

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Laura Baldassari, MD, MHS

Affiliation(s):

Division of Neurology 2, Office of Neuroscience, Office of New Drugs, Center for Drug Evaluation and Research, US Food and Drug Administration

Disclosures:

Nothing to disclose

Bio:

Dr. Baldassari is a Clinical Reviewer on the Multiple Sclerosis/Neuroimmunology Team in FDA/CDER's Division of Neurology 2. She completed her undergraduate degree in Biology/Biotechnology at Worcester Polytechnic Institute, Master of Health Science degree in Epidemiology at Johns Hopkins Bloomberg School of Public Health, and medical school at Georgetown University. She then pursued internship and Neurology residency at Washington University in St. Louis/Barnes Jewish Hospital, followed by a clinical fellowship in Multiple Sclerosis at the University of Utah funded by the National Multiple Sclerosis Society. She then completed a two-year Clinical Neuroimmunology fellowship at the Cleveland Clinic Mellen Center for Multiple Sclerosis Treatment and Research, where she was funded by a Sylvia Lawry Physician Fellowship grant through the National Multiple Sclerosis Society. During her fellowship, she also completed a Graduate Certificate in Clinical Research at Case Western Reserve University. She joined the FDA in 2019.

Joseph R. Berger, M.D., FACP, FAAN, FANA

Affiliation(s):

Professor of Neurology and Associate Chief of the MS Division, Perelman School of Medicine, University of Pennsylvania

Emeritus Professor, University of Kentucky

Disclosures:

Dr. Berger has received grant support from Biogen and Genentech/Roche. He has received honoraria as a consultant for Amgen, Biogen, Bristol Myers Squibb/Celgene, Dr. Reddy, EMD Serono, Encycle, Excision-Bio, Genentech/Roche, Genzyme, MAPI, Merck, Millennium/Takeda, Morphic, and Shire.

Bio:

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Joseph R. Berger, M.D., FACP, FAAN, FANA, is Professor of Neurology and Associate Chief of the Multiple Sclerosis Division of the Department of Neurology at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia. Dr. Berger is a summa cum laude graduate of the Pennsylvania State University – Jefferson Medical College 5 Year Accelerated Medical Program. He completed his residency in internal medicine at Georgetown University Hospital and his neurology residency at University of Miami School of Medicine and is board certified in both internal medicine and neurology. In 1981, he joined the faculty of the University of Miami School of Medicine serving in both the Departments of Neurology and Internal Medicine. At that institution, he held the Whigham-Berger Endowed Chair for the study of the neurological complications of HIV/AIDS, the first endowed chair for the study of the neurological complications of HIV/AIDS. From 1995 through 2013, Dr. Berger was the Chairman of the Department of Neurology at the University of Kentucky where he was the Ruth L. Works Professor of Neurology and director of the UK Multiple Sclerosis Clinic. His research interests include progressive multifocal leukoencephalopathy, the neurological complications of HIV/AIDS, multiple sclerosis, and other inflammatory disorders of the brain. He has published more than 260 refereed papers, more than 100 chapters, and has co-edited three textbooks. Dr. Berger co-founded and chaired the first international conference on the neurological complications of HIV, the Neuroscience of HIV meeting.

Ying Kuen (Ken) Cheung, PhD

Affiliation(s):

Columbia University Irving Medical Center

Disclosure:

Nothing to disclose

Bio:

Dr. Cheung is a biostatistician at Columbia University Irving Medical Center, where he collaborates extensively in clinical trials and implementation trials of treatments for stroke, movement disorders, infectious diseases, cardiovascular diseases, mental health, and cancer. His research focuses on innovative use of adaptive trial designs at all phases of drug development. Dr. Cheung completed his undergraduate (1995) and doctoral (2000) degrees in Statistics at the University of Wisconsin at Madison before joining the Columbia faculty. He is currently Professor of Biostatistics and Associate Dean for Faculty in the Mailman School of Public Health at Columbia University. He also serves as an associate director for trial innovation at the CTSA at the Irving Institute. He is a recipient of IBM Faculty Award on Big Data and Analytics, a Fellow of the American Statistical Association, and a Fellow of the New York Academy of Medicine

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Paola Cinque, M.D., Ph.D.

Affiliation(s):

Unit of Infectious Diseases, San Raffaele Scientific Institute, Milano (Italy)

Disclosures (past 24 months)

Research grants to the Institute or personal fees for speaker's bureau, scientific board or consultation in the field of HIV infection and PML from the following companies: Biogen, Cellevolve, Exevir, Gilead, Janssen, Pfizer, Polpharma, Shire, Takeda, Viiv Healthcare

Bio:

Dr. Cinque earned her Medical Degree and subsequent Specialization in Infectious Diseases at the University of Milano, and her PhD in Virology at Karolinska Institute, Sweden. She now works as a physician at the Infectious Diseases Unit and is responsible of the Neurovirology Research Unit of San Raffaele Scientific Institute, Milan.

