GVIRF

National Institute of Allergy and Infectious Diseases

Bill & Melinda Gates foundation

World Health Organization

Seminar Agenda

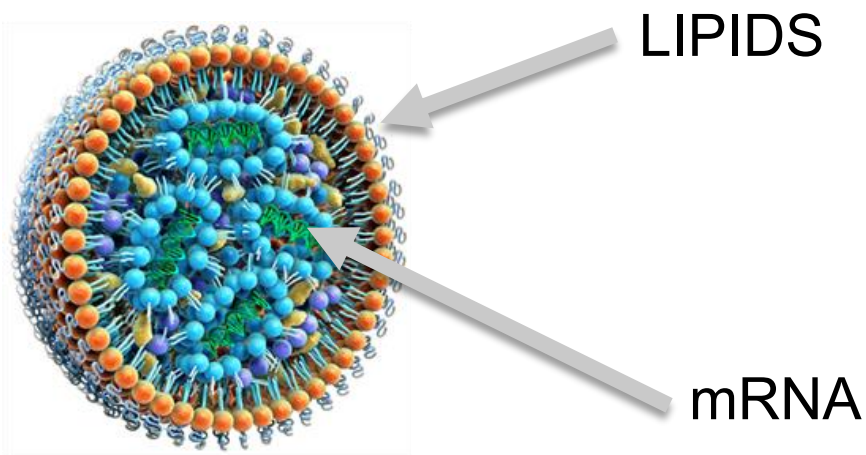
mRNA Vaccine Technologies for Global Health

DATE	TIME	LOCATION
Thursday, 14 October 2021	15:00 – 18:00 CET	Zoom Webinar

This GVIRF webinar is the first in a series of events hosted by the National Institute of Allergy & Infectious Diseases (NIH), the Bill & Melinda Gates Foundation (BMGF), and the World Health Organization (WHO). GVIRF is the central forum for research related to the Global Vaccine Action Plan (GVAP) and its successor, the Immunization Agenda 2030. GVIRF brings together the global vaccine and immunization research community, from basic immunology to implementation research, and from low to high income countries. The goals of GVIRF are the following:

- Track progress in vaccine research and development
- Identify gaps, opportunities, and actions to maximize the benefit of immunization
- Foster networking and collaboration to accelerate progress
- Support implementation of Immunization Agenda 2030

This webinar is the first of proposed recurring webinars to be held in the interim period between global meetings with hosting responsibilities rotating between NIH, BMGF, and WHO. The first webinar hosted by the BMGF will explore mRNA technologies for global vaccines beyond COVID-19. See just below for the agenda followed by short biographies for the presenters and panel participants. The meeting video and slide sets will be posted to https://www.technet-21.org/en/topics/gvirf after the meeting.



Webinar Agenda

15:00 CET	**Welcome and General Introduction**	**Peter Dull,** Bill & Melinda Gates Foundation
	Part I: mRNA Vaccine Development, Manufacturing, and Distribution	
15:05	Introduction and the vaccine manufacturing ecosystem	**Vivian Hsu,** Bill & Melinda Gates Foundation
15:10	Current status: mRNA vaccines development, regulatory, distribution, challenges and opportunities	**Martin Friede,** World Health Organization
15:20	mRNA vaccine manufacturing	**Ulrich Blaschke,** BioNTech
15:35	Extension of mRNA vaccines from COVID-19 to other global health challenges	**Allison August,** Moderna
15:50	mRNA manufacturing challenges for low- and middle-income countries	**Philippe-Alexandre Gilbert,** Bill & Melinda Gates Foundation
16:00	Q&A	
	Part II: Emerging mRNA Technologies	
16:10	Introduction: Emerging mRNA portfolios and technologies	**Holger Kanzler,** Bill & Melinda Gates Foundation
16:15	Assessing immunogenicity and protection of mRNA-1273-immunized nonhuman primates	**Robert Seder,** NIAID Vaccine Research Center
16:25	Self-amplifying mRNA vaccines for global health	**Robin Shattock,** Imperial College
16:40	Lipid nanoparticles for mRNA vaccines: Past, present and future	**Pieter Cullis,** University of British Columbia
16:55	mRNA vaccines in Africa	**Nicaise Ndembi**, Africa CDC
17:05	Q&A	
	Part III: Panel Discussion	
1715	**Melanie Saville,** Coalition for Epidemic Preparedness Innovation **Sanjay Singh,** Gennova Biopharmaceuticals **Renu Swarup**, Government of India **Richard Mihigo**, World Health Organization	**Lynda Stuart,** Bill & Melinda Gates Foundation
17:55	**Closing Remarks**	**Lee Hall,** NIAID Parasitology and International Programs Branch
18:00	**Meeting Ends**	

