Welcome and Meeting Goals

Veronica Miller, PhD
Dr. Veronica Miller is the Executive Director of the Forum for Collaborative HIV Research, an administrative unit of the University Of California, Berkeley School of Public Health. The Forum facilitates regulatory sciences in HIV and has expanded to other disease areas such as hepatitis C infection, liver fibrosis and cirrhosis, and human cytomegalovirus infection under Dr. Miller's leadership. In addition to leading the Forum, Dr. Miller teaches a course on the FDA and Drug Development and mentors interns and fellows pursuing health policy careers.

Dan Kuritzkes, MD
Dr. Dan Kuritzkes is a Professor of Medicine at Harvard Medical School and the Chief of the Division of Infectious Diseases at Brigham and Women's Hospital. He serves as the Director of AIDS Research for Brigham and Women's and leads the ACTG Network as Network Chair and Principal Investigator. Dr. Kuritzkes has published many articles on HIV antiretroviral therapy, drug resistance in HIV infection, and previously served as the chair of the Clinical Science Study Section Review Panel at the University of California, University–wide AIDS Research Program.

Facilitating Translational Research and the Co-evolution of Research and Regulatory Strategies - Stakeholder Perspectives

Karen Midthun, MD
Dr. Karen Midthun is the Director of the Center for Biologics Evaluation and Research (CBER) at the FDA. Under her leadership, CBER assesses the safety and effectiveness of vaccines, gene therapies, and other biological products. She previously served as the deputy director of CBER, the director of the CBER Office of Vaccines Research and Review, and was on the faculty at the Johns Hopkins Bloomberg School of Public Health.

Debra Birnkrant, MD
Dr. Debra Birnkrant is the Director of the Division of Antiviral Products (DAVP) at the FDA. She has represented the Agency at both national and international meetings on antiviral drug development for indications such as influenza, smallpox, and HIV prevention. She previously served as a medical officer and deputy division director for the DAVP and was recognized for her regulatory work on thalidomide with the Arthur S. Flemming Award for Science.

Daria Hazuda, PhD
Dr. Daria Hazuda is the Vice President and World Wide Discovery Head of Antiviral and Infectious Disease Research at Merck Research Laboratories. Previously, Dr. Hazuda was the Global Director of Scientific Affairs for Antivirals at Merck in the division of Global Human Health and served as co-site head of basic research for the Merck West Point research facility. She led a basic research effort that identified and developed the first in-class integrase inhibitor ISENTRESS™ and received the Prix Galien Award for her work.

Mark Harrington
Mr. Mark Harrington is the Executive Director of the Treatment Action Group (TAG), an independent AIDS research and policy think tank. As a co-founder of this organization, he has led efforts to advocate for better treatment, a vaccine, and a cure for AIDS. Before working with TAG, he planned demonstrations with ACT UP that brought awareness to HIV community health and ultimately affected change in how government agencies addressed these priorities.

Sarah Read, MD
Dr. Sarah Read serves as Director of the Therapeutics Research Program at the Division of AIDS (DAIDS) at the National Institute of Allergy and Infectious Diseases (NIAID). The program's research portfolio includes grants and contracts supporting preclinical development and clinical testing of therapies for HIV/AIDS, including therapeutic approaches to cure, as well as for HIV-associated co-infections and comorbidities. Prior to joining DAIDS, Dr. Read was an Associate Clinical Investigator in the Laboratory of Immunoregulation at NIAID where her research focused on immune activation and inflammation in treated HIV infection as well as on immune based therapies for HIV.

Paul Sato, MD, MPH
Dr. Paul Sato is the Coordinator of Research toward a Cure for HIV Infection across the NIH Institutes and Centers, based out of the NIH Office of AIDS Research (OAR). Previously, he served as the NIAID/DAIDS Medical Officer in the Maternal Adolescent and Pediatric Research Branch of the Therapeutics Research Program where he focused on vaccine research, adolescent prevention, and metabolic studies. He was a Senior Scientist at the Department of Defense Center for Deployment Health Research and a Medical Officer with the WHO Global Program on AIDS.

