

CAMB - Gene Therapy and Vaccine Program/ Immunology Graduate Program CAMB 6090/IMUN 6090: Vaccines and Immune Therapeutics – 2025

Prerequisites:

Biology, Biochemistry, or Immunology courses at the advanced college level, permission of the instructors

Directors/Professors: David Weiner, Paul Offit, Stanley Plotkin, and Emilio Emini

Class Coordinator: Ms. Jeneice Hubert (jhubert@wistar.org)

Vaccination is perhaps the most successful medical technological intervention. The goal of this course is to expand on students' general understanding of the immune system, and to focus this understanding on the application of modern vaccines and immune therapies in the 21st century. The course will provide the student a sense of how these principles are applied to vaccine and immune therapeutic development. The course covers basic vaccine science and describes how this science is translated through clinical, regulatory, ethical, and political issues to result in a final vaccine product. The courses' goal is to leave the student with an understanding of the implications of modern vaccines/immunotherapies and their impact on world health.

Initial lectures review immune mechanisms believed to be responsible for vaccine induced protection from disease. Subsequent lectures build on this background to explore the science of vaccines for diverse pathogens, including agents of bioterrorism as well as vaccines and immunotherapies for cancer. An appreciation for the application of laboratory science to clinical development and clinical trials of vaccines are provided. An important focus on the regulatory, safety, and ethical implications of vaccines in different world situations based on true world examples are presented. The financial implications of specific vaccines with these implications for global health is a focus of the course.

The course is presented in lecture style through distinguished guest lecturers who are experts/leaders in their particular area of vaccine development. There are required readings to provide the student context and background for the diverse lectures. Students are graded on *course participation*, and a final project/exam which the students will present. Their project for grading is to design a vaccine strategy for a current disease or pathogen of importance that does not yet have an effective vaccine or immune therapy and present this to the class. This will be assigned to the student later in the course. Strategies used to build their vaccine approach should build on the material presented in the class lectures.

The course is intended for graduate students or medical students in various MS, Ph.D., or MD/Ph.D. programs on the campus, as well as exceptional undergraduate and local scientists and professionals in the Wistar/UPENN extended community.

As a prerequisite, students should have taken biology, biochemistry, or immunology courses at the advanced college level. This course is offered in the fall semester.



Vaccines and Immune Therapy CAMB 6090/IMUN 6090

Course Directors/Instructors:

Dr. David Weiner <u>dweiner@Wistar.org</u>
Dr. Paul Offit <u>offit@email.chop.edu</u>

Dr. Stanley Plotkin <u>stanley.plotkin@vaxconsult.com</u>

Dr. Emilio Emini <u>emilio.emini@gatesmri.org</u>

Faculty Course Leaders:

Dr. Daniel Claiborne

Dr. Amelia Escolano

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Dr. Ebony Gary <u>egary@Wistar.org</u>

Dr. Elizabeth Parzych <u>eparzych@Wistar.org</u>

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Dr. Jesper Pallesen jpallesen@Wistar.org

Dr. Xiaoyu Zhou <u>xazhou@Wistar.org</u>

Course Coordinator:

Mrs. Jeneice Hubert-Brent jhubert@Wistar.org



CAMB/IMM 6090: Vaccines & Immune Therapy Fall 2025

Time: 3:30 PM - 5:30 PMLocation: The Wistar Institute

Grossman Auditorium / Zoom

Instructors: David Weiner, Paul Offit, Stanley Plotkin, Emilio Emini

Class Coordinator: Jeneice Hubert V-Virtual Lecture / IP – In Person Lecture

<u>Date</u>	<u>Title</u>	<u>Lecturer</u>
Sept 17	Welcome	David Weiner – Wistar IP
	Vaccine History	
Sept 18	Nucleoside Modified mRNA-LNP Therapeutics	Drew Weissman – UPENN IP
Sept 24	Cellular Immune Responses	Michael Betts – PENN IP
Sept 25	B Cells, Antibodies, & Humoral Immune Response	David Allman – PENN IP
Oct 1	Vaccine development against human Herpes viruses: Success and Challenges	Sita Awasthi — UPENN IP
Oct 2	Structural Approach for Vaccines	Jesper Pallesen – Wistar IP
Oct 8	ТВА	Kristen Feemster – Merck IP
Oct 9	NO CLASS - UPENN FALL BREAK	
Oct 15	Correlates of Protection by Vaccines	Stanley Plotkin – Emeritus IP
Oct 16	Rotavirus Vaccines	Paul Offit – CHOP IP
Oct 22	Case Studies in End-to-End Vaccine Research and Development	Annaliesa Anderson – Pfizer IP



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<u>Date</u>	<u>Title</u>	<u>Lecturer</u>
Oct 23	Required Reading - Books Distributed Final Exam Review & Topics	Jeneice Hubert-Brent - Class Coordinator IP
Oct 29	Vaccine Safety	Paul Offit – CHOP IP
Oct 30	TBA	Kara Bickham – IAVI IP
	TBA	Swati Gupta – IAVI IP
Nov 5	Cure-HIV	Luis Montaner – Wistar IP
	Technology and its role in influencing New Vaccines Research & Development	Sanjay Phogat – Merck IP
Nov 6	The Challenges of Vaccine Development: Technical, Financial, and Political	Emilio Emini – Biopharma vaccine consultant IP
Nov 12	Developing a SARS CoV-2 Vaccine at Warp Speed	Paul Offit – CHOP IP
Nov 13	Adoptive Cell Therapy for Cancer	Marco Ruella – UPENN IP
Nov 19	Vaccines for Infectious Diseases that Disproportionately Impact the Poor	Penny Heaton – Janssen IP
	Preventing Dengue at Last: The Complex Quest for a Dengue Vaccine	German Anez – Merck IP
Nov 20	Development of a COVID-19 mRNA Vaccine at Lightspeed	Kathrin Jansen - Consultant IP
	Meningococcal Vaccines	Sarah Schillie – CDC V
Nov 26	NO CLASS – THANKSGIVING HOLIDAY	
Nov 27	NO CLASS – THANKSGIVING HOLIDAY	



<u>Date</u> <u>Title</u> <u>Lecturer</u>

Dec 3 Matrix M Ruxandra Draghia-Akli – Novavax IP

Developing vaccines against emerging infections
outside of the usual regulatory framework

Gary Kobinger – IP

Dec 4 The Role of antibodies in RSV prevention: Tonya Villafana – AstraZeneca **IP**

The story of Nirsevimab

Passive Immunization with Suvratoxumab **TBD** – AstraZeneca **IP** To Prevent S. Aureus Ventilator Associated Pneumonias

Dec 10 Final Exam Event Course Examiners

Virtual Link:

CAMB-IMM 6090 Vaccines & Immune Therapy Course

Join Zoom Meeting

https://us02web.zoom.us/j/83326504808?pwd=OwkTjHKFbZpCIjJmpLaTt5WKnqvJlz.1



Course Requirements

- Reading Vaccinated: One Man's Quest to Defeat the World's Deadliest Diseases **book will be provided.
 - By Paul A. Offit, M.D.
- Please attend all classes
 - Please be on time
 - Attendance will be recorded through QR code registration
- Participate in class lectures opportunity to discuss with leaders in the field
- Final Exam (Design a vaccine)
 - Power Point or Poster Presentation



Final Exam: Project

- You will be assigned a Pathogen/ Disease for which there is no current vaccine/immune therapy.
- What is the pathogen and why is it important for a vaccine?
- Present the relevant immune response.
- Design a vaccine approach based on the class presentations and defend your platform in the deck.
- Experiments needed (if any)/animal model studies?
- Define your focus for a correlate of protection.
- Develop storage/release/potency criteria.
- Define your clinical trial study population. How will you advance through the trials to efficacy/licensure?
- What is the economic need of your vaccine Who does it benefit?
- How will you pay for its development? Who will fund your program and give the \$\$?
- MS/UG Students: 1 title + 1 reference + 6 slides printed for poster display & present at poster (9 Total slides) 9-minute talk at poster.
- ➤ Ph.D. Students: 1 title + 1 reference + 9 slides in an 11-minute lightening talk presentation (12 Total slides)
- Lastly, include 1 additional slide with a photo of who your favorite Vaccinologist is and state why? *Must have a licensed vaccine/immunotherapy*
- Everyone must submit their final exam PPT slides to Jeneice via email @jhubert@wistar.org by Monday, December 8th.



David B. Weiner, Ph.D.

