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NAME	JOB TITLE	PWS Tasks
Shaji Daniel	PATIO - Intermediate Scientist (Patient Engagement/Design)	7.1.1 - 7.1.6; 7.1.8-7.1.17;

Job Responsibility	Qualifying Skills
Cancer Research & Stakeholder Engagement: Lead and manage internal processes for cancer-related research, initiatives, and partnerships, ensuring alignment with broader Cancer Moonshot federal community goals.	· Led translational research in immunology and oncology, developing CAR-T cell therapies for cancer and autoimmune diseases at Cartesian Therapeutics. · Acted as a principal investigator and scientific leader, coordinating research with academic, industry, and federal partners on cancer vaccine development at NIH/NIAID. · Developed and optimized cell therapy approaches, including next-generation BCMA CAR-T cell products, improving cancer treatment efficacy.
Regulatory & Health System Compliance: Provide expertise in regulatory compliance, health system administration, and medical device development to guide project execution and ensure adherence to industry standards.	· Managed IND-enabling studies and regulatory filings, ensuring compliance with GLP, GMP, and FDA guidelines for cell and gene therapy product development. · Designed and validated clinical trial assays, including PK/PD, cytokine profiling, and immunophenotyping, for regulatory submission and patient monitoring. · Led preclinical vaccine studies under GLP regulations, establishing standardized immunization and testing protocols for FDA compliance at NIH.
Scientific & Translational Research Leadership: Develop and implement strategies for engaging stakeholders in healthcare, population health, and product development while integrating scientific and regulatory perspectives.	· Directed preclinical and clinical-stage product development, leading teams in translational oncology research at Cartesian Therapeutics. · Developed scientific roadmaps for vaccine and cancer immunotherapy projects, ensuring integration of regulatory and health system perspectives. · Published high-impact research in journals such as The Lancet Neurology, The Journal of Immunology, and Nature Biomedical Engineering, demonstrating leadership in scientific innovation.

Education

Ph.D. in Molecular Virology, Indian Institute of Science, Bangalore, India
Thesis Advisor: Prof. M. S. Shaila, Dept. Chairperson

Worked on Rinderpest Virus (RPV), a member of the NNS RNA virus group. Investigated the various interactions displayed by RPV N and P proteins, which is vital for transcription and replication of the viral genome - Virology 1999. Mapped the domains of both N and P protein, involved in P-P, N-N (virus like particle formation), soluble N-P and self-assembled N protein (virus like particle)-P interactions. This work enabled a complete visualization of all the different N and P protein interactions involved in both transcription and replication.

M.S. in Biotechnology, M.S. University of Baroda, Gujarat, India; Ranked 3rd in the University

B.S. in Microbiology, University of Bombay, Maharashtra, India; Ranked 1st in the College

Experience

Cartesian Therapeutics, Inc., Gaithersburg, MD **Aug 2019 – Aug 2024**
Director Translational Research (CAR-T cell therapy for cancer and autoimmune diseases)

Discovery work:

- Played a major role in advancing the company's product pipeline. Was the Project Lead on multiple discovery projects and tested out hundreds of CAR constructs in vitro for functional efficacy, performed IND enabling in vitro and in vivo studies, and helped in putting together the IND applications. Collaborated internally with QC, clinical operation and Manufacturing and externally with various CROs for pre-clinical and clinical work.
- Introduced a new line of products- next-generation CAR-T cell products targeting BCMA and other targets of interest showing 10-fold increase in CAR expression, these products include DC-15 and DCXX.
- Played a major role in development of DC-15- a BCMA CAR-T cell product (Clinical trial ID: NCT06304636; Patent filed), DC25- an allogeneic Mesenchymal Stem Cell product secreting a bispecific protein (Clinical trial ID: NCT05113342; Patent filed- WO2023010068A2 and Manuscript in resubmission to Nature Biomedical Engineering), DC-30- an allogeneic Mesenchymal Stem cell product secreting DNase1, and DNase1L3 proteins (Clinical trial ID: NCT04524962; Patent filed- WO2021211848A1) and DC-8 - a BCMA CAR-T cell product.

Assay Development work:

Developed and validated several qPCR, ELISA, ELLA, Legend Plex, Luminex, Flow cytometry and cell-based assays to analyze discovery, pre-clinical and clinical trial Blood, serum and PBMC samples for PK, PD and mode of action analysis. (Lancet Neurol. 2023 and unpublished data). Authored SOPs, validation protocols and reports.

