1994 – 2010	Lithuanian Physicians' Association  Member
1986 – 2010	Lithuanian Obstetricians-Gynecologists' Association
Meml	per
1996 – 2010	Interpreter for patients at NIH for Russian and Lithuanian languages

### **Honors:**

2004 Special Category Award for Language Interpreter, NIH Clinical Research Center, Volunteer Office

### C. Contributions to Science

- 1. Within the field of antifungal pharmacology and experimental therapeutics, our laboratory systematically investigated all major classes of antifungal agents, including polyenes, lipid formulations, triazoles, and echinocandins. I worked with rabbit models of invasive pulmonary, disseminated, CNS, esophageal, gastrointestinal, oropharyngeal, and catheter-related infections. These models closely replicate the conditions seen in profoundly immunocompromised patients, such as those with neutropenia or undergoing stem cell transplants in our oncology BMT population. The rabbit models for primary pulmonary aspergillosis, fusariosis, mucormycosis, and both disseminated, and catheter-related invasive candidiasis are highly accurate in their microbiological, histological, immunological, and radiological mimicry of human conditions. Specifically, the models of invasive pulmonary aspergillosis and mucormycosis have been instrumental in understanding the molecular, histological, antigenic, and microbiological correlates with CT diagnostic imaging for the diagnosis and treatment of these infections. These model systems have provided a foundation that has been predictive of therapeutic outcomes in numerous clinical trials.
  - a. **Petraitiene R,** Petraitis V, Zaw MH, Hussain K, Ricart Arbona RJ, Roilides E, Walsh TJ. Combination of systemic and lock-therapies with micafungin eradicate catheter-based biofilms and infections caused by *Candida albicans* and *Candida parapsilosis* in neutropenic rabbit models. J Fungi (Basel). 2024 Apr 17;10(4):293. doi: 10.3390/jof10040293. PMID: 38667964; PMCID: PMC11050883.
  - 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. **Petraitiene R**, Petraitis V, Groll AH, Sein T, Piscitelli SC, Candelario M, Field-Ridley A, Avilo N, Bacher J, Walsh TJ. Antifungal activity and pharmacokinetics of posaconazole (SCH 56592) in treatment and prevention of experimental invasive pulmonary aspergillosis: Correlation with galactomannan antigenemia. Antimicrob Agents Chemother. 2001 Mar;45(3):857-869. doi: 10.1128/AAC.45.3.857-869.2001. PMID: 11181372.
- d. **Petraitiene R**, Petraitis V, Groll AH, Candelario M, Sein T, Bell A, Lyman CA, McMillian CL, Bacher J, Walsh TJ. Antifungal activity of LY303366, a novel echinocandin B, in experimental disseminated candidiasis in rabbits. Antimicrob Agents Chemother. 1999 Sept;43(9):2148-2155. doi: 10.1128/AAC.43.9.2148. PMID: 10471556
- 2. Over the past decade, our research focus has expanded to include the investigation of new antibacterial agents targeting multidrug-resistant organisms. We recently achieved a significant milestone by developing the first rabbit models of ventilator-associated bacterial pneumonia caused by carbapenem-resistant Pseudomonas aeruginosa and Acinetobacter baumannii under the US Food and Drug Administration Broad Agency Announcement Agreement FDABAA-20-00123N. Collaborating with fellow researchers, we have conducted preclinical studies on several novel antimicrobial compounds. In these projects, I have played a pivotal 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 comprehensive investigations into the pharmacokinetics and tissue distribution of eravacycline and minocycline in rabbits, among other endeavors. Our research also included extensive studies on drug penetration and the optimization of dosing regimens, with a particular focus on understanding the penetration of various antimicrobial agents into the CNS. These efforts are crucial for developing effective treatments for infections caused by multidrug-resistant organisms and improving clinical outcomes.
  - a. 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. 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.
  - **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. Hope WW, Mickiene D, Petraitis V, Petraitiene R, Kelaher AM, Hughes JE, Cotton MP, Bacher J, Keirns JJ, Buell D, Heresi G, Benjamin Jr DK, Groll AH, Drusano GL, Walsh TJ. The pharmacokinetics and pharmacodynamics of micafungin in experimental hematogenous *Candida* meningoencephalitis: Implications for echinocandin therapy in neonates. J Infect Dis. 2008 Jan;197(1):163-171. doi: 10.1086/524063. PMID: 18171300.
- 3. I have dedicated part of my research career to developing and evaluating new biomarkers for monitoring and assessing therapeutic response to antifungal therapy, such as galactomannan and  $(1\rightarrow 3)$ - $\beta$ -D-glucans. I investigated the correlation between serum galactomannan levels and the therapeutic effects of various antifungal agents—including lipid formulations of amphotericin B, voriconazole, posaconazole, isavuconazole, and combination therapies. This work established an important foundation for clinical studies and practice, supporting the use of surrogate markers to gauge the response of invasive aspergillosis to antifungal treatment. I systematically characterized the in vitro and in vivo factors influencing the expression of circulating galactomannan, non-Aspergillus galactomannan, and

