

BIOGRAPHICAL SKETCH

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NAME: Salacz, Michael E.

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

POSITION TITLE: Associate Professor of Medicine, Program Director, Neuro-oncology

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
Cornell College of Engineering, Ithaca, NY	B.S.	12/1987	Industrial Engineering
UMDNJ - New Jersey Medical School, Newark, NJ	M.D.	06/1998	Medicine
University of Cincinnati School of Medicine, Cincinnati, OH	Internship	06/1999	Psychiatry
University of Cincinnati School of Medicine, Cincinnati, OH	Residency	06/2002	Internal Medicine
Medical College of Wisconsin, Milwaukee, WI	Fellowship	06/2005	Hematology/Oncology
Duke University School of Medicine, Durham, NC	Fellowship	06/2008	Neuro-Oncology

A. Personal Statement

I have the clinical expertise, training and experience necessary to serve as the Principal Investigator for the proposed phase II study sponsored by TVAX Biomedical, entitled "Neoantigen-specific Adoptive T-Cell Therapy (NACT) for Glioblastoma", seeking to evaluate the efficacy and toxicity of the TVI-Brain-1 approach in treating newly diagnosed patients with glioblastoma. I have been involved with clinical research throughout my 16 years of clinical practice as a neuro-oncologist, first at Saint Luke's Medical Center, a large tertiary health system in Kansas City where, as director of the Brain Tumor Center, I was PI for a number of clinical trials including the DC-Vax trial of autologous tumor vaccine and the Phase I study of TVI-Brain-1 an adoptive cell transfer approach. More recently, as Director of the Brain and Spine Tumor Program at the University of Kansas, I have served as principle investigator on multiple brain tumor trials, including several other immunotherapy trials including the Checkmate study (testing checkpoint inhibition), the Tocagen anti-tumor viral therapy trial and DC-Vax.

I joined the team at Rutgers, Cancer Institute of New Jersey (CINJ) in 2021, where I am program director for neuro-oncology. Rutgers/CINJ is an NCI designated, comprehensive cancer center and is part of the RWJBarnabas Health System, a 13-hospital partnership located in New Jersey. As the neuro-oncology program director, I lead the largest central nervous system specific tumor program in the region, with about 100 new patients seen annually. The multidisciplinary team comprises fellowship-trained skull-base neurosurgeons specializing in neuro-tumor surgeries along with board-certified neuropathologists, neuro-radiologists and radiation oncologists. As one of the only fellowship-trained and board-certified neuro-oncologists in the region, I have expertise not only of 16 years of clinical trial conduct, but also experience collaborating with the apheresis/BMT team and the early phase trials team in the conduct of clinical trials, and specifically with this particular vaccine/adoptive cell transfer approach. It is important to emphasize that my contributions to this study derive from my years of experience as a practicing clinical neuro-oncologist, my extensive experience conducting brain-tumor specific clinical trials generally and specifically serving as the principle investigator on multiple immunotherapy trials focused on adoptive cell transfer approaches.

B. Positions and Honors

2002 – 2004	Clinical Staff, Internal Medicine, Mercy Franciscan Hospital-Mt. Airy Campus, Cincinnati, OH
2004 – 2005	Clinical Staff, Hematology/Oncology, Saint Joseph's Hospital at West Bend, West Bend, WI
2005 – 2007	Clinical Staff, Neuro-Oncology, Hematology/Oncology, Palliative Medicine, Saint Luke's Medical Center, Kansas City, MO
2008 – 2013	Director Brain Tumor Center, Clinical Staff, Neuro-Oncology, Hematology/Oncology, Palliative Medicine, Saint Luke's Medical Center, Kansas City, MO
2013 – Present	Assistant Professor and Director Brain and Spine Tumor Program Neuro-Oncology, Clinical Staff Hematology/Oncology, University of Kansas Medical Center, Kansas City, KS
2019 – Jan 2021	Neuro-oncology Division Chief, University of Kansas Medical Center, Kansas City, KS
Mar 2021 - Present	Neuro-oncology Program Director, Rutgers, Cancer Institute of New Jersey, New Brunswick, NJ
2007-2008	Ruth L. Kirschstein Institutional National Research Service Award (Duke University)

Professional Qualifications

2013 - Present	United Council of Neurologic Subspecialties (Neuro-Oncology)
2006 - Present	American Board of Internal Medicine (Medical Oncology)
2005 - Present	American Board of Internal Medicine (Internal Medicine)

Other Professional Activities:

1988-1991	United States Navy, Naval Officer, Engineering Division, USS Mount Whitney
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C. Contributions to Science:

My scientific contributions that are relevant to my role in the clinical trial proposed in the current application are related to my expertise in the areas of treatment development and the implementation of clinical trials. Specifically, I have been the principle investigator in several trials evaluating effectiveness/toxicity of adoptive cell therapies including the randomized DC-Vax therapy. I have listed five of my recent publications in the areas of trial conduct/development.