Laboratory of Malaria Immunology and Vaccinology, NIAID, NIH, Rockville, MD **Jan 2018 – July 2019**
Scientist (Volunteer)

- Finished two publications from prior work at NIH in J Infect Dis. and Infect Immun.Placental Malaria Vaccine (PMV) Antigens:
- Compared mammalian expression vectors pCI-S and VRC8400 VAR2CSA (the leading PMV Vaccine candidate) N-terminal ID1-ID2a domain constructs for vaccine efficacy by DNA immunization of rats by electroporation and found that the immune IgG from VRC8400 construct immunized rats showed significantly higher staining of VAR2CSA protein expressed on Plasmodium falciparum infected erythrocyte surface by Flow Cytometry.
- Did Flow Cytometric analysis of immune IgG from rats immunized by DNA electroporation with VRC8400 constructs for six different alleles of full length VAR2CSA as well as VAR2CSA ID1-ID2a, NTS-DBL2x and DBL3-DBL6 domains and found out that the IgG from full length protein and the DBL3-DBL6 domain immunized rats showed highest staining of VAR2CSA protein expressed on Plasmodium falciparum infected erythrocyte surface.
- Based on in silico analysis of VAR2CSA protein structure in collaboration with VRC and DNA vaccination of rats by electroporation, found that IgG from rats immunized with multiple alleles of the VAR2CSA C-terminal DBL3-DBL6 domains induced vaccine activity against a significantly higher proportion of field isolates.

Laboratory of Malaria Immunology and Vaccinology, NIAID, NIH, Rockville, MD **Sept 2013 – Dec 2017**
Team Leader, Antigen Discovery Unit (Contractor)

- Responsible for preclinical and clinical Malaria Vaccine development targeting distinct stages of the malarial parasite life cycle.

Pre-erythrocytic vaccine (PEV) Antigens:

- Established in-house baculoviral mediated expression system to express vaccine antigens intracellularly in insect cells as well as in a secreted form in the culture medium.
- Constructed codon optimized DNA vaccine clones for DNA immunization by electroporation and gene gun, Expressed and purified proteins from insect cells and E. coli for various vaccination studies.

- Analyzed different modes of immunization (protein prime-Ad5 boost; DNA prime-Ad5 boost, etc.) in mice for optimizing the immunization regiment to maximize the level of protection displayed by the vaccine.
- Screened several promising pre-erythrocytic vaccine candidates by protein and DNA immunizations to examine their levels of protection against parasite challenge in mice and identified three candidates with higher sterile protection in combination with CSP (the leading PEV Vaccine candidate) compared to CSP protein alone. (Infect Immun. 2021).

Placental Malaria Vaccine (PMV) Antigens:

- By DNA (Gene Gun) and protein vaccinations of rats, localized a region at the N-terminus of VAR2CSA (the leading PMV Vaccine candidate) showing high levels of protection and examined the effect of protein glycosylation within this region on immune response. Used Flow cytometry to characterize the immune response against VAR2CSA on infected erythrocyte surface.
- Examined the infected erythrocyte membrane localization of PfCSA-L protein, a second promising PMV candidate using Flow cytometry and membrane analysis (J Infect Dis. 2022).
- Collaborated with GenVec, Inc. to generate Adenovirus expressing full length VAR2CSA.
- Managed Antigen Discovery Unit projects and scientific staff consisting of 4 scientists.
- Kept track of research activities and gave updates to other team leaders and section chief on a weekly basis, wrote project updates for the Board of Scientific Counselors Review report, scientific advisory board meeting, wrote annual project reports and gave project updates to funding agencies.

Retrovirox Inc, San Diego, California **March 2011 – July 2012**
Senior Scientist (Flowcytometry based HIV Drug Discovery)

- Identified compounds that inhibit Human Immunodeficiency Virus (HIV) by High Throughput FACS based Screening.
- Designed, developed and optimized cell based high throughput (HTS) assays using SUPT1 cells for screening small molecule inhibitors of HIV-induced CD4 and MHC class1 down-modulation using FACS in 96 well format.
- Performed drug screen of 27,000 drug-like compounds and validation of hits in lymphocytes, determined EC 50, CC 50 and TI values and performed mechanism of action studies. Secured a SBIR Phase I grant based on the screen results.
- Performed CRO projects in a timely manner adhering to GLP/cGMP guidelines: Purification and titration of HIV obtained by transfection of pro-viral DNA in large amounts using centrifugation and chromatography and Influenza NI assay.
- HIV titer determination by p24 ELISA and HeLa-CD4-LTR-ß-gal cell infectivity assay, replication assay and protease assay
- Evaluating toxicity of compounds by XTT cytotoxic assays.
- Expression and analysis of proteins using lentiviral vectors.

