

2021



KEY OVERVIEW

marked a year of resilience and a new normal.

Thank you for your continued

and unwavering support.

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The second year of the COVID-19 pandemic in 2021 saw a surge of the Delta variant that stretched global health capacities and resources. However, high vaccination rates in many developed countries and roll-out of booster doses helped significantly mitigate the impact on hospitalisation and mortality. In addition to effective vaccines, the biomedical research community also developed two promising oral therapeutics that may reduce the risk of progression to severe illness in COVID-19 patients. The effectiveness of vaccines and the promise of new therapeutics has given countries confidence to cautiously open up and ease restrictions. However, as 2021 ended, the emergence of the highly transmissible Omicron variant posed fresh challenges to populations and economies. This was a stark reminder that if low and middle income countries are unable to equitably receive adequate vaccination coverage, any progress made towards a transition to an endemic state risks being upended across all countries.

In this challenging local and global context, CoRE continued to function and even flourish through predominantly virtual platforms in our education programmes and think-tank activities. This enabled the Centre to reach a wider geographic range of overseas participants than before. Highlights of 2021 included the Inaugural Sir Alasdair Breckenridge lecture delivered by Sir Jeremy Farrar of the Wellcome Trust in a hybrid event that included a moving video tribute to the late Sir Alasdair, the launch of an education fund in his name, and the graduation of the 2020/21 cohort of our Graduate Certificate Programme. We also launched our inaugural medical devices workshops on In Vitro Diagnostics and Software as a Medical Device and two important workshops to facilitate the effective use of Good Reliance Practices by national regulatory authorities. We hosted our third regional multi-stakeholder roundtable on patient engagement after the successful launch of the Coalition to Accelerate Patient Engagement (CAPE) in Asia-Pacific in 2020. We actively contributed our voice and perspectives to pertinent COVID-19 discussions alongside regional and international thought leaders, through our webinar series, collaborative thought pieces, and interviews with various news and media providers.

The experience of the past two years of the pandemic has reinforced the critical need for regulators to move beyond a siloed approach to regulatory systems strengthening and public health emergency responses. There is now an opportunity to forge a new socio-economic-political compact in which well-trained regulatory professionals proactively participate as key and valued partners in helping to address major global health challenges such as this pandemic and future public health emergencies. To be ready for this new landscape, regulators need holistic skills in both regulatory science and the important soft skills to be adept at navigating the wider socio-political terrain and forging collaborative multi-stakeholder networks.

CoRE is committed to nurturing “future-ready” regulatory professionals through our education programmes and playing a major thought leadership role to stimulate wider thinking on the future of health products and systems regulation and policy innovation in the new normal.



Message from Executive Director Professor John Lim

We would like to express our appreciation to the visionary leaders on the Centre’s Advisory Board. Their strategic guidance and unceasing support since CoRE’s inception has contributed significantly to CoRE’s success.



Chair
Dr Margaret Hamburg
Chair, bio Advisory Group
Nuclear Threat Initiative
Former Commissioner
U.S. Food And Drug Administration



Prof Guido Rasi
Former Executive Director
European Medicines
Agency



Dr Mimi Choong
Chief Executive Officer
Health Sciences Authority
Singapore



Mr Michael Gropp
Former Chair
RAPS Global Advisory
Council



Dr Joseph Scheeren
Founder
Scheeren HealthCare LLC
Special Advisor, Former
President & Chief
Executive Officer
Critical Path Institute
(C-Path)



Dr Paul Huckle
Former
Chief Regulatory
Officer
& Senior Vice President
GlaxoSmithKline



Dr Peter Honig
Board Member
Sesen Bio
Former Senior Vice
President
Global Regulatory Affairs
Pfizer



Special Advisor
Mr Jean-Luc Butel
President
K8 Global

WELCOME TO OUR NEW SPECIAL ADVISORS

We are delighted to welcome Dr Yasuhiro Fujiwara and Adjunct Prof John Skeritt as Special Advisors.



Special Advisor
Dr Yasuhiro Fujiwara
Chief Executive
Pharmaceutical and Medical
Devices Agency
Japan

Dr Yasuhiro Fujiwara has been Chief Executive of Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) since 1 April 2019. He was elected Co-chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) on 1 October 2019.



Special Advisor
Adj Prof John Skeritt
Deputy Secretary
Health Products Regulation
Australian Department of Health

Adjunct Prof John Skeritt has been Deputy Secretary at the Australian Department of Health since 2012. He has been part of the national leadership of Australia’s response to the COVID-19 pandemic. He also has line responsibility as Head of the Therapeutic Goods Administration, Australia’s medicine, medical devices, cell and tissue and blood regulator, and leads the Australian Office of Drug Control. He is also Co-chair of the ICMRA.

Executive Director



Prof John CW Lim
Executive Director
CoRE
Duke-NUS Medical School
Core Lead (Policy)
SingHealth Duke-NUS Global Health Institute (SDGHI)
Senior Advisor
Ministry of Health, Singapore (MOH)
Chairman
Consortium for Clinical Research & Innovation, Singapore (CRIS)

Deputy Director



A/Prof Silke Vogel
Deputy Director
CoRE
Senior Associate Dean
Graduate Studies (PhD and Accredited Programmes)
Head
Centre for Lifelong Learning
Duke-NUS Medical School



Mr Neo Cherng Yeu
Senior Associate Director
Strategy and Operations



Asst Prof James Leong
Assistant Professor
Health Products & Regulatory Science



Ms Sherna Wadia
Associate Director
Stakeholder Engagement



Mr Aaron Choong
Associate Director
Administration



Ms Chen Lee San, Lisa
Assistant Senior Manager
Administration



Ms Lavanya Balan
Assistant Manager
Business Development

VISION

To be a leading Centre enhancing regulatory capability and scientific excellence for health products and systems in Asia.

STRATEGIC FOCUS

CoRE has established itself as a unique entity advancing regulatory excellence and policy innovation through our education programmes and think tank initiatives. Our focus is primarily on health products but is increasingly extending into wider health policy and systems issues.

