

DR SONALI KOCHHAR,

M.D.

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SECTION A: INDIVIDUAL INFORMATION

A.1. Personal Information

Name	Sonali Kochhar, MD
Post or Position	<ul style="list-style-type: none">• Medical Director, Global Healthcare Consulting• Clinical Associate Professor, Department of Global Health, University of Washington, Seattle
Employer, Research Institution or Affiliation	Global Healthcare Consulting; University of Washington, Seattle

A.2. Short Biography

Dr Sonali Kochhar, MD, Clinical Associate Professor, Department of Global Health, University of Washington, Seattle, and Medical Director, Global Healthcare Consulting has over two decades of leadership experience for global vaccine and drug development, including Phase I-IV clinical research, safety and epidemiology studies, and implementation research conducted in USA, Europe, Africa and Asia in adult, maternal, adolescent and pediatric populations; Infectious diseases (COVID-19, HIV/AIDS, tuberculosis, influenza, group B streptococcus, respiratory syncytial virus, middle east respiratory syndrome, rift valley fever, lassa, nipah, ebola, zika, chikungunya, pertussis, polio eradication, diarrheal diseases, and tropical diseases); maternal immunization (MI); safety, regulatory and ethical strategies for vaccines clinical research and implementation (including for epidemics, and pregnant women); pandemics and epidemics preparedness and response; introduction of new vaccines; increasing immunization coverage and acceptance; vaccine policy recommendations; translating research into impactful programs by policy, strategy and communications development and healthcare systems strengthening for immunization programs; clinical trial data sharing; and research with vulnerable and at-risk populations (including pregnant women, children and immunocompromised). Her work has informed global and country specific vaccine policy recommendations. She has been very involved in national, regional and global response efforts for COVID-19 including the development of COVID-19 vaccines, their safety assessment and implementation.

Dr Kochhar has led multiple research programs in Kenya, Uganda, Zambia, The Gambia, South Africa, the United States, Belgium, Germany, India, Bangladesh and Nepal, focusing on vaccines clinical research; safety evaluation of vaccines (including in pregnant women and immunocompromised); MI; introduction of new vaccines and increasing immunization coverage and acceptance. She provides expertise for vaccine research and development and safety (including for viral vectors, nucleic acid (DNA and RNA), inactivated, live-attenuated, protein vaccines and adjuvants).

She has led multi-country vaccines development programs in the private and non-profit sector, including the development and management of the clinical and regulatory strategies, clinical development plans, target product profiles, protocols, investigators brochures, informed consent, care and treatment guidelines, vaccine safety assessment, AESI and background rates determination, pharmacovigilance including risk management plans, risk evaluation and mitigation strategies and benefit-risk assessment pre- and post-licensure) for the global clinical development. She has been responsible for the design, implementation, and evaluation of the multi-country clinical research and successfully built and led large international clinical research teams.

She has co-authored internationally accepted guidance, research standards, protocol templates and adverse events case definitions for vaccine clinical research, MI and safety. She has led the development of standardized vaccine templates for the benefit-risk assessment of vaccines, which have been recommended by WHO's Global Advisory Committee on Vaccine Safety (GACVS), and are being utilized by COVID-19 and other vaccine developers. She helped set up and lead the Gates Foundation funded multi-year Global Alignment of Immunization Safety Assessment in Pregnancy (GAIA) network, a critical program for vaccine safety, with partners in over 90 countries. She helped develop 26 novel Maternal and Neonatal Case Definitions for adverse events detection and evaluation, ensuring their applicability in LMICs. The definitions and guidance are being utilized in clinical research, epidemiological studies and pharmacovigilance for vaccines and MI globally.

For COVID-19 vaccines, she is helping to develop the WHO SAGE policy recommendations for the use of the different vaccines. She helped lead the development of the "WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply" and the "WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination"; helped develop the "Critical Evidence Questions For COVID-19 Vaccines Policy Making" and the "WHO COVID-19 Vaccines Safety Surveillance Manual". This is work being utilized for international and national policy making and vaccine introduction globally.