Executive Vice President at The Wistar Institute, Director of The Wistar Vaccine Center, W.W. Smith Charitable Trust Professor in Cancer Research

Preeminent immunologist and vaccine expert, **David B. Weiner, Ph.D.,** is executive vice president of The Wistar Institute, Director of the Wistar Vaccine



Center, and the W. W. Smith Charitable Trust Professor in Cancer Research. Dr. Weiner directs a translational molecular immunology research team focused on synthetic nucleic acid-based approaches for disease prevention and treatment. His group is one of the founding research teams in the field of Nucleic Acid Vaccine and Immune therapies. They developed new technology and then created a pathway to the clinic enabling the first DNA vaccine trails for infectious diseases and for Cancer therapy. Using cutting edge synthetic DNA design + modifications of EP delivery his team has helped the field to mature. These developments included advancing studies as countermeasures for Emerging infectious Diseases and new biologics for treatment of cancer.

These include the first clinically advanced Zika vaccine, the first MERS vaccine, now in Phase II studies with CEPI, an Ebola Vaccine being advanced by DARPA, a SARS-CoV2 Vaccine funded by the DoD, and a novel HIV immunogen platform for in vivo self-assembly of complex structured immunogens funded by NIH, among others in the infectious disease arena. In oncology his laboratory has helped to develop new immune therapy approaches for applications against HPV disease, prostate disease, GMB immunotherapy currently in clinical trials. Studies developed from his group resulted in the first efficacious therapeutic DNA vaccine in a Phase II study (HPV CIN) (VGX3100) now in advanced trials.

Dr. Weiner's laboratory has published over 510 papers/chapters & reviews and provided > 650 lectures. He has received several awards/honors, including the WW Smith Family Chair in Cancer Research - 2016, Vaccine Industry Association Outstanding Academic Research Laboratory (2015 & 2016) (runner up 2017, 2018, 2019), Named Top 20 Translational Research Laboratories of the Year (Nature Biotechnology 2016, 2017, 2018, 2019 & 2020), Received the Stone family award for Cancer Research 2014, Received an NIH Directors Translational Research Award 2011 and received the Pennsylvania Life Sciences Achievement Award (2019). He is a Fellow of the American Association for the Advancement of Science 2011, a Fellow of the International Society for Vaccines (2018-2020).

He serves on the Executive Committee of the UPENN CFAR and served as chair of the prestigious Gene Therapy and Vaccine Training Program at the University of Pennsylvania (2004-2016). He is currently the Wistar Institute Professor, Director of the Vaccine and Immunotherapy Center and the Executive Vice President of the Wistar Institute, and a professor Emeritus at the University of Pennsylvania.

Dr. Weiner has been an avid teacher, trainer, advisor, and advocate for students and fellows and junior faculty as he is highly committed to developing the careers of young scientists. He has successfully trained over 100 students and Post Doctoral fellows over his career.

JENEICE HUBERT





Drew Weissman, M.D., Ph.D.

Nobel Prize Laureate Co-Director,

Penn Center for AIDS Research, Immunology Core Director of Vaccine Research, Infectious Diseases Division, Cell and Molecular Biology and Immunology Graduate Group Affiliations at Perelman School of Medicine, University of Pennsylvania Roberts Family Professor in Vaccine Research

Drew Weissman, M.D., Ph.D. is a professor of Medicine at the Perelman School of Medicine, University of Pennsylvania. He received his graduate degrees from Boston University School of Medicine. Dr. Weissman, in collaboration with Dr. Katalin Karikó, discovered the ability of modified nucleosides in RNA to suppress activation of innate immune sensors and increase the translation of mRNA containing certain modified nucleosides. The nucleoside-modified mRNA-lipid nanoparticle vaccine platform Dr. Weissman's lab created is used in the first 2 approved COVID-19 vaccines by Pfizer/BioNTech and Moderna. They continue to develop other vaccines that induce potent antibody and T cell responses with mRNA-based vaccines. Dr. Weissman's lab also develops methods to replace genetically deficient proteins, edit the genome, and specifically target cells and organs with mRNA-LNPs, including lung, heart, brain, CD4+cells, all T cells, and bone marrow stem cells.



Michael Betts, Ph.D.

Professor of Microbiology in the Microbiology Graduate Group Affiliations Department at University of Pennsylvania.

Dr. Betts earned his PhD in 1998 from the University of North Carolina in Dr. Jeffrey Frelinger's lab working on human T cell responses to HIV. He continued this work during his postdoctoral fellowship with Dr. Rick Koup at the University of Texas Southwestern Medical Center and then at the NIH Vaccine Research Center. In 2005 he started his lab at the University of Pennsylvania,



where he continues to research the immune response to HIV and other viral infections in humans, most recently working on COVID-19. He maintains active collaborations in Latin America, Europe, and Africa, where he is involved in both immunology research studies and training of new investigators.

Dr. Betts's laboratory studies human T lymphocyte function in order to understand the role of these cells in controlling or eliminating viral pathogens and providing protection from infection. Our primary interest is in determining how and if the human CD8+ T cell response to HIV controls viral replication. We also study the immune response against a variety of other human pathogens, including Epstein-Barr virus, cytomegalovirus, influenza, and vaccinia virus. Importantly, the techniques we utilize can be applied to the study of the cell-mediated immune response against any human pathogen, including emerging pathogens and bioterrorism agents. We are also very interested in characterizing the human T cell response to various vaccine regimens against a variety of human pathogens designed to generate cell-mediated immunity in order to understand the underlying principles of vaccine-mediated immune protection. We have also recently dived more into understanding the cellular phenotype of HIV reservoir in its basal and unmanipulated state using novel methodology including a multiomic single-cell ATACseq to identify HIV-infected cells.

Human T lymphocytes have numerous functions, including the ability to produce various cytokines and chemokines, as well as mediate cell death through perforin- or fas-mediated cytotoxicity. Our research utilizes the most cutting-edge techniques to measure human T lymphocyte responses through the use of polychromatic flow cytometry. This technique allows for the simultaneous examination of up to 18 separate parameters on lymphocytes. By measuring multiple T cell functions simultaneously, we can characterize the complexity of the CD4+ and CD8+ T cell response to HIV, EBV, CMV, Flu, and vaccinia. Not surprisingly, the T cell responses to these different viruses are quite variable; however, common response patterns do exist, and the importance of these patterns in the control of viral replication is the subject of future studies. The Betts Lab current direction is to determine the underlying mechanisms that control the cell fate and functional characteristics of disease specific T and B cells in different human diseases.



David M. Allman, Ph.D.

Associate Director of the Abramson Cancer Center Flow Cytometry Core Facility, Professor of Pathology and Laboratory Medicine in the Pathology and Laboratory Medicine Graduate Group Affiliations Department, Perelman School of Medicine at the University of Pennsylvania.

Dr. Allman obtained his bachelor's degree in microbiology at Pennsylvania State University and his Ph.D. in immunology at the University of Pennsylvania. The Allman Lab's main focus concerns the mechanism underlying differentiation within the B cell lineage. We are currently focusing on two aspects of B cell development and differentiation.



1) A central interest in my lab concerns the differentiation of antibody-secreting plasma cells from naïve and memory B cells. We are primarily interested in the following questions: a) How long to plasma cells live and what signals regulate their survival? b) Do plasma cells located at sites other than the bone marrow, such as within the gut mucosa, utilize the same survival mechanisms as those in the marrow? c) To what extent does persisting antigen or chronic infection promote lasting antibody responses? d) What are the regulatory networks, transcriptional and otherwise, that underwrite the differentiation of an activated B cell into an antibody-secreting plasma cell?

Background: High affinity neutralizing antibodies play central roles if combating infections and constitute the chief mechanism underlying the vast majority of effective vaccines. Once induced, antigen-specific antibodies can be found in the serum long after infection or vaccination. A key question in immunology is how this works: Are lasting antibody responses mediated by memory B cells, induced periodically to generate short-lived plasma cells by persisting antigen? Or does the durability of serum antibody titers reflect the activity of long-lived plasma cells?

It is generally accepted that, once generated in peripheral lymphoid tissues, some new plasma cells home to the bone marrow where they survive for months to years in mice, and perhaps decades in people. However, the vast majority of newly generated plasma cells fail to become long-lived. Given that certain vaccines fail to induce long-term protective immunity; it follows that these antigens or immunization strategies fail to induce the formation of long-lived plasma cells. We would like to understand why.

To this end, we are striving to understand the factors underlying plasma cell lifespans, and why some plasma cells become long-lived, while others do not. We are examining this issue on both the cellular and molecular levels. With a cellular perspective, we have developed strategies to identify newly formed versus long-lived plasma cells in the bone marrow. This capacity also allows us to evaluate different types of antigens and immunization strategies for their capacity to induce short- and long-lived plasma cells. From these experiments we have learned that the bone marrow plasma cell pool is exceptionally dynamic, containing large fractions of newly formed plasma cells that must compete effectively for presumably limiting survival niches. Hence, we are working to define the components of these niches and determine how to manipulate them. For a molecular perspective, we have also developed genome-wide gene



expression data sets for short- and long-lived plasma cells in the bone marrow and in the gut mucosa. These data that have inspired new hypotheses about the biochemical and transcriptional pathways underlying adoption of the plasma cell fate by naïve B cells and the role of mitosis in this process.