REGULATORY & HEALTH SYSTEMS STRENGTHENING

Strengthen
competencies
and
understanding
of regulatory
science

Promote
policy innovation and
promulgate best practices,
such as regulatory
convergence and agility

Create
awareness and
communicate
relevance

Encourage
collaboration
and
convergence

FOCUS AREAS

Patient Engagement | Digital Health | Innovative Therapies | Clinical Trials | Vaccines

Address
issues of strong
stakeholder demand and
interest

Amalgamate
efforts to achieve targeted
outcomes

Create
synergy between
education programmes
and think tank

MISSION

To establish regional platforms and networks to grow competencies, enhance collaboration and promote thought leadership in innovative regulatory science and health policy.



EDUCATION



Strengthening Regulatory Systems Through Education



Education in Numbers



Regulatory and Health Systems Strengthening



Medical Devices



Graduate Certificate in Health Products Regulation



Supporting Tomorrow's Leaders

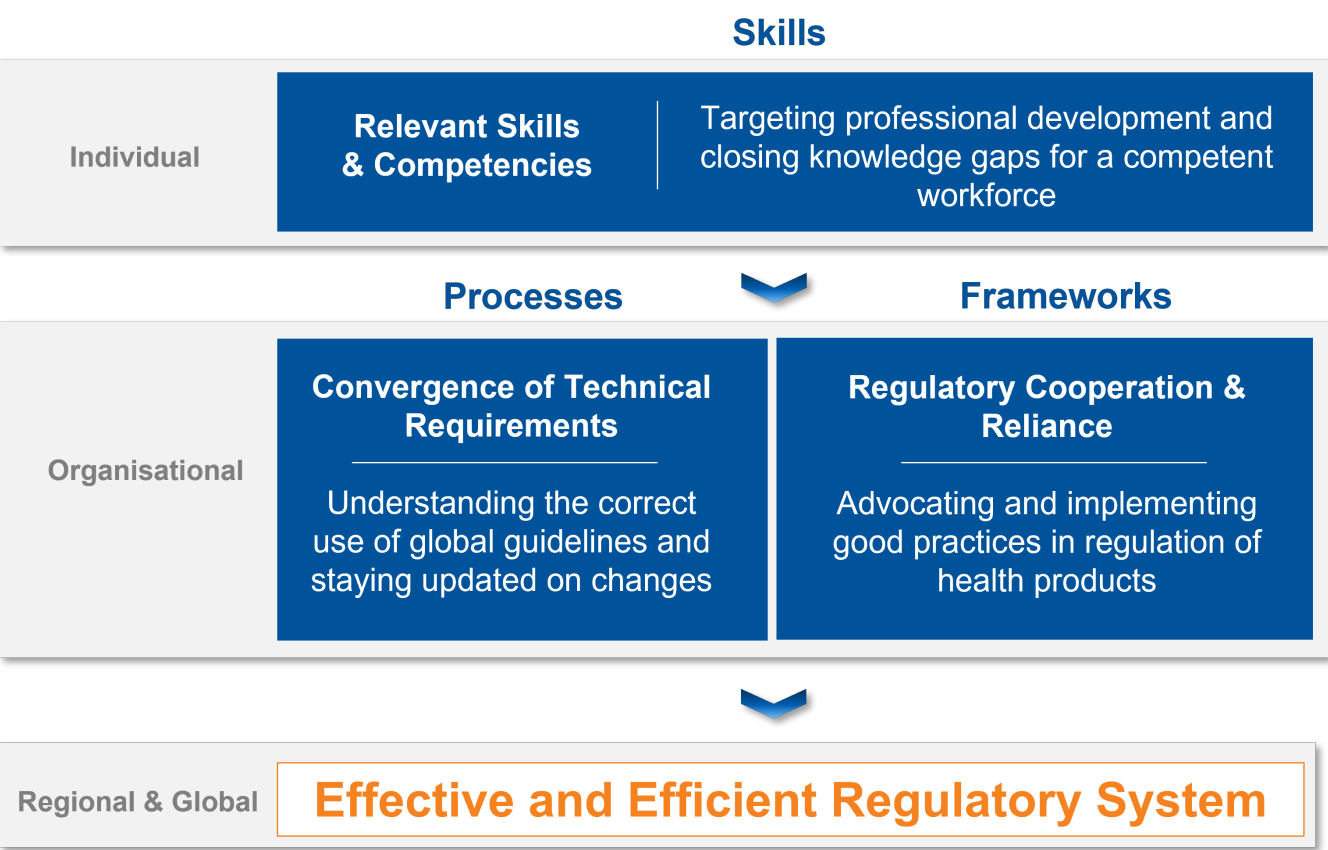


Inaugural CoRE Conversation with Ms Emer Cooke

STRENGTHENING REGULATORY SYSTEMS THROUGH EDUCATION

With the rapid advancements in science and public health measures, keeping updated on innovations, regulatory requirements and processes remains a key component in ensuring preparedness. Ongoing education and training is critical for continuous professional development and functional regulatory systems. As many have embraced virtual platforms as the main mode of education during these pandemic times, this increased acceptance had facilitated the successful adoption of online programmes for capacity building and systems strengthening.

Through identifying gaps in knowledge and understanding the current trends in regulatory processes, various training activities were conducted by CoRE to help regulatory professionals achieve the confidence and technical skills to carry out their work or transition to new regulatory roles effectively. An empowered workforce will help to increase the standard of regulatory practices and ensure efficient and effective regulatory systems to support public health and economic systems, as witnessed during the course of the COVID-19 pandemic.



