GVIRF Webinar Agenda

Artificial Intelligence (AI) in Vaccine Research & Development

November 21, 2024; 09:00 – 12:00 EST /5:00 – 18:00 CET

Register for Webinar

The biennial Global Vaccine and Immunization Research Forum (GVIRF) and the associated GVIRF Webinar series are global convenings that bring together the Vaccine and Immunization Research community, from basic immunology to implementation research, and from low to high income countries to address research challenges, innovations, and opportunities to facilitate vaccine research and development and maximize the benefit of immunization. Both the GVIRF and the Webinars are co-organized by the US National Institute of Allergy & Infectious Diseases (NIAID), the Bill & Melinda Gates Foundation (BMGF), and the World Health Organization (WHO), with the objective to facilitate progress towards the Strategic Goals of Immunization Agenda 2030 (IA2030).

This webinar is to discuss what is Artificial Intelligence (AI) and how AI is used to advance vaccine research and development. Expert panel discussions will focus on lessons learned, challenges, risks and opportunities using AI to accelerate vaccine development against global threats.

AGENDA

08:15- 8:50 EDT Audio and video check-in for speakers and panelists only

09:00 EDT Welcome and introduction
Kimberly Taylor, Senior Scientific Officer, NIAID, US

09:03 EDT Session I: Introduction to AI
Moderator: Purvesh Khatri, PhD, MS, Prof. Stanford University/ Inflammatix

What is AI and machine learning? Opportunities and challenges in biomedicine
Purvesh Khatri, PhD, MS, Prof. Stanford University/ Inflammatix

AI/Advanced computing and the future of vaccine development
Ted Schenkelberg, MPH, MBA, Managing Partner, Next Frontier Advisors

Considerations when using AI in early and late-stage vaccine development
Prof. Isabelle Bekeredjian-Ding, MD, EMBA, Philipps-University Marburg

Panel discussion: speakers and additional panelists, 20 mins
Additional panelist:
Nchangwi Syntia Munung, PhD, University of Cape Town, South Africa

10:00 EDT Session II: Vaccine Discovery/Design
Moderator: Tongqing Zhou, Chief, Structure Bioinformatics Core, NIAID, US

AI in systems vaccinology
Bali Pulendran, PhD, Director & Violetta L. Horton Professor, Stanford University School of Medicine

AI and structure-based antigen design and epitope prediction
Neil King, PhD, Associate Professor, Dept. Biochemistry, University of Washington School of Medicine

Using AI and immune correlates of protection for rational vaccine design
Galit Alter, PhD, Professor of Medicine, Ragon Institute of MGB, MIT, and Harvard

Panel discussion: speakers and additional panelists, 20 mins
Additional panelist: Thomas Trolle, PhD, Evaxion Biotech

11:00 EDT Session III: Vaccine Development
Moderator: Philippe-Alexandre Gilbert, PhD, Senior Program Officer, BMGF

AI in product optimization/ manufacturing
Matthieu Duvinage, PhD, Global Director AI Digital Twins & Intelligent Autonomous Systems, GSK

Applications of AI in clinical protocol design and operations
Demetris Zambas, Global Clinical Operations Leader, Pfizer

Regulatory landscape of AI submissions, FDA approach, risks of AI and machine learning
Hussein Ezzeldin, PhD, Senior Digital Health Expert, FDA, CBER
Manuel Osorio, PhD, Senior Scientist, Emerging Technologies & Medical Countermeasures, FDA, CBER

Panel discussion: 20 mins

12:00 Closing Remarks and Adjourn
Annie Mo, Senior Program Officer, NIAID

SPEAKER BIOSKETCH

Session I Introduction to AI

Purvesh Khatri, PhD, MS, Prof. Stanford University/ Inflammatix

Dr. Khatri is a Professor in the Institute for Immunity, Transplantation and Infection and Division of Biomedical Informatics Research in the Departments of Medicine and Biomedical Data Science at Stanford University. His research focuses on developing AI and machine learning methods for leveraging biological, clinical, and technical heterogeneity across independent publicly available heterogeneous data to accelerate clinical translation. His lab has applied these methods for identification of disease signatures that are diagnostic, prognostic, therapeutic and mechanistic across a broad spectrum of diseases including infections, autoimmune diseases, cancer, organ transplant, and vaccination.

Ted Schenkelberg, MPH, MBA, Managing Partner, Next Frontier Advisors

For over 20 years Ted has worked at the intersection of advanced biotech and global health building organizations seeking to make an impact on human health and equity. Currently, Ted is Managing Partner at Next Frontier Advisors, a strategic consulting firm focused on vaccines, immunology and global health advising groups across philanthropy, industry, academia and NGOs.

Previously Ted served as Co-founder, COO and Chief Strategy Officer at the Human Immunome Project, a global NGO using advanced computing/AI to decode the human immune system. Ted also led business planning efforts at the International AIDS Vaccine Initiative (IAVI) as the organization expanded its footprint to 21 countries, and played a key role in the creation of various international consortia. Early in his career, he served as a Health and Tech Analyst at a privately held asset management company with over $1 billion under management and administration.

