CoRE SCIENTIFIC CONFERENCE

Patients as Partners for Health:
Co-creating Equitable Access to Health Products and Services

5 - 6 October 2022 | 9.00AM*- 4.30PM SGT | Hybrid Event
Ngee Ann Kongsi Auditorium, Academia
20 College Rd, Singapore 169856

Session Chairs, Speakers, and Panellists

DukeNUS Medical School | Centre of Regulatory Excellence

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Welcome remarks by Scientific Chair	
Adj Prof John Skerritt	**Adjunct Professor, University of Sydney** **Deputy Secretary, Australian Department of Health** **Special Advisor, CoRE Advisory Board** **Australia** Adjunct Prof John Skerritt joined the Australian Department of Health in 2012 as a Deputy Secretary. In this role he has been part of national leadership of Australia's response to the COVID -19 pandemic as well as regular spokesperson on TV, radio, print and online media and with community groups. He also has line responsibility as head of Australia's medicine, medical devices, cell and tissue and blood regulator, the Therapeutic Goods Administration as well as leading the Australians Office of Drug Control. He was formerly a Deputy Secretary in the Victorian Government, Deputy CEO of a Commonwealth Statutory Authority, senior research manager in CSIRO and in industry joint venture partnerships. From 2009-2012, he was Chair of the Board of a global technical NGO, and a board member for two further years. Apart from development assistance and governance skills he has extensive experience in medical, agricultural and environmental policy, as well as regulation, research management, technology application and commercialisation. Prof Skerritt is an Adjunct Full Professor at three Australian Universities, has a PhD and a University Medal from the University of Sydney, and international qualifications (London Business School, IMD Switzerland) in management. Prof Skerritt has extensive experience in working in all countries of South East Asia, having travelled for business to various SE Asian countries over 150 times in the last 30 years. He has been awarded medals by the Vietnamese and Cambodian Governments for contributions to national technological and economic development of both countries. He was also the 2012 winner of the Rotary "Global Alumni Service to Humanity Award", for leadership of development assistance for education, food security and income generation in response to the East Timor crisis and the response to the South East Asian 2004 boxing day tsunami and leadership in the environmental NGO sector. Currently he leads a program of assistance to support regulatory strengthening, including in the response to COVID-19 in Asia-Pacific developing countries. Prof Skerritt is also chair of the Asian Development Bank's Regional Vaccine Advisory Group, established by the President and Board of ADB in response to the COVID-19 pandemic.

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Welcome remarks by Scientific Vice Chair	
Dr Lembit Rägo	**Secretary-General** **Council for International Organizations of Medical Sciences (CIOMS)** **Switzerland** Dr Lembit Rägo, MD, PhD, graduated from the Medical Faculty of Tartu University (Estonia) in 1979. He was Prof of Pharmacology and Clinical Pharmacology at Tartu University 1983—1999. He is also a founder of the Estonian Drug Regulatory Authority, the State Agency of Medicines and its first Director General 1991—1999. In December 1999, he joined the World Health Organization (WHO) Headquarters in Geneva as Coordinator of the Quality Assurance and Safety of Medicines (QSM) team. In 2001 he started the WHO Medicines Prequalification Program, which does the regulatory assessment of products for purchase by UN-funded programs. At WHO he led work to strengthen regulatory systems including combatting falsified medicines, and the development of pharmacovigilance and regulatory networks in Low- and Middle Income Countries. In September 2013, he was appointed as Head of the newly formed WHO unit - Regulation of Medicines and Other Health Technologies (today Department of Regulation and Prequalification), which, for the first time in WHO history, combined all regulatory activities for medicines, vaccines and diagnostics in one unit. Since 2000, he has served as an observer to the International Council for Harmonization (ICH), first representing WHO and now representing Council for International Organizations of Medical Sciences (CIOMS). In 2016, he was selected to the position of Secretary-General of CIOMS. CIOMS is very active in issuing international guidance documents in pharmacovigilance, product development and research ethics. At present CIOMS has seven active working groups. The latest CIOMS report from Working Group XI Patient Involvement in the Development, Regulation and Safe Use of Medicines was published in September 2022.
Opening speech by Guest of Honour	
Dr Janil Puthucheary	**Senior Minister of State** **Ministry of Communications and Information &** **Ministry of Health** **Singapore** Dr Janil Puthucheary, 49, was elected Member of Parliament in 2011. He is currently Senior Minister of State, Ministry of Communications and Information, and Ministry of Health. He chairs OnePeople.sg, which works to promote racial harmony in Singapore. His political roles include Chair of Young PAP (the youth wing of the People's Action Party), and Whip.
Plenary I - Patients as Active Partners in The Development, Regulation, and Use of Medicines	

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Prof John Lim	**Executive Director, Centre of Regulatory Excellence** **Duke-NUS Medical School** **Senior Advisor** **Ministry of Health, Singapore** **Chairman** **Consortium for Clinical Research & Innovation, Singapore (CRIS)** Prof John CW Lim is founding Executive Director of the Centre of Regulatory Excellence (CoRE) at the Duke-National University of Singapore Medical School (Duke-NUS), inaugural Chairman of the Consortium for Clinical Research & Innovation Singapore (CRIS), Senior Advisor at Singapore's Ministry of Health (MOH), and Policy Core Lead at the SingHealth Duke-NUS Global Health Institute (SDGHI). He is Prof of Practice at Duke-NUS and the NUS Saw Swee Hock School of Public Health. Formerly Chief Executive Officer of Singapore's Health Sciences Authority and Deputy Director of Medical Services (Industry & Research Matters) in MOH, Prof Lim has also held other senior positions in Singapore's Health and Education ministries. His current roles promote capacity building and scientific excellence for health products regulation, health policies and systems in Southeast Asia and the Asia-Pacific. Prof Lim is a member of the Singapore Food Agency Board, APEC Life Sciences Innovation Forum's Executive Board, Davos Alzheimer's Collaborative Leadership Group, US Pharmacopoeia (USP) Council of the Convention as Asia-Pacific Chapter Chair, USP Quality Institute's Advisory Group, Centre for Innovation in Regulatory Science's Scientific Advisory Council, and St Andrew's Mission Hospital Board. In 2018, Prof Lim received the Drug Information Association's Global Connector Inspire Award for leadership in promoting global collaboration to advance healthcare products to patients, and the Regulatory Affairs Professional Society's highest Founder's Award recognising substantial sustained impact in shaping regulatory practice and policy over the course of his career.
Mr François Houÿez	**Director** **Treatment Information and Access** **European Organisation for Rare Diseases (EURORDIS)** **France** Mr François Houÿez is working at the European Organisation for Rare Diseases (EURORDIS) where he is Director of Treatment Information and Access. He has always been working as a patient advocate since the early 90s, first in the HIV/AIDS advocacy, and in rare diseases since 2003. He pioneered patient advocacy with the European Medicines Agency as part of the first patients' delegation that engaged dialogue with the Agency back in 1996. As member of Community Advisory Boards, he reviewed 77 clinical trial protocols. He represents Eurordis at the Patients' and Consumers' Working Party at the European Medicines Agency (EMA). He has been involved in the European Network for Health Technology Assessment (EUnetHTA) since 2010.

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	He is member of the board of management of the Get Real Institute. His expertise includes Community Advisory Boards, compassionate use, drug repurposing, involvement of patients in regulatory and HTA activities, drug shortages, pharmacovigilance, marketing authorisation, HTA, pricing and reimbursement, cross-border care. He is one of the trainers at EURORDIS Summer School on clinical development. François is also a patient.
Dr Yasuhiro Fujiwara	**Chief Executive** **Pharmaceuticals and Medical Devices Agency** **Japan** Dr Yasuhiro Fujiwara has taken his position as Chief Executive of Pharmaceuticals and Medical Devices Agency (PMDA) since April 1, 2019. He has been elected Co-chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) from 1st October 2019. Dr. Yasuhiro Fujiwara was previously Director-General, Strategic Planning Bureau of the National Cancer Center, and Deputy Director of the Hospital, National Cancer Center Hospital. He is a medical oncologist, specializing in breast cancer. Before joining National Cancer Center Hospital, he was Deputy Director of the Evaluation Division II of the Pharmaceuticals and Medical Devices Evaluation Center of the National Institute of Health Sciences (PMDEC, which later merged with other organizations to form PMDA) of the Ministry of Health and Welfare and Labor between 1997 –2002, making his current position as Chief Executive his second appointment. Between Jan 2011 to Feb 2013, he was Deputy Secretary General of Office of Medical Innovation, Cabinet Secretariat of Japan, and led health policy issues regarding life science. Dr Fujiwara has authored or co-authored over 280 original articles in peer-reviewed journals including Nature Reviews Drug Discovery, Lancet Oncology, Journal of Clinical Oncology, Annals of Oncology. He is an active member of American Society of Clinical Oncology (between 2003 and 2006, he was International Affairs Committee's member), and Board Member of Japanese Society of Medical Oncology (JSMO) (He was the President of 2019 JSMO annual meeting, held in Kyoto). He is on the Editorial Board of Cancer Chemotherapy and Pharmacology; Cancer Science; Investigation New Drugs; Asian-Pacific Journal of Clinical Oncology; Japanese Journal of Clinical Oncology.
Dr Margaret Hamburg	**Chair, CoRE Advisory Board** **Former Commissioner** **U.S. Food and Drug Administration** **United States of America** Dr Margaret Hamburg is the former Commissioner of the U.S. Food and Drug Administration (FDA), where she served for almost six years. In that role, she was known for advancing regulatory science, streamlining and modernizing FDA's regulatory pathways, and globalization of the agency. Before joining FDA, Dr. Hamburg was founding vice president and senior scientist at the Nuclear Threat Initiative, a foundation dedicated to reducing nuclear, chemical and