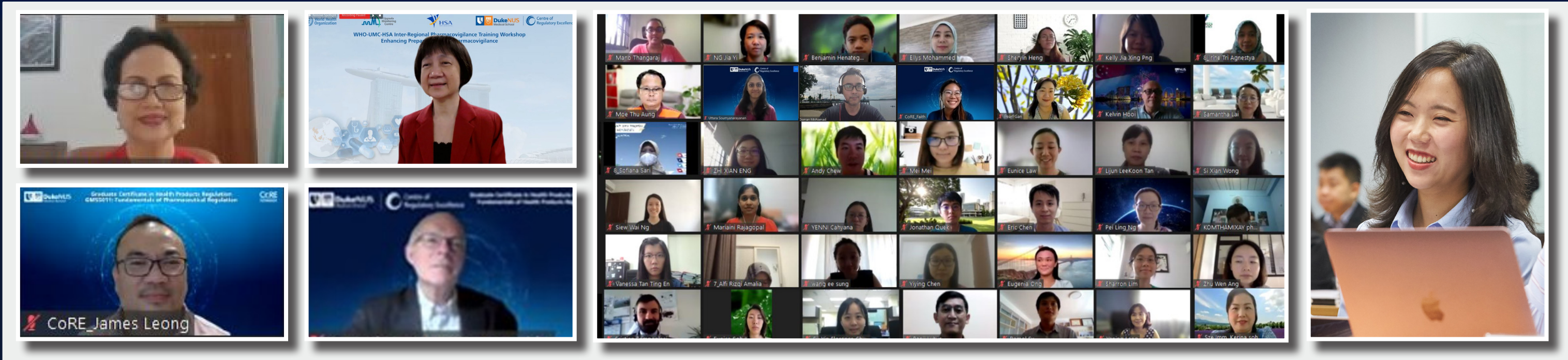
As CoRE continues to innovate and leverage on virtual platforms, there are now opportunities to develop more online programmes to cater to various needs of both younger and more experienced regulatory professionals, and increase our scope to cover foundational subjects to new trending topics. This comprehensive approach will help CoRE achieve its role of providing quality education and meeting the needs of regulatory professionals in Asia and other parts of the world.



Graduates at the 2021 Sir Alasdair Breckenridge Lecture & Graduation Ceremony.

EDUCATION IN NUMBERS

CAPACITY BUILDING



PARTICIPANTS & ECONOMIES

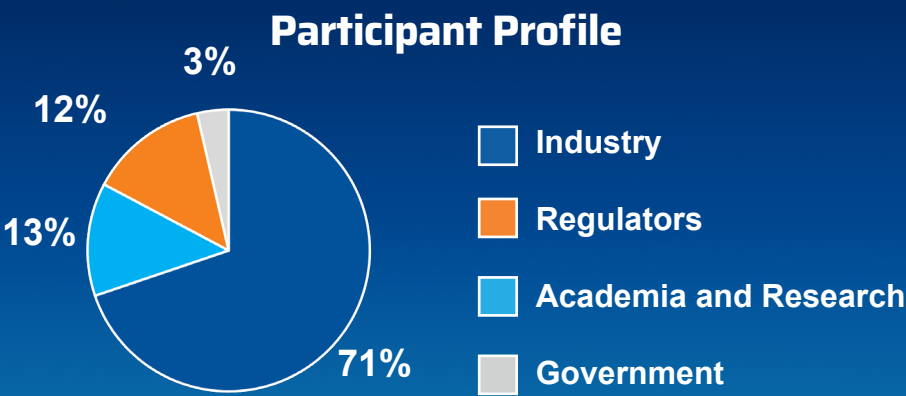
Training support provided to

>1900

participants* for our modules and workshops

>30

Economies represented



INTERNATIONALLY RECOGNISED FACULTY

CoRE taps into an international community of active and deeply experienced practitioners of regulatory affairs and biomedical science who provide comprehensive perspectives of the dynamically evolving regulatory and health systems environment. From governments and National Regulatory Agencies to academia and industry, these thought leaders provide culturally relevant examples and real-life experience to the curriculum, in line with Duke-NUS's hallmark TeamLEAD teaching strategy.

>180

Global expert faculty engaged with our participants

>70

Organisations partnered to provide real-world practice and application



*including those who have attended more than one module

REGULATORY AND HEALTH SYSTEMS STRENGTHENING

Understanding the needs of the regulatory ecosystem in Asia, CoRE expanded its education activities to include medical devices and technology, to facilitate patients’ access to health products as well as the important issue of appropriately applying Good Reliance Practices in differing contexts. The recognition of CoRE as a trusted provider of quality training has paved collaborations with global organisations in bringing these highly relevant workshops to professionals in this region and beyond.

Good Reliance Practices



Workshop 1 Implementing Reliance Approaches 12 - 14 JULY 2021

Attended by 40 regulators from 15 countries in Asia-Pacific, including ASEAN member states, Mongolia, South Africa and Sri Lanka, this workshop built upon the release of the World Health Organisation (WHO) Good Reliance Practices guidelines and was developed with inputs from numerous regulatory stakeholders. Together with representatives from WHO, senior health officers and regulators discussed the operational and practical implementation of collaborative regulatory processes to improve efficiency and effectiveness, which is urgently required in the current situation of a pandemic.



Workshop 2 Using Reliance Approaches for Product Evaluation 27 - 29 SEPTEMBER 2021

This workshop was the second part of the inaugural initiative to build capacity in regulatory cooperation in Asia and focused on the technical competence required to successfully carry reliance activities across the product life cycle. With 45 regulators across 16 countries as far reaching as Rwanda, experts shared their knowledge on the application of reliance in diverse regulatory functions. The conclusion of this workshop provided a platform to further engage interested countries to implement good reliance practices in their respective agencies.



Health Technology Assessment (HTA) & the Art of Decision Making 8 - 10 MARCH 2021

In collaboration with Singapore’s authority for HTA, the Agency for Care Effectiveness (ACE), and academic experts from the University of Adelaide, 42 participants from local healthcare institutions completed an online self-directed learning module as well as a 3-day workshop of intensive hands-on exercises. The discussions and sharing were enriched by the attendance of senior health officers who made up more than half the class.



WHO-UMC-HSA Inter-Regional Pharmacovigilance Training Workshop: Enhancing Preparedness for Pharmacovigilance 20 - 22 SEPTEMBER 2021

In continuing the commitment to enhance regulatory capacity in pharmacovigilance for Asia, this workshop focused on the trends and competencies required for responding to public health emergencies. Helmed by WHO, the Uppsala Monitoring Centre (UMC) and the Health Sciences Authority (HSA), a total of 72 participants (half of whom were regulators from ASEAN member states) attended this workshop. The combination of technical training and facilitated discussions effectively engaged the participants, and allowed better understanding of perspectives from regulators and industry in conducting pharmacovigilance during the current COVID-19 pandemic.