Her research group is mainly involved in the study of PML and HIV Infection of the Central Nervous System. In the field of PML she has contributed with assessment of molecular methodologies for quantification and characterization of JCV DNA in body fluids, investigation of host responses to JCV infection and evaluation of potential PML treatments. She is co-chair of the EACS Opportunistic Infections Guidelines, and member of the PML panel of the NIH/CDC/IDSA Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents.

David B Clifford, MD (pronouns he/him)

Affiliation:

Melba and Forest Seay Professor of Clinical Neuropharmacology In Neurology
Department of Neurology
Washington University in St Louis

Disclosures:

NIH Support: NINDS, NIMH, NIA, NIAID

Consultant: Biogen, Takeda, Genentech/Roche, GSK, MerckSerono, Inhibikase, Seagen
DSMB/PML Adjudication: Arena, Atara, Biogen, Roche/Genentech, Takeda, Wave, MerckSerono, Sanofi, Serono

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Bio:

Dr. Clifford is the Melba and Forest Seay Professor of Clinical Neuropharmacology in Neurology at Washington University in St. Louis. His interest in developing new therapies for brain disorders led him to focus on HIV/AIDS and its complications early in the HIV epidemic. He has been an AIDS Clinical Trials Group investigator, and Principal Investigator of the Washington University ACTU for some years. He developed an NIH fund consortium, the Neurologic AIDS Research Consortium (NARC) to coordinate trials relevant to the brain and peripheral nerves in HIV. His group performed a randomized trial of cytosine arabinoside for PML prior to cART therapy availability, and described the impact of cART and zidovudine on the course of HIV associated PML. When natalizumab associated PML emerged, he was part of the independent adjudication committee reviewing this problem, and has since that time been frequently called on to monitor diagnosis and management of PML worldwide. He helped organize the Biogen supported study of mefloquine and sits on multiple PML adjudication committees for PML.

Irene Cortese, MD

Affiliation(s):

Experimental Immunotherapeutics Unit, National Institute of Neurological Disorders and Stroke
NIH

Disclosures:

Dr. Cortese is a shareholder in Nouscom AG and Keires AG (not related to this work).

Bio:

Dr. Cortese is the director of the Experimental Immunotherapeutics Unit of NINDS, NIH. She earned her medical degree and completed a neurology residency (1998) from the Università di Roma Tor Vergata in Rome, Italy. She completed a neuroimmunology research fellowship at the NIH, followed by her US neurology residency and clinical neurophysiology fellowship at Johns Hopkins. She then returned to the NIH to complete a clinical neuroimmunology fellowship. She was the Director of the NINDS Neuroimmunology Clinic from 2011-2021.

Lori Dodd, PhD

Affiliation(s):

National Institute of Allergy and Infectious Diseases (NIAID)/ Division of Clinical Research (DCR)/Biostatistics Research Branch (BRB)/Clinical Trials Research Section.

Disclosures:

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

None

Bio:

Dr. Dodd is a statistician and section chief for the Clinical Trials Research Section within the Biostatistics Research Branch, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, where she primarily collaborates on infectious disease clinical trials. Most recently, Dr Dodd served as principal statistician for the Pamoja Tulinde Maisha (PALM; “Together, Save Lives”) randomized controlled trial of Ebola virus disease therapies and the Adaptive COVID-19 Treatment Trial (ACTT) series of randomized controlled trials. Prior to joining NIAID, she worked as a mathematical statistician at the National Cancer Institute. Dr Dodd earned her PhD from the Department of Biostatistics at the University of Washington.

Gloria von Geldern, MD, FAAN

Affiliation(s):

Department of Neurology, Adjunct Dept. of Rehabilitation Medicine, UW Multiple Sclerosis Center

Disclosures:

Current research funding National MS Society and PCORI. No other disclosures.

Bio:

Dr. von Geldern is Associate Professor of Neurology at the University of Washington in Seattle. She is a neuroimmunologist at the UW MS Center, where she treats patients with multiple sclerosis, transverse myelitis, neuromyelitis optica, CNS sarcoidosis, and other neuro-immunological diseases. In addition to providing clinical care, she is conducting clinical research in neuroimmunology and teaching medical students, residents and fellows. Dr. von Geldern earned her medical degree in Germany and completed her neurology residency at the University of Washington. She has pursued research in neuro-immunology and neurologic infections including PML in Germany and during her fellowships at Johns Hopkins and the National Institutes of Health.