- $(1\rightarrow 3)$ -β-D-glucans. Leading our laboratory, I developed an extensive and valuable body of translational research that spans from in vitro and in vivo studies to clinical research on biological markers for diagnosing and treating invasive mycoses, particularly invasive candidiasis, aspergillosis, trichosporonosis, and mucormycosis. The findings from these studies have been crucial in helping clinicians predict and interpret the clinical performance of these biomarkers and their potential use as markers of response to antifungal chemotherapy. Among our significant contributions from bench to bedside includes documenting galactomannan expression in serum during experimental primary pulmonary aspergillosis, establishing the correlation between therapeutic response of galactomannan and therapeutic outcomes, exploring the expression of  $(1\rightarrow 3)$ -β-D-glucans and its relationship to therapeutic responses in both experimental and clinical settings of disseminated candidiasis, demonstrating the relationship between  $(1\rightarrow 3)$ -β-D-glucans and central nervous system infections in children, establishing  $(1\rightarrow 3)$ -β-D-glucans as the first reliable CSF biomarker for pediatric hematogenous Candida meningoencephalitis.
  - a. **Petraitiene R**, Petraitis V, Bacher JD, Finkelman MA, Walsh TJ. Effects of host response and antifungal therapy on serum and BAL levels of galactomannan and (1 → 3)-β-D-glucan in experimental invasive pulmonary aspergillosis. Med Mycol. 2015 Aug;53(6):558-68. pii: myv034. Epub 2015 Jun 30. doi: 10.1093/mmy/myv034. PMID: 26129890.
  - b. **Petraitiene R**, Petraitis V, Witt JR 3rd, Durkin MM, Bacher JD, Wheat LJ, Walsh TJ. Galactomannan antigenemia after infusion of gluconate-containing Plasma-Lyte. J Clin Microbiol. 2011 Dec;49(12):4330-4332. doi: 10.1128/JCM.05031-11. PMID: 21976760.
  - c. Petraitiene R, Petraitis V, Hope WW, Mickiene D, Kelaher AM, Murray HA, Mya-San C, Hughes JE, Cotton MP, Bacher J, Walsh TJ. Cerebrospinal fluid and plasma (1 → 3)-β-D-glucan as surrogate markers for detection and monitoring of therapeutic response in experimental hematogenous *Candida* meningoencephalitis. Antimicrob Agents Chemother. 2008 Sep;52(11):4121-4129. doi: 10.1128/AAC.00674-08. PMID: 18779361.
  - d. Salvatore CM, Chen TK, Toussi SS, DeLaMora P, **Petraitiene R**, Finkelman MA, Walsh TJ.  $(1 \rightarrow 3)$ -β-D-glucan in cerebrospinal fluid as a biomarker for *Candida* and *Aspergillus* infections of the central nervous system in pediatric patients. J Pediatric Infect Dis Soc. 2016 Sep; 5(3):277-86. doi: 10.1093/jpids/piv014. Epub 2015 Mar 19. PMID: 26407252.

### Complete list of Published Work in Pubmed:

https://pubmed.ncbi.nlm.nih.gov/?term=petraitiene+r&sort=date