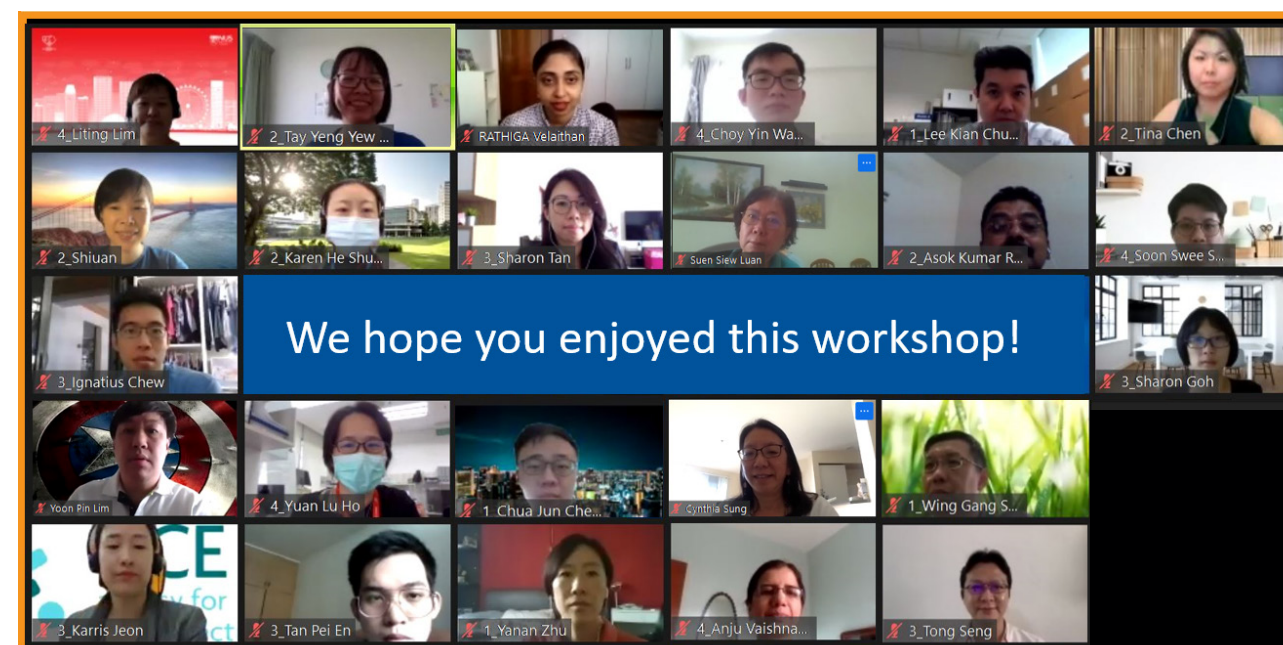


CoRE and A*STAR's Diagnostics Development (DxD) Hub inked an agreement in 2020 to develop a joint training programme for IVD and Medical Devices Software developers. Through online modules and short courses, this joint programme allows participants to integrate their knowledge of product development and regulatory requirements of IVD and SaMD together, readying themselves to enter the commercial market.

At CoRE and DxD, we envision that this project will advance and accelerate the commercialisation of up-and-coming IVD and SaMD technology in a safe and effective manner.

MEDICAL DEVICES

While medical devices form key health products alongside pharmaceuticals, regulations addressing their unique and broad spectrum of risks and challenges have yet to be fully implemented throughout the Asia-Pacific region. To respond to this need for competency and capacity building in both industry and regulatory agencies, CoRE launched its inaugural Medical Device workshops to lay the foundational understanding of regulating such medical innovations.



Regulation of In Vitro Diagnostic Devices (IVDs)

1 - 2 SEPTEMBER 2020

With the recent advances and growing significance of IVDs and precision medicine in a patients' healthcare journey, this two-day workshop provided an understanding of the principles behind effective regulation of IVDs for informed decision making throughout its lifecycle.



Top row from left: Ms Beverly Liew (Senior Regulatory Specialist, Health Sciences Authority), Dr Kelsen Bastari (Senior Regulatory Specialist, Health Sciences Authority), Ms Shelley Tang (Principal, Stellar Consulting), Dr Adelheid Schneider (Head Quality and Regulatory Asia Pacific, Roche Diagnostics Asia Pacific), Mr Varun Veigas (Regional Manager, Roche Diagnostics Asia Pacific), Ms Joyce Tan (Director, BD); **2nd row from left:** Mr Danny Ong (Senior Regulatory Specialist, Health Sciences Authority), Ms Sumati Randeo (Head, Roche Diagnostics India), Dr John Thornback (Chief Operating Officer, Diagnostics Development Hub), Prof John Lim (Executive Director, CoRE), Ms Maple Ye (Senior Manager, Diagnostics Development Hub), Mr Ananda Muthulagu (Associate II, CoRE); **3rd row from left:** Mr Praveen Kumar (Senior Assistant Director, Ministry of Health, Singapore), Dr Sethuraman Rama (Director, Health Sciences Authority), Dr Roberta Sarno (Manager, APACMed), Dr Nathan Carrington (Head of Digital Health and Innovation, Roche Diagnostics), Dr Lesley Maloney (Regulatory Policy Lead, Genentech), Dr Yuri Marichich (Chief Medical Officer, Pear Therapeutics); **Bottom row from left:** Mr Su Yinyao (Regulatory Affairs Manager, Health Sciences Authority), Mr Zhuang Guangyi (Senior Regulatory Specialist, Health Sciences Authority), Mr Lin Anle (Senior Regulatory Specialist, Health Sciences Authority), Mr Manan Hathi (Senior Manager Regulatory Affairs, Stryker), Mr Paul Chua (Cyber Security Officer, BD), Ms Siew Jie Yee (Senior Regulatory Specialist, Health Sciences Authority)

Regulation of Software as a Medical Device (SaMD)

1 - 2 DECEMBER 2020

As the emergence of novel digital health technology tools calls for regulatory oversight specific to SaMD that traditional medical device regulations are unable to cater to, this workshop elaborated on the key regulatory considerations in medical software development as well as relevant standards and guidelines for software verification and validation as a crucial tool for effective governance of such devices.



GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

Drawing on our strong and globe-wide network of prominent regulatory experts, CoRE played a crucial role in capacity building in the region through education and training workshops spanning various facets and categories of health products.





Continuing to stay relevant in the ever-evolving healthcare landscape, the Duke-NUS Graduate Certificate Programme in Pharmaceutical Regulations was enhanced to incorporate medical devices and technologies into its training curriculum, and is now known by its revised title of the Duke-NUS Graduate Certificate in Health Products Regulations.

While the existing programme has earned a positive reputation for educating and upskilling regulatory and healthcare professionals, CoRE recognises the importance of staying relevant in the flourishing biomedical landscape of Singapore, ASEAN and the Asia-Pacific. Further to this and our stakeholders' feedback, CoRE has redesigned the curriculum to feature three new modules covering state-of-the-art topics on medical devices, including IVDs and Precision Medicine, Regulation of Digital Health Products as well as Post-market processes for Medical Technologies.

CoRE aims to nurture a generation of future-ready regulatory professionals, who have a holistic understanding of end-to-end regulatory processes and are equipped with valuable skillsets that can adapt to changes in the health and biomedical landscape. With a wider selection of training modules and increased flexibility to attain the Graduate Certificate, CoRE offers participants a comprehensive and well-rounded education programme that facilitates gaining knowledge, communication and decision-making skills, along with networking and collaboration, thereby facilitating the growth of a community committed to health and regulatory excellence.

SUPPORTING TOMORROW'S LEADERS

Increasing Access and Opportunities

Funding support provided to
457
participants with scholarships
for our modules and workshops

113
Participants granted
scholarships for our
Graduate Certificate modules

12
Economies
represented



Dr Kongchack Phommachack
Technical officer
Drug and Medical Devices
Control Division
Food and Drug Department
Ministry of Health, Lao PDR



The support from the following partners allow regulatory professionals from both NRAs and industry to participate in CoRE’s Graduate Certificate in Health Products Regulation, augmenting competency enhancement programmes and organisational capacity building efforts.

ASEAN Regulators Tuition Support Scholarship Scheme

Established in 2018 to support staff from Ministries of Health and NRAs of ASEAN Member States to attend CoRE’s Graduate Certificate Programme.



Australian Indo-Pacific Regulatory Strengthening Program (RSP)

RSP seeks to improve partner countries’ regulatory capacity and hence lead to accessing better and safer medical products. CoRE has been engaged as an official training partner since 2019 and the RSP supports regulators from partner countries to attend CoRE’s Graduate Certificate Programme.



Developing Countries Vaccine Manufacturers Network (DCVMN)

DCVMN is a public-health-driven international alliance of manufacturers, working to strengthen vaccine manufacturers through various initiatives, one of which is professional training programmes. Since 2019, DCVMN supports their members’ professional development through attending CoRE’s Graduate Certificate and Online Programmes.



GIVE NOW

“Through CoRE’s initiatives to aid in the professional growth of regulators, I am grateful to be a recipient of the CoRE-RSP scholarship, which enables me to broaden and develop my knowledge of health products regulation, through the comprehensive and up-to-date Graduate Certificate programme. More importantly, the modules allow me to share the valuable knowledge gained with colleagues in my home country, which will improve our revisions and functions in our occupational capacities and ultimately benefit patients.

”

CoRE instituted a new series entitled CoRE Conversations featuring a one hour ‘fireside chats’ with outstanding global leaders in health products and health systems regulation and policy on their professional paths and experiences that have led them to their successful careers. Aligned with our education strand, this series is a career development initiative, to provide alumni and attendees with the opportunity to hear from the best on their career paths.

INAUGURAL CoRE CONVERSATION

WITH MS EMER COOKE

15 NOVEMBER 2021

We were honoured that Ms Emer Cooke, Executive Director of the European Medicines Agency (EMA), launched this series. In an enlightening and inspiring discussion with Prof John Lim, Ms Cooke talked about her significant professional milestones and shared important perspectives on the international regulatory landscape before, during and beyond the pandemic.

Over 200 people registered on Zoom and LinkedIn Live, comprising participants and alumni of our education offerings based in Singapore and the Asia-Pacific, in addition to a wider international audience. Dr Cooke readily addressed queries posed by the audience regarding her background, formative education and how it shaped her career in addition to sharing her deep knowledge of scientific, communication and socio-cultural issues.

She concluded with her ongoing aspirations and ambitions which could be a useful guide to inspire regulatory professionals in their career choices and also to grow as leaders.



Missed it? Rewatch the conversation!

“

My advice to whoever is looking to work towards a career in medicines regulation and global public health: be open to opportunities, including opportunities abroad, be brave, be adaptable, but remain true to yourself.

”

THINK TANK

-  Sir Alasdair Breckenridge Lecture
-  Health and Regulatory Systems Strengthening
-  Accelerating Patient Engagement
-  Digital Health and Vaccines
-  CoRE Webinar Series: Encouraging Exchange



Click to
read



SIR ALASDAIR BRECKENRIDGE LECTURE

The Sir Alasdair Breckenridge Lecture Series celebrates the illustrious career and legacy of the late Professor Sir Alasdair Breckenridge, a highly respected and globally recognized clinical pharmacologist, international scientist, and visionary regulatory professional.

The 2021 inaugural Sir Alasdair Breckenridge Lecture was delivered by Professor Sir Jeremy Farrar, Director of the Wellcome Trust on the topic of “Science, Innovation and Society”. Sir Jeremy highlighted the importance and inter-connectedness of these three themes in the context of COVID-19. This was very apt as the Lecture Series was launched during the pandemic as a hybrid event with a small in-person gathering in Singapore and a large online international audience. The Guest-of-Honour was A/Prof Kenneth Mak, Director of Medical Services at Singapore’s Ministry of Health.