Andrew D. Goodman, M.D., FAAN, FANA

Affiliation(s):

Professor of Neurology
Director, Multiple Sclerosis Center

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Chief, Neuroimmunology Division
Department of Neurology
University of Rochester Medical Center

Disclosures:

Biogen; Genzyme sanofi-- Research support
Janssen; Novartis—Consultant

Bio:

Dr. Goodman is Professor of Neurology, Chief of the Neuroimmunology Division, and Director of the Multiple Sclerosis (MS) Center at the University of Rochester. Dr. Goodman's research has emphasized clinical and experimental therapeutics studies in MS. He has been the lead investigator or member of the steering committee for various national and international clinical trials of new therapies for MS including natalizumab, dalfampridine, and ibudilast. He also has continued to investigate a possible role of viruses in CNS demyelinating disease pathogenesis over a span of 3 decades in collaboration with Dr. Steven Jacobson (intramural NINDS, NIH).

Patrick Harrington, PhD

Affiliation(s):

Division of Antivirals, Office of Infectious Diseases, Office of New Drugs, Center for Drug Evaluation and Research, US Food and Drug Administration

Disclosures:

Nothing to disclose

Bio:

Dr. Harrington is a Senior Clinical Virology Reviewer at the FDA Center for Drug Evaluation and Research, Division of Antivirals. At the FDA, Dr. Harrington reviews nonclinical and clinical virology data and clinical trial protocols for antiviral drugs. He is also actively involved in the establishment of FDA policies and guidance on antiviral drug development. Prior to joining the FDA in 2008, Dr. Harrington was a Research Assistant Professor in the Department of Microbiology and Immunology at the University of North Carolina (UNC) at Chapel Hill. Dr. Harrington also received his Ph.D. and postdoctoral training at UNC-Chapel Hill. He has research and regulatory review experience with a variety of viruses, including HCV, HIV/SIV, noroviruses, flaviviruses, alphaviruses, coronaviruses, and poxviruses.

Luca Isabella

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Affiliation(s):

None

Disclosures:

None

Bio:

Luca Isabella is an Italian Management Advisor with over 30 years of experience both in business consultancy and management of medium and big size companies, where the foundations of his professional skills were laid. In 2015, he caught a rare and fatal disease, PML. He could not walk, talk, think for two years, but he won the battle and now he's back on track to share his experience to support anyone in emotional distress or struggling to cope. His specialties are Communication, Coaching and Counselling. He's the administrator of the facebook page "Progressive Multifocal Leukoencephalopathy - PML Survivors" and of the related private group "PML (Progressive Multifocal Leukoencephalopathy) Survivors & Supporters" whose mission is to raise awareness on PML through the sharing of personal experiences. He strongly believes that sharing experiences is key for fighting PML and its consequences and one of the best sources of information.

Igor J. Koralnik, M.D. FAAN, FANA

Affiliation(s):

Archibald Church Professor of Neurology
Chief, Division of Neuro-Infectious Diseases & Global Neurology
Davee Department of Neurology
Director, Global Neurology Program
Global Health Institute
Feinberg School of Medicine
Northwestern University
Northwestern Medicine

Disclosures: Dr. Koralnik has received royalties from UpToDate chapters on Progressive multifocal encephalopathy (PML). Aside from this, he has nothing else to disclose.

Bio:

Dr. Igor Koralnik is the Archibald Church Professor of Neurology, Northwestern University, as well as Chief of the Division of Neuro-Infectious diseases & Global Neurology at Northwestern Memorial Hospital in Chicago. He is the outgoing President of the International Society of Neuro Virology. Dr. Koralnik's laboratory is investigating how viruses affect the nervous system. These include the polyomavirus JC (JCV), the etiologic agent of progressive multifocal leukoencephalopathy (PML). Dr. Koralnik's COVID clinic, which opened in May, focuses on

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

treating patients who have neurological complications associated with the disease. When he was at Harvard Medical School, Dr. Korolnik initiated in 2010 a Global Neurology research program at the University Teaching Hospital in Lusaka, Zambia. Over the years, this program has grown tremendously and become a Multi-institutional consortium, the Zambia Institute for Neurological Care, Research, and Education (ZINCARE).

NgocDiep Le, MD, PhD

Affiliation(s):

Employee of NeImmuneTech

Member of American Society of Clinical Oncology, American Society of Hematology, and American Association for Cancer Research

Disclosures:

Dr. Le is an employee and stockholder of NeImmuneTech, Inc.