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	biological threats. Previous government positions include Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Health Commissioner for New York City, and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health. Dr Hamburg currently serves on numerous boards and advisory committees. She recently completed service as President/Chair of the American Association for the Advancement of Science and as Foreign Secretary, National Academy of Medicine. Dr Hamburg earned her B.A. from Harvard College and her M.D. from Harvard Medical School. Professional recognition includes numerous awards, honorary degrees and elected memberships.
Dr Juan Garcia Burgos	**Head** **Public and Stakeholders Engagement Department** **European Medicines Agency** **The Netherlands** Dr Juan García Burgos is a Qualified Medical Doctor from the University of Autonoma in Madrid, specialised in urology. Juan worked as a urologist surgeon at the hospital Gregorio Maranon in Madrid. He joined the European Medicines Agency (EMA) in 2002 in the scientific Units and was responsible for coordinating the preparation of EU clinical guidelines for drug development. He took up new responsibilities in 2005 where he was appointed Head of Medical and Health Information, being directly involved in the interaction with Patients, Consumers and HealthCare Professionals' Organisations and the preparation of information on benefit-risk of medicines for lay audiences. In January 2017, he was appointed Head of Public and Stakeholders Engagement Department and is Co-chair of the EMA patients' and healthcare professionals' working party.
Session 1 – Preclinical and Clinical Development	
Dr Joseph Scheeren	**Founder** **Scheeren HealthCare LLC** **Special Advisor, Former President and Chief Executive Officer** **Critical Path Institute** **United States of America** Dr Joseph Scheeren is the Founder of Scheeren HealthCare LLC and is a Special Advisor of Critical Path Institute (C-Path) Institute where he was President and CEO from April 2019 to April 2021. He is also a Non-Executive Director and Board Member of VacciTech since April 2021. In 2004, Dr Scheeren joined Bayer Pharmaceuticals as Senior Vice President, Head Global Regulatory Affairs and US Development. From 2012 to 2015, he was based in Beijing, China in a similar role for Asia. He combined the role Head Global Regulatory Affairs for Pharma and Consumer Care from 2015-2017. He left Bayer at the end of 2018 as Senior Advisor for R&D. Dr Joseph Scheeren draws his experience from his long career in the pharmaceutical industry, including senior positions in Servier, Serono and Aventis. Since January 2019, he is Adjunct Professor at Peking University for Regulatory Sciences in the Department of Clinical Research. In

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	addition, Dr Scheeren serves on Advisory Boards at the Center for Innovation in Regulatory Science, the Regulatory Affairs Track at Yale University, the Center of Regulatory Excellence in Singapore and the College of Pharmacy at the University of Arizona. He is also a foreign member of the Academie Nationale de Pharmacie in France, a member of the Forum of the National Academy of Sciences and a lecturer at Yale University. Dr Scheeren studied pharmacy at the University of Leiden.
Mr Jan Geissler	**Founder and CEO** **Patvocates** **Germany** As a CML patient since 2001, Mr Jan Geissler co-founded the patient advocacy organisations LeukaNET, European Cancer Patient Coalition, CML Advocates Network, Acute Leukemia Advocates Network and Workgroup of European Cancer Patient Advocacy Networks (WECAN). He was Director of the European Patients' Academy (EUPATI) and manages the German EUPATI platform. Jan represents patient perspectives in committees e.g. in the European Cancer Organisation, EHA, EuroBloodNET, iCMLf, German National Decade Against Cancer and the Ethics Committee of the Bavarian Chamber of Physicians. He is CEO of Patvocates, a think tank, consultancy and social enterprise on patient advocacy, health policy and patient engagement in research. He is work package leader in the IMI big data projects HARMONY and HARMONY-PLUS.
Dr Kimberley Kallsen	**Head of Global Clinical Development and Operations and Site Engagement** **Boehringer Ingelheim** **Germany** Dr Kimberley Kallsen is a cell biologist with public health expertise and +9 years international pharma industry experience. She has a proven track record in patient-centricity and clinical development, with strong engagement of healthcare professionals and patients, as well as cross-functional collaboration and international networking. Currently, she is Head of Global Clinical Development & Operations Patient & Site Engagement at Boehringer Ingelheim. In this role, she is leading the global patient- and site-centric clinical development strategy to create the best trial experience for patients and trial sites.
Ms Helen Green	**Senior Director** **Patient Experience** **Syneos Health** **United Kingdom** Ms Helen Green is the Senior Director of Patient Engagement Strategy Syneos Health. Currently based in the UK, she joined Syneos in the middle of the COVID pandemic back in 2020. Prior to joining Syneos, Ms Green was a Director at the Patient Recruitment Agency Langland, where she lead the US office in New York. Ms Green has over a decade of experience in patient recruitment and engagement, supporting indications from Oncology to CNS. She has always believed that patients should understand the options available to them, and see clinical trials as a potential path to treatment. She has

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	endeavoured to bring this passion into her work, and raise awareness of trials globally.
Session 2 – Benefit and Risk Assessment	
Mr Michael Gropp	**Member** **CoRE Advisory Board** **United States of America** Mr Michael Gropp was special representative for international affairs of the Advanced Medical Technology Association (AdvaMed) (Washington, D.C.) and Chair of the Eucomed (Brussels) International Affairs Task Force. He was a member of the Global Harmonization Task Force (GHTF) Steering Committee from its inception in 2000 until GHTF was disbanded in 2012, and a member of GHTF Study Group 1 (pre-market controls). He was also an active contributor to the Asia Harmonization Working Party from its founding in 1994. Mr. Gropp led work on medical device regulatory harmonisation in the Asia-Pacific Economic Cooperation (APEC) Life Sciences Innovation Forum and was a member of the advisory board to the APEC Harmonization Center in Seoul. Mr Gropp was the Co-Chair of the Global Medical Technology Alliance (GMTA), a group of national medical technology associations focused on international policy advocacy. In 2015-2017, Mr. Gropp served as a temporary adviser to the World Health Organization, Geneva, in development of the WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices (2017). Mr Gropp was Vice President, Global Regulatory Strategy with Medtronic, Minneapolis, USA, from November 2006 until retiring in May 2013. In October 2010, Mr Gropp received the Regulatory Affairs Professionals Society (RAPS) Richard E. Greco Award for his work to harmonise global medical device regulations and advocate for regulatory professional development. In 2010-2011, he chaired the RAPS Global Advisory Council to develop regulatory capacity, especially in less developed economies.
Ms Marilyn Metcalf	**Senior Director** **Patient Engagement** **GSK** **United States of America** Ms Marilyn Metcalf leads GSK's oncology patient engagement, partnering with patients as experts and colleagues. Together they enhance innovative treatments for people living with cancer and promote understanding of these medicines. She co-chaired US Patients as Partners in 2020 and 2021: co-chaired the National Academies of Sciences, Engineering, and Medicine Science of Patient Input Action Collaborative workshop; and is a lead author of CIOMS Working Group XI's guidance for patient involvement in the development and safe use of medicines. Previously she was Family Health International's project director of the NIH master contract for HIV vaccine research, was the head of GSK's international Decision Sciences team, led Centocor's Decision Sciences and R&D Portfolio Management team, led GSK's Benefit Risk Evaluation team, and was the head of GSK's Pharmacovigilance Centre of Innovation. She began her current role in June 2017.

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Dra Rr Maya Gustina Andarini	**Deputy for Control of Drugs, Narcotics, Psychotropics, Precursors and Addictive Substances** **Badan POM Indonesia** Dra. Rr. Mayagustina Andarini, Apt., M.Sc. served as Deputy Chairperson for Drugs, Narcotic, Psychotropic, Precursor and Addictive Substance Control, Indonesian FDA, since October 6, 2021. Previously, she is Chief Inspector from 2018 until 2021. She was born in Yogyakarta, Indonesia, on August 13, 1966. She graduated from Universitas Gadjah Mada, Yogyakarta, with a Bachelor of Pharmacy and Pharmacist Professional. In 2007, she completes her Master of Science degree in Molecular Toxicology from Vrije Universiteit Amsterdam. In her career journey, she awarded as The Best Poster Presenter Competition in The International Symposium on Molecular Targeted Therapy, Title: Inhibition of Human Cyp 2d6 Isoenzyme by Curcumin Analogues, Docking Simulations to The Cyp 2d6 Homology Model and Quantitative Activity Relationships in 2008. In cross-sectoral relations, she is involved in national organizations including Expert Council of the Indonesian Pharmacists Association (PP IAI) and General Secretary of the Association of Indonesian Cosmetic Scientists (PP HIKI).
Dr Iris Conela Tagaro	**Head, Clinical Research Section** **Food and Drug Administration** **Philippines** Dr Iris Conela A. Tagaro is a Pediatrician, and the current Head of the Clinical Research Section (CRS) – Product Research and Standard Development Division, Center for Drug Regulation and Research, Food and Drug Administration (FDA) – Philippines. She graduated from University of the Philippines (UP) - Los Banos with a Bachelor of Science in Biology (Major in Cell and Molecular Biology) in 2007. She pursued medical studies at the West Visayas State University, underwent medical internship training at the Philippine General Hospital from 2011 - 2012, and passed the Medical Board Exam in 2012. Following her interest in public health, Dr Tagaro joined the Doctors to the Barrios Program of the Philippine Department of Health (DOH) and was deployed for two years in the coastal-island Municipality of Villareal, Samar. During her service she managed the healthcare of a district with a population >30,000, including handling the public health emergency after Supertyphoon Haiyan. During that time, she also pursued a Master's Degree in Public Management (Major in Health Systems and Development) and graduated in 2014. Following her deployment, Dr. Tagaro underwent Pediatric residency training from 2015 to 2017 at the Medical City Manila, and is a Diplomate of the Philippine Pediatric Society. Currently she is pursuing a Master's Degree in Clinical Epidemiology at the UP - Manila. Her research interests lie in Clinical Protocols Improving Patient Care, Nutrition, Immunology, Clinical Epidemiology and Public Health.