Department Of Microbiology and Immunology **Jan 2007 – Dec 2010**
Indiana University School of Medicine, Indianapolis, Indiana
Postdoctoral Fellow and Research Associate (Molecular Immunology)

Principle Investigator: Prof. Randy R. Brutkiewicz

- Studied the CD1d molecule, a cell surface glycoprotein that is structurally related to major histocompatibility complex (MHC) class I molecule. These molecules present lipid antigens to a subpopulation of T cells called NKT cells.
- Analyzed the mechanism of HIV-1 Nef mediated down regulation of human CD1d (hCD1d). In line with earlier observations, my work using transfection of mammalian cells, site directed mutagenesis and FACS, emphasized the importance of the N-terminal myristoylation motif of Nef protein and Nef residues important for MHC Class1 and CD4 down regulation, in functional expression of hCD1d.

- It was found that the T322 residue in the human CD1d tail is a major signal controlling transport to the cell surface and thus its functional expression. The results demonstrate an important role of a heretofore unknown signal in the cytoplasmic tail of CD1d that may have relevance to other type I integral membrane proteins that traverse through the endocytic pathway - The Journal of Immunology, 2010. Techniques used included FACS, purification of human NKT cells from blood and in vitro mouse and human APC–NKT cell assay and cytokine ELISA.
- The VSV-M protein rapidly decreases CD1d mediated Ag presentation by altering the intracellular distribution of murine CD1d molecules, resulting in qualitative (but not quantitative) changes in cell surface CD1d expression. The M protein was distributed throughout the infected cell, and it was found to activate the mitogen-activated protein kinase (MAPK) p38 very early post infection. Thus, it was found that the VSV
- -M protein plays an important role in permitting the virus to evade CD1d mediated Ag presentation by regulating specific MAPK pathways - J Virol. 2008. Analyzed interaction of VSV proteins with CD1d using yeast two-hybrid system, isolated bone marrow dendritic cells from mice.
- It was also found that MHC class I physically associates with mouse CD1d molecule and regulates its functional expression on the cell surface - PLoS One, 2013. Analyzed MHC class1 and CD1d interaction by radio immunoprecipitation. Isolated liver mononuclear cells from mice.

Virology Section, Dept. of Molecular Genetics **March 2000 – Dec 2006**
Lerner Research Institute, Cleveland Clinic, Cleveland, Ohio
Postdoctoral Fellow and Research Associate (Molecular Virology)

Principle Investigator: Dr. A. K. Banerjee, Chairman, Virology Section

- Studied, Vesicular Stomatitis Virus (VSV), in vitro transcription and replication. VSV is a prototype non-segmented negative strand (NNS) RNA virus. This virus group includes many human pathogens like rabies, measles, mumps, human Para influenza, influenza and many others.
- Research using Baculoviral mediated insect cell expression and purification of VSV proteins and immuno-affinity purification of VSV proteins from BHK infected cell lysates lead to the identification of two distinct polymerase complexes, transcriptase synthesizing capped mRNAs and replicase synthesizing uncapped genome and antigenome RNAs, respectively. These observations formed the basis for a two-polymerase complex-based model unlike the current single polymerase model for NNS RNA viruses. As per the new model, two RNA polymerase complexes that differ in their content of virally and host encoded proteins are separately responsible for transcription and replication of NNS RNA virus genome. This work was published in J. of Virol. and PNAS. Techniques used included immuno-affinity purification of protein complexes, in vitro replication and transcription using radio nucleotides.

PATENTS

Engineered cells secreting therapeutic enzymes (DC-30 product) Patent Filed- WO2021211848A1.

Multiprotein-engineered cells secreting a multi-specific antibody (DC-25 product) Patent Filed- WO2023010068A2.

CD3 effector domains for prolonged CAR expression (DC-15 product) Patent Filed.