She is providing support for pharmacovigilance and health systems strengthening in LMICs for the introduction of COVID-19 vaccines. She has led immunization programs strengthening by policy, strategy and communications development and healthcare systems strengthening (including evaluation, capacity building, supply chains strengthening, and new technology development and implementation). She has led work on increasing immunization coverage and acceptance in LMICs, and new vaccine introduction, working in close collaboration with the National EPI teams.

Dr Kochhar has helped set up international strategic partnerships, and led policy development, institutional strengthening, and advocacy with government partners and ministries of health, regulatory bodies (including the FDA, EMA, African and Asian National Regulatory Authorities), ethical committees, scientific organizations, international aid agencies (including the Gates Foundation (BMGF), USAID, Wellcome Trust and MRC), public health authorities, international and bilateral organizations (including WHO, NIH, CDC, World Bank), pharmaceutical companies, key opinion leaders, local communities, patient groups and the media. She has a track-record for launching and coordinating public private vaccine

development partnerships to accelerate the development, clinical research, registration, introduction and commercialization of vaccines and drugs of public health importance for LMICs, including with international pharmaceutical companies, and national government partners.

She serves on several advisory panels including the WHO Strategic Advisory Group of Experts on Immunization (SAGE); WHO SAGE Working Group on COVID-19 vaccines; WHO Global Advisory Committee on Vaccine Safety (GACVS) Working Group on COVID-19 Vaccines Safety Preparedness; Co-Chair of the WHO ACT (Access to COVID-19 Tools)-Accelerator Ethics & Governance Working Group; Wellcome Trust's Independent Review Panels for Clinical Study Data Requests, and Vivli (Centre for Global Clinical Research Data Sharing); international executive Committees including the International Network of Special Immunization Services (INSIS) Steering Committee; MRC funded Immunizing Pregnant Women and Infants (IMPRINT) network and the co-lead for the challenge on vaccine safety monitoring in LMIC; International Alliance for Biological Standardization, Switzerland's Human Vaccine Committee; and Vice-Chair and elected member of the International Brighton Collaboration Science Board. She is a Research Committee member of the Infectious Diseases Society of America (IDSA); Expert Evaluator for the European Commission; Medical Research Council, UK; and Canadian Institutes of Health Research; and a Medical Advisory Panel member of Group B Strep Support, UK. She was an Expert Committee member of the National Academies of Science, Engineering, and Medicine on Clinical Trial Data Sharing; served on the International Steering Committee of the WHO Consultation on Safety of Immunization in Pregnancy in Mothers and Newborn Children; BMGF's Global Health Clinical Consortium Leadership Group; Expert Working Group of the Wellcome Trust funded PREVENT (Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies) Project; Core Planning Team of the BMGF funded Maternal Immunization Pharmacovigilance programs for LMICs and Harvard University's Multi-Regional Clinical Trial Group.

Kochhar serves as Guest Faculty for International Vaccinology Programs, as a reviewer for journals like Lancet, Nature, Vaccine etc. and has published over 115 publications and reviews (including in the Lancet, Nature, JAMA, Annual Review of Virology), and book chapters on vaccine research, MI, safety, health systems strengthening and COVID-19. She is a member of academic societies, including the Infectious Diseases Society of America (IDSA), American Academy of Pediatrics and the European Society of Pediatric Infectious Diseases (ESPID).

She has received multiple awards including the Yale World Fellowship for 2011 (Yale University's International Leadership Program); Vaccinology Fellowship Award for significant achievements in Vaccinology from Fondation Mérieux and University of Geneva; Global Leadership Awards from Eli Lilly & Company, Indianapolis, U.S.A; Bharat Jyoti (Light of India) Award for medical achievements and the Serviers Young Investigator Award from Institut de Recherches Internationales, Servier, France.

SECTION B: DISCLOSURES

B.1. Financial Interests

None

B.2 Other Real or Potential Conflicts of Interest

None