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	Dr Tagaro worked under the Health Regulation Team (HRT) of the DOH as a Medical Officer from 2018 to 2020. The HRT is the oversight of the agencies involved in the regulations such as the FDA, Pharmaceutical Division, and the Health Facilities and Services Regulatory Bureau. At the start of the COVID-19 Pandemic, Dr. Tagaro joined the FDA as a medical specialist and was appointed as the Head of the CRS of the FDA Center for Drug Regulation and Research. The unit is involved in clinical trial regulations, review of non-clinical and clinical data as well as risk management plans and post authorization studies for new drug applications and emergency use authorization. Dr Tagaro has been a speaker in trainings, workshops, and conferences on Clinical Trial Regulations and access to drugs and vaccines during the COVID-19 pandemic.
Dr Marco Greco	**President** **European Patients' Forum** **Italy** Dr Marco Greco has been President of the European Patients' Forum since 2014. He was chairman of the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) from 2008 to 2014. He was the founder of the EFCCA Youth Group, and its leader from 2003 till 2007. He was appointed as patient representative by the European Commission in the Pharmacovigilance Risk Assessment Committee at the European Medicines Agency (EMA) from 2013 to February 2019. He has recently been selected as patient representative to EMA's Management Board for a three-year term starting on 15 June 2019. He holds a degree in Law from UCSC MILAN and a Ph.D. in Law and Religious Freedom. He is currently working as an attorney in his law firm.
Lunch Talk: Unlocking the Potential of Gene Therapy for Rare Diseases (Sponsored by Pfizer)	
Dr Roy Gomez	**Rare Disease Medical Lead for Emerging Asia** **Pfizer** **Singapore** Dr Roy Gomez is the Emerging Asia Medical Lead for Rare Diseases at Pfizer. After academia, Dr Gomez has had a career in the pharmaceutical industry for the last 25 years. His responsibilities included leading teams in the field of clinical development and clinical research from PI – IV in multiple disease areas and from proof of concept to assessing long term safety and efficacy of therapeutic agents. His specialist research interests include disease activity modelling and growth disorders. Dr Gomez was elected as a Co-Chair for the European Society of Endocrinology to represent the Pharma Industry (2019 – 2021) and is

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	a Fellow of the Institute for Clinical Research. He has authored many peer-reviewed articles in the field of Rare Diseases.
Dr Koh Ai Ling	**Consultant** **KK Women's and Children's Hospital** **Singapore** Dr Koh Ai Ling is an Associate Consultant Paediatrician in the Genetics Service, Department of Paediatrics at KK Women's and Children's Hospital. Her clinical and research areas include rare genetic disorders and inherited metabolic disorders. She has a strong interest in medical education and provides regular genetics and metabolic teaching for paediatric residents. She currently serves as a trainer in the Genetics Education for Healthcare Professionals workshop at SingHealth Academy which focuses on the application of a wide range of genetic tests, and the understanding of roles in genetic counselling and the legal framework regulating genetic testing.
Mr Rajakanth R	**Executive Director** **Rainbow Across Borders Ltd** **Principal Consultant** **Manifeste LLP** **Singapore** Mr Rajakanth R has 20 years of experience in healthcare advocacy, policy and governance. As Executive Director of Rainbow Across Borders, he has created and led specific illness patient access programmes and campaigns. He has also initiated and built an extensive network comprising policy makers, industry players, healthcare professionals and patients with regional and local platforms. As Principal Consultant at Manifeste LLP, Mr Rajakanth has been creating solutions for multiple stakeholders in economically and culturally diverse countries in the Asia Pacific region. He has been able to revitalise strategies to overcome a multitude of challenges in the healthcare sector. Mr Rajakanth strongly believes in the power of the patient voice and the need for a patient-centric community. Over the years, he has been actively supporting the patient community by creating opportunities for patient support groups to train, connect and collaborate in the Asia Pacific region.
Session 3 – HTA and Access	
Ms Fiona Pearce	**Senior Advisor** **HTA and Consumer Engagement and Education** **Agency for Care Effectiveness** **Ministry of Health** **Singapore** Ms Fiona Pearce is a Senior Advisor to the Agency for Care Effectiveness (ACE), Singapore's national HTA agency. She is one of the founding members of ACE and was responsible for developing the HTA methods and processes which the agency uses to conduct evaluations of drugs and vaccines to inform national subsidy decisions. She was also involved in establishing Singapore's national Rare

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	Disease Fund in 2019 which provides long-term, financial support to patients with rare genetic diseases, and more recently, has established the Consumer Engagement and Education (CEE) workstream in 2021 to encourage patient involvement in ACE's work. Prior to joining ACE, Ms Pearce was a Technical Advisor at the National Institute for Health and Care Excellence (NICE) for seven years, providing technical leadership on appraisals of medicines within the National Health Service (NHS) in the United Kingdom. She also established NICE's methods and processes to evaluate highly specialised technologies (ultra-orphan medicines) in 2013. Before NICE, Ms Pearce worked for the Cochrane Collaboration (renal group) in Australia and in the private sector in various market access functions to achieve reimbursement of drugs and vaccines in Australia and across the Asia-Pacific region. She has formal training in health economics, epidemiology and public health, completed in Australia and has had adjunct appointments at the National University of Singapore and Monash University Malaysia.
Ms Ann Single	**Chair** **HTAi Patient and Citizen Involvement in HTA Interest Group Coordinator and Advisory Committee Member** **Patient Voice Initiative** **Australia** Ms Ann Single is chair of the HTAi Patient & Citizen Involvement in HTA Interest Group. She is a very experienced patient and public involvement in health technology assessment professional. Over the past 20 years she's worked on policy and practice in Australia and overseas, beginning with directing communication and public involvement when health technology assessment was first established in Scotland. A contributor to many resources in use internationally, her focus is supporting patients, carers and their representatives to find and define their space in health technology assessment and ensuring their involvement is underpinned by a robust evidence base and appropriate processes. As Coordinator and Advisory Committee member of the Patient Voice Initiative, she develops and delivers capacity building workshops, webinars and resources for patients and their communities to promote practical actions to drive forward a culture of valuing patients in decision making in Australia. Ms Single has also authored many texts in this field, including co-editing the first book on patient involvement in health technology assessment. Her current wider work includes trialling plain language information about HTA applications to support more effective patient input about medicines being considered for reimbursement and co-developing and trialling a mentoring program for consumer members on Australian committees.

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	She is co-chair of the International Scientific Program Committee for HTAi 2022 Annual Meeting.
Dr Annabelle Borromeo	**Director** **The Centre for Nurse Impact and Patient Outcomes Action Lab Philippines** Dr. Annabelle R. Borromeo is a nurse by profession and an avid patient advocate by vocation. She graduated her basic nursing degree from the Philippines and continued with her post-graduate studies in 3 universities in the United States. While pursuing a nursing career, she quicky realized the importance of patient-centered care and the need to champion the patient's voice. She is currently the Citizen's Representative of the Core Committee, Health Technology Assessment Council (HTAC) of the Philippines. The role of the Citizen's Representative is to present the patient's/caregiver's perspective and to ensure that this view is considered in the deliberations. She also holds the position of Head of Quality and Patient Safety in the largest hospital network in the Philippines, the MetroPacific Hospital Holdings, Inc.
Dr Sophie Werkö	**Manager, International Relations & Patient Engagement SBU** **Swedish Council on Health Technology Assessment** **Sweden** Dr Sophie Werkö has an MSc in Business Administration and a PhD from the University of Stockholm. She has a longstanding engagement with HTA and started in HTA as Project Director at The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU). In 2012 she was appointed Manager of International Relations at SBU, responsible for coordinating SBU's international work. She has also led the work on Patient Involvement at SBU, being very active in the work on Patient Involvement, both in Sweden and internationally. As Chair of the International Network of Agencies for Health Technology Assessment (INAHTA) until 2020, she had an important role of leading the global network of publicly funded HTA agencies. She has participated in the work of the European network for Health Technology Assessment (EUnetHTA) since 2009 and represents Sweden in the EU HTA Network (HTAN). Recently she acted as regional advisor to the WHO Egypt office and the WHO in the EMRO Region. She publishes frequently in scientific journals and acts as reviewer and associate or deputy editor in several journals.
Dr Yot Teerawattananon	**Founder** **Thai Ministry of Public Health's Health Intervention & Technology Assessment Program** **Co-founder, Asia's Health Technology Assessment Network & International Decision Support Initiative** **Thailand** Dr Yot Teerawattananon is a medical doctor and health economist. He found the Thai Ministry of Public Health's Health Intervention and Technology Assessment Program (HITAP). He is also a co-founder of the Asia's health technology assessment (HTA) network, HTAsiaLink, and the international Decision Support Initiative (iDSI). These works have been used to inform health benefits package development in

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	Thailand and elsewhere across the globe. He has provided capacity building on HTA in low- and middle-income countries in Asia and Africa. Since 2018, he has been a visiting professor at Saw Swee Hock School of Public Health at National University of Singapore.
Mr Richard Vines	**Founder and Chairman** **Rare Cancers Australia** Mr Richard Vines and his wife, Ms Kate, established Rare Cancers Australia (RCA) in June 2012. The not-for-profit provides support to all Australian patients diagnosed with a rare or less common cancer - because rare does not mean you have to be alone. Mr Vines is a career and passionate advocate as he has experienced first-hand the lack of information, resources, support, research and treatment options available for patients, carers and families living with a rare or less common cancer, following Kate's diagnosis of Medullary Thyroid Carcinoma in 1991. He knows the power of lived experience and pairs this with his extensive experience and expertise in the business and not-for-profit sectors to partner with patients, experts and industry to improve the lives and outcomes of patients with rare and less common cancers. A graduate of the University of Melbourne where he studied maths and statistics, Mr Vines initially trained as an Actuary and worked in IT for several years, forming his own software company which he then sold in 1990 before embarking on a second successful software venture in Europe. Mr Vines returned to Australia in 1996 where he was retained by an American company to establish a presence in Australia. In 2001, he left the IT industry to work in a number of not-for-profits associated with politics and health, before establishing RCA where he currently holds the roles of Chair and Chief Executive Officer. His strong advocacy achievements in policy reform around research and access to treatments, wide influence and significant expertise have also led to Richard taking on several other leadership roles within peak oncology and research bodies including: • Convener and Chair of the National Oncology Alliance • Chair of the Australian Genomics Health Alliance's Community Advisory Board Deputy Chair of the Australian Genomics Cancer Medicines Program (Omico) • Advisory Board member of Medicines Australia • Committee Member of the Patient Voice Initiative Mr Vines also serves as an associate investigator on a number of research projects and is a highly sought-after speaker and spokesperson for cancer patient advocacy issues, both in Australia and across the Asia Pacific region.
Session 4 – Communication in Safety and Healthcare Delivery	
Dr Juan Garcia Burgos	**Head** **Public and Stakeholders Engagement Department** **European Medicines Agency** **The Netherlands**

