Nominations for Appointment to the Grants Working Group (GWG)

NEW APPOINTMENTS
Vijay G. Bhoj, MD, PhD
Assistant Professor, University of Pennsylvania

Referral: Dr. Bhoj was referred by Dr. Avery Posey.

Expertise Relevance to CIRM GWG: Dr. Bhoj's expertise in cellular immunotherapy will be invaluable in reviewing Translational and Clinical stage program awards.

Prior Service in CIRM Reviews: Dr. Bhoj has participated in Translational stage program reviews.

Bio:
Dr. Vijay Bhoj is Assistant Professor in the Department of Pathology and Laboratory Medicine and the Center for Cellular Immunotherapy at the Perelman School of Medicine at the University of Pennsylvania. His clinical expertise is in transfusion medicine and his research expertise lies in cellular immunotherapy, particularly preclinical development of immunotherapy that employ engineered immuno-receptors (e.g., chimeric antigen receptors) for the treatment of cancer and of non-malignant conditions such as autoimmunity and transplant rejection. He conducts preclinical in vitro and in vivo studies using animal models as well as correlative studies in patients undergoing immunotherapy to study the immune impact of such therapies.

Dr. Bhoj earned his MD and his PhD in Immunology at University of Texas Southwestern Medical Center. He completed his residency in Clinical Pathology and fellowship in Transfusion Medicine at the Hospital of the University of Pennsylvania. He holds board certification in Clinical Pathology and Blood Banking/Transfusion Medicine. Among many awards and honors, he has received the AABB Scholar Award, Gift of Life Award from the Ree-Wynn Foundation, the Distinguished Young Investigator Award from the Immuno-Oncology Young Investigators' Forum, the William Pepper Fellowship in Pathology and Laboratory Medicine from the University of Pennsylvania, and the NIH National Institute of Allergy and Infectious Diseases National Research Service Award.

Almira Chabi, MD, EGMP
Chief Medical Officer and Chief Development Officer, Hanall Biopharma International

Referral: Dr. Chabi was referred by Dr. Barbara Wirostko.

Expertise Relevance to CIRM GWG: Dr. Chabi's expertise in ophthalmology, drug development, artificial intelligence, regenerative medicine, neurology (AD, PD), immunology and oncology will be invaluable in reviewing Discovery to Clinical stage program awards.

Prior Service in CIRM Reviews: Dr. Chabi has participated in Clinical and Translational stage program reviews.

Bio:
Dr. Almira Chabi, MD, EGMP, currently serves as Chief Medical Officer and Chief Development Officer at Hanall Biopharma International, a global biopharmaceutical company with a mission of making meaningful contributions to patients' lives by introducing innovative, impactful therapies to address severe unmet medical needs. Dr. Chabi leads research in oncology, immunology, neurology, and ophthalmology as well as other sectors. She has extensive experience in all phases of drug discovery and development. Prior to Hanall, she served as the therapeutic area head for Glaucoma & Neuroprotection, lead for Artificial Intelligence Programs within Global Biomedical Science for

Santen. She has also previously served in multinational pharmaceutical and biotechnology companies such as Merck and Genentech.

Dr. Chabi received her undergraduate and medical school education at the University of Wisconsin. In addition to completing residency training in ophthalmology and surgical fellowship training in cornea & external diseases, she completed a research fellowship at Cornell University, and has served as adjunct clinical staff at Wills Eye Hospital as well as Stanford University. Dr. Chabi is also an alumna of Wharton Business School's Management Program.

Diana M. Colleluori, PhD, MBA
Senior CMC Consultant, Biologics Consulting Group

Referral: Dr. Colleluori was referred by Dr. Chris Scull.

Expertise Relevance to CIRM GWG: Dr. Colleluori's expertise in regulatory affairs and chemistry, manufacturing and controls will be invaluable in reviewing Translational and Clinical stage program awards.

Prior Service in CIRM Reviews: Dr. Colleluori has participated in Clinical and Translational stage program reviews.

Bio:
Dr. Diana Colleluori is a Senior CMC Consultant at Biologics Consulting Group, a regulatory and product development consulting firm for biologics, pharmaceuticals, and medical devices. Dr. Colleluori has over 20 years of domestic and global experience in analytical methods, quality control, CMC, regulatory affairs, and strategic planning focused on biotechnology products, including cell and gene therapy products. Her key technical experience includes potency assays, release and characterization assays, stability, specifications, raw materials, and all associated quality documentation. She has experience authoring IND/IMPD and BLA/MAA sections and briefing documents.