Biographies

Allison August, MD, Clinical Head, RSV and hmPV/PIV3 vaccines & Medical Lead, SARS-CoV-2 Phase 3 COVE study, Moderna

Allison is the Clinical Head, RSV and hMPV/PIV3 vaccines as well as the medical lead for the SARS-CoV-2 Phase 3 COVE study at Moderna. Since joining Moderna in April 2017, Allison has worked on multiple mRNA vaccines and monoclonal antibodies in the Moderna pipeline. Dr. August is an Obstetrician Gynecologist with more than twenty-five years of experience in academic, private practice and industry medicine, all with a strong focus on maternal-child health. Prior to Moderna, Dr. August led the maternal immunization and pediatric vaccine platforms for Novavax (2014-2017). Prior to Novavax, Dr. August served in roles of increasing responsibility at Novartis Vaccines & Diagnostics, where she spearheaded the GBS Maternal Immunization safety program and was part of the team that brought the Menveo infant quadrivalent meningococcal vaccine to licensure, with her final role serving as the Head of Early and Exploratory Clinical Development team. Prior to Novartis, Dr. August served as Medical Director at PAREXEL International, and worked for more than ten years as a consultant on early-stage biopharmaceutical products in women's health for MEDACorp, Leerink Swann Healthcare. Dr. August is a graduate of Bryn Mawr College and received her Doctor of Medicine degree from the University of Chicago, Pritzker School of Medicine. She trained in obstetrics and gynecology at Brown University, and in addition to serving as CEO of her own clinical practice, held staff positions at both Brown and Harvard Medical School.

Ulrich Blaschke, PhD, VP of Technical Development, BioNTech

Ulrich Blaschke joined BioNTech in December 2019 as VP of Technical Development. In this role, he is responsible for the implementation of an integrated CMC development strategy for the BioNTech portfolio, working closely with the technical functions and CMC regulatory affairs. Besides the technical aspects, he is specifically interested in the evolving global regulatory framework for this new class of therapeutic molecules. Prior to BioNTech, Ulrich worked for various pharmaceutical companies in Germany and in the US, including CureVac, Boehringer Ingelheim, Cinfa Biotech, and Stada Arzneimittel. Ulrich studied chemistry and biochemistry at the Westfälische-Wilhelms University in Münster, Germany, followed by a postdoctoral fellowship in the field of synthetic protein chemistry at the Rockefeller University, New York.

Pieter R. Cullis, Ph.D. FRSC, FNAI (USA), Scientific Director & CEO, NanoMedicines Innovation Network, Canada's National Centre of Excellence in nanomedicines; Professor, Department of Biochemistry and Molecular Biology, University of British Columbia

Dr. Cullis and co-workers have been responsible for fundamental advances in the design and development of nanomedicines employing lipid nanoparticle (LNP) technology for cancer therapies and gene therapies. This work has contributed to five drugs that have been approved by regulatory agencies in the U.S., Europe and Canada. Dr. Cullis has co-founded ten biotechnology companies that now employ over 300 people, has published over 350 scientific articles and is an inventor on over 60 patents. He also co-founded the Centre for Drug Research and Development, a Centre of Excellence for the Commercialization of Research (now AdMare) in 2004, the Personalized Medicine Initiative (PMI) in 2012 and the NanoMedicines Innovation Network in 2019. Dr. Cullis was elected a Fellow of the Royal Society of Canada in 2004 and was also awarded the Prix Galien, Canada's premier prize for achievements in pharmaceutical R&D, in 2011. Two recently approved drugs that are enabled by LNP delivery systems devised by Dr. Cullis, members of his UBC laboratory and colleagues in the companies he has co-founded deserve special emphasis. The first is Onpattro which was approved by the US FDA in August 2018 to treat the previously fatal hereditary condition transthyretin-induced amyloidosis (hATTR). Onpattro is the first RNAi drug to receive regulatory approval. The second is BNT162b2, the COVID-19 vaccine developed by Pfizer/BioNTech that has now (December 2020) received emergency approval in many jurisdictions including Canada, the USA, the UK and Europe. It is anticipated that more than 2B doses of BNT162b2 will be administered worldwide in 2021 and will play a major role in ending the global Covid-19 pandemic.