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	Dr Juan García Burgos is a Qualified Medical Doctor from the University of Autonoma in Madrid, specialised in urology. Juan worked as a urologist surgeon at the hospital Gregorio Maranon in Madrid. He joined the European Medicines Agency in 2002 in the scientific Units and was responsible for coordinating the preparation of EU clinical guidelines for drug development. He took up new responsibilities in 2005 where he was appointed Head of Medical and Health Information, being directly involved in the interaction with Patients, Consumers and HealthCare Professionals' Organisations and the preparation of information on benefit-risk of medicines for lay audiences. In January 2017, he was appointed Head of Public and Stakeholders Engagement Department and is Co-chair of the EMA patients' and healthcare professionals' working party.
Ms Ai Ling Sim-Devadas	**Co-Chair** **SingHealth Patient Advocacy Network** **Global Patient and Family Advisory Board Member** **Beryl Institute** **Singapore** Ms Ai Ling Sim-Devadas is the founding Co-Chair of the SingHealth Patient Advocacy Network (SPAN) and is a cancer survivor. She is passionate about what patients and families can do to make healthcare better, safer and more patient and family centered. She has been shaping the role of SPAN in Singapore's healthcare system by bringing the voices of patients and families to the heart of healthcare to improve patient experience. To enable patient engagement in healthcare improvement projects, she has worked with healthcare teams to drive training programmes for patient advocates as well as develop a patient engagement guide for healthcare professionals. With a strong professional background in healthcare communications, patient experience and volunteer management, she brings valuable perspectives from both ends of the care spectrum – that of a healthcare provider and a patient. Ms Sim-Devadas is a Certified Patient Experience Professional (CPXP). Beyond Singapore's shores, Ms Sim-Devadas is active in the global patient experience field. She serves as a Member of The Beryl Institute Global Patient and Family Advisory Board as the first Asian member on the board and aims to bring patients and families' perspectives from this region. The Beryl Institute is a global leading organization committed to elevating the human experience in healthcare. Besides patient advocacy she also volunteers with palliative care charities. She is a Board Member for Ambulance Wish Singapore, a charity for fulfilling last wishes for terminally ill patients.
Ms Adena Lim	**Deputy Director (Vigilance & Compliance)** **Health Sciences Authority** **Singapore** Adena Lim is the Deputy Director of the Vigilance and Compliance Branch of the Health Sciences Authority, Singapore (HSA). She had

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	participated as a trainer and speaker at the following local and international workshops and courses: the APEC Harmonisation Centre's Pharmacovigilance Workshop and Training, the APEC RHSC Centre of Excellence workshop "Multiregional Clinical Trials", the Inaugural in-country Regional Pharmacovigilance Training in Lao PDR and Cambodia, organised by DUKE-NUS Centre of Regulatory Excellence (CoRE), the Fourth Asia Pacific Pharmacovigilance Training Course organized by JSS University and the Uppsala Monitoring Centre and the Duke-NUS CoRE Graduate Certificate course in the Fundamentals in Pharmaceutical Regulation. She is currently a member of the International Coalition of Medicines Regulatory Agencies (ICMRA) Vaccines Pharmacovigilance Network which is a platform for international regulators to share on safety signals from COVID-19 vaccines surveillance and its related communications, and also a member of the WHO Member State Mechanisms (MSM) Risk Communications Working Group. She was also a member of the ICH E2C Expert Working Group and Implementation Working Group on Periodic Benefit Risk Evaluation Report (PBRER). Adena has been working in the field of Pharmacovigilance (PV) for 16 years, with special interest in risk communications. During this time, she has overseen the major developments and advancement in the PV processes in Singapore and recently led her team in establishing PV processes for the post-market surveillance of the COVID-19 vaccines which harnesses the capabilities of the spontaneous reporting system as well as novel active surveillance tools to detect safety signals in the local population. She was also previously tasked with the post-market surveillance of the H1N1-2009 pandemic vaccine and the dengue vaccine. Adena has established the Risk Communications functions in HSA, largely overseeing safety communications to healthcare professionals, members of the public and industry stakeholders. Adena leads the Risk Communications team in her Branch and was the editor of the HSA Adverse Drug Reaction News Bulletin and the HSA Medical Device Alert circular. Adena had received the Masters of Pharmacy (Clinical Pharmacy) degree from the National University of Singapore. Prior to her current position in HSA, she was a clinical pharmacist in Singapore General Hospital for 6 years.
Dr Marco Greco	**President** **European Patients' Forum** **Italy** Dr Marco Greco has been President of the European Patients' Forum since 2014. He was chairman of the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) from 2008 to 2014. He was the founder of the EFCCA Youth Group, and its leader from 2003 till 2007. He was appointed as patient representative by the European Commission in the Pharmacovigilance Risk Assessment Committee at the European Medicines Agency (EMA) from 2013 to February

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	2019. He has recently been selected as patient representative to EMA's Management Board for a three-year term starting on 15 June 2019. He holds a degree in Law from UCSC MILAN and a Ph.D. in Law and Religious Freedom. He is currently working as an attorney in his law firm.
Plenary II – Putting the Patient at the Forefront of Patient Engagement	
Mr Rajakanth R	**Executive Director** **Rainbow Across Borders Ltd** **Principal Consultant** **Manifeste LLP** **Singapore** Mr Rajakanth R has 20 years of experience in healthcare advocacy, policy and governance. As Executive Director of Rainbow Across Borders, he has created and led specific illness patient access programmes and campaigns. He has also initiated and built an extensive network comprising policy makers, industry players, healthcare professionals and patients with regional and local platforms. As Principal Consultant at Manifeste LLP, Mr Rajakanth has been creating solutions for multiple stakeholders in economically and culturally diverse countries in the Asia Pacific region. He has been able to revitalise strategies to overcome a multitude of challenges in the healthcare sector. Mr Rajakanth strongly believes in the power of the patient voice and the need for a patient-centric community. Over the years, he has been actively supporting the patient community by creating opportunities for patient support groups to train, connect and collaborate in the Asia Pacific region.
Dr Elisabeth Oehrlein	**Founder and CEO** **Applied Patient Experience, LLC** **United States of America** Dr Elisabeth Oehrlein, Ph.D., MS, is a mixed-methods researcher with expertise in patient engagement and the role of patient experience data in drug development, value/health technology assessment, and real-world research. Before founding Applied Patient Experience, LLC, Dr. Oehrlein served on the senior leadership team at the National Health Council, where she was responsible for research and education programs. She has spoken widely on the topic of patient-centered research, including invited presentations at the National Academy of Sciences, the Council for International Organizations of Medical Sciences, and various Congressional Briefings. She is an active member of HTAi's Patient and Citizen Involvement Group, as well as the International Society for Pharmacoeconomics and Outcomes Research, where she has held leadership roles in the Patient-Centered and Real-World Evidence Special Interest Groups and is faculty for the short course "An Introduction to Patient-Focused Medical Product Development." She has published widely in medical, economic, and health policy journals and serves as an Associate Editor of Value in Health.

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	Dr. Oehrlein holds a BA from Franklin & Marshall College, an MS in Epidemiology from the University of Maryland School of Medicine's Department of Epidemiology and Human Genetics, and a Ph.D. in Pharmaceutical Health Services Research from the University of Maryland School of Pharmacy.
Prof Carmencita D Padilla	**Chancellor** **College of Medicine** **University of Philippines** Dr Carmencita D Padilla is a Professor of Pediatrics at the College of Medicine and currently Chancellor of the University of the Philippines Manila. She is the Founding Director of the Institute of Human Genetics and the Newborn Screening Reference Center at the National Institutes of Health. Recognizing her varied contributions to the academic growth of genetics in the Philippines, she was conferred Academician of the National Academy of Science and Technology (NAST) in 2008. Dr Padilla is a pioneer in genetics in the Philippines and the Asia Pacific region. In the Philippines, she is responsible for setting up the clinical genetic services at the Philippine General Hospital in 1990 and the various genetic laboratories now housed at the Institute of Human Genetics – National Institutes of Health (www.ihg.upm.edu.ph). She is also responsible for setting up of national newborn screening services in the Philippines, currently available in 7400+ health facilities in the country and being served by 7 newborn screening laboratories and 14 continuity clinics that monitor the long term care of the patients. In the Asia Pacific region, she is part of the pioneering group that established the Asia Pacific Society for Human Genetics and served as president in 2008-2010. Dr Padilla is council member of the Human Genome Organization, an international organization of scientists from 69 countries (www.hugo-international.org). In 2010, she was appointed country representative of NAST to the InterAcademy Partnership for Health, a global network of more than 150 academies in the world (www.interacademies.org). Dr Padilla has been a recipient of international and national awards. In 2019, she received the Robert Guthrie Award, Most Outstanding Professional of the Year in Medicine, and the Eric C. Nubla Excellence Award from the Professional Regulation Commission. Dr Padilla has more than 150 publications. In the area of policy making, she is responsible for the Newborn Screening Act of 2004 (Republic Act No. 9288) and the Rare Disease Act (Republic Act No. 10747).
Adj Prof Tarun Weeramanthri	**President** **Public Health Association of Australia** **Governing Council, World Federation of Public Health Association** **School of Population and Global Health** **University of Western Australia** Adj Prof Tarun Weeramanthri is President of the Public Health Association of Australia, a member of the Governing Council of the World Federation of Public Health Associations, and an adjunct professor in the School of Population and Global Health at the University of Western Australia.