School of Public Health
UNIVERSITY OF CALIFORNIA, BERKELEY

Forum for Collaborative HIV Research

Arriving at a Common Language: Clarity of Definitions, Expectations and Goals

John Mellors, MD
Dr. John Mellors is a Professor of Medicine, Pathology, Infectious Diseases, and Microbiology at the University of Pittsburgh School of Medicine. He is currently the Chief of the Infectious Diseases Division and directs primary care and clinical research activities in HIV/AIDS at the University of Pittsburgh Medical Center Health System. Dr. Mellors is the principal investigator for the Adult AIDS Clinical Trials Unit and helps conduct trials of new antiretroviral therapies.

Mike Miller, PhD
Dr. Mike Miller is an Executive Director of Infectious Disease Early Antiviral Discovery at Merck Research Laboratories where he is responsible for the early antiviral drug discovery programs. He joined Merck as a Senior Research Biochemist with the goal of helping translate basic studies on HIV integrase into the development of novel antiretroviral chemotherapeutic agents and was a member of the discovery and development teams for ISENTRESS™, Merck's first-in-class HIV-1 integrase inhibitor. He previously studied HIV-1 integrase in Dr. Frederic Bushman's laboratory at The Salk Institute.

Damon Deming, PhD
Dr. Damon Deming is a Clinical Virology Reviewer at the Division of Antiviral Products within the FDA. He was previously involved in academic research at the Swanstrom Lab within the Department of Microbiology and Immunology at UNC Chapel Hill, focusing on HIV molecular biology and evolution.

Susan Fiscus, PhD
Dr. Susan Fiscus is a professor in the Department of Microbiology and Immunology at the UNC School of Medicine and is the Director of the UNC Center for AIDS Research Virology Core Laboratory. She is a principal investigator for the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) and serves as a Director of the Center for HIV/AIDS Vaccine Immunology Repositories.

Joe Fitzgibbon, PhD
Dr. Joe Fitzgibbon is a Microbiologist and Program Officer in the Division of AIDS at NIAID. He is a member of the DAIDS Clinical Laboratory Oversight Team and serves as the Contracting Officer's Representative overseeing the Virology Quality Assurance Contract. He has been working in the field of HIV/AIDS research for 25 years, first as a Postdoctoral Fellow and later as an Assistant Professor at Robert Wood Johnson Medical School in New Jersey, where he was a Pediatric AIDS Foundation Scholar conducting research on HIV drug resistance, and served as Director of the HIV Culture Laboratory.

Richard Jefferys
Mr. Richard Jefferys joined the Treatment Action Group (TAG) in 2001 and works on the Michael Palm Basic Science, Vaccines, and Cure Project. He has written on the pathogenesis and immunology of HIV infection and publishes critiques and policy statements relating to vaccine and treatment interruption research. Previously, he worked for the AIDS Treatment Data Network and coauthored *The Access Project Report*, the first report to assess the availability of HIV and AIDS therapies and nutritional supplements through AIDS Drug Assistance Programs and Medicaid in every state.

Rowena Johnston, PhD
Dr. Rowena Johnston is the Vice President and Director of Research at the American Foundation for AIDS Research (amfAR) where she oversees the Foundation's research program and serves as a liaison between the research committee and other committees. Under her leadership, the research program has prioritized the improvement of HIV prevention and treatment interventions while supporting the career development of young researchers in the field. Before joining amfAR, Dr. Johnston worked as a scientific advisor at the Michael J. Fox Foundation/Parkinson's Action Network.

Ethics and Fairness in Trial Recruitment, Participant Education and Informed Consent

David Evans
Mr. David Evans is the Director of Research Advocacy for Project Inform, a non-profit HIV and viral hepatitis community-based information and advocacy organization. He has provided input to academic and industry researchers on HIV and hepatitis C clinical trial design and helped develop one of the first HIV treatment educators certification programs in the United States.

Tim Henrich, MD
Dr. Tim Henrich is an Associate Physician at Brigham and Women's Hospital and an Assistant Professor at Harvard Medical School. He specializes in Infectious Disease with clinical interests in HIV/AIDS and sexually transmitted infections.

Nikos Dedes
Mr. Nikos Dedes is a founding member and President of Positive Voice, the association of people living with HIV in Greece. He serves on various committees related to HIV research including the European Clinical Trials Network for HIV. Mr. Dedes previously served as the President of the European AIDS Treatment Group (EATG) and the coordinator of the Patient and Consumer Commission of the European Medicines Agency.