In related work, we are focused on elucidating the influence of microbe-lymphocyte interactions in the gastrointestinal tract on systemic immunity, particularly the generation and maintenance of serum IgA responses.

2) The second main focus in my laboratory concerns how specific transcription factors promote the earliest phases of B cell development from multipotent progenitors.

Background: To generate early B-lineage cells, the development of alternative lineages such as T cells, innate lymphoid cells, and myeloid lineage cells must be suppressed. Previous work on this question concentrated heavily on the transcription factor Pax5 and its capacity to both promote B cell differentiation and inhibit alternative fates. However, we recently showed that Early B Cell Factor-1 (EBF), another transcription factor required for early B lymphopoiesis, both promotes B cell development and represses myeloid and T-lineage development independently of Pax5. Recent work in the lab has shown that EBF accomplishes this task by actively and directly repressing the T cell and innate lymphoid cell-requisite transcription factor Gata3. To test this hypothesis further we developed synthetic Zincfinger proteins to perturb interactions between EBF and discrete cis elements in the Gata3 locus and test the impact of these perturbations on early B and T cell development. The latter studies revealed a general strategy for perturbing interactions between known transcription factors and relevant regulatory cis elements in a wide variety of experimental systems; we are applying this general approach to several differentiation pathways including early plasma cell differentiation.



Sita Awasthi. Ph.D.



Dr. Awasthi is a Research Associate Professor in the Department of Medicine, Infectious disease division, Perelman School of Medicine (PSOM) at the University of Pennsylvania. She has been studying human herpes viruses and their strategies to evade host immune systems for over two decades. With Dr. Friedman and collogues, she has exploited the viral immune evasion mechanisms to develop vaccine candidates against genital herpes. In more recent years, she combined mRNA-LNP vaccine technology and immune evasion strategy and led a candidate prevention vaccine against genital herpes from preclinical to early phase clinical trial.

Dr. Awasthi is an active participant in the wider scientific community in many educational and advisory capacities including biotech companies. She has served on many national and international grant review study sections. She has been on the board of Association of Women in Science, Philadelphia Chapter.

Dr. Awasthi received her masters and Ph.D. in Biochemistry from Devi Ahilya University, India and post-doctoral training at Baylor college of Medicine, Houston, Texas and Rocky Mountain Laboratory (NIH), Hamilton Montana.





Jesper Pallesen, MBA, Ph.D.

Assistant Professor, Vaccine & Immunotherapy Center at The Wistar Institute

Dr. Pallesen has expertise in the fields of virology, immunobiology, and structural biology, using cryoelectron microscopy; computational modeling; and atomic-level analysis of protein structures to discern the underlying architecture of proteins and viruses — an understanding that is crucial to his goal of developing vaccine-design technology.

Dr. Pallesen received his Ph.D. degree from Aarhus University. He received his postdoctoral training at Columbia University and The Scripps Research Institute, where he specialized in cryo-electron microscopy of bio-molecular protein complexes relating to infectious disease and immunobiology. In parallel to his postdoctoral training, he has extensive experience as a technical consultant in IP law and he received his M.B.A. from Rady School of Management with specialization in statistics, finance and management. At Wistar, his group studies infectious disease, cancer, develops vaccines, and Immunotherapeutics from a structural biology guided approach.

Dr. Pallesen is also interested in better understanding of immune system function, including response-triggering signals and the pathogen-clearing process.





Kristen A. Feemster, M.D., M.P.H., M.S.H.P.

Kristen is executive director of global medical affairs for pneumococcal vaccines at Merck Research Laboratories and an adjunct associate professor of pediatrics (infectious diseases) at the University of Pennsylvania and Children's Hospital of Philadelphia.

Kristen completed her residency and fellowship training at CHOP and Penn in 2010. After several years as an academic physician at CHOP and Penn, she transitioned to a full-time public health role as medical director of the Acute Communicable Diseases and Immunizations Programs at the Philadelphia Department of Public Health. In June 2020, she joined Merck & Co., Inc., in Global Medical and Scientific Affairs. Her research interests have included vaccine policy, vaccine hesitancy, and the epidemiology of vaccine-preventable diseases.

Kristen is committed to helping communities, especially through promoting public health awareness. She is the author of *Vaccines: What Everyone Needs to Know*, has published more than 100 peer-reviewed manuscripts and invited chapters and commentaries, and has regularly provided vaccine education to a wide range of audiences.





Stanley A. Plotkin, MD

Dr. Stanley A. Plotkin is Emeritus Professor of Pediatrics at the University of Pennsylvania. Until 1991, he was Director of Infectious Diseases and Senior Physician at the Children's Hospital of Philadelphia. He maintained laboratories at both CHOP and Wistar. In 1991, Dr. Plotkin left the University to join the vaccine manufacturer, Pasteur-Mérieux-Connaught (now called Sanofi Pasteur), where for seven years he was Medical and Scientific Director, based at Marnes-la-Coquette, outside Paris.

Dr. Plotkin received the Bruce Medal in Preventive Medicine of the American College of Physicians, the Distinguished Physician Award of the Pediatric Infectious Diseases Society, the Clinical Virology Award of the Pan American Society for Clinical Virology, the Richard Day Master Teacher in Pediatrics Award of the Alumni Association of New York Downstate Medical College, and the Marshall Award of the European Society for Pediatric Infectious Diseases. In June 1998, he received the French Legion of Honor Medal.

His bibliography includes over 900 articles, and he has edited several books including the standard textbook on vaccines, now in its 8th edition and now titled "Plotkin's Vaccines."

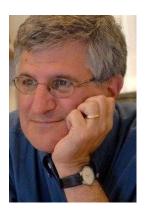
Dr. Plotkin developed the rubella vaccine now in standard use throughout the world, is co-developer of the pentavalent rotavirus vaccine also used in the United States and elsewhere and has worked extensively on the laboratory development and application of other vaccines already licensed or in development including anthrax, oral polio, rabies, varicella, pertussis, Lyme disease and cytomegalovirus.

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Paul A. Offit, M.D.

Director of the Vaccine Education Center Attending Physician in the Division of Infectious Diseases at the Children's Hospital of Philadelphia, Maurice R. Hilleman Professor of Vaccinology, Professor of Pediatrics at the Perelman School of Medicine at the University of Pennsylvania.



Dr. Offit is an internationally recognized expert in the fields of virology and immunology and was a member of the Advisory Committee on Immunization Practices to the Centers for Disease Control and Prevention. He is a member of the Food and Drug Administration Vaccines and Related Biological Products Advisory Committee, and a founding advisory board member of the Autism Science Foundation and the Foundation for Vaccine Research, a member of the Institute of Medicine and co-editor of the foremost vaccine text, *Vaccines*.

Dr. Offit is a recipient of many awards, including the J. Edmund Bradley Prize for Excellence in Pediatrics from the University of Maryland Medical School, the Young Investigator Award in Vaccine Development from the Infectious Disease Society of America, and a Research Career Development Award from the National Institutes of Health. Dr. Offit has published more than 160 papers in medical and scientific journals in the areas of rotavirus-specific immune responses and vaccine safety. He is also the co-inventor of the rotavirus vaccine, RotaTeq, recommended for universal use in infants by the CDC; for this achievement Dr. Offit received the Luigi Mastroianni and William Osler Awards from the University of Pennsylvania School of Medicine, the Charles Mérieux Award from the National Foundation for Infectious Diseases; and was honored by Bill and Melinda Gates during the launch of their Foundation's Living Proof Project for global health. In 2009, Dr. Offit received the President's Certificate for Outstanding Service from the American Academy of Pediatrics.

In 2011, Dr. Offit received the Humanitarian of the Year Award from the Biologics Industry Organization (BIO), the David E. Rogers Award from the American Association of Medical Colleges, the Odyssey Award from the Center for Medicine in the Public Interest and was elected to the Institute of Medicine of the National Academy of Sciences. In 2012, Dr. Offit received the Distinguished Medical Achievement Award from the College of Physicians of Philadelphia and the Drexel Medicine Prize in Translational Medicine for the Drexel University College of Medicine. In 2013, Dr. Offit received the Maxwell Finland award for Outstanding Scientific Achievement from the National Foundation for Infectious Diseases, the Distinguished Alumnus award from the University of Maryland School of Medicine, and the Innovators in Health Award from the Group Health Foundation. In 2015, Dr. Offit won the Lindback Award for Distinguished Teaching from the University of Pennsylvania and was elected to the American Academy of Arts and Sciences.