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	He is a trained specialist in internal medicine and public health, and has a PhD in social medicine. He was Chief Health Officer in Western Australia (WA) from 2008 to 2018, and previously in the Northern Territory (NT) from 2004 to 2007. In 2014, he was awarded the Sidney Sax Medal by the Public Health Association of Australia for his contribution to public health nationally, and in 2022 he was made a member of the Order of Australia for service to public health administration. Over the last few years, he has focused on addressing the health impacts of climate change and assisting the COVID-19 response in various Australian states and nationally, including through major reviews on contact tracing and quarantine.
Session 5 – Strengthening the Culture of Patient Engagement in Health Systems in the Region	
Ms Nidhi Swarup	**Founder and President** **Crohn's and Colitis Society of Singapore** Ms Nidhi Swarup is the Founder and President of the Crohn's & Colitis Society of Singapore (CCSS) since 2012. The charity focuses on patient education, public awareness, patient support group and promotes research into Crohn's Disease, Ulcerative Colitis, and related inflammatory bowel diseases (IBD). She has facilitated the formation of IBD Patient Support Groups in Thailand, Malaysia, Philippines, and recently in India. She has been interviewed by leading Newspapers, TV, and Radio channels. Recently she launched the CCSS Podcast: 'Life Takes Guts' with Nidhi Swarup. As the President of the Rotary Club of Raffles City 2016-17 she raised S$160,000 to invite experts in Chromoendoscopy from USA to train about 100 Gastroenterologists from nine countries of the Asia Pacific Region. In January 2021 she was appointed to the Fee Benchmarks Advisory Committee, Ministry of Health. Ms Swarup is currently the Co-Chair Designate (International Collaboration), SingHealth Patient Advocacy Network (SPAN). An established Healthcare Thought Leader, she launched Nidhi-Kintsugi Pte Ltd in April 2021 and has been representing the Patient Voice as a panelist, speaker, and moderator at various local, regional, and global conferences, as well as seminars. Ms Swarup has two Master's Degrees: one in Operations Research and the other in Finance. She has coauthored the following papers: 1) Forming a support group for people affected by inflammatory bowel disease, Patient Prefer Adherence, 2017. 2) Hand in Hand: Tackling the burden of mental health issues in those living with Inflammatory Bowel Disease in Asia Pacific, Asian Organization for Crohn's and Colitis (AOCC), 2019. 3) Landscape of inflammatory bowel disease in Singapore, Intestinal Research, 2022.
Mr Rajakanth R	**Executive Director** **Rainbow Across Borders Ltd** **Principal Consultant** **Manifeste LLP** **Singapore**

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	Mr Rajakanth R has 20 years of experience in healthcare advocacy, policy and governance. As Executive Director of Rainbow Across Borders, he has created and led specific illness patient access programmes and campaigns. He has also initiated and built an extensive network comprising policy makers, industry players, healthcare professionals and patients with regional and local platforms. As Principal Consultant at Manifeste LLP, Mr Rajakanth has been creating solutions for multiple stakeholders in economically and culturally diverse countries in the Asia Pacific region. He has been able to revitalise strategies to overcome a multitude of challenges in the healthcare sector. Mr Rajakanth strongly believes in the power of the patient voice and the need for a patient-centric community. Over the years, he has been actively supporting the patient community by creating opportunities for patient support groups to train, connect and collaborate in the Asia Pacific region.
Ms Jenny Zhang	**Director of International Affairs** **House086 (China Lymphoma Patient Group)** **China** Driving by "patient-centered", Ms Jenny Zhang and her colleagues are committed to promoting patient advocacy for lymphoma patients in China.
Ms Doreen Tan	**Global Specialty Care Public Affairs Lead** **for China and International** **Sanofi** **Malaysia** Ms Doreen Tan is currently with Sanofi as Global Public Affairs Lead for China and International, Specialty Care Global Public Affairs. Prior to joining the global team, Ms Tan was Head of Market Access Thailand, Malaysia & Singapore and Head of Public Affairs Malaysia & Singapore where she led the access and public affairs strategies across the multi country organization. Ms Tan has over 20 years of pharmaceutical industry experience spanning regulatory affairs, public affairs, immunization policy and market access at both local and regional levels. She led the teams to set and execute partnership strategies driving a shared vision and value in advancing healthcare solutions. Ms Tan started her early career at Pfizer and Ministry of Health Malaysia. Doreen received her Bachelor's Degree in Pharmacy with Honors from University Science of Malaysia.
Dra Lucky Slamet	**Visiting Expert, CoRE Duke-NUS Medical School** **Former Head** **National Agency of Food and Drug Control** **Indonesia** Dra Lucky S. Slamet got her degree in Pharmacy (Degree Dra, 1978) and professional Pharmacist (Degree Apotheker, 1979) from the University of Indonesia, Jakarta. She had her post graduate study at Queen's University at Kingston Canada, majoring in Community Health and Pharmaco-Epidemiology studies (Degree MSc, 1991). She participated in several international trainings on regulatory aspects of

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	medicinal products, including vaccines (for example, WHO Global Learning Opportunity, WHO Global Benchmarking Tools for Assessors, Drug Policy Issues in Developing Countries, Clinical Trial, Drug Evaluation, Adverse Drug Reaction Monitoring, WTO TRIPs and Dispute Settlement Mechanism). Recently, she got the certificate for WHO GBT assessor from the WHO Training Workshop for WHO GBT Assessor conducted by WHO HQ, Istanbul Turkey, June 2022 For more than 30 years, she worked as regulator of medicinal products, including vaccine at the Indonesian Food and Drug Authority (BPOM), with the last 2 positions as the Deputy Head for Therapeutic Products and Narcotics, Psychotropics, and Hazardous from 2001-2011 and the Head of BPOM from 2012-2013 (June) until her retirement. Since 2013 (July) up till now, she dedicates her professional expertise as the technical / independent consultant for BPOM and as core member of the Indonesian National Drug and Vaccine Evaluation Committee. Since 1998 up till now, she has been a lecturer for master program (majoring, National Drug Policy, Regulation and Ethics in Pharmaceutical) in the leading national Indonesian Universities (Faculty of Pharmacy University of Gajah Mada, Indonesia; Faculty of Pancasila, Indonesia). She has lots of professional regulatory experiences in national, regional, and global level. Her major professional experiences at the national level among other, involvement in the Standardization and Regulation for Medicinal Products including Vaccine from 2001 till now (for examples, Development of the Indonesian Pharmacopeiea, Guideline on Drug Registration, Guideline on Biosimilar, Informatorium on COVID-19 Medicines and Vaccine, Guidance for Evaluation of Antibacterial Drug, Good Regulatory Practice). She was member of the Indonesian National Research Board (2012-2014); and WHO STC at the National Development Planning Agency (Bappenas) to conduct the Indonesian Health Sector Review for the Formulation on Background Study for National Medium Term Development Plan 2020 – 2024, Theme Area 7 : Drug and Food Control, including Food Safety (2018-2019). At the regional and global level, she was member of WHO ECBS / Expert Committee of Biological Standardization (2009 – 2016) and member of WHO ECSPP / Expert Committee on Specification for Pharmaceutical Preparations (2010 – 2013). She was chair of SEAR Member States Working Group of Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit (SSFFC) medical products (2010-2011); She was appointed as a WHO Short Term Consultant (APW) on many regulatory activities, such as on the assessment of the implementation of ASEAN Harmonization on Pharmaceutical under WHO-ASEAN Project (2015-2016), on the Development of Action Plan for Capacity Building & Strengthening Regulatory Mechanism for Drug & Pharmaceutical Trade in SEA region (2015), on Regulations of Medicinal Product Advertisement including via Internet in Malaysia and Other Countries (2019), on strengthening the Marketing Authorization function of the NMRA Sri Lanka (2020), on formulation of a Human Resource Plan for the NMRA Sri Lanka (2021), on the revision of Circular 32/2018/TT-BYT of the Ministry of Health Viet Nam on Marketing Authorization of Drugs and Medicinal Ingredients (2021). She participated as member of WHO NRA Assessment Team of the Vaccine and Medicine Regulatory System in some countries (The

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	Philippines 2000; China 2014; Mexico 2015; Papua New Guinea 2016; Viet Nam 2018). She was a trainer/facilitator for WHO Vaccine Global Learning Opportunities (GLO) (2014-2017) on Clinical Data Evaluation (in Indonesia, Jordan, Viet Nam); on Clinical Trial Authorization (in Indonesia); and on Quality and non-Clinical Data Evaluation (in Vietnam, UEA, Tunisia, Turkey, Greece). Up till now, she is a visiting expert, in the Centre of Regulatory Excellence (CoRE) – NUS Medical School, Singapore for Training on Fundamental Pharmaceutical Regulation (2018-2022), and a board member of the Concept Foundation, Thailand/ Switzerland (2015-2022). She is now still involved with some regulatory activities under the USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program and the World Bank as Short Term Consultants.
Session 6 – Using Patient-Generated Health Data (PGHD) and Real-World Evidence (RWE) to Accelerate Patient Engagement	
Adj Prof Meredith Smith	**Senior Director** **Implementation Science Group Lead** **Patient-Centered Research** **Evidera, Inc. PPD, a part of Thermo Fisher Scientific** **Adjunct Professor, School of Pharmacy** **University of Southern California** **United States of America** Adj Prof Meredith Smith is a Senior Director at Evidera, Inc., a division of PPD, Thermo Fisher Scientific Inc. where she heads the Implementation Science Team within the Patient-Centered Research Group. She is a behavioral scientist and health services researcher by training. Her professional experience includes stints in public health (New York City Health Department and the US Centers for Disease Control), in academic medicine (faculty at Memorial Sloan-Kettering Cancer Institute and Mt. Sinai Medical School), and in the biopharmaceutical industry where she led initiatives to embed patient-centricity within the organization. She has served on numerous US Food and Drug Administration expert panels, on three CIOMS Working Groups(WGs) including WG XI (Patient Involvement in the Development, Regulation and Safe Use of Medicines), and on IMI-PREFER where she was the industry lead for the Non-Small Cell Lung Cancer case study and led an initiative to return case study results back to patients. She has published widely, including in the areas of patient outcomes assessment, implementation science and patient-centered safety risk management. She is a board member of the Rutgers University BioPharma Educational Initiative in the School of Health Professions, and an adjunct professor at the University of Southern California School of Pharmacy.
Dr Mehmet Burcu	**Senior Principal Scientist** **Epidemiology** **Merck** **United States of America** Dr Mehmet Burcu is a Senior Principal Scientist in the Department of Epidemiology at Merck & Co., Inc., Rahway, NJ, United States. In his current role, he works with large, automated database studies as well as global multi-country real-world data studies to support clinical development and regulatory decision making. He has published extensively on a wide range of epidemiology methods, drug safety, policy, and patient-centered real-world evidence topics. He received his doctoral degree in the Department of Pharmaceutical Health