Philippe-Alexandre Gilbert, PhD, CMC, Vaccines Development and Surveillance, The Bill & Melinda Gates Foundation

Philippe is a biochemistry graduate of the University of Ottawa. He subsequently received his Master's degree in Molecular Biology and his Ph.D. in Chemical Engineering at Laval University. For more than 20 years, Philippe has built a solid expertise in bioprocess development for the production of vaccines, gene

therapy vectors and oncolytic viruses for cancer therapy. He had the privilege of working for both Academia (Robarts-Schulich in Canada and the Emerging Pathogen Institute at the University of Florida) and the private sector with Sanofi-Pasteur, MedImmune Vaccines, Novartis Vaccines and GSK Vaccines. In both North America and Europe, Philippe led task forces on the development of vaccines for HIV, RSV, CMV, SARS, Influenza and COVID. Philippe, just recently, was responsible for the Flu Technology Group at Sanofi Pasteur for the development of the Next Generation Flu vaccine. He joined the Vaccine Development and Surveillance (VDS) group at the Bill and Melinda Gates Foundation as Senior Program Officer CMC.

Fenton ("Lee") Hall, MD, PhD, FIDSA, Chief, Parasitology and International Programs Branch, NIAID, NIH

Lee Hall is Chief of the Parasitology and International Programs Branch (PIPB) in the Division of Microbiology and Infectious Diseases (DMID) at the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). Dr. Hall's responsibilities include leadership and oversight of extramural research programs to better understand, diagnose, treat and prevent parasitic diseases. These programs span the full range from basic research to translational and clinical research and development, and field studies, and operate both domestically and internationally. Trained originally as an immunologist and infectious diseases physician-scientist, Dr. Hall has had a longstanding commitment to development of vaccines not only for parasitic diseases but also for global health more generally. He has served on numerous committees, review panels and advisory boards, for NIH, federal and international organizations involving biomedical R&D, tropical medicine, and global health, and has chaired and participated in numerous symposia on these issues at national and international meetings and conferences. Over the past decade he has had extensive involvement with the Decade of Vaccines Collaboration, the Global VacciImpne Action Plan, the Global Vaccine and Immunization Research Forum, and most recently, the Immunization Agenda 2030 (IA2030). Dr. Hall received his AB magna cum laude in economics from Harvard College, and his MD and PhD in Immunology from the New York University School of Medicine. He completed his residency in Internal Medicine at the Johns Hopkins Hospital, and infectious diseases subspecialty training at the NIAID and Yale University School of Medicine. He is a Fellow of the Infectious Diseases Society of America.

Martin Friede, PhD, Coordinator, Initiative for Vaccine Research at the World Health Organization

Martin Friede is the scientific officer responsible for vaccine delivery systems within the Initiative for Vaccine Research (IVR) at the World Health Organization in Geneva, Switzerland. In this position he is the WHO focal point for matters related to the development of technologies to improve vaccines including adjuvants, stabilization methods needle-free vaccine delivery systems. Prior to joining WHO Dr Friede held several positions in the vaccine industry: He was Vice President of Development for Apovia Inc. a Californian vaccine development company, prior to which he was responsible for vaccine formulation and vaccine delivery research at Smithkline Beecham Biologicals (now GlaxoSmithKline). Martin Friede received his PhD in biochemistry from the University of Cape Town in South Africa.