Further to this, CoRE colleagues authored an article that was published in Clinical Pharmacology & Therapeutics. The article reflects on our four key take-aways from Sir Jeremy’s inaugural lecture that will stand us in good stead for the current COVID-19 pandemic and as we prepare for other global health challenges ahead.



Following the inaugural lecture, Dr Margaret Hamburg, Chair of CoRE introduced the Alasdair Breckenridge Fund which will provide study awards for regulatory and healthcare professionals from South-East Asia and Asia-Pacific national regulatory authorities and ministries of health to attend courses tenable at CoRE.

In keeping with Sir Alasdair’s interest in promoting regulatory capacity building and professional excellence, the lecture was organised in conjunction with the 2020/21 graduation ceremony of CoRE’s Health Products Regulation Graduate Certificate Programme, to celebrate the achievements of the graduating cohort and affirm their commitment to pursuing regulatory excellence.



A moving video tribute to Sir Alasdair from many of his colleagues and friends.



Missed the Inaugural Lecture? Click here to watch the full video.



This perspective draws from the speech Professor Sir Jeremy Farrar delivered at the inaugural lecture. Click to read the article.



Congratulations to our 2020/2021 graduating cohort of the Graduate Certificate Programme in Health Products Regulation! Click here to view photos.



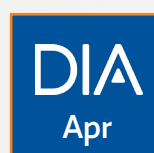
HEALTH AND REGULATORY SYSTEMS STRENGTHENING

The COVID-19 pandemic brought to greater attention the importance of robust and agile health and regulatory systems. Building on our strength and initial focus on health products regulation and regulatory system strengthening, CoRE has expanded into exploring issues related to global health, health policies, and health systems, especially where regulation can play an enabling role.

Regulatory Systems Strengthening

CoRE actively promoted and explored issues related to regulatory cooperation, convergence, reliance and recognition, agility, and how regulatory excellence can play an enabling role to facilitate responsive access to health products.

Publication



Measuring Progress of Regulatory Convergence and Cooperation Among Asia-Pacific Economic Cooperation (APEC) Member Economies in the Context of the COVID-19 Pandemic

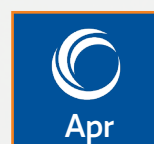
Sannie Siaw Foong Chong, Mirinea Kim, Michelle Limoli, Eric Obscherning, Patricia Wu, Lila Feisee, Nobumasa Nakashima & John C. W. Lim

CoRE Regulatory Perspective



Regulatory Agility and Global Coordination to Meet the Challenge of Covid-19 Variants: Preparing for the Next-Generation Vaccines

Nokuthula Kitikiti and Uttara Soumyanarayanan



Whither ASEAN regulatory agility and convergence in the ongoing COVID-19 pandemic?

John C. W. Lim

Drug Information Association (DIA)



DIA Europe 2021: Regulatory Science Innovation Trends & the Significance of Regulatory Agility



2021 DIA-CoRE Singapore Annual Meeting: Catalyst for Changes – Preparing for the Future of Healthcare

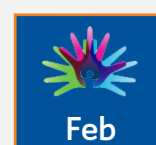
External Speaking Engagements & Dialogues



Government-led and Multilateral Platforms



Biannual meetings of the APEC Regulatory Harmonisation Steering Committee (RHSC) and Life Sciences Innovation Forum (LSIF)



National Health Security Office and MOH Thailand: Rare Disease Day Thailand - Enabling Regulatory Agility for Rare Diseases



APEC Harmonisation Centre (AHC): 2nd APEC workshop on Facilitated Regulatory Pathways

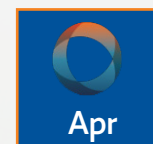


AHC: APEC Roundtable Dialogue on Post-Pandemic Regulatory Innovation & Convergence



Vietnam MOH, Vietnam Health Economics Association & EuroCham Vietnam: Workshop on Sharing Good Regulatory Practices on Drug Registration

Non-Government Organisations



Lake Nona Institute Impact Forum: Moving Towards Greater Regulatory Coordination - Why Regulation Matters



Healthcare Information and Management Systems Society: webinar on Enabling Regulatory Agility and Innovation for more Personalised Health Care



10th Asia Partnership Conference of Pharmaceutical Associations: Regulatory Agility during and after COVID-19



China Pharma Innovation & Research Development Association: 2021 China International Fair for Trade in Services sub-forum - Promoting Regulatory Excellence and Promoting Policy Innovation in Singapore and across Asia-Pacific

Industry

SingHealth Duke-NUS Global Health Institute (SDGHI)



Serving as the Policy Core of SDGHI

Developed health policy excellence and generate awareness on important global health issues such as universal health coverage, health security and health equity.



World Health Organisation (WHO) Global Health Foresight

Contributed to the WHO project which aims to conduct a global horizon scan on emerging technologies and trends relevant to global public health, so as to assist member states to engage in building futures-thinking into their strategic health planning frameworks.



U.S. Pharmacopeia (USP) Convention Asia Pacific Regional Chapter

Prof John Lim is a member of the USP Council of the Convention and chairs the USP Asia Pacific Regional Chapter which provides member organisations a platform to have targeted exploration of issues related to healthcare and pharmaceutical supply chain.



FutureProofing Healthcare Initiative

Contributed expert insights to the initiative set up and funded by Roche but independently driven by experts. The initiative aims to build new, personalised, data-driven and resilient health systems that are ready for the future.



ACCELERATING PATIENT ENGAGEMENT

CoRE has come together with like-minded partners to jointly establish CAPE to advance systematic and meaningful patient involvement in health systems across the Asia-Pacific region. CAPE is a multistakeholder partnership hosted at Duke-NUS Medical School. This platform provides an effective, neutral and safe engagement channel for raising awareness, convening and building capacity for patient engagement among all stakeholders in healthcare delivery, health products development and regulation, and HTA.

How does patient engagement support sustainable health systems?



What more can be done to enhance patient engagement?