George Hanna, MD
Dr. George Hanna is Vice President of HIV Development within Virology Global Development and Clinical Research at Bristol-Myers Squibb where he is responsible for the overall strategy and development of HIV drugs that are in clinical-stage development. Dr. Hanna served in the Division of Infectious Diseases at the University of Pittsburgh School of Medicine before joining Bristol-Myers Squibb, Dr. Hanna's Research Dr. Hanna's research interests have included drug development and resistance mechanisms of HIV nucleoside and non-nucleoside reverse transcriptase inhibitors, protease inhibitors, and attachment inhibitors.

Gail Henderson, PhD
Dr. Gail Henderson is the Chair of the Department of Social Medicine at UNC and is Co-Director of the International Core of the UNC Center for AIDS Research. She has conducted research on health and healthcare in China since the 1980s, serving as a consultant to the China CDC National Center for AIDS Prevention and Control as well as the Malawi National Health Research Council.

Richard Klein
Mr. Richard Klein is the Director of the Patient Liaison Program in the Office of Health and Constituent Affairs at the FDA. This program ensures patient community representation in policy decisions pertaining to drug access, product safety, and clinical trial design and assists patients seeking access to investigational products. Mr. Klein previously managed the HIV/AIDS program for the Patient Liaison Program and was involved in the Human Research Subject Protection policy development.

Jeremy Sugarman, MD, MPH
Dr. Jeremy Sugarman is the Deputy Director for Medicine and the Harvey M. Meyerhoff Professor of Bioethics and Medicine at the Johns Hopkins Berman Institute of Bioethics. He serves on the Board of Directors of Public Responsibility in Medicine and Research and as chair of the Ethics Working Group of the HIV Prevention Trials Network. Previously, Dr. Sugarman was a Professor of Medicine and philosophy at Duke University where he was the founding director of the Trent Center for Bioethics, Humanities, and History of Medicine.

Cure Research in Maternal/Pediatric Setting

Deborah Persaud, MD
Dr. Deborah Persaud is an Associate Professor of Pediatrics at the Johns Hopkins School of Medicine and is the Chair of the HIV Cure Committee of the International Maternal, Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network. Her research focuses on understanding mechanisms behind HIV persistence in children and developing strategies to prevent mother-to-child transmission of the virus. Dr. Persaud recently received the Elizabeth Glaser Scientist Award in recognition of her collaborative effort in developing the first functional cure of HIV in an infant.

Sandra Nusinoff Lehrman, MD
Dr. Sandra Lehrman is the Global Director for Scientific Affairs for Antivirals in the Office of the Chief Medical Officer and is responsible for providing scientific input into the Global Infectious Diseases Franchise strategy, and developing a global scientific leadership engagement strategy focusing on Merck's portfolio of drugs to manage HIV and HIV/HCV co-infection. Additionally, Dr. Lehrman serves as co-chair of the Forum's Executive Committee. Prior to joining Merck, Dr. Lehrman was Director of the Therapeutic Research Program in the Division of AIDS within the U.S. National Institute of Health and served as the President and CEO of Genzyme Transgenics Corporation.

Yvonne Bryson, MD
Dr. Yvonne Bryson is the Chief of Pediatric Infectious Diseases and Professor of Pediatrics at the David Geffen School of Medicine at UCLA and Mattel Children's Hospital. She is the Director of the Los Angeles Brazil AIDS Consortium and serves as the chair of the NIH Network IMPAACT Prevention of Mother-to-Child Transmission of HIV Committee. Dr. Bryson previously served as one of the original members of the Elizabeth Glaser Pediatric AIDS Foundation health advisory board, helping to start the foundation.

Ellen Chadwick, MD
Dr. Ellen Chadwick is a Professor in Pediatric Infectious Diseases at the Northwestern University Feinberg School of Medicine and serves as the Associate Director for the Section of Pediatric, Adolescent, and Maternal HIV Infection at the Ann & Robert H. Lurie Children's Hospital of Chicago. She has traveled to many African nations to lead trainings regarding prevention of mother-to-child transmission of HIV and is the chairperson of an IMPAACT committee investigating new antiretroviral agents, other therapies, and "functional cure."