- a. Cloughesy TF, Petrecca K, Walbert T, Butowski N, Salacz ME, Perry J, Damek D, Bota D, Bettegowda C, Zhu JJ, Iwamoto, F, Placantonakis D, Kim L, Elder B, Kaptain G, Cachia D, Moshel Y, Brem S, Piccioni D, Landolfi J, Chen CC, Gruber H, Rao A, Hogan D, Accomando W, Ostertag D, Montellano TT, Kheoh T, Kabbinar F, Vogelbaum MA. "Effect of Vocimagene Amiretrorepevec in Combination With Flucytosine vs Standard of Care on Survival Following Tumor Resection in Patients With Recurrent High-Grade Glioma: A Randomized Clinical Trial." *JAMA Oncol.* Published online October 29, 2020. doi:10.1001/jamaoncol.2020.316
- b. LM Liou; DD Tran; JL Campian; JE Trusheim; CS Cobbs; JA Heth; ME Salacz; S Taylor; SD D'Andre; FM Iwamoto; EJ Dropcho; YA Moshel; KA Walter; CP Pillainayagam; R Aiken; R Chaudhary; SA Goldlust; DA Bota; P Duic; J Grewal; H Elinzano; SA Toms; KO Lillehei; T Mikkelsen; T Walbert; SR Abram; AJ Brenner; SBrem; MG Ewend; SKhagi; J Portnow; LJ Kim; WG Loudon; RC Thompson; DE Avigan; KL Fink; FJ Geoffroy; S Lindhorst; J Lutzky; AE Sloan; G Schackert; D Krex; HJ Meisel; J Wu; RP Davis; C Duma; AB Etame; D Mathieu; S Kesari; D Piccioni; M Westphal; DS Baskin; PZ New; M Lacroix; SA May; TJ Pluard; V Tse; RM Green; J Villano; M Pearlman; K Petrecca, "First results on survival from a large Phase 3 clinical trial of an autologous dendritic cell vaccine in newly diagnosed glioblastoma." *J Transl Med.* 2018 May 29; 16(1): 142.
- c. Salacz ME, Kast RE, Saki N, Brüning A, Karpel-Massler G, Halatsch ME, "Toward a noncytotoxic glioblastoma therapy: blocking MCP-1 with the MTZ Regimen", *Onco Targets Ther.* 2016 Apr 27; 9:2535-45.

- d. Nabors LB, Fink KL, Mikkelsen T, Grujicic D, Tarnawski R, Nam DH, Mazurkiewicz M, Salacz M, Ashby L, Zagonel V, Depenni R, Perry JR, Hicking C, Picard M, Hegi ME, Lhermitte B, Reardon DA. "Two cilengitide regimens in combination with standard treatment for patients with newly diagnosed glioblastoma and unmethylated MGMT gene promoter: results of the open-label, controlled, randomized phase II CORE study." *Neuro Oncol.* 2015 May; 17(5): 708-17.
- e. Penas-Prado M, Hess KR, Fisch MJ, Lagrone LW, Groves MD, Levin VA, De Groot JF, Puduvalli VK, Colman H, Volas-Redd G, Giglio P, Conrad CA, Salacz ME, Floyd JD, Loghin ME, Hsu SH, Gonzalez J, Chang EL, Woo SY, Mahajan A, Aldape KD, Yung WK, Gilbert MR; on behalf of the MD Anderson Community Clinical Oncology Program and the Brain Tumor Trials Collaborative, "Randomized phase II adjuvant factorial study of dose-dense temozolomide alone and in combination with isotretinoin, celecoxib, and/or thalidomide for glioblastoma.", *Neuro Oncol.* 2015 Feb; 17(2): 266-73.

Research Support: None