Bio:

Dr. Le is the Executive Vice President and Chief Medical Officer (CMO) at NeImmuneTech (NIT) where she has been responsible for providing the clinical vision and establishing the strategy and Clinical Development Plan for NT-17, the only clinical-staged long-acting human IL-7, in Oncology and Infectious Diseases. Prior to joining NIT in 2018, Dr. Le served as the CMO at Verastem where she led the company's first NDA submission and successful approval of COPIKTRA™ in multiple indications. Prior to Verastem, she was the Vice President in Immuno-Oncology Innovative Medicines at MedImmune/AstraZeneca, served as Global Clinical Program Head at Novartis Oncology, and Executive Medical Director at GSK where she successfully led the clinical development program for the MEK inhibitor trametinib (MEKINIST™) from the first-in-human study through FDA approval. Dr. Le began her industry career at Amgen as Medical Sciences Medical Director in Early Development Oncology. She received her B.S. in Biology with honors from the California Institute of Technology, earned her MD and PhD in Cancer Biology from Stanford University School of Medicine. Dr. Le completed a Medical Oncology Fellowship at the Duke University Comprehensive Cancer Center and was a faculty member at Duke University prior to joining biopharmaceutical industry.

Paul Lee, MD, PhD

Affiliation(s):

Division of Neurology 2, Office of Neuroscience, Office of New Drugs, Center for Drug Evaluation and Research, US Food and Drug Administration

Disclosures:

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Nothing to disclose

Bio:

Dr. Lee is Team Lead of the Neuroimmunology Team and Deputy Director in the Division of Neurology 2. Under his leadership, Dr. Lee's team has approved the first effective treatments for pediatric multiple sclerosis and neuromyelitis optica spectrum disorder. Dr. Lee joined the FDA in December 2016 as a Clinical Reviewer in the Division of Gastroenterology and Inborn Errors Products. He completed his undergraduate degree in Psychology (Neuroscience) at Princeton University. After a year as an Intramural Research Training Award fellow at the National Institute of Mental Health, Paul enrolled in the combined M.D./Ph.D. Program at the University of Maryland School of Medicine. Paul completed a Ph.D. in Neuroscience with a focus on hormonal effects on neurodevelopment in 2004. He graduated with his M.D. in 2006 and entered an abbreviated residency in pediatrics at Sinai Hospital of Baltimore. He subsequently completed a residency in Child Neurology at the Johns Hopkins Hospital in 2011 and was the co-recipient of the Slotkin award for best resident research project for an investigation of cerebrospinal fluid (CSF) B-cell phenotypes in multiple sclerosis. Dr. Leethen pursued a fellowship in Neuroimmunology at the National Institute of Neurological Disorders and Stroke (NINDS). He worked in the laboratory of the NINDS Clinical Director Dr. Avi Nath and studied endogenous retroviral activation in multiple sclerosis brain lesions, neuroinfectious associated with multiple sclerosis treatments, and mechanisms to explain how CSF from patients with MS could be neurotoxic. Dr. Lee completed his Neuroimmunology fellowship in 2014 and joined the National Human Genome Research Institute's Undiagnosed Diseases Program as a Staff Clinician. He studied rare manifestations of congenital and neuroimmunology diseases.

Jennifer Lyons , MD

Affiliation(s):

Employee of Biogen

Disclosures:

Dr. Lyons is a full-time employee of Biogen and holds stock/stock options. The statements and views she expresses are her own and may not reflect the position or viewpoint of Biogen.

Bio:

Jennifer Lyons is a Senior Medical Director in Global Medical Safety at Biogen in Cambridge, MA. She obtained her MD from Georgetown University School of Medicine in 2008, completed internal medicine internship and neurology residency at Harvard University in 2012, and completed a fellowship in Neurological Infections and Neuroimmunology at Johns Hopkins University in 2013. She directed the Division of Neurological Infections and Inflammatory

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Diseases at the Brigham and Women's Hospital from 2013 – 2018 as an Assistant Professor of Neurology at Harvard University. She then joined Biogen in 2018, where she currently leads a team of safety physicians for MS products in the Global Safety and Regulatory Sciences division.

Eugene O. Major, PhD

Affiliation(s):

Scientist Emeritus, NINDS, NIH

Disclosures:

Independent Adjudication Committees and Science Advisory Boards:

- Takeda Pharma/Millennium Pharmaceuticals
- Roche/Genentech
- GSK
- Novartis
- Shire
- DRL, USA
- Seagen, Inc
- Generation Bio Co.