Mark Cotton, MD, PhD

Dr. Mark Cotton is the Head of the Division of Pediatric Infectious Diseases and the Director of the Children's Infectious Diseases Clinical Research Unit at Tygerberg Children's Hospital, Faculty of Health Sciences, Stellenbosch University. He has conducted laboratory-based research on apoptosis in pediatric HIV under the supervision of Dr. Terri Finkel at the National Jewish Center for Respiratory Diseases and Immunology. He completed his PhD on the role of apoptosis in pediatric HIV infection and has since conducted a number of multicenter trials focusing on TB and HIV in children.

Linda Lewis, MD

Dr. Linda Lewis is the Medical Team Leader of the Division of Antiviral Products at the FDA where she coordinates the multi-disciplinary reviews for new antiviral drugs submitted to the FDA for approval and provides secondary clinical review for these products. She is the senior pediatrician in DAVP and provides advice to pharmaceutical sponsors on various aspects of pediatric drug development. Previously, Dr. Lewis was on the staff of the Pediatric HIV Working Group of the National Cancer Institute at NIH and worked as a pediatric infectious diseases consultant at the DuPont Hospital for Children in Wilmington, DE and Thomas Jefferson University Hospital in Philadelphia.

Boris Renjifo, MD, PhD

Dr. Boris Renjifo is the Medical Director of Virology at AbbVie. He previously worked at the Harvard AIDS Institute where he was a principal investigator and co-investigator in basic research projects as well as clinical trials in Tanzania. Additionally, he has worked in medical affairs at Boehringer Ingelheim and Gilead Sciences. Dr. Renjifo's research interests have included global distribution and recombination of HIV subtypes in Africa as well as viral genetic determinants in mother-to-child transmission of HIV subtypes.

Seema Shah, JD

Ms. Seema Shah is a faculty member in the Department of Bioethics in the NIH Clinical Center with a joint appointment in the Division of AIDS. She serves as a consultant for the Division of AIDS on its clinical sciences review committee and as an ethics consultant for the Clinical Center. Her research focuses on the ethics of international research, the ethics of research with children, and the intersection of law and bioethics. She previously served as a federal law clerk in the Eastern District of California and a predoctoral fellow in the NIH Department of Bioethics.

Managing Risk Benefit in Clinical Trials

Joe Eron, MD
Dr. Joe Eron is the Director of the Clinical Core at the UNC Center for AIDS Research, the Associate Director of the General Clinical Research Unit, and a Professor of Medicine in the Division of Infectious Diseases at the UNC School of Medicine. As Principal Investigator of the UNC AIDS Clinical Research Group, he has conducted both investigator-initiated and industry-sponsored clinical research studies in addition to collaborating on a CFAR supported Clinical and Research Database encompassing information from HIV-infected patients in North Carolina.

Jintanat Ananworanich, MD, PhD
Dr. Jintanat Ananworanich is a member of the Military HIV Research Program (MHRP) leadership team and is the Associate Director for Therapeutics Research where she oversees the Clinical Trials Unit under the ACTG. Dr. Ananworanich previously served as the Director of SEARCH and Deputy Director of Scientific Affairs at the HIV Netherlands Australia Thailand Research Collaboration (HIV-NAT) while working at the Thai Red Cross in Bangkok.

Lynda Dee, JD
Ms. Lynda Dee is the founder of AIDS Action Baltimore, a non-profit organization dedicated to supporting and educating people living with HIV. As a licensed attorney, she provides legal assistance to the LGBT community and those living with HIV. Ms. Dee is the co-chair of the Maryland Hepatitis Coalition and a member of the Maryland State ADAP Formulary Advisory Committee. She serves on the Fair Pricing Coalition, AIDS Treatment Activists Coalition, and the ACTG.

Ron Mitsuyasu, MD
Dr. Ron Mitsuyasu is the Director of the Clinical AIDS Research and Education (CARE) Center, Associate Director of the UCLA AIDS Institute, and a Professor of Medicine in Hematology-Oncology at UCLA. He is the Group Chair of the AIDS Malignancy Consortium and is the Director of the State of California UCLA Collaborative Center for HIV/AIDS Research (Network for AIDS Research in Los Angeles).