Ted was trained at Johns Hopkins (MPH, Infectious Disease), the University of Chicago (MBA), and Grinnell College (BA), and held a post as a Visiting Scientist at the Harvard Chan School. He has served on various Boards including the African Services Committee, the Human Immunome Project European Foundation, MyImmunome and Doctors of the World. He has extensive experience working across the US, Europe, Africa and India.

Isabelle Bekeredjian-Ding, MD, EMBA, Philipps-University Marburg

Prof. Isabelle Bekeredjian-Ding is a physician specialized in medical microbiology and immunology and holds an MBA degree from Mannheim and ESSEC Business Schools. She attended Medical School at the University of Heidelberg with stays in Padova, Italy and Mt. Sinai Medical School in NYC. After graduation and her doctoral thesis in immunology Prof. Bekeredjian-Ding worked as physician at the Großhadern Hospital in Munich, as postdoctoral fellow at the Baylor Institute for Immunology Research in Dallas and in clinical pharmacology at the University of Munich. In 2005, she moved to Heidelberg as research group leader in the Department for Infectious Diseases. In 2012, she joined the Institute of Medical Microbiology, Immunology and Parasitology in Bonn as deputy medical director. In 2015, she was appointed head of the Division of Microbiology at the

Paul-Ehrlich-Institut, the German regulatory agency for biomedicines where she served in many offices such as EMA Vaccines Working Party and pandemic Task Force and Chair of the subgroup on infectious pathogens of the German Blood working group. She was further elected Chair of the IMI2 Scientific Committee (2017-2021) where she engaged in transforming the Innovative Medicines Initiative (IMI2), a public private partnership in pharmaceutical research sponsored by the European Commission and EFPIA. In light of the pandemic, she became founding director of the Center for Pandemic Vaccines and Therapeutics (ZEPAI), a unit responsible for procurement, demand forecast, storage and distribution of COVID19 vaccines and pandemic preparedness contracts with vaccine manufacturers (2021-2023). Since 2024, Prof. Bekeredjian-Ding is full Professor and Chair of Medical Microbiology at the Philipps-University Marburg.

Nchangwi Syntia Munung, PhD, University of Cape Town, South Africa

Nchangwi Syntia Munung is a Bioethics Researcher at the Faculty of Health Sciences, University of Cape Town, South Africa and coordinate the ethics research activities for the SickleAfrica Coordinating Centre. Her research focus areas are: ethics of genomics and data science in health; infectious disease ethics; governance of biomedical and translational health research.

Session II Vaccine Discovery/Design

Tongqing Zhou, PhD, Chief, Structural Bioinformatics Core, NIAID

Dr. Tongqing Zhou joined the Dale and Betty Bumpers Vaccine Research Center in 2001, became a Staff Scientist in 2005, and was promoted to the position of chief, Structural Bioinformatics Core in 2018. Dr. Zhou received his Ph.D. in Cell Biology from the Chinese Academy of Sciences and M.Sc in Electronic and Computer Controlled Systems from Wayne State University. He is joined by the two co-heads of the core, Drs. Gwo-Yu Chuang and Chen-Hsiang Shen. Dr. Gwo-Yu Chuang received his Ph.D. training under the mentorship of Dr. Sandor Vajda, Boston University. Dr. Shen received his Ph.D. training under the mentorship of Dr. Irene Weber, Georgia State University. Drs. Peter Kwong and Lawrence Shapiro also serve as advisory mentors to this core.

Bali Pulendran, PhD, Director and the Violetta L. Horton Professor, Stanford University School of Medicine

Bali Pulendran is the Director and the Violetta L. Horton Professor at the Stanford University School of Medicine, and a member of the Institute for Immunology, Transplantation and Infection, and the Departments of Pathology and Microbiology & Immunology. His research interests include learning how the evolutionarily ancient innate immune system regulates the workings of its relatively recent partner, the adaptive immune system, and how to harness that new understanding to designing improved and novel vaccines. He has co-authored nearly 300 peer-reviewed journal articles, many in front-line publications such as Nature, Science and Cell, and has trained more than 50 postdoctoral scholars and graduate students. Furthermore, Dr. Pulendran is the recipient of numerous grants from the National Institutes of Health and from The Bill and Melinda Gates Foundation.

Neil King, PhD, Associate Professor, Department of Biochemistry, University of Washington School of Medicine

Early in his career, Neil established the first general computational method for designing novel self-assembling protein nanomaterials with atomic-level accuracy. Building upon this foundation, his group designs novel protein-based systems for i) structure-based vaccine design and ii) targeted delivery of drugs and biologics. A major and unique focus of their work is tailoring the supramolecular structure of these materials to specific applications. They have recently been applying cutting-edge AI-based protein design algorithms to structure-based antigen design. In addition to leading his group at the Institute for Protein Design, Neil co-founded Icosavax and chaired its scientific advisory board until the company was acquired by AstraZeneca in 2024.