Consulting Agreements with Intellectual Property Law firms in: Munich, Germany, EU; London, England, UK; Amsterdam, Netherlands; San Francisco, CA. USA

Bio:

Dr. Major is Senior Advisor to NINDS/NIH, Director of CLIA Laboratory of Molecular Medicine and Neuroscience, and is Scientist Emeritus at NINDS. Since joining NINDS in 1981, Dr. Major's research focus has been on the biology of virus infections in nervous system cells derived from the human brain and the regulation which controls viral and cellular gene expression, specifically on JC Virus/PML-1 and HIV-1/AIDS. In addition to publishing over 260 papers and contributing to numerous books, Dr. Major has over 20 patents on novel composition and technology for JC Virus and cells of the human brain and directs CLIA certified laboratory diagnostic assays for PML including the development of the Ultrasensitive Multiplex qPCR assay for JCV and BKV. Dr. Major is a Founding Member of the International Society for Neurovirology and has served as Co-Chair of the White House Office of Science and Technology Policy Inter-Agency Committee on Prion Science.

Christina M. Marra, MD

Affiliation(s):

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Professor Emeritus, Neurology
Vice Chair (Academic Affairs), Neurology
University of Washington School of Medicine

Disclosures:

Dr. Marra receives royalties from Wolters Kluwer, and is on the panel that writes the PML guidelines for hivinfo.nih.gov.

Bio:

Dr. Marra completed residency training in Neurology and fellowship training in Infectious Diseases at the University of Washington, in Seattle, Washington, USA. She is currently Professor Emeritus and Vice Chair for Academic Affairs in Neurology at the University of Washington. Dr. Marra's research has focused on infections of the nervous system, in particular neurosyphilis, and central nervous system infections in persons living with HIV. She provides general neurological and neuro-infectious disease care in inpatient and outpatient settings.

Roland Martin, MD

Affiliation(s):

University Hospital Zurich, Zurich, Switzerland
University of Zurich, Zurich, Switzerland

Disclosures:

Advisory board (or similar committee) membership:

- Cellerys AG, Schlieren,
- Switzerland (co-founder)
- Abata Therapeutics,
- Cambridge, MA (co-founder)
- Novartis, Basel, Switzerland
- Third Rock Ventures

Speaker's bureau membership

- Roche, Basel, Switzerland
- Merck Darmstadt
- Bristol Myers Squibb
- Sanofi Aventis
- Biogen
- Teva
- Neuway Pharma

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

- Cell Protect

Unrestricted Grants from Biogen, Novartis, Third Rock, and Roche

Patents: I am listed as inventor on patents for methods of antigen-specific tolerization; patents are held by the University of Zurich; I also listed as inventor on a patent for using anti-CD25 antibodies in multiple sclerosis; the patent is held by NIH.

Clinical Trials: I have participated in multiple clinical trials in the last 20 years. A recent trial is related to outfounding the start-up company Cellerys from the University of Zurich and for the purpose of developing antigen-specific tolerization for MS.

Bio:

Dr. Martin is full professor and head of the Multiple Sclerosis (MS) Center at the University Hospital Zurich, Switzerland. He has studied medicine and trained in neurology at the University of Würzburg, Germany, spent post-doctoral fellowships in virology/immunology at the Department of Virology and Immunology in Würzburg and in neuroimmunology at the Neuroimmunology Branch, NINDS, NIH, Bethesda, and previously worked at University Hospitals in Würzburg, Tübingen, Hamburg, Germany, Baltimore, USA, Barcelona, Spain, and as tenured senior investigator at NINDS, NIH. His research focuses on disease mechanisms of MS and neuroinfectious diseases including progressive multifocal leukoencephalopathy (PML), cellular immunology and antigen recognition by T cells, and treatment development until early clinical proof-of-concept including the development and patenting of active- and passive candidate vaccines for PML.

Guillaume Martin-Blondel, MD, PhD

Affiliation(s):

Department of Infectious and Tropical Diseases, Toulouse University Hospital, Toulouse, France

Toulouse Institute for Infectious and Inflammatory Diseases (Infinity), Team "Inflammatory diseases of the central nervous system: mechanisms and therapies"

Disclosures:

None

Bio:

Dr. Martin-Blondel graduated in internal medicine and infectious diseases in Toulouse, France, in 2009. He then obtained a PhD in immunology from the University of Toulouse in 2014 and performed a postdoctoral fellowship at the University of Zurich, Switzerland. He became

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

professor of infectious diseases at the Toulouse University Hospital in 2018. He is member of the Toulouse Institute for Infectious and Inflammatory Diseases (Infinity). His focus is on immunology and immunotherapy of infectious diseases of the CNS.

Farrah J. Mateen, MD, PhD

Affiliation(s):

Dept. of Neurology, Massachusetts General Hospital

Disclosures:

I have received grant funding from the NIH, National MS Society, Sumaira Foundation, Fondation Pierre Fabre, Biogen, and Vilea Bio. I have received research funding for clinical trials from Genentech and EMD Serono via IQVIA. I have received consultancy payments from Horizon Therapeutics, Genentech, and Biogen. None of this support is directly related to PML.