Rob Murphy, MD
Dr. Rob Murphy is the Director of the Center for Global Health and is a Professor of Medicine at Northwestern University. His primary research and clinical interest is in viral infections, and his research includes drug development of new antiretroviral drugs and vaccines for HIV and viral hepatitis. Dr. Murphy serves as the Principal Investigator for the NIAID Adult AIDS Clinical Trials Group (ACTG) at

Northwestern and Special Advisor to the President's Emergency Plan for AIDS Relief (PEPFAR) program in Nigeria.

Adam Sherwat, MD
Dr. Adam Sherwat is the Acting Team Leader in the Division of Antiviral Products at the FDA. He previously served as a Medical Officer in both the Division of Antiviral Products and the Vaccine Clinical Research Branch of DAIDS at NIAID. In the past, Dr. Sherwat was an Assistant Professor in the Department of Medicine in the Division of Infectious Diseases at Georgetown University Medical Center.

Neil Shortman
Mr. Neil Shortman is Vice President and Head of Regulatory Affairs at ViiV Healthcare and has been involved in Pharmaceutical R&D for over 30 years, with the past 26 spent in regulatory affairs. He has been involved in the development and support of HIV medicines since 1995 working at Glaxo Wellcome and then GlaxoSmithKline andmoved to his current position in 2009 when ViiV Healthcare was created. Mr. Shortman has been an industry member of the HAART Oversight Committee for over 10 years and Co-chair of the committee since 2009.

Case Study: Kick and Kill - REDUC Trial

Lars Østergaard, MD, PhD

Dr. Lars Østergaard is a Clinical Professor of infectious diseases in the Institute of Clinical Medicine at Aarhus University and serves as a senior consultant with the Department of Infectious Diseases at Aarhus University Hospital. He pioneered the first DNA copying method to detect chlamydia in patient samples and surveyed clinical applications for this technique and through his research he seeks to understand the relationship between vaccines and the body's response to microorganisms to ultimately develop a vaccine for HIV.

Janet Siliciano, PhD

Dr. Janet Siliciano is an Associate Professor of Medicine, Division of Infectious Diseases, Johns Hopkins School of Medicine, where she studies HIV infection, virus latency, antiretroviral therapy, and disease reservoirs. Her research on diseases reservoirs has led to a fundamental change in HIV treatment strategy, and her findings regarding the integration of latent HIV-1 genomes into cellular genes changed how we think about mechanisms of latency. She completed postdoctoral fellowships at Harvard Medical School and the Johns Hopkins University School of Medicine before joining the faculty at Johns Hopkins.

Giulio Maria Corbelli

Mr. Giulio Maria Corbelli is a member of European AIDS Treatment Group (EATG) where he serves on the Steering Committee of both the European Community Advisory Board (ECAB) and the Policy Working Group. He is a member of the Executive Committee for the PARTNER Study, is a member of the Community Advisory Group for INSIGHT network, and is a member of AVAC's project pxROAR Europe. In Italy he is a member of the Board of Directors of Plus, the first network of LGBT people living with HIV, and works as a freelance journalist for many Italian community magazines and websites.

Romas Geleziunas, PhD

Dr. Romas Geleziunas is a Director in the Clinical Virology Department at Gilead Sciences, Inc. where he has led multidisciplinary HIV antiviral drug discovery and early drug development programs. He established and led Gilead's HIV eradication program and is currently the head of the HIV Advanced Therapies group. Prior to joining Gilead, he worked on a number of drug discovery programs at DuPont Pharmaceuticals and Merck Research Laboratories.

Gail Henderson, PhD

Dr. Gail Henderson is the Chair of the Department of Social Medicine at UNC and is Co-Director of the International Core of the UNC Center for AIDS Research. She has conducted research on health and healthcare in China since the 1980s, serving as a consultant to the China CDC National Center for AIDS Prevention and Control as well as the Malawi National Health Research Council.

Filip Josephson, MD, PhD

Dr. Filip Josephson is a clinical assessor at the Swedish Medical Products Agency (MPA) where he focuses on the regulatory assessment of antiviral agents. He reports on the ongoing revision of the EMA/CHMP guidelines on the clinical evaluation of medicinal products for the treatment of chronic Hepatitis C. He previously served as the pharmacology consultant at the HIV policlinics of Stockholm, Sweden.