Galit Alter, PhD, Professor of Medicine, Ragon Institute of MGB, MIT, and Harvard

Dr. Alter's training, at McGill and Harvard, focused on defining the role of innate and adaptive cytotoxic cells in the control of HIV infection. However, it was not until her faculty appointment at Harvard that Dr. Alter began her pioneering work in defining the role of antibodies in directing anti-microbial immunity via antibody interactions with the innate immune system. Specifically, Dr. Alter developed Systems Serology, a novel Systems Biology tool, aimed at comprehensively mapping the mechanism by which the polyclonal humoral immune responses direct the anti-microbial activity of the innate immune system. In conjunction with her systems biology level antibody engineering, Dr. Alter has defined – often unexpected, correlates of immunity against HIV, tuberculosis, malaria, Flu, RSV, Ebola and many others.

Thomas Trolle, PhD, Evaxion Biotech

Thomas joined Evaxion in 2016 and is currently leading the development of Evaxion's AI-Immunology™ platform for designing vaccines against cancer and infectious diseases. He holds a PhD in Immunological Bioinformatics from the Technical University of Denmark, where he worked on developing novel tools and methods for the prediction of T-cell epitopes.

Session III

Vaccine Development

Philippe-Alexandre Gilbert, PhD, Senior Program Officer CMC, BMGF

Dr. Gilbert is an experienced bioprocess engineer with a 20-years track record of success in propelling breakthrough process improvements for biotech industries in Canada, US and Europe. As Senior Program Officer of the Bill and Melinda Gates Foundation, Dr. Gilbert is responsible for implementing technical solutions that speed and de-risk the development of appropriate vaccine candidates for global health needs. He has previously served as the COVID 19 CMC lead on emergency assignment with Sanofi Pasteur where he also has served as the Head Flu New Technology leader and previously Senior Director of Manufacturing Technology (2015-2020). He has served as the Head of Upstream Development with Novartis Vaccines and Diagnostics (2013-2015) as well as Assistant Director / Senior Manager with GlaxoSmithKline Vaccines (2011-2013). From 2008-2011 he served as the Senior Scientist and Group Leader for the Vaccine Section of

Medimmune and developed the Flu mist Technology with the first swine flu H1N1 vaccine on the market. He is an expert in vaccine production systems, process design, cost-reduction strategies, disposable process and quality by design processes. He is known for innovative problem solving, complex troubleshooting and skillful relationship-building with cross-functional teams and industrial partners. Dr. Gilbert received his PhD in Biochemical Engineering and Masters in Molecular Biology from Laval University in Quebec, Canada.

Matthieu Duvinage, Prof. PhD, Global Director AI Digital Twins & Intelligent Autonomous Systems at GSK

Demetris Zambas, Global Clinical Operations Leader, Pfizer

Demetris started his career as a Laboratory Scientist and transitioned into the Clinical Development where he held roles of increasing responsibilities in Monitoring, Trial Management and Data Management. He has led multiple Clinical Operations integrations resulting from mergers and acquisitions as well as technology, process and organizational re-engineering projects during his tenures at Schering Plough, Merck, Novartis and Pfizer. Since 2017 Demetris leads Pfizer's Data Sciences and Risk Based Monitoring functions in a transformation to an internal operating model across multiple geographies. He currently serves on multiple Boards, including SCDM's Advisory Board, has served on the Board of Trustees and was the 2016 Chair.

Hussein Ezzeldin, PhD, Senior Digital Health Expert, FDA, CBER

Hussein Ezzeldin joined the FDA, Office of Biostatistics and Pharmacovigilance (OBPV) in the Center for Biologics Evaluation and Research (CBER) in 2013. Dr. Ezzeldin works on advancing the science of patient input as part of the FDA regulatory-science strategic goals, and he is leading the natural history study for metachromatic leukodystrophy, HOME. Currently, Dr. Ezzeldin co-leads the Biologics Effectiveness and Safety Innovative Methods Initiative (BEST IM), which aims to develop new and innovative methods for a semi-automated adverse events (AEs) reporting system for CBER-Regulated Biological Products. Dr. Ezzeldin is the acting CBER Lead for the digital health technology review team (DHT-RT), supporting the use of DHTs in regulatory submissions.

Manuel Osorio, PhD, Senior Scientist, Emerging Technologies and Medical Countermeasures, FDA, CBER

Manuel Osorio is currently the lead for the Advanced Manufacturing Technologies portfolio in the Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration (FDA). Prior to this role, Dr. Osorio was a researcher/reviewer for 16 years in the Office of Vaccines Research and Review in CBER. He received a BS degree from UCLA in Biochemistry and PhD degree in cellular immunology from the University of California at Santa Cruz. He was a postdoctoral fellow at the National Institutes of Health for two years before joining the FDA.