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SECTION A: INDIVIDUAL INFORMATION

A.1. Personal Information

Name	Sonali Kochhar, MD
Post or Position	• 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 25 years of leadership experience for global vaccines development in the pharmaceutical industry, product development partnerships and consulting. This includes leading Phase I-IV clinical research, safety studies and implementation research conducted in USA, Europe, Africa and Asia in adult, maternal, adolescent, and pediatric populations; vaccines for infectious diseases (including H5 avian influenza, Mpox, Lassa, Middle East Respiratory syndrome, Rift Valley fever, Nipah, COVID-19, HIV/AIDS, Tuberculosis, Chikungunya, Group B Strep, Respiratory Syncytial virus, Ebola, Zika, Measles, Mumps, Rubella, Shigella and other diarrheal and tropical diseases); maternal immunization (MI); safety, regulatory and ethical strategies for novel 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, advocacy, building functional pharmacovigilance (PV) systems, 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 novel vaccines including the development of the vaccines, their safety assessment, policy development and implementation.

Dr Kochhar has led vaccine research programs in Kenya, Uganda, Zambia, The Gambia, South Africa, the United States, Belgium, Germany, India, Bangladesh and Nepal. She provides expertise for vaccine research and development and safety (including for viral vectors, nucleic acid (DNA and RNA), inactivated, live-attenuated, protein vaccines, adjuvants and vaccines inducing mucosal immunity).

She has led multi-country clinical development programs, including the development and management of the clinical and regulatory strategies, clinical development plans, target product profiles, protocols, investigators brochures, participant care and treatment guidelines, safety assessment, AESI and background rates determination, Pharmacovigilance including AESI and background rates determination, risk management plans, risk evaluation and mitigation strategies, benefit-risk assessment pre-and post-licensure, and use of innovative clinical trial designs for global vaccine development. She has been responsible for the design, implementation, and evaluation of multi-country vaccine clinical research programs and has successfully built and led large international teams for clinical research, registration and post marketing support.

She has co-authored internationally accepted guidance, research standards, protocol templates and case definitions for vaccine clinical research, MI and safety. She is working on determining how to develop novel vaccines that will elicit mucosal immunity. She is helping characterize the clinical risk factors and biomarkers associated with rare AEFIs and determine the best way to immunize individuals with risk factors for AEFIs. She is helping set up a pregnancy registry in a low-income country in Africa to help in the introduction of new vaccines for pregnant women in LMICs. She has led the development of a standardized module for vaccine benefit-risk assessment, which is being utilized by vaccine developers, funders and LMIC National Regulatory Authorities. She is determining the benefit-risk for novel vaccines for vaccine developers, funders and LMIC regulators for decision making. She had led the development of standardized templates for the safety assessment of vaccines from different platforms, which have been recommended by WHO's Global Advisory Committee on Vaccine Safety (GACVS), and are being widely utilized by vaccine developers and funders. She has developed over 30 standardized case definitions for AEFIs for use in high income and LMICs and developed expedited case definitions for priority AEFIs for use in outbreaks. She helped set up and lead the Global Alignment of Immunization Safety Assessment in Pregnancy (GAIA) network, a critical program for MI 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, PV, epidemiological studies and implementation research for vaccines and MI globally. She helped develop the "WHO COVID-19 Vaccines Safety Surveillance Manual" which is being used for vaccine pharmacovigilance globally.

For vaccine policy development and to help mitigate delays in post-licensure vaccine implementation, she helped lead the development of the WHO Evidence Considerations for Vaccine Policy (ECVP) framework, to help in early (pre-phase 3 trial design) alignment between regulators, policy makers and the national, regional and global stakeholders on the clinical trial and observational data or evidence needed for policy and program decisions for new vaccine classes. She helped lead the development of the ECVP for TB vaccines for adolescents and adults, and is helping in the development of the ECVP for GBS vaccines and Measles-Rubella Microarray Patches.

She is providing support for new vaccines implementation and strengthening vaccine safety activities in LMICs. She has led immunization programs strengthening by policy and strategy 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 advocacy for vaccine development 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 BMGF, CDC, 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 Product Development for Vaccines Advisory Committee (PDVAC); Chair of the WHO SAGE Working Group (WG) on COVID-19 vaccines; Co-Chair of the WHO Technical Advisory Group on Evidence for Clinical and Policy Considerations for New Tuberculosis Vaccines, Advisory Board for Bill & Melinda Gates Medical Research Institute for the TB Vaccine Phase 3 trial; Gavi Independent Review Committee; WHO ad-hoc Technical Expert Group on H5 avian influenza vaccines; WHO Technical Advisory Group on Measles and Rubella Microarray Patches (MR-MAPs); WHO Emergency Research Ethics Committee; WHO Expert Steering Committee on Safety Surveillance in Pregnancy in LMICs; WHO Technical group for AESI background rate protocol development; Co-Chair of the WHO Expert Group on ethics & governance of infectious disease outbreaks and other emergencies of public health importance; Chair of the Independent Review Panels for Clinical Study Data Requests, and Vivli-Centre for Global Clinical Research Data; 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; and invited expert for a US Congressional Briefing on vaccines. 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 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 Gavi's Vaccine investment Strategy (VIS) Steering Committee; Co-Chair, Gavi VIS WG on Immunization Platforms; Co-Chair of the WHO Evidence Considerations for Vaccine Policy (ECVP) WG; Co-Chair of the WHO Technical Advisory Group on GBS Vaccine Development; WHO Global Advisory Committee on Vaccine Safety (GACVS) Working Group on COVID-19 Vaccines Safety Preparedness; Chair of the Brighton Collaboration Science Board; Co-Chair of the WHO COVID-19 Ethics & Governance WG; WHO Technical Advisory Group on the Development of a Roadmap for Global Introduction of New TB Vaccines; Co-Chair of the WHO Ethics and Monkeypox WG; 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 funded PREVENT (Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies) Project; Core Planning Team of the BMGF funded MI PV 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 and Nature etc. and has published over 160 publications and reviews (including in the Lancet, Nature and Annual Review of Virology), and book chapters on vaccine research, MI, vaccine safety and PV, with a h-index of 56. 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