Dr. Colleluori earned her PhD in Biochemistry at Temple University School of Medicine and her MBA, concentration in Pharmaceutical and Healthcare Business, at the University of the Sciences in Philadelphia. Prior to her role at Biologics Consulting, she worked at Iovance Biotherapeutics, which focused on T cell-based therapies for cancer, and bluebird bio, which utilized lentiviral platforms for late-stage cell and gene therapy. While working at Merck, she was responsible for 3 worldwide QC hubs managing biologics and vaccines critical reagents for global commercial supply. She has also led the execution for the construction of new GMP QC laboratories for multiple companies.

Sue Preston
Founder and President, X'Elas BioDevelopment LLC

Referral: Ms. Sue Preston was referred by Dr. Abla Creasey.

Expertise Relevance to CIRM GWG: Ms. Preston's expertise in regulatory affairs will be invaluable in reviewing Translational and Clinical stage program awards.

Prior Service in CIRM Reviews: Ms. Preston has participated in Clinical stage program reviews.

Bio:
Ms. Sue Preston is an experienced pharmaceutical executive based in Houston, Texas. She has introduced successful development strategies for novel technologies for biopharmaceuticals, small molecules, drug delivery systems, and diagnostics. Ms. Preston started her career with the NIH with a subsequent 8 years at FDA/CBER responsible for review and approval of biologics and polymers including the first therapeutic, monoclonal antibody. After moving into industry, she has 20+ years implementing innovative regulatory and quality strategies for timely product approval and life-cycle management for a variety of globally marketed products. Ms. Preston gained broad therapeutic and technology experience in oncology, respiratory, infectious diseases, autoimmune diseases, neurology, and critical care. Working in industry, Ms. Preston was responsible for regulatory and quality strategies for over 60 products marketed in over 40 countries. She has held positions of increasing responsibility at Baxter Healthcare, Medarex, Alpha Therapeutic Corporation, and Chiron Corporation. Ms. Preston has represented manufacturers and industry organizations in testimony before three Congressional Committees and the General Accounting Office.

Akshay Sharma, MBBS
Assistant Member, St. Jude Children's Research Hospital

Referral: Dr. Sharma was referred by Dr. Mitch Weiss.

Expertise Relevance to CIRM GWG: Dr. Sharma's expertise in gene therapy and non-malignant hematological conditions will be invaluable in reviewing Translational and Clinical stage program awards.

Prior Service in CIRM Reviews: Dr. Sharma has participated in Discovery and Translational stage program reviews.

Bio:
Dr. Akshay Sharma is an Assistant Member in Bone Marrow Transplantation and Cellular Therapy at St. Jude Children's Research Hospital in Tennessee. His research interests include gene therapy, gene editing, bone marrow transplantation for patients with non-malignant hematological conditions and the development of novel reduced intensity and non-myeloablative conditioning regimens. His long-term goal is to develop curative therapies for inherited disorders of the hematopoietic system, such as sickle cell disease (SCD) and bone marrow failure syndromes, using graft engineering and genome editing.

Dr. Sharma earned his MBBS in Medicine and Surgery at Kasturba Medical College Mangalore, Mangalore, Karnataka. He completed his postdoctoral training in Tumor Immunology and Transplantation at Emory University, in the laboratory of Edmund Waller where he studied the mechanisms of antigen presentation in the setting of allogeneic hematopoietic cell transplantation (HCT) to improve the safety of allogeneic HCT and reduce immunological adverse effects. He completed his residency in Pediatrics at the University of Kentucky. He completed his clinical fellowship in Pediatric Hematology and Oncology at St. Jude Children's Research Hospital, conducting research in the laboratory of Mitchell J. Weiss using CRISPR-Cas9–based genome-editing technology to identify novel regulatory regions of the genes associated with the hemoglobin switch through funding from the American Society of Hematology (ASH) Research Training Award. Among many honors, he was selected for the competitive American Society for Transplantation and Cellular Therapy (ASTCT) Clinical Research Training Course and received the H. Jean Khoury Award for Scholarly Excellence. He was also awarded the ASH Scholar Award to develop a clinical trial to evaluate the safety and efficacy of CRISPR/Cas9-mediated disruption of a BCL11A repressor binding motif in the g-globin gene promoters in SCD patient HSC to induce therapeutic levels of fetal hemoglobin in red blood cell progeny and potentially cure SCD. He has led several clinical trials of novel cellular and genetic therapies for children with hematological disorders for blood disorders. His group was one of the first to show that plerixafor can be safely used to mobilize hematopoietic stem cells (HSC) in individuals with SCD, and they continue to improve techniques to collect HSCs in individuals with SCD via apheresis for genetic manipulation, which is a major bottleneck in ex vivo genetic therapies.

Carolyn A. Wilson, PhD
Adjunct Professor, George Mason University

Referral: Dr. Wilson was referred by Dr. Andra Miller.