In 2016, Dr. Offit won the Franklin Founder Award from the city of Philadelphia and The Porter Prize from the University of Pittsburgh School of Public Health. Dr. Offit was a member of the Advisory Committee on Immunization Practices to the Centers for Disease Control and Prevention and is a founding advisory board member of the Autism Science Foundation and the Foundation for Vaccine



Research. He is also the author of seven medical narratives: *The Cutter Incident: How America's First Polio Vaccine Led to Today's Growing Vaccine Crisis* (Yale University Press, 2005), *Vaccinated: One Man's Quest to Defeat the World's Deadliest Diseases* (HarperCollins, 2007), for which he won an award from the American Medical Writers Association, *Autism's False Prophets: Bad Science, Risky Medicine, and the Search for a Cure* (Columbia University Press, 2008), *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All* (Basic Books, 2011), which was selected by Kirkus Reviews and Booklist as one of the best non-fiction books of the year, *Do You Believe in Magic?: The Sense and Nonsense of Alternative Medicine* (HarperCollins, 2013), which won the Robert P. Balles Prize in Critical Thinking

from the Center for Skeptical Inquiry and was selected by National Public Radio as one of the best books of 2013, *Bad Faith: When Religious Belief Undermines Modern Medicine* (Basic Books, 2015), selected by the New York Times Book Review as an "Editor's Choice" book in April 2015; and *Pandora's Lab: Seven Stories of Science Gone Wrong* (Random House, 2017). The book, *Lost in Translation: Some Hard-Earned Advice About How to Communicate Science to the Public*, is in preparation.



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Breakthroughs that change patients' lives



Annaliesa Anderson, PhD, FAAM, is the Senior Vice President and Chief Scientific Officer of Vaccine Research and Development at Pfizer Inc, and a member of Pfizer's Worldwide Research, Development and Medical leadership team. With over 30 years of pharmaceutical research experience,



Dr. Anderson leads a fully integrated, global vaccine research and development organization, with responsibilities ranging from discovery to registration and post-marketing commitments. She manages a clinical vaccines portfolio that includes vaccines to prevent or treat diseases of significant unmet medical need. These include vaccine programs directed at the prevention of diseases due to Streptococcus pneumoniae, Neisseria meningitidis, Clostridioides difficile, Escherichia coli, Respiratory Syncytial Virus, SARS-CoV-2, and Influenza, among many others, as well as the development of PAXLOVID®, the first authorized oral COVID-19 antiviral treatment.

Dr. Anderson earned her doctorate in biological sciences at the University of Warwick, England, in collaboration with AstraZeneca in the field of microbial ecology. She completed two post-doctoral fellowships funded by the UK natural environmental council and the Royal Society, with sabbaticals at CromaXome Corporation and Kaiserslautern University. Prior to joining Pfizer, she worked at Merck Research Laboratories in Rahway, NJ, where she founded Merck's prokaryotic bio-combinational engineering laboratory.

Dr. Anderson has over 120 publications and an extensive patent portfolio in the areas of vaccine and antiinfective research and development. She is a member of the Microbiology Society, the American Society for Microbiology, a Fellow of the Royal Society of Medicine, and an elected fellow to the American Academy of Microbiology. In addition, she serves on the Microbiology and Infectious Disease Steering Committee at the New York Academy of Sciences, as well as the American Society for Microbiology Service Awards Selection Committee.







Dr. Kara BickhamChief Development Officer at IAVI

Kara Bickham, M.D., is responsible for defining and overseeing execution across all aspects of product development for IAVI.

Prior to joining IAVI, Bickham was vice president of vaccine clinical research and development at Pfizer where she was responsible for overall pipeline strategy, product delivery, and life cycle management for the Prevnar pneumococcal vaccine portfolio. Additionally, she served as franchise lead for the GBS6 vaccine, a six-valent Group B streptococcal vaccine being developed for low- and middle-income countries in partnership with the Bill & Melinda Gates Foundation. Prior to that, Bickham was the chief medical officer at Affinivax, a clinical stage biotech acquired by GSK, with responsibilities for the overall pipeline strategy and execution. Bickham also held several roles at Merck Vaccines, where among other responsibilities, she led the Vaxneuvance pediatric program team and the Zostavax product development team.

Bickham holds a B.S. from Texas Christian University and M.D. from the University of Texas Southwestern Medical Center. She pursued post-graduate training in pediatric infectious diseases at Weill Cornell Medical College and a postdoctoral fellowship in Ralph Steinman's laboratory at The Rockefeller University.





Swati Gupta

Vice President and Head of Emerging Infectious Diseases and Epidemiology

Swati Gupta, DrPH, MPH, leads IAVI's Emerging Infectious Disease product portfolio and the development of the organization's overall scientific strategy. She has a particular focus in leveraging IAVI's recombinant vesicular stomatitis virus (rVSV) platform and expertise to expand product development efforts beyond HIV, including leading the vaccine development programs for other emerging infectious diseases such as Lassa Fever, Marburg, and most recently SARS-CoV-2.

Previously, Gupta was an executive director with Merck Vaccines, where she worked on the development of innovative partnership models to address cross-cutting issues related to vaccine science and technology. As part of this role, she worked with key external stakeholders to facilitate accelerated Ebola vaccine development efforts to enhance preparedness for the ongoing public health crisis and for potential future outbreaks.

From 2000 to 2014, Gupta was in the Department of Epidemiology at Merck Research Laboratories where she led a number international, prospective cohort studies in support of vaccine and infectious disease products in development, including research on diseases such as HIV, HPV, influenza, dengue, and *C.difficile*. From 1998 to 2000, Gupta worked as a scientist in HIV Surveillance at the Communicable Disease Surveillance Centre (British equivalent of the U.S. CDC) in the U.K. She has also worked at the Bureau of Tuberculosis Control at the New York City Department of Health.

Gupta holds a doctorate in epidemiology from the Johns Hopkins Bloomberg School of Public Health and a Master of Public Health in infectious disease epidemiology from Yale University School of Medicine.



Dr. Luis J. Montaner is Executive Vice President for Scientific Operations, Herbert Kean, M.D. Family Professor, and Director of the HIV Cure and Viral Diseases Center at The Wistar Institute, the nation's first independent research institution devoted solely to biomedical science and a world leader in cancer, immunology, virology, and infectious disease research.

Dr. Montaner studies the mechanisms of disease in HIV-1 infection, cancer, COVID-19, and emerging viral infections (monkeypox), exploring new strategies to boost the natural function of the immune system in order to combat viral-associated disease or cancer progression.



Montaner obtained his D.V.M., Veterinary Medicine from Kansas State University in 1989, and his D.Phil. in Experimental Pathology from University of Oxford, U.K., in 1995. He joined The Wistar Institute in 1995 as an assistant professor and was promoted to professor in 2007. Montaner was named the Herbert Kean, M.D., Family Endowed Chair Professorship in 2015.

At Wistar, the Montaner laboratory focuses on immune system-based research using laboratory models of virus infection, animal models of infection and/or cancer, and clinical cohort studies to provide a clinic-to-bench research program that informs new strategies to combat HIV and or cancer. The Montaner lab is also a leading center of a Martin Delaney Collaboratory focused on HIV cure-directed research (see beat-hiv.org). Patient-and animal-based collaborative studies extend from Philadelphia across the United States and Puerto Rico, Mexico, Europe, South America, Southern Africa, and Vietnam. Current research focuses on:

- Identifying new strategies to reverse mechanisms of immunodeficiency caused by viral infection and/or cancer processes via testing new immune-enhancing strategies in patient-based studies (specimens, clinical trials), and animal models (humanized mice models, non-human primates).
- Exploring new ways to augment HIV-1 control beyond current therapies in order to achieve durable remission and/or permanent control of infection without the need for continued antiretroviral therapy.
- Understanding the role of targeting myeloid cells in cancer progression.
- Determining the impact of substance use disorder therapy on immune functionality and HIV reservoir retention in opioid-dependent persons living with HIV.
- Determining the impact of COVID-19 infection and/or vaccination on immune activation and HIV reservoirs in persons living with HIV.
- Antiviral discovery strategies based on natural products and small molecule lead optimization.



Sanjay Phogat, Ph.D. GSK

Vice President, GlaxoSmithKline Research & Development Viral vaccines and monoclonal.

He was Discovery Performance Unit (DPU) Head until April 2022. As DPU Head along with his team, he drove the discovery portfolio which includes bacterial, fungal vaccines and monoclonal antibodies against infectious diseases.



Sanjay is an infectious diseases expert with over twenty years of experience and a strong understanding of vaccine research and development. Has a proven track record of discovering and creating as well as improving existing systems, effectively leading cross-functional teams, and delivering results. Sanjay's unique experience covers a broad range of organizations varying from academia, government, not-for-profit and pharma. His ability to guide, mentor and lead is unparalleled, and he is well regarded by his peers and executive team for his leadership abilities and his passion for delivering results.

