DR SONALI KOCHHAR
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SECTION A: INDIVIDUAL INFORMATION

A.1. Personal Information

Name	Sonali Kochhar, MD
Post or Position	• Clinical Professor, Department of Global Health, University of Washington, Seattle • Medical Director, Global Healthcare Consulting
Employer, Research Institution or Affiliation	Global Healthcare Consulting; University of Washington, Seattle

A.2. Short Biography

Dr Sonali Kochhar, MD, Clinical Professor, Department of Global Health, University of Washington, Seattle, and Medical Director, Global Healthcare Consulting, is a physician-scientist with over 26 years of leadership experience in global vaccines and drugs development, safety studies, policy and implementation in the pharmaceutical industry, product development partnerships and international consulting organizations. Her work has influenced the development, evaluation, licensure, introduction and safe implementation of vaccines and drugs globally, shaping international and national immunization policies, clinical research standards and immunization programs across low-and-middle-income countries (LMICs).

She has led Phase I-IV clinical research, safety studies and implementation research conducted in USA, Europe, Africa and Asia in adult, maternal, adolescent, and pediatric populations. Dr Kochhar works on vaccines for infectious diseases (including Tuberculosis, Ebola Bundibugyo, H5 influenza, Mpox, Lassa, Middle East Respiratory syndrome, Rift Valley fever, Nipah, COVID-19, HIV, Chikungunya, Dengue, Group B Strep, Respiratory Syncytial virus, Ebola, Zika, Measles Rubella MAPs, diphtheria vaccines for outbreak response, Shigella and other diarrheal and tropical diseases); maternal immunization ; 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, capacity building of national committees, National Regulatory authorities and EPI program leadership, building functional pharmacovigilance (PV) systems, and healthcare systems strengthening for immunization programs; clinical trial data sharing; and research with at-risk populations (including pregnant women, children, and immunocompromised).

Dr Kochhar has led vaccines research programs in Kenya, Uganda, Zambia, The Gambia, South Africa, the United States, Belgium, Germany, India, Bangladesh and Nepal. She has extensive expertise across multiple vaccine platforms, including viral vectors, nucleic acid (DNA and

RNA), inactivated, live-attenuated and protein-based vaccines and novel adjuvants. She has led work to accelerate the development of novel vaccines to elicit mucosal immunity for priority respiratory, enteric and genitourinary pathogens.

She has led multi-country clinical development programs from early development through licensure and post-marketing evaluation, 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 risk management plans, risk evaluation and mitigation strategies, benefit-risk assessment pre-and post-licensure, and innovative clinical trial designs. She has been responsible for the design, implementation, and evaluation of multi-country vaccine clinical research programs and has built and led large multidisciplinary international teams for clinical research, registration and post licensure evidence generation.

Dr. Kochhar has contributed to advancing global vaccine safety science. She has co-authored internationally adopted guidance documents, research standards, protocol templates and standardized case definitions for vaccine clinical research, maternal immunization and safety. Combining clinical approaches with systems biology adversomics, she is helping to identify biomarkers associated with rare adverse events following immunization (AEFI) to inform risk-benefit assessment, identify at risk populations and predict potential for AEFIs with new vaccines before implementation. She has led the development of a standardized module for vaccine benefit-risk assessment and is determining the benefit-risk for novel vaccines for vaccine developers, funders and LMIC regulators for decision making. She has supported the establishment of a pregnancy registry in a low-income country in Africa to help in the introduction of new vaccines for pregnant women in LMICs.

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, including CEPI funded programs. She has contributed to the development of over 34 standardized case definitions for AEFIs for use in high income and LMICs and developed expedited case definitions for priority AEFIs. Dr Kochhar helped set up and lead the Global Alignment of Immunization Safety Assessment in Pregnancy (GAIA) network, a critical program for maternal immunization 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, pharmacovigilance, epidemiological studies and implementation research for vaccines and maternal immunization globally. She helped develop the "WHO COVID-19 Vaccines Safety Surveillance Manual" which supports vaccine pharmacovigilance globally.

For vaccine policy development and to help mitigate delays in post-licensure vaccine implementation, she co-led development of the WHO Evidence Considerations for Vaccine Policy (ECVP) framework, which promotes early (pre-phase 3 trial design) alignment between regulators, policy makers, vaccine developers and public health stakeholders regarding the

evidence needed for policy recommendations and vaccine introductions. She co-led 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 successfully helped launch and coordinate public private vaccine development partnerships to accelerate the development, clinical research, registration and introduction of vaccines and drugs of public health importance for LMICs, including with international pharmaceutical companies, and national government partners.

Dr Kochhar serves on numerous international scientific and policy advisory bodies including the WHO Strategic Advisory Group of Experts on Immunization (SAGE); WHO Product Development for Vaccines Advisory Committee (PDVAC); Chair Independent Review Panels for Vivli-Centre for Global Clinical Research Data, and Clinical Study Data Requests; Chair WHO expert group on diphtheria outbreak response vaccination; Co-Chair of the WHO Technical Advisory Group on Evidence for Clinical and Policy Considerations for New Tuberculosis Vaccines; Gavi Independent Review Committee; 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; Steering Committee of the International Network of Special Immunization Services (INSIS). She is a Research Committee member of the Infectious Diseases Society of America (IDSA); International Society for Pharmacoepidemiology (ISPE) Public Policy Committee; Expert Evaluator for the European Commission; Medical Research Council, UK; and a Medical Advisory Panel member of Group B Strep Support, UK. She has served on expert committees for the US National Academies of Science, Engineering, and Medicine; Chair of the WHO SAGE Working Group (WG) on COVID-19 vaccines; Advisory Board for Bill & Melinda Gates Medical Research Institute for the TB Vaccine Phase 3 trial; served on the WHO Technical Expert Group on H5 avian influenza vaccines; MRC funded Immunizing Pregnant Women and Infants (IMPRINT) network and the co-lead for the challenge on vaccine safety monitoring in LMIC; invited expert for a US Congressional Briefing on vaccines; 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.

Dr Kochhar serves as Guest Faculty for International Vaccinology Programs, as a reviewer for journals like The Lancet and Nature and has authored numerous publications and reviews (including in The Lancet, Nature and Annual Review of Virology), and book chapters on vaccine development, maternal immunization, vaccine safety and pharmacovigilance with over 1,40,000 citations and a h-index of 66. 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