Bio:

Dr. Mateen is an Associate Professor at Harvard Medical School. She pursued adult neurology residency at the Mayo Clinic in Minnesota and holds fellowships in Medical Ethics (Harvard University) and Neuroimmunology & Neuroinfectious Diseases (Johns Hopkins Hospital) as well as a PhD in International Health Epidemiology (Johns Hopkins Bloomberg School of Public Health). Clinically, at the Massachusetts General Hospital's Department of Neurology, she sees patients with multiple sclerosis and neuromyelitis optica, where she enjoys caring for patients with diagnostically and therapeutically complex conditions. Dr. Mateen is the past chair of the American Neurological Association International Outreach Committee and of the American Academy of Neurology's Global Health Section and Ethics Sections. Dr. Mateen has published >140 academic manuscripts to advance neurological disease research and patient care. She is the lead author on several manuscripts on PML and rare central nervous system demyelinating diseases and a principal investigator on several investigator-initiated clinical trials.

Avindra Nath, MD

Affiliation(s):

Clinical Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, MD

Adjunct Professor, Department of Neurology, Johns Hopkins University, Baltimore, MD

Disclosures:

I hold a patent on the use of antisense oligonucleotides for treatment of PML

Bio:

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Dr. Avi Nath is the Clinical Director of the National Institute of Neurological Diseases and Stroke (NINDS) and Chief of the Section of Neurological Infections. His research is focused on the pathophysiology and treatment of infections of the nervous system particularly neurological complications of HIV infection including opportunistic infections.

Gina Norato, ScM

Affiliation(s):

National Institutes of Health, National Institute of Neurological Disorders and Stroke

Disclosures:

No disclosures

Bio:

Ms. Norato is a statistician in NIH/NINDS Clinical Trials Unit where she assists multiple research groups with data management and data analysis. Prior to joining NIH in 2016, Ms. Norato performed clinical research at both Georgetown University and University of Arizona, doing data collection for several large stroke trials. Ms. Norato earned her undergraduate degree in neuroscience at Dickinson College (2012) and her master's degree in biostatistics at Johns Hopkins School of Public Health (2016).

Joan Ohayon, MSN, CRNP, MSCN

Affiliation(s):

National Institutes of Health, National Institute of Neurological Disorders and Stroke

Disclosures:

No disclosures

Bio:

Ms. Ohayon is a Senior Nurse Consultant (nurse practitioner) as well as a certified multiple sclerosis nurse working in Neuroimmunology at the NIH since 1993 and conducts research into the cause and treatment of immunologically-mediated diseases of the central nervous system. Ms. Ohayon is an associate investigator on research studies focused on multiple sclerosis, HTLV myelopathy, PML and other neuroimmunological diseases. She serves on the Board of Trustees, National Medical Advisory Committee and on the Healthcare Provider Council for the National Multiple Sclerosis Society. Through research and education, she hopes to improve overall quality of life for people living with MS and other neuroimmunological diseases.

Derrell D. Porter, MD

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Affiliation(s):

Executive Officer: Cellevolve Bio, Inc.

Disclosures:

Shareholder & Executive Officer: Cellevolve Bio, Inc

Bio:

Dr. Porter is the Founder and CEO of Cellevolve Bio, an early-stage cell therapy commercialization company in San Francisco, CA. Cellevolve is focused on neurodegenerative and hematological diseases. Prior to launching Cellevolve, Dr. Porter was Chief Commercial Officer at Atara Bio, an off-the-shelf cell therapy company in late-stage development with its first potential therapeutic, tab-cel, targeting rare EBV driven lymphomas. He has prior experiences at Gilead Sciences, AbbVie, Amgen, and McKinsey & Company. He is currently on the boards of Passage Bio, Inc. (Nasdaq: PASG) and Portal Innovations. Additionally, he is on the University of Pennsylvania's Medical Alumni Advisory Committee. Dr. Porter earned an M.D. from University of Pennsylvania's Perelman School of Medicine, where he was a Gamble Scholar, and an M.B.A. in Health Care Management from The Wharton School. He earned his Bachelor of Science in Neuroscience from UCLA.