CAPE Multi-Stakeholder Roundtable: Embedding Patient Engagement for Sustainable Health Systems

7 October 2021



In partnership with Rainbow Across Borders, the Milken Institute, Patient Focused Medicines Development and SDGHI, over 50 participants attended the third regional multi-stakeholder roundtable on Patient Engagement, themed “Embedding Patient Engagement for Sustainable Health Systems”. This year’s virtual meeting and discussion focused on the potential of patient engagement to improve health systems and ways to optimise sustainability through patient-centric organisational cultures, patient involvement in HTA, and effective use of patient experience data.

Engagement with the wider Patient Engagement community

CAPE has also participated in regional and global events related to Patient Engagement, sharing our perspective from Singapore and the Asia-Pacific context with an emphasis on health products development and access and health policy. Events where CAPE participated as speaker and/or panellist include:

- Lymphoma Coalition Global Summit (October)
- The Singapore Experience Exchange with Patient Organisations (SEPO) (October)
- Asia Pacific Patients Congress (November)
- Milken Institute Partnering for Patients Forum (December)



Dialogue with the Agency for Care Effectiveness (ACE) Consumer Engagement & Education (CEE) Team: The Future of Patient and Public Involvement in HTA in Singapore

18 November 2021



ACE is the national HTA agency in Singapore, reviewing clinical and economic evidence to determine how well health technologies (such as drugs, vaccines and medical devices) work in relation to how much they cost. In 2021, the CEE team was set up at ACE to help patients, carers and the public become involved in the work conducted by ACE. CoRE and ACE partnered to host the first dialogue with over 70 members of patient and volunteer organisations in Singapore to introduce them to HTA, the work of ACE, and how they can be involved in HTA processes.

DIGITAL HEALTH

The rapid advancement of information and communications technologies and the corresponding digitalisation of communities around the world present great opportunities in helping the world achieve better health outcomes through digital health solutions.

CoRE closed-door Roundtable: Enabling Digital Health Adoption in Asia-Pacific



Allard W de Smalen, Nokuthula Kitikiti, Ananda P Muthalagu, Cherng Yeu Neo, Hishamuddin Badaruddin, Silke Vogel, John CW Lim

In partnership with Roche, CoRE convened a closed-door roundtable to bring together regulators, policy makers, industry, and other stakeholders in the Asia-Pacific to initiate a broad-based dialogue on Digital Health adoption in the region. Healthcare data policies, data security, and cybersecurity, and digital health regulation were identified as key enablers of digital health adoption. A comprehensive whitepaper based on the roundtable was released in May 2021 with added supplementary information.

Speaking Engagements



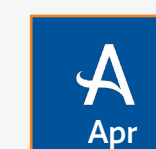
Centre for Innovation in Regulatory Science (CIRS): Virtual Workshop on “Digital Technologies – Enabling Evidence Generation in Clinical Development for Regulatory and Reimbursement Decisions” “Digital Health Regulation: The View from the Asia-Pacific”



DIA Middle East & North Africa Conference: “Looking at the Future of Digital Health: Regulatory Perspectives from the Asia-Pacific”

VACCINES

Vaccines was a common topic of great interest for both health professionals and the general public as it became apparent that they will play a significant part in the fight against COVID-19. Discussions, collaboration, and understanding focused on issues ranging from accelerated development, regulatory agility, and emergency approvals – all important issues for promoting equitable access as well as to prevent spread of misinformation.



CoRE article in Asian Scientist: Rapid, Rigorous and Robust: How Singapore Approved Its COVID-19 Vaccines

Prof John Lim explained how the approval of the COVID-19 vaccines was expedited and how decades of work behind the scenes have positioned regulators to respond both rapidly and rigorously to outbreaks

External Speaking Engagements and Platforms



Member of The Influenza Vaccines R&D (IVR) Roadmap International Taskforce



EuroCham Singapore: webinar on COVID-19 Vaccination – Facts and Fiction



APEC Life Sciences Innovation Forum (LSIF) Webinar Series on the Role of Vaccination in Maintaining Health and the Economy - Building the Right Regulatory Environment for COVID-19 Response & Long-Term Health Resilience



CoRE webinar: Safety signal detection and analysis for COVID-19 vaccines at the Uppsala Monitoring Centre



Panelist on the virtual European Scientific Working group on Influenza (ESWI) 2021 Satellite Symposium “The Influenza Vaccines R&D Roadmap: Framework for a Flu-Free Future”



CORE WEBINAR SERIES: ENCOURAGING EXCHANGE

As the pandemic gave rise to uncertainties about the current state and the future of healthcare, the demand for expert opinion on the latest developments, regulatory efforts and innovations grew. In response, CoRE presented a series of live webinars, to share key insights and perspectives of leading healthcare and regulatory professionals on COVID-19 topics pertinent to Singapore, East Asia, and the rest of the world.



Top row from left: Dr Margaret Hamburg (21st Commissioner, U.S. Food and Drug Administration (FDA)), Mr Luc Debruyne (Strategic Advisor to the CEO, Coalition for Epidemic Preparedness Innovations (CEPI)), Dr Susann Roth (Advisor and Chief, Asian Development Bank (ADB)), Ms Karen Alparce-Villanueva (Board Secretary, International Alliance of Patients' Organizations (IAPO)), Dr Peter Honig (Senior Vice President, Pfizer); Bottom row from: Prof John Lim (Executive Director, CoRE)



From left: Adj Asst Prof Srinivasan Kallathur (Director, Health Sciences Authority (HSA)), Adj Asst Prof Danny Soon (Chief Executive Officer, Consortium for Clinical Research and Innovation Singapore (CRIS)), Dr Sudipto Bari (Senior Project Administrator, Advanced Cell Therapy and Research Institute Singapore), Dr Francesca Lorraine Lim (Consultant, SingHealth Duke-NUS Transplant Centre), Mr Wong Kum Cheun (Head, Novartis)



From left: Prof John Lim (Executive Director, CoRE), Mr Low Teng Yong (Branch Head, National Centre for Food Science, Singapore Food Agency), Professor Steven G Rozen (Associate Dean, Duke-NUS Medical School), Mr Johnny Yeung (Scientist, National Centre for Food Science, Singapore Food Agency)

COVID-19 Vaccines - Global Solidarity to Enable Access to Vaccines During a Pandemic

4 FEBRUARY 2021

Key experts representing regulators, NGOs, industry and patient advocates shared their perspectives on how to facilitate transition from emergency use authorisation to full authorisation of COVID-19 vaccines, ensure equitable access and bolster public trust and confidence in vaccines.