Most recently he along with the VIR-GSK team developed monoclonal antibody Sotrovimab from research to launch within a year. He is recognized for creating partnerships of internal and external stakeholders critical to achieving organizational objectives. He also co-led the discovery and characterization of novel potent and broad neutralizing antibodies-considered a major advancement in the HIV field.

He has effectively le projects and managed alliances working in highly diverse public-private partnership involving Pharma (Novartis, GSK), biotech (Immune Design, Thera clone sciences), not-for-profit (gates Foundation, IAVI), Govt. (US, Eu, Thai, RSA), and multiple academic institutions etc. He spearheaded the establishment of IAVI-India lab for HIV vaccine R&D. He is Scientific advisor for not-for-profit and co-founder of Global Alliance of Indian biomedical professional and NIH visiting fellow committee. He has served as editor/co-editor/review of several publications and has published over 80 scientific papers; many are highly cited and in very high impact journals. He holds a Master of Science degree in Biotechnology from the Madurai Kamaraj and a Ph.D. in Genetics from the University of Delhi. He conducted post-doctoral studies at Uniformed services University of Health sciences and at National Institute of Health.



Emilio A. Emini, Ph.D., FCPP, FAAM,

Biopharma Vaccine Consultant

Dr. Emini is an independent vaccine consultant, serving on the Scientific Advisory Boards of multiple small and large biopharma organizations involved in vaccine R&D. He also serves as a Board member of Dynavax, Inc. and Centivax.



Emilio is the former Chief Executive Officer of the Bill & Melinda Gates Medical Research Institute, where he led the research and development of novel products and interventions for diseases disproportionately impacting the world's most vulnerable populations. He joined the Institute following a six-year tenure at the Bill & Melinda Gates Foundation as the Director of the foundation's Tuberculosis and HIV Program, leading the foundation's efforts focused on accelerating the reduction in the incidence of HIV and TB in high-burden geographies, with the goal of achieving sustained epidemic control. Emilio joined the foundation in 2015 following a greater than 30-year career in the biopharmaceutical industry during which he held multiple senior positions in anti-infectives and vaccines R&D. At the Merck Research Laboratories, from 1983 to 2004, Emilio led the biological research that developed the first of the highly active antiretroviral therapies for HIV and led multiple vaccine research teams that participated in the successful development of a multiple vaccines, including vaccines for human papillomavirus and rotavirus. Following a two-year leave from the industry at the International AIDS Vaccine Initiative, Emilio joined Wyeth/Pfizer as the Senior Vice President of Vaccine R&D where he led the development of the Prevenar 13 vaccine for prevention of pneumococcal disease in infants and adults.

Emilio is a recipient of the Distinguished Alumnus Award from the Cornell University Graduate School of Medical Sciences. He is an elected Fellow of the American Academy of Microbiology, and the College of Physicians of Philadelphia. He is a former Trustee of the National Foundation for Infectious Diseases and served as a member of the National Preparedness & Response Science Board. Emilio also served as a strategic advisor to the U.S. COVID vaccine response effort.



Marco Ruella, MD

Assistant Professor,
Division of Hematology/Oncology,
Center for Cellular Immunotherapies
Scientific Director,
Lymphoma Program at the
Hospital of the University of Pennsylvania

Marco Ruella, MD, is Assistant Professor of Medicine in the Division of Hematology/Oncology and the Center for Cellular Immunotherapies and Scientific Director of the Lymphoma Program at the Hospital of the University of Pennsylvania.



Dr. Ruella treats patients affected by hematological cancers and specializes in immunotherapy approaches. His Laboratory focuses on the study of the mechanisms of relapse after chimeric antigen receptor T cell (CART) immunotherapies with the goal of rationally designing combined innovative immunotherapies for relapsing/refractory leukemia and lymphoma. Dr. Ruella obtained his medical degree with high honors and completed his specialization in clinical hematology at the University of Torino, Italy. After completing his fellowship, he was an attending physician in the Hematology and Cell Therapy Division of the Mauriziano Hospital and an instructor at the Biotechnology School at the University of Torino. From 2012, he was a postdoctoral fellow, and then an instructor at the University of Pennsylvania in the Center for Cellular Immunotherapies where he worked with Drs. June and Gill. From 2017 to 2018 he served as Associate Director of Dr. June's laboratory. In 2018, Dr. Ruella was appointed Assistant Professor of Medicine in the Division of Hematology/Oncology and the Center for Cellular Immunotherapies and Scientific Director of the Lymphoma Program at the Hospital of the University of Pennsylvania. Dr. Ruella was awarded many awards and honors, including the inaugural SITC EMD-Serono Cancer Immunotherapy Clinical Fellowship (2014), the AACR-BMS Oncology Fellowship in Clinical Cancer Research (2015), the ASH Scholar Award (2016), a NIH K99-R00 award (2017), the "Paola Campese" Award Leukemia Research (2017), the Cancer Support Community Award (2018), the 2018 ASH Joanne Levy, MD, Memorial Award for Outstanding Achievement, the Gilead Sciences Research Scholar in Hematology/Oncology and the Gabrielle's Angel Foundation Award (2020), and the Leukemia and Lymphoma Society, Translational Research Program (2021). Dr. Ruella is the author of numerous peer-reviewed publications on targeted immunotherapies for hematological cancers and is an inventor in several patents on CART therapy and the Scientific Founder of viTToria biotherapeutics.







Penny Heaton, M.D.
Global Therapeutic Area Head, Infectious Diseases & Vaccines
Janssen Research & Development

Penny Heaton, M.D., is the Global Therapeutic Area Head, Infectious Diseases & Vaccines at Janssen Research & Development. In this role, she leads a global team focused on developing transformational prevention methods, vaccines and treatments for some of the world's most threatening infectious diseases.

Penny holds two decades of infectious diseases and vaccine research and development experience. Prior to this role, she served as the Chief Executive Officer for the Bill & Melinda Gates Medical Research Institute (Gates MRI), where she led the development of investigational products from pre-clinical through late-stage development against multiple diseases including TB, malaria and enteric diseases and also served as Director of Vaccine Development at the Gates Foundation, working to address additional infectious diseases including HIV, pneumonia and polio. She has also led vaccine clinical research and development for companies including Novartis, Merck and Novavax. Notably, during her time at Merck, Penny co-developed a rotavirus vaccine which has been licensed in more than 100 countries and universally recommended by the World Health Organization for infants worldwide.

Penny began her career at the U.S. Centers for Disease Control and Prevention conducting diarrheal disease surveillance and investigating outbreaks of foodborne and diarrheal diseases, influencing her lifelong passion for infectious diseases and vaccine development.

A graduate of the University of Louisville School of Medicine in Kentucky, Penny is board-certified in Pediatrics and Pediatric Infectious Diseases. She is a member of the Pediatric Infectious Diseases Society and a fellow of the American Academy of Pediatrics.



Germán Áñez, MD, FIDSA

Dr. Áñez is an Executive Director (Distinguished Scientist) at

Merck Research Laboratories, Merck & Co., Inc. His work is focused on Vaccines R&D, and he is the Product Development Team Leader for Merck's V181 Dengue Vaccine program. Dr. Áñez is a virologist, clinical development physician-scientist and biopharmaceutical product development leader with over 17 years of experience in U.S. and international academic, government, and biopharmaceutical industry settings. He has been involved in the pre-clinical and clinical evaluation of several vaccines, monoclonal antibodies, anti-infective therapies, and diagnostic products for infectious diseases.

Dr. Áñez earned his medical degree from the University of Zulia in Maracaibo, Venezuela. His basic and clinical research interests during medical training included the fields of tropical medicine, clinical virology and immunology, focusing mainly on arboviruses. After practicing medicine in rural, underserved areas of the Colombia-Venezuela border, Dr. Áñez moved to the U.S. where he completed post-doctoral fellowships in molecular viral biology and immunology; first, at the Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), where he worked on the characterization of dengue vaccine candidates and monoclonal antibodies against flaviviruses of importance for public health, and then at the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA), where he continued his research work on arboviruses and became a regulatory reviewer, earning the CBER/FDA Director's Honor Award for Scientific Achievements, and the FDA Commissioner's Special Citation for his regulatory science activities and review work.

Before joining Merck, Dr. Áñez was at Sanofi Pasteur, where he was a clinical team leader in the Meningococcal (MenQuadfi®), Dengue (Dengvaxia®), and Zika vaccine programs, and then at Novavax, Inc., where he was a clinical development leader in the NVX-CoV2373 (Nuvaxovid[™]) COVID-19 vaccine program, leading its pediatric clinical development program and contributing to the licensure of this protein-based vaccine in the U.S. and globally. Dr. Áñez has over 50 peer-reviewed publications, more than 100 presentations at scientific events, and is an ad hoc reviewer for numerous journals including the New England Journal of Medicine, JAMA Journals, Journal of Infectious Diseases, among others. He is a member of the Infectious Diseases Society of America (IDSA), the American Society of Tropical Medicine and Hygiene, the European Society of Clinical Microbiology and Infectious Diseases, and the Venezuelan Society for Microbiology. Dr. Áñez has been honored as a 2022 Aspen Ideas: Health Fellow by The Aspen Institute, and as a Fellow of the IDSA (FIDSA). JENEICE HUBERT



Kathrin U. Jansen, Ph.D.