Walter Royal III, MD

Affiliation(s):

Morehouse School of Medicine
Professor and Chair, Department of Neurobiology
Director, Neuroscience Institute

Disclosures:

Biogen, Inc: Advisory board
Medflix: Paid director

Bio:

Dr. Walter Royal, III, received his undergraduate training in biochemistry at Harvard College, then completed his medical degree at Dartmouth/Geisel Medical School in Hanover, New Hampshire. Following medical school, Dr. Royal did a residency in internal medicine at the Brigham and Women's Faulkner Hospital in Boston. He then did a post-doctoral fellowship in neurovirology/neuroimmunology and, subsequently, a residency in neurology at The Johns Hopkins University. This was followed by faculty positions in the neurology departments at Johns Hopkins, research and regulatory experiences at, respectively, the NIH and FDA, and then by faculty appointments the University of Maryland and Morehouse School of Medicine. It was during his fellowship training that Dr. Royal became interested in understanding and treating

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

the neurological manifestations of HIV infection, including progressive multifocal leukoencephalopathy (PML). He contributed several important early papers to the field, including a manuscript describing a phase 2 trial of topotecan in AIDS-related, biopsy proved PML, which was published in the Journal of Neurovirology. Dr. Royal's research interest include the mechanisms of neurodegeneration in neuroinflammatory disorders, mechanisms of addiction, and sex/gender differences on the risk for neurocognitive impairment. Dr. Royal is a founding member of the International Society of NeuroVirology, and he serves on several boards and professional advisory committees. Dr. Royal now serves as Director of the Neuroscience Institute and the Chair of Neurobiology at Morehouse School of Medicine.

Virginia Sheikh, MD, MHS

Affiliation(s):

Division of Antivirals, Office of Infectious Diseases, Office of New Drugs, Center for Drug Evaluation and Research, US Food and Drug Administration

Disclosures:

Nothing to disclose

Bio:

Dr. Sheikh is a medical officer in FDA/CDER's Division of Antivirals where she has reviewed various antiviral products including several HIV products for the treatment of a rare subgroup of patients with multidrug-resistant HIV infection. Prior to joining the FDA in 2016, Dr. Sheikh performed clinical research in the HIV Pathogenesis Section at NIAID where she focused on the immunopathogenesis and management of a rare disease called idiopathic CD4 lymphocytopenia (ICL) and advanced HIV/AIDS. Dr. Sheikh earned her master's degree in microbiology and immunology at Johns Hopkins School of Public Health (2000) and her medical degree at Eastern Virginia Medical School (2005). She trained in internal medicine at Columbia Presbyterian Hospital (2008) and in infectious diseases at NIAID (2011).

Bryan Smith, MD

Affiliation(s):

National Institute of Neurological Disorders and Stroke, NIH

Disclosures:

None

Bio:

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Dr. Smith is the head of the Clinical Neuro-HIV research program at NIH/NINDS. Before coming to the NIH in 2014, he was an Assistant Professor of Neurology at Johns Hopkins University School of Medicine where he had completed his neurology residency and fellowship training the division of Neuroimmunology and Neurological Infections.

Serena Spudich, MD

Affiliation(s):

Yale University, Department of Neurology, Division of Neurological Infections and Global Neurology

Disclosures:

None

Bio:

Dr. Spudich is Gilbert H. Glaser Professor of Neurology and Chief, Division of Neurological Infections and Global Neurology at Yale University. Her clinical and translational research explores effects of HIV and other viral infections in the nervous system, focusing on effects of acute infection, antiviral and immune treatments, and cure strategies on viral pathogenesis and persistence in the central nervous system (CNS). She collaborates with colleagues of multiple disciplines in studies in the United States and in international settings, exploring questions of inflammation, injury, and viral reservoirs within the central nervous system. She has been active in the AIDS Clinical Trials Group (ACTG) Neurology and HIV Reservoirs and Eradication committees, co-leads the International NeuroHIV Cure Consortium, serves on the US DHHS Antiretroviral Treatment Guidelines Committee, CROI Program Committee, and leads multidisciplinary projects addressing the pathobiology of HIV and SARS-CoV-2 in the CNS. She also is a neurology physician who cares for patients with viral infections and neurological disorders in clinics at Yale.

Sabrina Tan, MD

Affiliation(s):

Division of Infectious Disease
Center for Virology and Vaccines Research
Beth Israel Deaconess Medical Center
Harvard Medical School

Disclosures:

Scientific Advisory Board – Cellevolve

Bio:

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Dr. Tan is a physician scientist at the Division of Infectious Diseases and Center of Virology and Vaccine Research at the Beth Israel Deaconess Medical Center, Harvard Medical School. As an Infectious Disease physician, Dr. Tan's clinical interest focuses on Transplant Infectious Diseases. Dr. Tan's research focus on opportunistic viruses in immunocompromised patients and neuro immune responses to these viral infections. Dr. Tan obtained her medical degree from the New York University; and completed her Infectious Disease Fellowship at Beth Israel Deaconess Medical Center.