Vivian Hsu, Deputy Director Strategy Planning and Management, Vaccine Development & Surveillance and Enteric & Diarrheal Diseases

Vivian Hsu has been at the Bill & Melinda Gates Foundation since 2016 and is currently the Deputy Director of Strategy, Planning and Management for the Vaccine Development and Surveillance and Enteric and Diarrheal Diseases teams. In this capacity, she manages the strategy and business operations for the teams whose core focus is investments in Enteric Disease vaccines and surveillance, new vaccine manufacturing technologies, infectious disease surveillance, epidemic preparedness and control, HPV and Polio product development, and other vaccine development innovations. Her portfolio of work spans the spectrum of driving day-to-day business management to leading major cross-foundation initiatives. Currently, she is also coordinating the Gates Foundation COVID-19 vaccine development efforts and supporting the foundation-wide COVID-19 response. Vivian's career has centered around the healthcare industry, beginning as a consultant in the US pharmaceutical industry prior to moving to Hong Kong to join McKinsey and Company. There, she spent the majority of her three years developing China market strategies for various multinational pharmaceutical and hospital corporations. In 2013, Vivian joined Evolent Health, a population health services company. With her team, she built Evolent's payer partnership practice

which partnered with hospitals to design value-based care infrastructure and negotiate population-based contracts with private insurance companies, Medicare and state Medicaid agencies. Vivian graduated from Yale University in 2006 with a degree in political science and East Asian studies and from Wharton School of Business at the University of Pennsylvania with a Masters in Business Administration in Healthcare Management.

Richard Mihigo, MD, MPH, Coordinator, Immunization and Vaccines Development (IVD) Programme, WHO Regional Office for Africa

Dr. Mihigo is a senior public health specialist with over 25 years of experience in designing, implementing and evaluating disease control programmes at national and international levels. He joined WHO in July 2004 and is currently the Coordinator of Immunization & Vaccines Development (IVD) in the WHO Regional Office for Africa in Brazzaville, Congo; a position he has held since 2014. In this position, Dr Mihigo coordinates WHO's technical support to Member States in the African Region in the planning, monitoring, and evaluation of immunization programmes. This includes supporting the development of policies, norms, and standards for national immunization programmes including vaccine regulation and research, establishing and strengthening partnership coordination mechanisms between countries and supporting resource mobilization efforts for national immunization programmes. Since the beginning of the COVID-19 pandemic in January 2020, Dr Mihigo has been supporting WHO's response to COVID-19 in the African Region as Deputy Incident Manager and is coordinating WHO's efforts to support countries' preparedness and deployment of COVID-19 vaccines. Dr Mihigo holds a Doctorate in Medicine from the University of Kisangani, DR Congo and a Master's degree in Public Health from the University of Boston, Massachusetts, USA. A national from Rwanda, Dr. Mihigo has worked from 1994 to 2003 at various senior level positions in the national health system of his native country including managing the National Immunization Programme from 2000-2003.

Nicaise Ndembi, MD, Chief Science Advisor, Africa Centers for Disease Control and Prevention

Dr. Ndembi serves as Chief Science Advisor to the Africa Centers for Disease Control and Prevention. He is an Adjunct Associate Professor, Division of Epidemiology and Prevention at the IHV, University of Maryland School of Medicine, Baltimore, US. Dr. Ndembi is a member of the PharmAccess Technical Advisory board for the Pan-African Study for Evaluation of Resistance in Africa and WHO Resistance Network (WHO ResNet). He is the co-chair of the Africa Taskforce for novel Coronavirus (AFCTOR) on Science and regulations and leads the Partnerships for Africa Vaccine Manufacturing (PAVM) in Africa.
Dr. Ndembi is a graduate of Kanazawa University School of Medicine, Department of Viral Infection and International Public Health. He is a Principal Investigator on numerous grants including US National Health Institute (NIH). He has authored/co-authored more than 140 publications in peer-reviewed journals. He is the Editor in Chief of the Journal of Public Health in Africa (JPHIA), and AIDS Research and Therapy (ARTY). Dr. Ndembi main research interest includes vaccine research especially understanding protective immune responses, genomics epidemiology, microbiome, Emerging and Re-Emerging Infectious Diseases, HIV diversity, and resistance to Antiretroviral Therapy.

Melanie Saville, MB, BS, Director, Vaccine Research and Development, CEPI

Melanie Saville joined the Coalition for Epidemic Preparedness Innovations (CEPI) in November 2017. She is the Director of Vaccine Research and Development, and leads the technical teams supporting the vaccine development and enabling science projects funded by CEPI and is the R&D and Manufacturing workstream leader for COVAX. Melanie is a physician specialized in virology with 20 yrs of experience in the development and licensure of vaccines for the developed and developing world. Over the years, she has contributed to the development and licensure of several vaccines for seasonal and pandemic influenza, pediatric combinations, Rabies, Japanese Encephalitis, Ebola and Dengue vaccine in Europe, US and the international area.