PROFESSIONAL AWARDS

- Ruth L. Kirschstein National Research Service Award form NIH (NRSA; May 2008 to April 2010)
- Dr. K. S. Krishnan Junior and Senior research fellowship Awards from Department of Atomic Energy, Government of India.
- Council of Scientific and Industrial Research (CSIR) fellowship Award from Government of India
- Fellowship from Indian Institute of Science for research work towards Ph.D.
- Awarded Graduate aptitude test in Engineering (94.9 percentile score).

PUBLICATIONS

Volkan Granit, Michael Benatar, Metin Kurtoglu, Miloš D Miljković, Nizar Chahin, Gregory Sahagian, Marc H Feinberg, Adam Slansky, Tuan Vu, Christopher M Jewell, Michael S Singer, Murat V Kalayoglu, James F Howard Jr, Tahseen Mozaffar; MG-001 Study Team. Safety and clinical activity of autologous RNA chimeric antigen receptor T-cell therapy in myasthenia gravis (MG-001): a prospective, multicenter, open-label, non-randomized phase 1b/2a study. Lancet Neurol. 2023 Jul;22(7):578-590.

C. Andrew Stewart, Shaji Daniel, et al. Allogenic MSCs engineered with mRNA enable coordinated delivery of T cell engagers and therapeutic cues. (Manuscript in re-submission to Nature Biomedical Engineering).

Gladys J Keitany, Bethany J Jenkins, Harold T Obiakor, Shaji D, Atis Muehlenbachs, Jean-Philippe Semblat, Benoit Gamain, Justin Y A Doritchamou, Sanjay A Desai, Nicholas J MacDonald, David L Narum, Robert Morrison, Tracy Saveria, Marissa Vignali, Andrew V Oleinikov, Michal Fried, Patrick E Duffy. An Invariant Protein That Colocalizes with VAR2CSA on Plasmodium falciparum-Infected Red Cells Binds to Chondroitin Sulfate A. J Infect Dis. 2022 Jun 1; 225(11): 2011–2022.

Shaji D, Alexander Pichugin, Holly Torano, Jonathan P. Renn, Jennifer Kwan, Matthew V. Cowles, Solomon Conteh, Lynn E. Lambert, Nada Alani, Nicholas J. MacDonald, Weili Dai, Kendrick Highsmith, Charles Anderson, J. Patrick Gorres, Javonn Musgrove, Brandi Butler, Nouf Althubaiti, Saurabh Dixit, Stasya Zarling-Bejma, Urszula Krzych, Patrick E. Duffy. Plasmodium Preerythrocytic Vaccine Antigens Enhance Sterile Protection in Mice Induced by Circumsporozoite Protein. Infect Immun. 2021 Nov; 89(11): e00165-21. P

Renukaradhya GJ, Khan MA, Gallo RM, Shaji D, Liu J and Brutkiewicz RR. Forming a complex with MHC class I molecules interferes with mouse CD1d functional expression PLoS One, 2013 Aug 29;8(8): e72867

Liu J, Shaji D, Cho S, Du W, Gervay-Hague J, Brutkiewicz RR. A Threonine-Based Targeting Signal in the Human CD1d Cytoplasmic Tail Controls Its Functional Expression. The Journal of Immunology, 2010, 184, 4973 -4981

Renukaradhya GJ, Khan MA, Shaji D, and Brutkiewicz RR. Vesicular Stomatitis Virus Matrix Protein Impairs CD1d-Mediated Antigen Presentation through Activation of the p38 MAPK Pathway J Virol. 2008 December; 82(24): 12535–12542.

Shaji D, Qanungo KR, Mathur M, Banerjee AK. Two RNA polymerase complexes from vesicular stomatitis virus-infected cells that carry out transcription and replication of genome RNA. Proc Natl Acad Sci U S A. 2004 Apr 20; 101(16): 5952-7. (The first two authors have equal contribution.)

Gupta AK, Shaji D, Banerjee AK. Identification of a novel tripartite complex involved in replication of vesicular stomatitis virus genome RNA. J Virol. 2003 Jan; 77(1):732-8.

Shaji, D., and Shaila, M. S. Domains of Rinderpest Virus Phosphoprotein involved in interaction with itself and the Nucleocapsid protein. Virology 1999 258:415-424.

OVER 15 ORAL AND POSTER PRESENTATIONS

Presentations at the Annual Meetings of American Society for Tropical Medicine and Hygiene, American Association of Immunologist, American Society for Virology, and Indian Society of Biological Chemists.