Kim Struble, PharmD

Dr. Kim Struble is a Medical Team Leader in the Division of Antiviral Products at the FDA. She oversees the evaluation of safety and efficacy data from IND and NDA submissions for drug products used in the prevention and treatment of HIV and other viral infections. As the HIV and Hepatitis Focus Group Leader, she discusses issues concerning HIV and hepatitis drug development with other Medical Officers and Team Leaders. She serves on the HHS HIV Treatment Guidelines Panel and is the FDA representative to the CDC for the occupational and non-occupational PEP public health service working group.

Case Study: VRCO1 and Analytical Treatment Interruption in Early/Acutely-infected Patients - RV397 Protocol

Jintanat Ananworanich, MD, PhD
Dr. Jintanat Ananworanich is a member of the Military HIV Research Program (MHRP) leadership team and is the Associate Director for Therapeutics Research where she oversees the Clinical Trials Unit under the ACTG. Dr. Ananworanich previously served as the Director of SEARCH and Deputy Director of Scientific Affairs at the HIV Netherlands Australia Thailand Research Collaboration (HIV-NAT) while working at the Thai Red Cross in Bangkok.

Pablo Tebas, MD
Dr. Pablo Tebas is a Professor of Medicine and the Director and Principal Investigator of the AIDS Clinical Trial Unit (ACTU) of the University of Pennsylvania. Specializing in infectious diseases, Dr. Tebas' research interests include the treatment of HIV infection and the study of metabolic complications associated with HIV infection.

Steve Deeks, MD
Dr. Steve Deeks is a Professor of Medicine at the University of California, San Francisco and is a faculty member in the Positive Health Program at San Francisco General Hospital. He co-directs the Population and Clinical Sciences Core of the UCSF-Gladstone Institute of Virology and Immunology Center for AIDS Research and the UCSF SCOPE cohort. His research investigates the immunopathogenesis of antiretroviral-treated HIV infection, and he is additionally interested in individuals who are able to control HIV replication without therapy.

Jeff Taylor
Mr. Jeff Taylor is the CARE Coordinator at the UNC Community Advisory Board (CAB). He previously served on the National Cancer Institute's AIDS Malignancy Consortium, the University of California – San Diego (UCSD) Antiviral Research Center, and on the Department of Health and Human Services (DHHS) Antiviral Guidelines Panel. He started his career in HIV research advocacy as a member of the AIDS Clinical Trials Group Advisory Board.

Nicole Frahm, PhD
Dr. Nicole Frahm is the Associate Director for Laboratory Science for the HIV Vaccine Trials Network and is an Assistant Professor of Global Health at the University of Washington. She serves on the Graduate Faculty for the University of Washington and is an Associate Member of the Vaccine and Infectious

Disease Division of the Fred Hutchinson Cancer Research Center. Previously, Dr. Frahm was an instructor at Harvard Medical School and served as an assistant in Immunology at Massachusetts General Hospital.

Filip Josephson, MD, PhD
Dr. Filip Josephson is a clinical assessor at the Swedish Medical Products Agency (MPA) where he focuses on the regulatory assessment of antiviral agents. He reports on the ongoing revision of the EMA/CHMP guidelines on the clinical evaluation of medicinal products for the treatment of chronic hepatitis C. He previously served as he pharmacology consultant at the HIV policlinics of Stockholm, Sweden.

Carol Weiss, MD, PhD
Dr. Carol Weiss has been regulating viral vaccines at the Center for Biologics Evaluation and Research (CBER) of the FDA for the past 20 years. She focuses on vaccines for HIV/AIDS and influenza. She manages a research program that investigates virus entry and antibody neutralization of HIV and influenza. Before joining the FDA, Dr. Weiss did postgraduate training at UCSF, studying HIV in the laboratory of Dr. Jay Levy. Her interest in HIV/AIDS grew out of her clinical experience treating patients during her residency in internal medicine at St. Vincent's Hospital & Medical Center in New York City.