Robert A. Seder, MD, Chief, Cellular Immunology Section, Vaccine Research Center, NIAID, NIH

Dr. Seder received his BA degree from Johns Hopkins University, his MD degree from Tufts University, and his residency in Internal Medicine at Cornell Medical Center. Dr. Seder is currently the Chief of the Cellular Immunology Section in the Vaccine Research Center in the NIAID. Dr. Seder's work focuses on the cellular and molecular mechanisms by which vaccines mediate protective immunity in animal models of HIV, malaria, tuberculosis and cancer. Dr. Seder has translated his scientific discoveries with "first in

human" clinical trials using intravenous vaccination to generate protective immunity with an attenuated malaria vaccine and more recently showing that a monoclonal antibody can prevent malaria infection. Over 18 months, Dr. Seder led a series of studies in a non-human primate model of SARS-CoV2 using the mRNA 1273 vaccine from Moderna. This work has defined the immune correlates and mechanisms of protection, and determined the durability of protection against the Beta and Delta variants.

Sanjay Singh, PhD, Chief Executive Officer, Gennova Biopharmaceuticals

Dr. Sanjay Singh is the Chief Executive Officer of Gennova Biopharmaceuticals Ltd, Pune, India, a biotechnology company dedicated to the development and commercialization of safe, efficacious, and affordable biotherapeutics. As a founder CEO, since 2006, at Gennova, Dr. Singh focused on innovations in bio-manufacturing technologies that culminated in the commercialization of seven life-saving bio-therapeutics in the cardiovascular, neurology, nephrology, and oncology market. Under his leadership, his team pioneered the work that led to its approval of tenecteplase for Acute Ischemic Stroke (AIS) — the first time globally, securing global patents. The Department of Biotechnology (DBT), Govt. of India recognized this innovation for the 'Biotech product, process development and commercialization award 2019' and it found its way in the list of drugs for emergency care for stroke management in the guideline —'Prevention and Management of Stroke,' issued by the Ministry of Health and Family Welfare, Govt. of India. Under him, Gennova has directed their research to cater to vaccine development of neglected diseases, in particular Malaria, HPV, Leishmaniasis, and Tuberculosis, in partnership with various national and global organizations, including the NIH, US-FDA etc. Dr. Singh is currently a member of various important committee of national relevance, which notable include the Scientific Advisory Board of the National Center for Cell Sciences (NCCS), Pune, Research Council of the Indian Institute of Toxicology Research (CSIR-IITR), Lucknow, National Committee for Biotechnology- Confederation of Indian Industry (CII), New Delhi. Additionally, he is an invited member of the Indo-US Vaccine Action Program (VAP). Contributing towards the national interests, Dr. Singh served as a member of the committee for the development of the India Guidelines on Similar Biologics (Regulatory Requirements for Marketing Authorization) constituted by the Department of Biotechnology (DBT), Ministry of Science and Technology (Govt of India) and Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and family welfare (Govt. of India). Contribution of this committee led to the establishment of a transparent path for successful development (clarity for Biotech Industry) and approval process (clarity of guidelines for regulatory agencies) to market the biosimilar drug product in India. Dr. Singh holds a Ph.D. degree in Biochemistry from Central Drug Research Institute (CDRI), Lucknow, India. Before joining Gennova, he headed the Antigen Research Section at the Malaria Vaccine Development Unit of the National Institutes of Allergy and Infectious Diseases (NIAID), NIH, USA.

Robin Shattock, PhD, Professor, Mucosal Infection and Immunity,Imperial College London

Robin Shattock has over 30 years' experience in research and development of vaccines and antiviral therapeutics. He is a Professor of Mucosal Infection and Immunity at Imperial College, London. The focus of his research is the development of vaccines to prevent pandemic threats and poverty related diseases. His publications include over 200 peer-reviewed scientific papers published in a range of peer review journals. Prof Shattock has led large multi-centre programs funded by the Wellcome Trust, MRC, EPSRC, CEPI, NIH, European Commission, and the Bill and Melinda Gates Foundation. His academic research portfolio includes vaccine projects on HIV, Ebola, Lassa fever, Marburg and rabies viruses and chlamydia. He has a strong track record of translation research having taken a wide range of vaccine products through from discovery into clinical testing. The Shattock group was the first in the world to test a self-amplifying RNA vaccine against COVID-19 in phase I/II clinical trials. He is Chair of the Board of directors for the Vaccine Manufacturing and Innovation Centre (VMIC) and Founder of VaxEquity Ltd an Imperial spin-out focused on development of RNA vaccines against human infectious diseases. Robin is an elected fellow of the Academy of Medical Sciences.