Expertise Relevance to CIRM GWG: Dr. Wilson's expertise in regulatory affairs for cell and gene therapy will be invaluable in reviewing Translational and Clinical stage program awards.

Prior Service in CIRM Reviews: Dr. Wilson has participated in Translational stage program reviews.

Bio:
Dr. Carolyn Wilson currently is a member of the Department of Bioengineering, George Mason University (GMU). In support of the Department, she currently plays several roles: 1) lead instructor for Biomanufacturing (a newly offered course she developed for the Department); 2) part of a team, teaching regulatory policy for medical products; 3) Acting Executive Director for the Bioengineering Alliance, a body of external advisors to the Department; and 4) the Department's internship coordinator. Prior to working at GMU, Dr. Wilson supported public health with a 30-year career in government. Between 2007-2020, she served as the Associate Director for Research (ADR) at the Center for Biologics Evaluation and Research (CBER), FDA. As ADR, Dr. Wilson ensured that CBER's research was relevant, high quality and provided CBER with the appropriate scientific expertise, tools, and data to support regulatory decision-making and policy development. Dr. Wilson joined CBER/FDA initially in 1993, working as a researcher-reviewer in the Division of Cellular and Gene Therapies (DCGT). As a researcher-reviewer in DCGT, she reviewed regulatory submissions, and developed policy and guidance documents in novel product areas: cell and gene therapies and xenotransplantation. From 1993 until 2016, Dr. Wilson also was the lead scientist of a team of

researchers performing laboratory studies on retroviruses that are either used as vectors for gene therapy clinical trials or are of concern in pig to human clinical xenotransplantation.

Prior to joining the FDA, Dr. Wilson performed her post-doctoral research at the National Institutes of Mental Health, NIH, on retrovirus-receptor interactions. She holds a Ph.D. in Genetics from The George Washington University. While obtaining her PhD, she worked in Dr. Robert Gallo's laboratory at the National Cancer Institute and collaborated with Dr. Maribeth Eiden at the NIMH/NIH to perform her doctoral dissertation research on retroviral vectors. The outcome of her doctoral research resulted in her co-authorship on and award of two patents. The retroviral vector she developed in her doctoral research, that is also the subject of one of the patents, is still being used in gene therapy clinical trials. Dr. Wilson currently serves on the MS Program Advisory Board for the George Washington University's Department of Bioinformatics and Molecular Biochemistry. In addition, she is an avid cyclist and serves the community to create a safer environment for pedestrians and cyclists through her participation on the Steering Committee for the Families for Safe Streets. She also supports her condominium through volunteering on the Environmental Committee where she develops programs to reduce the environmental impact of the community.

REAPPOINTMENTS

CIRM is seeking the reappointment of the individuals listed in the table below. Their updated biographies follow.

Proposed Reappointments to GWG

Last	First	Term	Years	Expertise
Kotton	Darrell	3	6	Stem Cell & Gene Therapy; Lung Developmental Biology; Pulmonary Disease

Darrell N. Kotton, MD
Dr. Darrell Kotton is the founding director of the Center for Regenerative Medicine of Boston University and Boston Medical Center. He is a physician-scientist trained in pulmonary and critical care medicine and is the David C. Seldin Professor in the Department of Medicine and in the Department of Pathology and Laboratory Medicine at Boston University School of Medicine. Dr. Kotton is an Allen Distinguished Investigator, a Paul G. Allen Frontiers Group advised program of the Paul G. Allen Family Foundation. He is also an elected member of the American Society of Clinical Investigators and the Association of American Physicians. He leads a basic research laboratory, funded continuously by the NIH for the past 18 years, focused on lung regeneration and stem cell biology, and he serves on the NIH's National Heart Lung and Blood Institute's Board of External Experts. Clinically, he focuses on critical care medicine, general pulmonary medicine and alpha-1 antitrypsin deficiency, the most common heritable cause of emphysema.

Dr. Kotton earned his MD at Washington University School of Medicine, completed his internship and residency at the University of Pennsylvania, his fellowship at Boston University and his postdoctoral research fellowship at Harvard Medical School. He is the recipient of the American Thoracic Society's "Recognition Award for Scientific Accomplishments" (2018), the AAMC inaugural national "Research Resources Sharing Award" (2017), the Alpha-1 Foundation's "Researcher of the Year" (2013) and "Shillelagh" (2010) Awards, Boston University's Graduate Medical Sciences Educator of the Year Award (2018), and the Robert Dawes Evans Senior Research Mentor Award from Boston University.

Dr. Kotton has been a GWG member for 10 years. He has reviewed for Discovery stage program awards, and Research Leadership and Tissue Collection for Disease Modeling awards.