Vaccines Consultant

Former Senior Vice President and Head for Vaccine Research and Development at Pfizer Inc./ member of Pfizer's Worldwide Research and Development leadership team.

With over 28 years of pharmaceutical experience in Vaccine R&D, Dr. Jansen oversees a fully integrated, global vaccine research and development organization, with responsibilities ranging from discovery to registration and post-marketing commitments of first-in-class or best-in-class vaccines to prevent or treat diseases of significant unmet medical need. More recent accomplishments are the global licensures of Prev(e)nar13® to prevent pneumococcal diseases and the development and licensure of Trumenba®, the first vaccine licensed in the United States to prevent invasive disease caused by Neisseria meningitides serogroup B. Before the Wyeth

acquisition by Pfizer in 2009, Dr. Jansen served as Senior Vice President at Wyeth Pharmaceuticals and on Wyeth's R&D Executive Committee since 2006 and was responsible for Dr. Jansen oversees a fully integrated, global vaccine research and development organization, with responsibilities ranging from discovery to registration and post-marketing commitments of first-in-class or best-in-class vaccines to prevent or treat diseases of significant unmet medical need. More recent accomplishments are the global licensures of Prev(e)nar13® to prevent pneumococcal diseases and the development and licensure of Trumenba®, the first vaccine licensed in the United States to prevent invasive disease caused by Neisseria meningitides serogroup B. Before the Wyeth acquisition by Pfizer in 2009, Dr. Jansen served as Senior Vice President at Wyeth Pharmaceuticals and on Wyeth's R&D Executive Committee since 2006 and was responsible for vaccine discovery, early development and clinical testing operations.

Dr. Jansen also briefly worked at Vaxgen as Chief Scientific Officer and Senior Vice President for Research and Development with responsibility for the company's late stage development programs. Prior to joining Vaxgen, Dr. Jansen spent 12 years at Merck Research Laboratories where she directed or supported a number of vaccine efforts, including Merck's novel bacterial vaccine programs and viral vaccine programs (rotavirus, zoster and mumps, measles and rubella). Dr. Jansen initiated and led the development of Gardasil®, the world's first cervical cancer vaccine. Dr. Jansen received her doctoral degree in microbiology, biochemistry & genetics from Phillips University, Marburg, Germany, in 1984. Following completion of her formal training, she continued her postdoctoral training at Cornell

University working on the structure/function of the acetylcholine receptor. She then joined the Glaxo Institute for Molecular Biology in Geneva, Switzerland, where she focused on basic studies of a receptor believed to be a drug target to treat allergies. Dr. Jansen has over 120 publications in peer reviewed journals and was appointed an Adjunct Professor at the University of Pennsylvania – School of Medicine in 2010.



Sarah F. Schillie, M.D., M.P.H., M.B.A.

Domestic Meningococcal Vaccine Policy Lead Epidemiologist, Bacterial Diseases Division at the Centers for Disease Control and Prevention (CDC)

Sarah Schillie, MD, MPH, MBA is the Domestic Meningococcal Vaccine Policy Lead for CDC's Division of Bacterial Diseases. Dr. Schillie is a graduate of the University of Missouri School of Medicine. She completed her pediatrics residency



training at Pennsylvania State University and her preventive medicine residency training at SUNY-Stony Brook. She received her MPH from Columbia University and her MBA from Long Island University. Dr. Schillie served as the Director of Performance Improvement for the Suffolk County Department of Health Services in New York from 2003-2007 and joined CDC as an Epidemic Intelligence Service Officer in 2007. Prior to that, CAPT Sarah Schillie served as the Director of Performance Improvement for the Suffolk County Department of Health Services in New York. CAPT Schillie developed guidance for ensuring Hepatitis B protection for healthcare personnel and for strengthening Hepatitis B vaccine birth dose recommendations. She serves as the senior editor of Epidemiology and Prevention of Vaccine-Preventable Diseases, also known as the "Pink Book." Her professional interests include immunizations, medication errors, developmental pediatrics, and viral hepatitis.



Ruxandra Draghia-Akli, M.D., Ph.D.

Executive Vice President and Head of Research & Development at Novavax (November 2024)

Ruxandra Draghia-Akli,

Dr. Draghia-Akli has experience in both established pharmaceutical and smaller biotechnology companies. She most recently served as Global Head of Global Public Health R&D at Johnson & Johnson where she spearheaded initiatives to



accelerate drug discovery and development across several disease areas, including Dengue, tuberculosis, leprosy and coronaviruses.

Previously, Dr. Draghia-Akli also served as Vice President, Global Vaccines at Merck where she contributed to advancing innovative vaccines against Ebola, pneumococcal disease and human papilloma virus. She also worked with the European Commission supporting programmatic, legislative, regulatory and policy issues in research and innovation.

She also held roles of increasing responsibility and was responsible for securing start-up funding and grants at Advisys, Inc. (now a part of Inovio Pharmaceuticals). Dr. Draghia-Akli focused on research early in her career at Baylor College of Medicine, University Rene Descartes (Paris) and University Carol Davilla (Romania).

Dr. Draghia-Akli has served on numerous boards and committees over her career to help shape thinking on vaccine and public health issues. Currently, she is part of the 100 Days Mission, Science and Technology Expert Group of the International Pandemic Preparedness Secretariat; the Chair, Scientific Advisory Board of INTREPID Alliance; and the Chair, Scientific Advisory Board of Every Cure.

Dr. Draghia-Akli holds a M.D. from Carol Davila University, Romania, and a Ph.D. in human genetics from the Romanian Academy of Medical Sciences. She undertook doctoral training at University Rene Descartes in Paris, France and a postdoctoral training at Baylor College of Medicine, Houston, Texas, with a focus on rare diseases, molecular biology, gene therapy and novel vaccines. Ruxandra was honored to be recognized in 2022 as one of the top Women in Biopharma, engaged in drug discovery and development worldwide. Ruxandra has authored and co-authored more than 100 papers and holds over 100 patents.

About Novavax:

Novavax, Inc. (Nasdaq: NVAX) promotes improved healthy by discovering, developing, and commercializing innovative vaccines to help protect against serious infectious diseases. Novavax, a global company based in Gaithersburg, MD., U.S., offers a differentiated vaccine platform that combines a recombinant protein approach innovative nanoparticle technology and Novavax's patented Matrix-M adjuvant to enhance the immune response. The Company's portfolio includes its COVID-19 vaccine, and its pipeline includes COVID-19-Influenza Combination and stand-alone influenza vaccine candidates. In addition, Novavax's adjuvant is included in the University of Oxford and Serum Institute of India's R21/Matrix-M malaria vaccine. Please visit Novavax.com for more information.



Gary Kobinger, Ph.D.

Director, Galveston National Laboratory
Professor, Department of Microbiology, and Immunology
John Sealy Distinguished University Chair in Tropical and
Emerging Virology at The University of Texas Medical Branch
https://www.utmb.edu/microbiology/faculty/gary-kobinger-phd

(Brief bio – 2021 update)

Gary Kobinger is the new Director of the Galveston National Laboratory at the University of Texas Medical Branch. Dr. Kobinger has co-authored over 300 peer-reviewed scientific manuscripts and 20 years of experience working in or managing high-containment laboratories. His work presently focuses on developing and testing new vaccine platforms and



immune treatments against pathogens of high consequences to global public health. Serving the international community, Dr. Kobinger sits on several committees such as the STAG-IH advisory board to the Deputy Director-General, the High Priority Pathogen advisory board, and ad-hoc advisor to the SAGE committee all within the World Health Organization.

Gary Kobinger obtained his Ph.D. from the University of Montreal in 1998 before completing a post-doctoral fellowship at the University of Pennsylvania. In March 2005, Gary was the Chief of the Special Pathogens Biosafety Level 4 program at the National Microbiology Laboratory where he worked for 11 years. He is now the Director of the Galveston National Laboratory of the University of Texas, Medical Branch. Prior to this role, Dr. Kobinger was a professor and the Director of the Infectious Disease Research Centre at the Université Laval and has an appointment of associate professor at the University of Manitoba and adjunct professor at the University of Pennsylvania.