Lynda Stuart, MD, PhD, Deputy Director, Vaccine and Biologics Discovery, Global Health, the Bill & Melinda Gates Foundation

Lynda Stuart leads Vaccine and Biologics Discovery and Translation at the Bill & Melinda Gates Foundation, with oversight of a broad portfolio of vaccines, biologics and correlates of protection across the Foundation's priority areas of focus. She also heads an initiative called the Global Health discovery

Collaboratory that seeks to use cutting edge technologies to help solve global health problems. Since 2020 she has co-led the Foundation's COVID19 vaccine response team. She is an academic and physician-scientist who received her medical degrees from the University of Cambridge and the University of London and PhD from the University of Edinburgh. She is trained in internal medicine in the UK. Her research career has focused on the role of the innate immune system in control of autoimmune and infectious diseases, the interplay between innate and adaptive immunity and on host-pathogen biology. She was a recipient of numerous academic awards including a Wellcome Trust Clinical Research Fellowship, Wellcome Trust Clinician Scientist Award, Howard M Goodman Award and the Massachusetts General Hospital Research Scholars Award. She is a member of the Royal College of Physician in the UK and a Fellow of the American Society of Clinical Investigation. Prior to coming to the Foundation she was a member of the faculty at Massachusetts General Hospital/Harvard Medical School where she was co-director of the Laboratory of Developmental Immunology, was an affiliate of the Broad Institute of Harvard and MIT and sat on the Massachusetts General Hospital Executive Committee for Research. She remains actively involved in basic research with an affiliated appointment at the Benaroya Research Institute in Seattle.

Renu Swarap, PhD, Director, Department of Biotechnology, Ministry of Science and Technology, India

Dr Renu Swarup is presently Secretary, Department of Biotechnology (DBT), Government of India. Having served in Department of Biotechnology for over 30 years, she also holds the position of Chairperson, Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Company incorporated by the Government to nurture and promote innovation research in the Biotech Enterprise with special focus on Start-ups and SMEs. A PhD in Genetics and Plant Breeding, Dr. Renu Swarup completed her Post Doctoral at The John Innes Centre, Norwich UK, under Commonwealth Scholarship and returned to India to take up the assignment of a Science Manager in the Department of Biotechnology, Ministry of Science and Technology, GoI, in 1989. As a Science Manager issues related to policy planning and implementation were a part of her assignment. She was actively engaged as the convenor in formulation of National Biotechnology Vision and Strategy in 2001, 2007 and 2015. Dr. Renu Swarup has been instrumental in the planning and implementation of some major National programmes such as Spatial Characterization of Biodiversity, Second Generation Bioethanol, Drugs from Microbes, National Biopharma Mission, Antimicrobial Resistance, Genome India to name a few. She was also a member of the Task Force on Women in Science constituted by the Scientific Advisory Committee to the Prime Minister. As the Secretary of Government of India, Department of Biotechnology, she leads a Network of 16 Autonomous Research Institutes, 2 Public Sector Undertaking and a R&D Network of more than 5000 projects across more than 100 research institutes, Universities and Laboratories. In the recent COVID Pandemic situation she has led the COVID Vaccine and Diagnostic Mission. The Public Sector BIRAC, for which she is the founding Managing Director and now Chairperson, has supported nearly 3000 Startups and over 50 Incubators. A Fellow of the National Academy of Sciences (NASI) India, A Life Member of Trust for Advancement of Agricultural Sciences (TAAS) and a Member of the Organization for Women in Science for the Developing World (OWSD), she was awarded the "BioSpectrum Person of the Year Award" in 2012. "National Entrepreneurship Awards 2017", TiE WomENABLER Award 2018, "Dr. P. Sheel Memorial Lecture Award" 2018 by NASI and the TWAS Regional Office Prize on Science Diplomacy in 2018. She has been awarded the Agriculture Research Leadership Award 2019.