Brian Woodfall, MD
Dr. Brian Woodfall is the Head of Development and Global Medical Affairs within the Infectious Diseases and Vaccines Department of Janssen Pharmaceutical Companies of Johnson & Johnson. Previously, he held the role of Vice President for Medical Affairs for Janssen covering the Europe, Middle East and Africa region and served as head of the Medical Department at Tibotec where he had responsibilities across global development in the areas of HIV, hepatitis C and tuberculosis. Before joining the pharmaceutical industry, Dr. Woodfall co-founded Spectrum Health Care Ltd. in Vancouver, BC, where he was instrumental in the conception, funding, implementation and day-to-day management of the integrated multi-disciplinary clinic dealing with HIV disease.

Hypothetical Case Study: Combination Protocol - vorinostat and CAR-modified CD8+ T cells

Jeff Murray, MD, MPH
Dr. Jeff Murray is the Deputy Director of the Division of Antiviral Products at the FDA where he has reviewed and approved applications for numerous HIV drugs, influenza drugs, and applications for hepatitis B and C products. He has co-authored FDA guidance documents in HIV drug development, development of HIV drugs for the President's Emergency Plan for AIDS Relief (PEPFAR), and development of drugs for the treatment of influenza.

Sharon Lewin, PhD
Dr. Sharon Lewin is the Director of the Infectious Diseases Unit at The Alfred Hospital and a Professor of Medicine at Monash University. She serves as the Co-head of the Center for Biomedical Research at the Burnet Institute and is an Australian National Health and Medical Research Council (NHMRC) practitioner fellow. Her laboratory focuses on HIV persistence in patients on antiviral therapy and strategies to cure HIV infection. Previously, Dr. Lewin served as the president of the Australasian Society for HIV Medicine.

Yuman Fong, MD
Dr. Yuman Fong is the Chair of City of Hope's Department of Surgery and the Associate Director for International Relations at the Comprehensive Cancer Center. He is the Chair of the Recombinant DNA Advisory Committee (RAC). Previously, Dr. Fong served as the Murray F. Brennan Chair in Surgery and a professor of surgery at Weill Cornell Medical College.

Ilan Irony, MD
Dr. Ilan Irony is the Chief of the General Medicine Branch within CBER at the FDA. He joined the FDA as a clinical reviewer before transferring to the Division of Metabolism and Endocrinology Products in CDER and becoming a clinical team leader. Dr. Irony wrote FDA draft and final guidances and actively participates in scientific and regulatory working groups within and outside FDA. He previously worked in a group medical practice in the Washington DC area.

David Margolis, MD
Dr. David Margolis is a Professor at the UNC School of Medicine where he serves as the Director of the Program in Translational Clinical Research at the Institute for Global Health and Infectious Diseases. As

the principal investigator for the Collaboratory of AIDS Researchers for Eradication, he investigates the host-virus interaction and molecular mechanisms behind HIV persistence.

Matt Sharp
Matt Sharp works as an independent HIV education and advocacy consultant. He previously served as the Director of Treatment and Education at Project Inform, volunteered with the AIDS Treatment Activist Coalition, served as the outreach coordinator for clinical trials at San Francisco General Hospital, and worked with ACT UP Golden Gate. He was education director at Test Positive Aware Network and has an extensive history of advocating for AIDS treatment and writing about AIDS.

Geoff Symonds, PhD
Dr. Geoff Symonds is the Chief Scientific Officer at Calimmune, leading research and development. He previously led HIV and cancer programs at Johnson & Johnson Research and managed a research group at the Children's Medical Research Institute in Sydney. Dr. Symonds has published extensively on HIV gene therapy and holds many patents in the field.

Closing Remarks and Meeting Discussion

David Margolis, MD
Dr. David Margolis is a professor at the UNC School of Medicine where he serves as the Director of the Program in Translational Clinical Research at the Institute for Global Health and Infectious Diseases. As the principal investigator for the Collaboratory of AIDS Researchers for Eradication, he investigates the host-virus interaction and molecular mechanisms behind HIV persistence.

Veronica Miller, PhD
Dr. Veronica Miller is the Executive Director of the Forum for Collaborative HIV Research, an administrative unit of the University Of California, Berkeley School of Public Health. The Forum facilitates regulatory sciences in HIV and has expanded to other disease areas such as hepatitis C infection, liver fibrosis and cirrhosis, and human cytomegalovirus infection under Dr. Miller's leadership. In addition to leading the Forum, Dr. Miller teaches a course on the FDA and Drug Development and mentors interns and fellows pursuing health policy careers.