Gary was granted several awards including scientists of the year award from Radio Canada (CBC), the Order of Manitoba in 2016 and the Meritorious Service Cross (civil division) of the Governor General of Canada also in 2016. Gary co-authored around 200 peer-reviewed scientific manuscripts, and gave numerous invited seminars in universities, national and international funding agencies, departments of national defenses, the White House, Singapore NEA and the World Health Organization (WHO) concerning research on high consequence pathogens and the development of new public health policies and recommendations.

In 2013-2017, 60 minutes, National Geographic, BBC Horizon, NOVA, France 2, PBS, CBC, RC and others featured the leading work on successful treatment of Ebola infection that was developed by Gary and his team and the VSV-based Ebola vaccine to which he also contributed to bring to clinical trials including a Phase III efficacy study in Guinea.



Dr. Tonya Villafana

Tonya Villafana serves as the Vice President, Global Franchise and Medical & Scientific Affairs, Vaccines & Immune Therapies, AstraZeneca.

She has dedicated her career to protecting people around the world from the most challenging infectious diseases.

Dr. Villafana has led the development of several vaccine and monoclonal antibody



programs targeting areas of distinct unmet medical need, including influenza, malaria, HIV, Ebola, COVID-19 and RSV. Most notably, Dr. Villafana led the development of nirsevimab, a novel monoclonal antibody which, for the first time, can offer protection against RSV disease in all infants entering their first RSV season.

Dr Villafana was seconded to the World Bank and served as the International Federation of Pharmaceutical Manufacturers and Associations World Bank Fellow, where she supported the Global Medicines Regulatory Harmonization Initiative with a focus on strengthening regulatory systems in Africa and co-authored the Bank's position on Non-Communicable Diseases for the 2011 UN High Level Meeting on NCDs.

In collaboration with Oxford University and AstraZeneca colleagues she received the Copley Award and in 2023 was named as one of Fierce Biopharma's Top 20 Women in R&D.

Dr. Villafana received a PhD in immunology from Weill Cornell University Graduate School of Medical Sciences and an MPH from Harvard School of Public Health. Dr. Villafana's work has been published in leading scientific journals including the *NEJM*, *The Lancet* and *Nature Medicine*.



THE WISTAR INSTITUTE



Therese Takas Senior Global Clinical Operations Program Director at AstraZeneca

Therese has over 25 years of experience both in clinical development and clinical operations in leading biopharmaceutical companies ranging from mid-size to large global organizations. She has broad experience with most types of clinical trials from small and large molecules, to diagnostic and device. Therese has extensive clinical operations and innovation experience across several therapeutic indications including but not limited to oncology, immunology, rheumatology, cardiovascular and infectious diseases.

In the last 14 years, Therese's leadership roles in clinical operations have been with MedImmune/AstraZeneca where she successfully led high performing clinical operations and study management teams on several programs in the Vaccine and Immune Therapy unit. She successfully led the global clinical program for Vaxzevria and continues to lead successful programs such as FluMist and most notably Beyfortus® where she led the global clinical program from early research through to approval in over 45 countries.



2024 Examiners

Sita Awasthi, Ph.D.
Research Associate Professor
Department of Medicine, Infectious disease division,
Perelman School of Medicine (PSOM) at the University of Pennsylvania
Course Faculty Lecturer, (bio on page 13)

Emilio Emini, Ph.D., FCPP, FAAM, Biopharma Vaccine Consultant 2016 – Present Course Faculty Lecturer, (bio on page 24)

David B. Weiner, Ph.D.
Course Instructor & Faculty Lecturer, (bio on page 8)
Professor, Weiner Laboratory
Executive Vice President, Director,
Vaccine & Immunotherapy Center,
Wistar Institute

Michelle Goveia, M.D., M.P.H. Executive Director, Global Medical and Scientific Affairs Merck Vaccines 2019-2024 Course Faculty Lecturer & Examiner

Michelle Goveia, MD, MPH is an Executive Director in the Global Medical and Scientific Affairs department at Merck Vaccines. She joined Merck in 2002 supporting the clinical development and regulatory interactions for numerous vaccines including rotavirus, hepatitis A, and varicella-containing vaccines. She is currently responsible for leading the efforts to increase global access to Merck's pediatric and hepatitis vaccines worldwide, which includes managing vaccine-related scientific data and recommendations for rotavirus, MMR, varicella, hepatitis A and B, Hib, and a hexavalent combination vaccine.

Prior to joining Merck, she was an Epidemic Intelligence Service Officer at the Centers for Disease Control and Prevention, stationed at the California State Health Department. While there she worked with environmental and occupation health issues, including investigation of a new disease among renal patients, was involved in surveillance activities after the World Trade Center events and in the anthrax investigations in New York City and Washington DC.

Dr. Goveia received her B.S. Honors degree from the University of Michigan, medical and public health degrees from the George Washington University in Washington, DC, is pediatric board-certified and a Fellow of the American Academy of Pediatrics. Her interest in pediatric



environmental health has led her to work with the White House and the US Environmental Protection Agency.

Natalie Silmon de Monerri, Ph.D. Associate Director, Pfizer's Vaccines Research and Development

Dr. Silmon de Monerri is a microbiologist with >15 years of experience in basic research in infectious diseases in academic and industry settings. She received her undergraduate master's degree in molecular and Cellular Biology from the University of Bath, United Kingdom. During her undergraduate years, she developed a passion for infectious diseases and protein biochemistry, while focusing on *Staphylococcus aureus* mechanisms of immune evasion. She received her PhD in Infection and Immunity in 2010 from the MRC National Institute for Medical Research in London, United Kingdom, which focused on proteases that regulate the malaria parasite life cycle. In 2011, Dr. Silmon de Monerri moved to New York for her postdoctoral training at Albert Einstein College of Medicine, focused on posttranslational modifications and epigenetic regulation using molecular genetics and computational biology approaches in the parasite *Toxoplasma gondii*.

Dr. Silmon de Monerri joined Pfizer in 2017 to focus on microbial genomics and transcriptional regulation in bacterial pathogens. She has been the Molecular Biology team lead for Pfizer's Bacterial Vaccines group since 2018, and heads a team of bench scientists focused on early-stage antigen development and preclinical research. Dr. Silmon de Monerri is the Research Scientific Lead for the Group B Streptococcus vaccine program, where she is responsible for leading internal and external research projects and scientific strategy to support licensure of the GBS vaccine.

Megan Wise, Ph.D. Senior Director, Global Regulatory Affairs Merck Vaccines

Megan Wise is a Senior Director, Global Regulatory Affairs at Merck. In her role, Megan is responsible for overseeing a diverse portfolio of products at Merck. Her portfolio includes small molecule and monoclonal antibody-based treatments for infectious diseases. She is involved in managing and navigating the regulatory processes for these products at a global level, ensuring compliance with relevant regulations and guidelines throughout all phases of development. Prior to joining Merck in 2019, Megan served as a staff scientist at Inovio Pharmaceuticals, where her work primarily focused on designing and testing novel DNA vaccines targeting HIV.



She also explored the potential of DNA-encoded antibodies targeting HIV envelope for both prevention and treatment purposes.

Megan earned her PhD in Microbiology from the University of Pennsylvania.

Kevin Egan, Ph.D.
Senior Research Investigator,
Laboratory of Harvey Friedman, M.D.
Division of Infectious Disease
University of Pennsylvania

Dr. Egan is a senior research investigator interested in vaccines and host pathogen interactions Our lab has developed a preventative vaccine to prevent genital herpes infections caused by HSV-1 and HSV-2. This novel vaccine targets and blocks immune evasion proteins on the surface of the virion.

His research focus is on exploring the T-cell responses to HSV antigens encoded as mRNA. We believe that T-cell responses will provide a vital contribution to vaccine efficacy in preventing new infections and controlling recurrent infections. He is currently developing a system to test guinea pig T-cell responses by flow cytometry. This will allow us to establish correlates of protection against recurrent genital disease. His research has focused on studying animal models of Herpes simplex virus infections.

Daniel Claiborne, Ph.D.
Assistant Professor, Vaccine & Immunotherapy Center
Scientific Director, Histotechnology Facility,
Immunology, Microenvironment & Metastasis Program,
Ellen and Ronald Caplan Cancer Center

Dr. Claiborne is an immunologist focused on understanding how the function of T cells is modulated to create improved immunotherapies, including CAR T cell therapies, against HIV. Dr. Claiborne earned his B.S. in Biochemistry from Florida State University and a Ph.D. in Immunology and Molecular Pathogenesis from Emory University. He completed his postdoctoral training at the Ragon Institute of MGH, MIT, and Harvard and joined The Wistar Institute in 2021 as a Caspar Wistar Fellow.

Jilian R. Melamed, Ph.D.
Post Doctoral Fellow, Weismann Laboratory
University of Pennsylvania

Dr. Melamed is a postdoctoral researcher in the lab of Dr. Drew Weissman developing new mRNA vaccines to prevent autoimmune diseases such as type 1 diabetes and multiple sclerosis.