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	Services Research with a focus on Pharmacoepidemiology at the University of Maryland, Baltimore (UMB). In addition to his doctoral training, he holds a B.A. in Biochemistry from Ohio Wesleyan University and an M.S. in Clinical Research and Epidemiology from the University of Maryland School of Medicine, Department of Epidemiology and Public Health. He has served as an epidemiologist on the advisory board of the National Health Council projects, and served in leadership roles in committees and working groups of various scientific cross-sector organizations.
Dr Laura Pizzi	**Associate Chief Science Officer** **International Society for Pharmacoeconomics and Outcomes** **United States of America** Dr Laura Pizzi is Associate Chief Science Officer for ISPOR and Research Professor at Rutgers, The State University of New Jersey in the Ernest Mario School of Pharmacy and Rutgers School of Public Health. For the past 25 years, she has led interdisciplinary teams of methodologists, statisticians, and clinicians to design and conduct outcomes research analyses on healthcare interventions and is a frequent author, speaker, and mentor on the topic. Much of Dr Pizzi's primary research has entailed working directly with local community organizations to engage underrepresented populations towards improving health equity. At ISPOR, she provides executive leadership to the organization's global scientific strategy and initiatives, including content planning and oversight of ISPOR's Special Interest Groups, Patient Council and Patient Regional Patient Representative Roundtables, Digital Health strategy, and scientific publications. She also co-led the development of ISPOR's Competency Framework for health economics and outcomes research professionals and liaises students and faculty members worldwide to apply this framework in the training and development of new professionals.
Dr Søren Skovlund	**Senior Director, Head, Patient Engagement** **Patient-Centered Research, Evidera, Inc.** **PPD, a part of Thermo Fisher Scientific** **Denmark** Dr Søren Skovlund has two decades of experience driving patient-centred initiatives within both public and private sectors. For 17 years he was leading patient-centric initiatives across the value chain in the health care industry, with focus on health outcomes, clinical development, public affairs, patient advocacy and support, multi-stakeholder partnerships, and corporate responsibility. He is widely acknowledged as an advocate for raising the patient's voice and equitable access to patient-centred healthcare. He draws on wide public and private sector experience to unify stakeholders around the shared goal of achieving better health outcomes through true collaboration. Dr Skovlund has degrees in neurobiology, psychology as well as in patient engagement in health research. He has co-authored more than 45 scientific research articles in the field of patient-centricity, patient-reported outcomes, and psychosocial aspects of health care and has

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	led multi-national partnership programs to advance patient-centred research and care including within the Asia-Pacific region. Dr Skovlund was awarded the EyeForPharma Lifetime Achievement Award in 2016 by patient groups and peers for his efforts to advance patient-centricity within and beyond the health industry. Dr Skovlund holds a doctorate degree from the Medical Faculty of Aalborg University, Denmark on the topic of systematic engagement of people with lived experience in the multi-stakeholder co-development of a national patient-centred value-based care model in Denmark. Dr Skovlund is the chairman of the European Interest Group for Patient Reported Outcomes in Diabetes, expert advisor to the International Consortium of Health Outcomes Measurement (ICHOM) and the Pan-European Multi-stakeholder EU-IMI National Observatories Initiative (H2O). Dr Skovlund was part of the European Academy for Therapeutic Innovation (EUPATI) and co-developer of the global quality guidance for patient engagement of the Patient Focused Medicines Development (PFMD) initiative.
Session 7 – Development Priorities for Patient Engagement in Asia-Pacific	
Asst Prof James Leong	**Head** **Health Products and Regulatory Science** **CoRE, Duke-NUS Medical School** **Singapore** As the Head of Education at the Centre of Regulatory Excellence, Asst Prof James Leong is in charge of identifying the educational needs for the various stakeholders involved in regulatory affairs in the Asia Pacific region, and establishing education roadmaps, priorities and deliverables. He draws his regulatory experience from his years as a senior regulatory specialist with the Health Sciences Authority of Singapore, where he is a clinical reviewer in addition to managing the post-market benefit-risk assessments and regulatory actions. In addition to his Masters in clinical pharmacy, Asst Prof Leong is also Board-certified in pharmacotherapy. His previous clinical experiences include leading the hospital drug information services and heart failure clinic. He obtained his PhD from Cardiff University, focusing on benefit-risk assessment frameworks, communication of regulatory decisions and innovation of regulatory approaches.
Ms Tan Ping-Tee	**Senior Specialist** **Consumer Engagement and Education** **Agency for Care Effectiveness** **Ministry of Health** **Singapore** Ms Tan Ping-Tee is Senior Specialist in Consumer Engagement and Education (CEE) and Health Technology Assessment (HTA) at the Agency for Care Effectiveness (ACE), Ministry of Health Singapore. She is one of the founding members of ACE since its establishment. She is responsible for developing initiatives for patient involvement in HTA as well as conducting HTA assessments and cost-effectiveness analyses to inform national subsidy decisions. Prior to joining ACE, Ms Tan was a senior hospital pharmacist at Tan Tock Seng Hospital.
Mr Richard Vines	**Founder and Chairman** **Rare Cancers Australia**

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	Mr Richard Vines and his wife, Ms Kate, established Rare Cancers Australia (RCA) in June 2012. The not-for-profit provides support to all Australian patients diagnosed with a rare or less common cancer - because rare does not mean you have to be alone. Mr Vines is a career and passionate advocate as he has experienced first-hand the lack of information, resources, support, research and treatment options available for patients, carers and families living with a rare or less common cancer, following Kate's diagnosis of Medullary Thyroid Carcinoma in 1991. He knows the power of lived experience and pairs this with his extensive experience and expertise in the business and not-for-profit sectors to partner with patients, experts and industry to improve the lives and outcomes of patients with rare and less common cancers. A graduate of the University of Melbourne where he studied maths and statistics, Mr Vines initially trained as an Actuary and worked in IT for several years, forming his own software company which he then sold in 1990 before embarking on a second successful software venture in Europe. Mr Vines returned to Australia in 1996 where he was retained by an American company to establish a presence in Australia. In 2001, he left the IT industry to work in a number of not-for-profits associated with politics and health, before establishing RCA where he currently holds the roles of Chair and Chief Executive Officer. His strong advocacy achievements in policy reform around research and access to treatments, wide influence and significant expertise have also led to Richard taking on several other leadership roles within peak oncology and research bodies including: • Convener and Chair of the National Oncology Alliance • Chair of the Australian Genomics Health Alliance's Community Advisory Board Deputy Chair of the Australian Genomics Cancer Medicines Program (Omico) • Advisory Board member of Medicines Australia • Committee Member of the Patient Voice Initiative Mr Vines also serves as an associate investigator on a number of research projects and is a highly sought-after speaker and spokesperson for cancer patient advocacy issues, both in Australia and across the Asia Pacific region.
Mr Satoshi Miki	**Board Member** **Patient and Public Involvement** **Japan** Mr Satoshi Miki is one of the Board members of "General Incorporated Association PPI (Patient & Public Involvement) JAPAN" and concurrently he provides consulting services to the pharmaceutical industry as the owner of MAPD (Medical Affairs & Product Development) Consulting. Over the past 40 years he has gained broad experiences in drug development and product lifecycle management such as Pharmacy R&D, Clinical Research & Development, Regulatory Affairs, Medical Marketing, Project Management and Medical Affairs. Through such experiences, he has become an active

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	advocate for PPI/PE (patient engagement), particularly over the past 6 years through his exposures to EUPATI (European Patients' Academy in Therapeutic Innovation). He graduated from Tokyo University of Pharmacy & Life Science and is a certified Pharmacist in Japan.
Mr Neil Wildman	**Senior Director Patient Advocacy** **Asia Pacific and Africa Middle East** **Team Lead** **Pfizer** **Australia** Over the last 18 years Mr Neil Wildman has worked with national and international multi-national pharmaceutical companies in various regional and international corporate affairs roles, including an extensive 13-year career with Pfizer Inc. During his Pfizer career, Mr Wildman has led public affairs efforts in several therapeutic areas including oncology, vaccines, rare diseases, and internal medicine, across Asia Pacific, Europe, Africa, and the Middle East. Mr Wildman has also previously worked at Pfizer's New York Headquarters as part of Pfizer's Global Oncology Public Affairs Leadership Team. In Mr Wildman's current role, he leads a team responsible for Pfizer's Patient Centricty efforts in the Asia Pacific and Africa Middle East regions. Mr Wildman also sits on the Global Patient Advocacy Enterprise-Wide Leadership Team, which is responsible for implementing patient-centricity and patient advocacy focused initiative across Pfizer's global workforce.
Dr Izzuna Mudla	**Deputy Director** **Medical Development Division, Ministry of Health Malaysia** **Head, Malaysian Health Technology Assessment Section** **Malaysia** Dr Izzuna Mudla is the Deputy Director of the Medical Development Division, Ministry of Health Malaysia, and the Head of the Malaysian Health Technology Assessment Section (MaHTAS). She is a Public Health Physician and joined MaHTAS in 2007. Since then, she has conducted reviews on various types of health technologies. She also plays a key role in planning and implementation of health technology assessment, development, and implementation of clinical practice guidelines, and was the responsible person to set up horizon scanning of emerging health technologies activity for the Ministry of Health Malaysia. She was the Head of Horizon Scanning, Communication, and Information Unit at MaHTAS from 2013 until 2020. Dr Izzuna Mudla is actively involved at the local and international levels. She is a visiting lecturer at the University of Malaya, University of Science Malaysia, and Cyberjaya University. She is also a member of various committees at the national level including Cluster of Emerging Technologies, Nutritional Research, National Technology Innovation Sandbox, and National Rare Disease Committee. At the international level, she is currently the Chair of International Society for Pharmacoeconomics and Outcome Research (ISPOR) HTA Roundtable Asia Pacific, Vice President of HTAsiaLink, Regional Coordinator for AsiaScan, the regional group for the Asia Pacific Region of the International Health TechScan (i-HTS), and a member of the organizing committee for HTAi Asia Policy Forum. She has also published articles on public health matters and health technology assessment.