Kiran Thakur, MD

Affiliation(s):

Winifred Mercer Pitkin Assistant Professor of Neurology
Division of Critical Care and Hospitalist Neurology
Columbia University Irving Medical Center-New York Presbyterian Hospital

Disclosures:

Funding support from the National Institutes of Health, Center for Disease Control and Prevention

Bio:

Dr. Thakur is the Winifred Mercer Pitkin Assistant Professor of Neurology and Director of the Program in Neuroinfectious Diseases at Columbia University Irving Medical Center-New York Presbyterian Hospital. She is actively involved in translational and clinical research on neuroinfectious diseases and has a specialized interest in emerging and re-emerging neurotropic infections. Dr. Thakur is heavily involved in efforts to provide equitable care to those suffering from neuroinfectious diseases, including PML, across resource limited settings.

Suzanne Tobin

Affiliation(s):

None

Disclosures:

None

Bio:

For a description of Ms. Tobin's initial PML experience, please refer to the April 20, 2015 Washington Post article titled "Medical Mysteries: Like a slow-motion stroke".

https://www.washingtonpost.com/national/health-science/medical-mysteries-like-a-slow-motion-stroke/2015/04/20/11588492-cbe6-11e4-8c54-ffb5ba6f2f69_story.html

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Most of Ms. Tobin's professional career was spent as a copy editor and layout editor at The Washington Post, where she worked her way up the professional ladder from 1976-2008, when she accepted a buyout for early retirement due to the changing media landscape. In 2009, she became an editor at the nonprofit AARP (American Association of Retired Persons) in Publications for the AARP Bulletin, the newspaper its members receive 10 times a year. Her short-term memory issues and other deficits (such as her inability to type with her left hand) caused by PML made her decide to take disability retirement several years after her illness and to make recovery her full-time job. She started and occasionally posts entries to a brain injury blog on her local county's website (<https://www.mymcmedia.org/category/access-voices/local-blogs/my-new-normal/>) and attends the monthly meetings of the Brain Injury Support Group of Montgomery County through Adventist Rehabilitation Hospital of Maryland.

Mike P. Wattjes, MD

Affiliation(s):

Dept. of Neuroradiology, Hannover Medical School, Hannover, Germany

Disclosures:

Personal fees from Novartis, Sanofi-Genzyme, Genilac, Bayer Healthcare, Roche, Biogen, Biologix, Celgene/Bristol Myers Squibb, Merck Serono, Icometrix, Imcyse, IXICO, Medison, outside the submitted work.

Bio:

After finishing his study of Medicine at Hannover Medical School in Germany, Dr. Wattjes started his internship in Neurology at the Department of Neurology, University Hospital Bonn, Germany in 2001. In 2002, he started his residency in Radiology at the Department of Radiology, University Hospital Bonn. During his residency he started his research activities in the field of high field MRI applications in Neuroradiology, particularly focusing in neuroinflammatory diseases such as multiple sclerosis. In 2007, he started a research fellowship at the MS and Alzheimer Center of the VU University Medical Center in Amsterdam supported by the Exchange Program of the European Society of Neuroradiology. Later he became a clinical fellow Neuroradiology and was appointed as a senior staff radiologist in 2009. In July 2017 he started his new senior staff position at Department of Neuroradiology at Hannover Medical School, Germany. He has been appointed as a Professor of Neuroradiology in February 2019. His primary research and clinical interest included neuroinflammatory and neurodegenerative diseases as well as neurooncology. He serves a reviewer for several high impact journals and for institutions including the Medical Research Council, UK, and the Federal Ministry of Research in Germany.

Clemens Warnke, Dr. med.

Affiliation(s):

**Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs FDA Workshop
Speaker, Panel Discussant, and Moderators: Affiliations, Disclosures, and Bios**

Department of Neurology, Faculty of Medicine, University Hospital of Cologne, Cologne, Germany

Disclosures:

C.W. has received institutional support from Novartis, Alexion, Sanofi Genzyme, Biogen, Roche and Merck. Personal compensation from BioNTech for participating to an educational discussion.

Bio:

Since 2017, Dr. Warnke is consultant of Neurology at the Department of Neurology, University Hospital of Cologne. At his current affiliation, Dr. Warnke is head of the clinical trial office neurology, and co-head of the MS center including an outpatient MS clinic. The overall focus of his research is clinical neuroimmunology. This includes clinical MS research, neurovirology with a focus on progressive multifocal leukoencephalopathy (PML), and the new topic of neurological implications of the SARS-CoV-2 pandemics. Dr. Warnke was previously trained at the Department of Neurology, University of Duesseldorf. During his specialized training in Neurology, he spent a two-years research fellowship (2011-2012) at the Karolinska Institute in Stockholm, Sweden. Dr. Warnke acquired his medical license in 2007, after graduating from medical school at the University of Wuerzburg, Germany.