She received her PhD in Biomedical Engineering from the University of Delaware in 2018 and subsequently worked as a postdoctoral researcher at Carnegie Mellon University, where she discovered her passion for mRNA delivery. She is currently the Roberts Family-Katalin Kariko Fellow in Vaccine Development.

Taylor Cohen, Ph.D. Global Team Lead at Asta Zeneca

Dr. Cohen is an experienced team leader/builder, with a background in inflammation, innate immunity and host-pathogen interaction. Currently leading efforts to develop novel antibodies for prevention and treatment of COVID-19. Taylor Cohen earned his PhD in Bioengineering from the University of Pennsylvania, following his undergraduate and Masters degrees in Mechanical Engineering at Washington University in St. Louis. He continued at Columbia University where he did a Post-doc with Alice Prince, working on host pathogen interaction in the lung. His work focused on the type III interferon and inflammasome signaling pathways contributed to the pathology following acute bacterial infection. Dr. Cohen joined MedImmune to develop antibodies targeting bacterial pathogens. He also continued to publish, demonstrating how opportunistic bacterial pathogens cooperate to potentiate infection and uncovering a novel mechanism through which a bacterial toxin modifies mitochondrial function to prevent anti-microbial activity in phagocytes. He built a team and lead efforts to utilize the microbiome as an engine to identify and develop novel therapeutics for the treatment of metabolic, renal and cardiovascular diseases. Currently, Dr. Cohen leads global teams aimed at discovering and developing antibodies and vaccines for the treatment and prevention of respiratory viruses such as COVID-19 and influenza. He also serves as an Adjunct Professor at McGill University and is a board member at the Society of Mucosal Immunology.

Avijit Ray, Ph.D. Scientific Director Infectious Diseases Research Vaccines R&D and Infectious Disease Research GSK

Avijit Ray did his PhD in immunology working on vaccine/adjuvant potential of an outer membrane protein from Shigella (a gram-negative bacteria). Post PhD, he worked as postdoctoral researcher and Research Assistant Professor at Baylor College of Medicine (Houston), and Medical College of Wisconsin & Blood research Institute (Milwaukee), respectively, focusing on immune regulation in the context of autoimmune diseases (Multiple Sclerosis, Inflammatory bowel disease, etc). He is presently a Director in Vaccine R&D and Infectious Disease research group at GSK and leads a team of immunologists supporting early research and clinical stage programs for combating infectious diseases. Prior to GSK, he led early discovery research team in Immuno-oncology at Abbvie (North Chicago).



Robert G. K. Donald, Ph.D.
Senior Director,
Dept. of Bacterial Vaccines and Technology at Pfizer

In my 15 years at Pfizer, I have supported numerous preclinical vaccine research programs as manager of molecular biology and immunogenicity assay teams. I have also been the early research lead for several exploratory vaccines, including C. difficile, Enterococcus, GBS and E. coli/ Klebsiella. Previously, I worked for ten years at Merck on drug discovery initiatives aimed at identifying novel lead compounds to combat parasitic, fungal and bacterial infections. I began my research career at the U. Pennsylvania and U.C. Berkeley where I did consecutive post-docs in plant molecular biology, plant virology, and molecular parasitology labs.

David Zuzga, Ph.D., Associate Dean of Biomedical Studies Wistar Institute

Dr. David Zuzga, PhD is the Associate Dean of Biomedical Studies at The Wistar Institute and works to expand and enhance its life science education programs spanning high school, workforce development and apprenticeship, graduate education, and postdoctoral training. Prior to joining Wistar, Dr. Zuzga was Associate Professor and Chairperson of the Biology and Integrated Science, Business & Technology Departments at La Salle University. He previously co-founded BioDetego, a start-up company focused on developing IVD tests to identify cancer patients at risk of relapse. Dr. Zuzga is a Partnership for Undergraduate Life Science Education (PULSE) fellow and collaborates with key opinion leaders in undergraduate biology education to promote alignment of undergraduate life sciences programs with best educational practices. Dr. Zuzga is also co-chair of the post-secondary education workgroup and a steering committee member of the Philadelphia STEM Equity Collective.

Jason Diaz, Ph.D.,
Director of Education and Inclusive Excellence,
Huber J.P. Schoemaker Education and Training Center,
Assistant Professor, Genome Regulation and Cell Signaling Program,
Ellen and Ronald Caplan Cancer Center
Wistar Institute

Director of Education and Inclusive Excellence in the Wistar Institute's Hubert J.P. Schoemaker Education, and Training Center. Diaz earned his PhD in Cell and Molecular Biology with a focus on tumor virology and remembers the Vaccines and Immune Therapy course as his favorite course while a graduate student at Penn.



Ami Patel, Ph.D., Assistant Professor, Vaccine and Immunotherapy Center Wistar Institute

Patel holds a B.Sc. in microbiology & immunology from McGill University, Canada, an M.Sc. in Medical Microbiology from London School of Hygiene & Tropical Medicine, University of London, U.K., and a Ph.D. in medical microbiology from the University of Manitoba, Canada. She received postdoctoral training at the San Raffaele Telethon Institute for Gene Therapy, Milan, Italy, the University of Pennsylvania and The Wistar Institute. She was promoted to research assistant professor at The Wistar Institute Vaccine & Immunotherapy Center; named a Caspar Wistar Fellow in 2020; and promoted to Assistant Professor in 2023. Patel researches next generation solutions for emerging infectious diseases, including DNA vaccines and DNA-encoded monoclonal antibodies.

Amelia Escolano, Ph.D., Assistant Professor, Vaccine and Immunotherapy Center Wistar Institute

Dr. Amelia Escolano is an Assistant Professor in the Vaccine & Immunotherapy Center and a Wistar Institute Assistant Professor in Microbiology at the University of Pennsylvania.

Escolano obtained her BS degree in Biochemistry from the University of Oviedo, Spain and a master's degree from Centro de Biologia Molecular Severo Ochoa in Madrid, Spain. She received additional training at the University of Turku, Finland and the Genome Research Institute in Cincinnati, Ohio. Escolano obtained her PhD in biochemistry and molecular biology from Autonoma University of Madrid after completing her pre doctoral studies at the Spanish National Center for Cardiovascular Research (CNIC) in Madrid. She trained as a postdoctoral fellow in the laboratory of Michel Nussenzweig at The Rockefeller University in New York and joined The Wistar Institute as an Assistant Professor in 2021. Escolano is a Pew Biomedical Scholar, a recipient of the regional Blavatnik award for young scientists (finalist) and has been recognized with a NIH Director's New Innovator Award (DP2).

The Escolano Lab investigates novel vaccination strategies against highly mutating viruses. We are interested in understanding the unique features of the humoral and cellular immune responses to sequential immunization, with special focus on the process of antibody affinity maturation in the germinal centers. Our goal is to rationally design vaccination approaches to induce potent and long-lasting antibody responses against pathogens that diversify over time.



Elizabeth Parzych, Ph.D. Associate Staff Scientist, Weiner Laboratory Vaccine & Immunotherapy Center, Wistar Institute

Francesco Paolo Pennino, Ph.D.
Post-Doctoral Fellow, Claiborne Laboratory
Vaccine & Immunotherapy Center
Wistar Institute

Postdoctoral Fellow in the Claiborne Laboratory at The Wistar Institute in Philadelphia. Originally from Naples, Italy, I migrated to the United States in October 2018. I graduated from Federico II University of Naples, collaborating on a joint project with the University of Pennsylvania. In my current role, I am engaged in cutting-edge biotechnology research focusing on HIV and cancer immunotherapies, such as CAR-T cells, Bispecific T cell engagers, mRNA and lipidic nanoparticles.

Shushu Zhao, Ph.D.
Post-Doctoral Fellow, Weiner Laboratory
Vaccine & Immunotherapy Center
Wistar Institute

Shushu Zhao obtained her PhD from Fudan University in 2021. She focused on cancer immunotherapies and immune regulations by targeting regulatory T cells during her PhD studies. She currently is working as a post-doctoral fellow in The Wistar Institute. After joining David B. Weiner's lab, her research specializes in development and evaluation of cancer immunotherapies including monoclonal antibodies and bispecific T cells engagers by targeting novel cancer antigens and immune checkpoint.

Rumi Habib Pre-Doctoral Trainee, Kulp Laboratory Vaccine & Immunotherapy Center Wistar Institute

Rumi Habib is a 5th year PhD candidate in the labs of Dr. Daniel Kulp and Dr. George Shaw working on HIV-1 vaccine development. He uses primate models of HIV-1 to study the coevolution of the virus and the adaptive immune response and combines these studies with structure-guided design and directed evolution techniques to generate novel HIV-1 immunogens.

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