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Lunch Talk: Key findings of the EIU White Paper – Implications for Patient Engagement across Asia-Pacific (Sponsored by Johnson & Johnson)	
Mr Rajakanth R	**Executive Director** **Rainbow Across Borders Ltd** **Principal Consultant** **Manifeste LLP** **Singapore** Mr Rajakanth R has 20 years of experience in healthcare advocacy, policy and governance. As Executive Director of Rainbow Across Borders, he has created and led specific illness patient access programmes and campaigns. He has also initiated and built an extensive network comprising policy makers, industry players, healthcare professionals and patients with regional and local platforms. As Principal Consultant at Manifeste LLP, Mr Rajakanth has been creating solutions for multiple stakeholders in economically and culturally diverse countries in the Asia Pacific region. He has been able to revitalise strategies to overcome a multitude of challenges in the healthcare sector. Mr Rajakanth strongly believes in the power of the patient voice and the need for a patient-centric community. Over the years, he has been actively supporting the patient community by creating opportunities for patient support groups to train, connect and collaborate in the Asia Pacific region.
Ms Amy Jackson	**Senior Director** **Government Affairs & Policy** **Janssen (formerly head of PhRMA Japan)** Ms Amy Jackson joined J&J as the Head of Government Affairs and Policy for Pharmaceuticals for the Asia Pacific region in October 2021. She also currently serves as a Vice President of the American Chamber of Commerce in Japan (ACCJ) and as a member of the Maureen and Mike Mansfield Foundation Board of Directors. From January 2016-September 2021, Ms Jackson was the Japan Representative for the Pharmaceutical Research and Manufacturers of America (PhRMA) association. For six years before that, Ms Jackson served as the President of the American Chamber of Commerce in Korea (AMCHAM Korea). Ms Jackson was awarded an Industrial Service Medal by South Korean President Lee Myung-bak in 2012 and was inducted as an honorary citizen of Seoul in 2013. Prior to joining AMCHAM Korea, Ms Jackson was a Director at Crowell & Morning International, a trade and investment consulting firm based in Washington D.C. From 1998-2005, Ms Jackson worked at the Office of the U.S. Trade Representative (USTR), first serving as the Director of Japanese Affairs and later as the Deputy Assistant USTR for Korea. Prior to that, Ms Jackson worked in the International Relations Division at the National Aeronautics and Space

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	Administration (NASA). Ms Jackson served as a Mansfield Fellow from 1995-1997. Ms Jackson has a master's degree in International Relations from Johns Hopkins University and a bachelor's degree in Government from Pomona College.
Puan Anita Abu Bakar	**Founder and President** **Mental Illness Awareness & Support Association** **Malaysia** Puan Anita Abu Bakar is the Founder and President of the Mental Illness Awareness & Support Association (MIASA). She is a strong and known advocate for Mental Health and social issues in Malaysia and internationally. She initiated the first Peer-led Mental Health Advocacy and Support Group in Malaysia. As Puan Anita was born and raised overseas, she subsequently pursued her tertiary education at Tulsa University, Oklahoma in the United States. She obtained a bachelor's degree in Computer Information Systems, with a minor in Management Information Systems. Upon her return to Malaysia, Puan Anita pursued a career path as an Investment banker, and worked in the corporate field for over 10 years. She also holds an MBA in Islamic Banking and Finance from the International Islamic University of Malaysia (IIUM). Through MIASA, Anita champions the recovery model and the human-rights based approach simultaneously striving for non-coercive treatments and deinstitutionalization. In her passion in shaping the Mental Health Ecosystem towards a recovery model approach, she established the 'The Orchid Clubhouse', Malaysia's first Mental Health Crisis management and Activity Centre which is Peer-led and Peer-run. Anita also initiated the National Advocacy for Mental Health Association (NAMhA) in 2021 and was appointed as the Chairperson for NAMH, the first peer-based mental health alliance in Malaysia. Inspired by the United Nations Convention on the Rights of Persons with Disabilities (UN CRPD), this Alliance aspires to provide a constructive platform for a louder voice to promote, protect and ensure the rights of PWDs and work towards the Inclusion of mental health peers in various aspects of life including education, employment, housing, social protection and health, home and family and more. The various support services and activities that Puan Anita help initiate include MIASA's 24/7 Crisis Helpline (120 Crisis Team members are mobile across the nation), conducting home visits, Peer Support, Family Support, Circle Time, Spiritual Therapy, Art Therapy, Expressive Dance Therapy, Drama and Speech classes, Supported Employment programme, Mental Health programme on the Radio, Food Baskets for the B40 groups and homeless folks, volunteering opportunities and more.
Ms Ann Single	**Chair** **HTAi Patient and Citizen Involvement in HTA Interest Group** **Coordinator and Advisory Committee Member** **Patient Voice Initiative** **Australia** Ms Ann Single is chair of the HTAi Patient & Citizen Involvement in HTA Interest Group.

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	She is a very experienced patient and public involvement in health technology assessment professional. Over the past 20 years she's worked on policy and practice in Australia and overseas, beginning with directing communication and public involvement when health technology assessment was first established in Scotland. A contributor to many resources in use internationally, her focus is supporting patients, carers and their representatives to find and define their space in health technology assessment and ensuring their involvement is underpinned by a robust evidence base and appropriate processes. As Coordinator and Advisory Committee member of the Patient Voice Initiative, she develops and delivers capacity building workshops, webinars and resources for patients and their communities to promote practical actions to drive forward a culture of valuing patients in decision making in Australia. Ms Single has also authored many texts in this field, including co-editing the first book on patient involvement in health technology assessment. Her current wider work includes trialling plain language information about HTA applications to support more effective patient input about medicines being considered for reimbursement and co-developing and trialling a mentoring program for consumer members on Australian committees. She is co-chair of the International Scientific Program Committee for HTAi 2022 Annual Meeting.
Session 8 – Building and Using Regional Multi-Stakeholder Platforms to Progress Patient Engagement in the Region	
Dr Lembit Rägo	**Secretary-General** **Council for International Organizations of Medical Sciences** **Switzerland** Dr Lembit Rägo, MD, PhD, graduated from the Medical Faculty of Tartu University (Estonia) in 1979. He was Prof of Pharmacology and Clinical Pharmacology at Tartu University 1983—1999. He is also a founder of the Estonian Drug Regulatory Authority, the State Agency of Medicines and its first Director General 1991—1999. In December 1999, he joined the World Health Organization (WHO) Headquarters in Geneva as Coordinator of the Quality Assurance and Safety of Medicines (QSM) team. In 2001 he started the WHO Medicines Prequalification Program, which does the regulatory assessment of products for purchase by UN-funded programs. At WHO he led work to strengthen regulatory systems including combatting falsified medicines, and the development of pharmacovigilance and regulatory networks in Low- and Middle Income Countries. In September 2013, he was appointed as Head of the newly formed WHO unit - Regulation of Medicines and Other Health Technologies (today Department of Regulation and Prequalification), which, for the first time in WHO history, combined all regulatory activities for medicines, vaccines and diagnostics in one unit.

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	Since 2000, he has served as an observer to the International Council for Harmonization (ICH), first representing WHO and now representing Council for International Organizations of Medical Sciences (CIOMS). In 2016, he was selected to the position of Secretary-General of CIOMS. CIOMS is very active in issuing international guidance documents in pharmacovigilance, product development and research ethics. At present CIOMS has seven active working groups. The latest CIOMS report from Working Group XI Patient Involvement in the Development, Regulation and Safe Use of Medicines was published in September 2022.
Dr Ritu Jain	**Co-chair** **Agency for Care Effectiveness Consumer Panel** **President, DEBRA International & DEBRA Singapore** Dr Ritu Jain is co-chair of the Agency for Care Effectiveness Consumer Panel and the president of the EB patient support organisation DEBRA International and DEBRA Singapore. She also serves on the boards of APARDO, RDI, IADPO/Globalskin, and IRDiRC. In her various roles, she is invested in supporting the healthcare needs of patients and promoting health equity for invisible populations such as those with rare disorders. Outside of her volunteer work, Dr Ritu Jain works at the Nanyang Technological University, Singapore.
Ms Ranjit Kaur Pritam Singh	**Immediate Past President** **Breast Cancer Welfare Association Malaysia** **Founding President of Together Against Cancer Association Malaysia** **Board Member, Reach to Recovery International** **Board Member, Advanced Breast Cancer Global Alliance Malaysia** Ms Ranjit Kaur Pritam Singh, a breast cancer survivor since 1998, has a basic qualification in Physiotherapy, and a Master of Science degree in Community Disability Studies (University College London, UK) in 1996. Ms Kaur is: • Patient advocate • Immediate Past President, Breast Cancer Welfare Association Malaysia. • Founding (and past) President of Together Against Cancer Association Malaysia • Member of Board of Visitors, KPJ, Damansara Specialist Hospital • Board Member, Reach to Recovery International, a global breast cancer support and advocacy programme. • Board Member, Advanced Breast Cancer Global Alliance • Peer Reviewer for the Package of Interventions for Rehabilitation for Cancer (mainly LMICs) led by the World Health Organisation • Patient Advocate for the Union for International Cancer Control (UICC) Past positions: President, Reach to Recovery International (2003-2007) Board Member, Union for International Cancer Control (UICC) (2006-2010). President, Breast Cancer Welfare Association Malaysia (2002-2022)

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	Awards: • Outstanding UICC Volunteer Award (2004) • Theresa Lasser Award conferred by Reach to Recovery International (2011) Ms Kaur conducts training in Reach to recovery peer support and peer navigation in cancer care, Doctor-Patient communication skills for medical students and moderator for international forums. She is a consultant and trainer for regional and global cancer related groups. Her article on Cancer - My Personal Account was published in The Lancet, Issue no. 9472, May 14th 2005, Vol 365, Page 1742.
Dr Nichiren Pillai	**Medical Affairs Lead, Malaysia & Singapore** **Boehringer Ingelheim** **Malaysia** Nichiren was born in Kuala Lumpur, Malaysia and in 2007, he left Malaysia to pursue his studies and career in France under a full scholarship by the Malaysian & French Government. He spent 10 years in France and completed his Higher National Diploma in Engineering (HNDE) in Biochemical - Biological Engineering at the University Institute of Technology Clermont Ferrand, France then followed by degrees in Molecular and Cellular Biology and finally, Human Pathophysiology - Cell Engineering at the University of Bordeaux, France. He worked in the National Institute of Health and Medical Research of France (INSERM), France as a medical engineer for oncology and rare pulmonary disease. In 2022, he completed his Master's in Business Administration (MBA) focusing his research on Pharmaceutical Management at Veritas University College, Malaysia. In 2016, he returned to Malaysia and joined the pharmaceutical industry working in the Medical Affairs Department. He is currently working in Boehringer Ingelheim as the Medical Affairs Lead for Singapore & Malaysia. He is passionate about Medical Affairs and how it can bridge the Pharmaceutical Industry, Hospitals, Academic Institutions and most importantly, patients together. During his career in the industry, he has worked with his team to elevate Rare Disease Awareness in the region through Registry Studies, Screening Development, Real World Data Generation, and now, Rare Disease Patient Advocacy Development. In 2021, he was listed in the 3rd Edition of Young Successful People in Malaysia by the British Publishing House Ltd.
Closing Plenary – Reflecting on the Draft Consensus Statement and Next Steps	
Adj Prof John Skerritt	**Adjunct Professor, University of Sydney** **Deputy Secretary, Australian Department of Health** **Special Advisor, CoRE Advisory Board** **Australia** Adjunct Prof John Skerritt joined the Australian Department of Health in 2012 as a Deputy Secretary. In this role he has been part of national leadership of Australia's response to the COVID -19 pandemic as well

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	as regular spokesperson on TV, radio, print and online media and with community groups. He also has line responsibility as head of Australia's medicine, medical devices, cell and tissue and blood regulator, the Therapeutic Goods Administration as well as leading the Australians Office of Drug Control. He was formerly a Deputy Secretary in the Victorian Government, Deputy CEO of a Commonwealth Statutory Authority, senior research manager in CSIRO and in industry joint venture partnerships. From 2009-2012, he was Chair of the Board of a global technical NGO, and a board member for two further years. Apart from development assistance and governance skills he has extensive experience in medical, agricultural and environmental policy, as well as regulation, research management, technology application and commercialisation. Prof Skerritt is an Adjunct Full Professor at three Australian Universities, has a PhD and a University Medal from the University of Sydney, and international qualifications (London Business School, IMD Switzerland) in management. Prof Skerritt has extensive experience in working in all countries of South East Asia, having travelled for business to various SE Asian countries over 150 times in the last 30 years. He has been awarded medals by the Vietnamese and Cambodian Governments for contributions to national technological and economic development of both countries. He was also the 2012 winner of the Rotary "Global Alumni Service to Humanity Award", for leadership of development assistance for education, food security and income generation in response to the East Timor crisis and the response to the South East Asian 2004 boxing day tsunami and leadership in the environmental NGO sector. Currently he leads a program of assistance to support regulatory strengthening, including in the response to COVID-19 in Asia-Pacific developing countries. Prof Skerritt is also chair of the Asian Development Bank's Regional Vaccine Advisory Group, established by the President and Board of ADB in response to the COVID-19 pandemic.
Prof John Lim	**Executive Director, CoRE** **Duke-NUS Medical School** **Senior Advisor** **Ministry of Health, Singapore** **Chairman** **Consortium for Clinical Research & Innovation, Singapore (CRIS)** Prof John CW Lim is founding Executive Director of the Centre of Regulatory Excellence (CoRE) at the Duke-National University of Singapore Medical School (Duke-NUS), inaugural Chairman of the Consortium for Clinical Research & Innovation Singapore (CRIS), Senior Advisor at Singapore's Ministry of Health (MOH), and Policy Core Lead at the SingHealth Duke-NUS Global Health Institute (SDGHI). He is Prof of Practice at Duke-NUS and the NUS Saw Swee Hock School of Public Health.

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	Formerly Chief Executive Officer of Singapore's Health Sciences Authority and Deputy Director of Medical Services (Industry & Research Matters) in MOH, Prof Lim has also held other senior positions in Singapore's Health and Education ministries. His current roles promote capacity building and scientific excellence for health products regulation, health policies and systems in Southeast Asia and the Asia-Pacific. Prof Lim is a member of the Singapore Food Agency Board, APEC Life Sciences Innovation Forum's Executive Board, Davos Alzheimer's Collaborative Leadership Group, US Pharmacopoeia (USP) Council of the Convention as Asia-Pacific Chapter Chair, USP Quality Institute's Advisory Group, Centre for Innovation in Regulatory Science's Scientific Advisory Council, and St Andrew's Mission Hospital Board. In 2018, Prof Lim received the Drug Information Association's Global Connector Inspire Award for leadership in promoting global collaboration to advance healthcare products to patients, and the Regulatory Affairs Professional Society's highest Founder's Award recognising substantial sustained impact in shaping regulatory practice and policy over the course of his career.
Dr Lembit Rägo	**Secretary-General** **Council for International Organizations of Medical Sciences** **Switzerland** Dr Lembit Rägo, MD, PhD, graduated from the Medical Faculty of Tartu University (Estonia) in 1979. He was Prof of Pharmacology and Clinical Pharmacology at Tartu University 1983—1999. He is also a founder of the Estonian Drug Regulatory Authority, the State Agency of Medicines and its first Director General 1991—1999. In December 1999, he joined the World Health Organization (WHO) Headquarters in Geneva as Coordinator of the Quality Assurance and Safety of Medicines (QSM) team. In 2001 he started the WHO Medicines Prequalification Program, which does the regulatory assessment of products for purchase by UN-funded programs. At WHO he led work to strengthen regulatory systems including combatting falsified medicines, and the development of pharmacovigilance and regulatory networks in Low- and Middle-Income Countries. In September 2013, he was appointed as Head of the newly formed WHO unit - Regulation of Medicines and Other Health Technologies (today Department of Regulation and Prequalification), which, for the first time in WHO history, combined all regulatory activities for medicines, vaccines and diagnostics in one unit. Since 2000, he has served as an observer to the International Council for Harmonization (ICH), first representing WHO and now representing Council for International Organizations of Medical Sciences (CIOMS). In 2016, he was selected to the position of Secretary-General of CIOMS. CIOMS is very active in issuing international guidance documents in pharmacovigilance, product development and research ethics. At present CIOMS has seven active working groups. The latest CIOMS report from Working Group XI Patient Involvement in the Development, Regulation and Safe Use of Medicines was published in September 2022.

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Mr Ekawat Suwantaroj	**Committee Member** **Hemophilia Foundation of Thailand** Mr Ekawat Suwantaroj, now 46 years old, was diagnosed with severe haemophilia when he was four months old. He is a graphic designer and owner of a graphic designs company in Bangkok. Mr Suwantaroj is currently the Vice President of the Thai Hemophilia Patient Club and a committee member of the National Hemophilia Foundation of Thailand. He is active with other local support groups and is now setting up the Thai Rare Disease Foundation to increase the awareness of rare diseases in his country. He is also active internationally with the ASEAN Hemophilia Network (AHN) and has participated in several international workshops with the WFH over the last decade. Mr Suwantaroj is recently Board of Directors as a lay member of the World Federation of Hemophilia (WFH).
Ms Fatima Garcia-Lorenzo	**Co-founder and Board of Advisers** **Philippine Alliance of Patient Organizations** **Co-Founder, Kythe Foundation Inc.** **Philippines** Ms Maria Fatima Garcia-Lorenzo is a Certified Child Life Specialist and is a member of the Association of Child Life Specialists, USA. She completed her Child Life internship at the University of California San Francisco Hospital. Ms Fatima Garcia-Lorenzo finished her graduate studies on Child and Family Psychology at the Ateneo de Manila University in Quezon City. She is a Philippine-licensed Child and Family Psychologist. Ms Garcia-Lorenzo advocates for patient's rights and is engaged in health policy development. Ms. Garcia-Lorenzo is the co-founder of the Philippine Alliance of Patients' Organization (PAPO), an umbrella organization of disease-specific patient groups, representing about a million patients nationwide. Fatima is a member of the Department of Health's Technical Working Group on Patient Safety and Palliative and Hospice Care. The Union of International Cancer Control (UICC) chose Ms Garcia-Lorenzo as one of the patient leaders to represent the Philippines in their Asia-Pacific (APAC) Patient Group Mentoring Program. She was also chosen by the DUKE-National University of Singapore Centre of Regulatory Excellence to represent the Philippines in the Coalition to Accelerate Patient Engagement (CAPE). Ms Garcia-Lorenzo holds the distinction of being the first Filipino Ashoka Fellow. Ashoka is a global organization based in the USA, which recognizes outstanding achievements of social innovators. Ms Garcia-Lorenzo was chosen because she co-founded Kythe Foundation, an organization which addresses the needs of more than 17,000 children with cancer and other chronic illness a year, in eight partner hospitals nationwide. Ms Garcia-Lorenzo has been caring for children with cancer and other chronic-illness for over 30 years.