Infrastructure to Facilitate Access to Advanced Therapies

24 JUNE 2021

Recent innovations in medical care include cell, tissue and gene therapies, which reflect the advances in clinical sciences and align to the new paradigm of precision medicine. This webinar discussed aspects of facilitating access to advanced therapies, ranging from health system policies, manufacturing facilities, regulations, to healthcare professionals and industry.

Smart Regulations in Context of Singapore Food Agency's Food Safety System

8 AUGUST 2021

This presentation provided an overview of the Singapore Food Agency's (SFA) 3 principle considerations underpinning Singapore's food safety system and how these enable SFA to practice smart regulations for food safety and facilitate regulatory innovations such as Singapore being the first country in the world to approve a cell-cultured meat product.



Top row from left: Prof John Lim (Executive Director, CoRE); A/Prof Hsu Li Yang (Vice Dean (Global Health), NUS Saw Swee Hock School of Public Health), Bottom row from left: Mr Fabio La Mola (Partner and Global Healthcare Co-Head, L.E.K. Consulting, Singapore), Ms Lin Yueh Nuo (Deputy Director, National Centre for Infectious Diseases), Mr Barry Weinman (Regional Market Access Lead, MSD)

Managing Antimicrobial Resistance in Asia: Identification and Implementation of Breakthrough Solutions

29 OCTOBER 2021

Antimicrobial resistance has been recognised by WHO to be a priority public health issue that may be the next major threat to healthcare systems globally. This webinar brought together experts from industry, academia, and government agencies to understand the efforts to address antimicrobial resistance in Asia, and what practical steps can be taken to prepare our healthcare systems.

1125

Combined participants

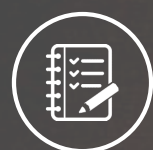
59%

Global attendance

>40

Economies

Development



The CoRE Campaign



Opportunities to Collaborate in 2022 and Beyond



International Partnerships



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#Thankstoyou
The CoRE Campaign

CoRE's pursuit for excellence is driven by enabling a world where everyone has access to good, safe and effective health products and healthcare. Your generosity will leave a lasting and tangible impact on the lives of patients, populations, and broader health systems.

Be a part of the CoRE Campaign! Give now.

Enabling a World Where Everyone Has Access to Good, Safe, and Effective Health Products

To continue in our mission and effect sustained, meaningful change as a leading education and think tank hub in Asia-Pacific, The CoRE Campaign #Thankstoyou has been established. We welcome unrestricted support through the Regulatory Excellence Fund and current-use commitments for study awards through the Alasdair Breckenridge Fund, established in memory of CoRE's inaugural Chairman.



This fund will play an important role in enabling the Centre to sustainably address region-wide issues, explore new opportunities for innovation and impactful change, and promote long-lasting cooperative solutions in a time where regulatory agility, convergence, and reliance are key.

Contributions will facilitate meaningful regulatory behavioural changes, by allowing the Centre to convene thought leaders and innovators to generate roadmaps and champion ideas that advance regulatory practice including new emerging topics. Contributions to this fund will also continue to elevate the region's regulatory capabilities by enabling the Centre to constantly enhance education programmes, as well as address new needs and imbue future readiness among the region's regulatory and healthcare professionals, academics and researchers.



In keeping with the late Professor Sir Alasdair Breckenridge's vision and interest of promoting professional excellence, this fund is established to further regulatory capacity building through study awards tenable at CoRE.

Current-use contributions to the Alasdair Breckenridge Fund will support and finance healthcare professionals from national regulatory authorities, ministries of health, and related organisations in ASEAN and Asia-Pacific to enrol in courses run by CoRE. This will enhance their professional development and strengthen the regulatory capacity of their organisations.

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OPPORTUNITIES TO COLLABORATE IN 2022 AND BEYOND

At CoRE, we work closely with a diverse network of partners from international and regional organisations to promote capacity development and innovation through strategic multi-stakeholder partnerships and collaborations. Leveraging on our expertise and network, we strongly support our stakeholders in driving scientific and regulatory excellence, policy innovation and leadership. Our platform offers many exciting possibilities and collaboration opportunities to engage with key thought leaders, decision makers, and like-minded individuals in the ecosystem.

CoRE looks forward to partner with organisations and associations that see value in our work and would like to collaborate with us. We welcome you to connect with us and become a partner of CoRE. For more information on the various collaboration opportunities and to explore possible partnership engagement, please contact us.

CoRE cultivates multi-stakeholder partnerships and offers a diverse range of collaboration opportunities.



Education

Online Training Programme

CoRE recognises the evolving training needs in the region and offers comprehensive high quality online programmes to suit the competency needs among regulatory professionals. CoRE is developing an online course on Vaccines and will continue to offer more online programmes. Exciting new opportunities for Executive Certificate courses are also in the pipeline.

Bespoke workshop

Bespoke training workshops are a valuable asset to our education offerings and provides customisable learning experiences for our students. CoRE convenes various in country and regional workshops on topics including Good Reliance Practice, Medical Device Regulations, and many more.



CoRE Scientific Conference

CoRE Scientific Conference

The CoRE Conference platform provides immense potential for engaging with experts and leaders across the globe. Building on the success of past CoRE Scientific Conferences, the 2022 CoRE Scientific Conference will be centered on the theme of “Patients as Partners for Sustainable Health Systems” and regarded as the first of its kind rooted in Asia to provide a unique multi-stakeholder platform to share insights, experiences, and best practices on patient engagement and advance systematic and meaningful patient involvement in health systems across the Asia-Pacific region. CoRE offers sponsorship opportunities for you to be a part of this conference and position yourself as a key thought leader and showcase your expertise.



Think Tank

Patient Engagement Roundtable

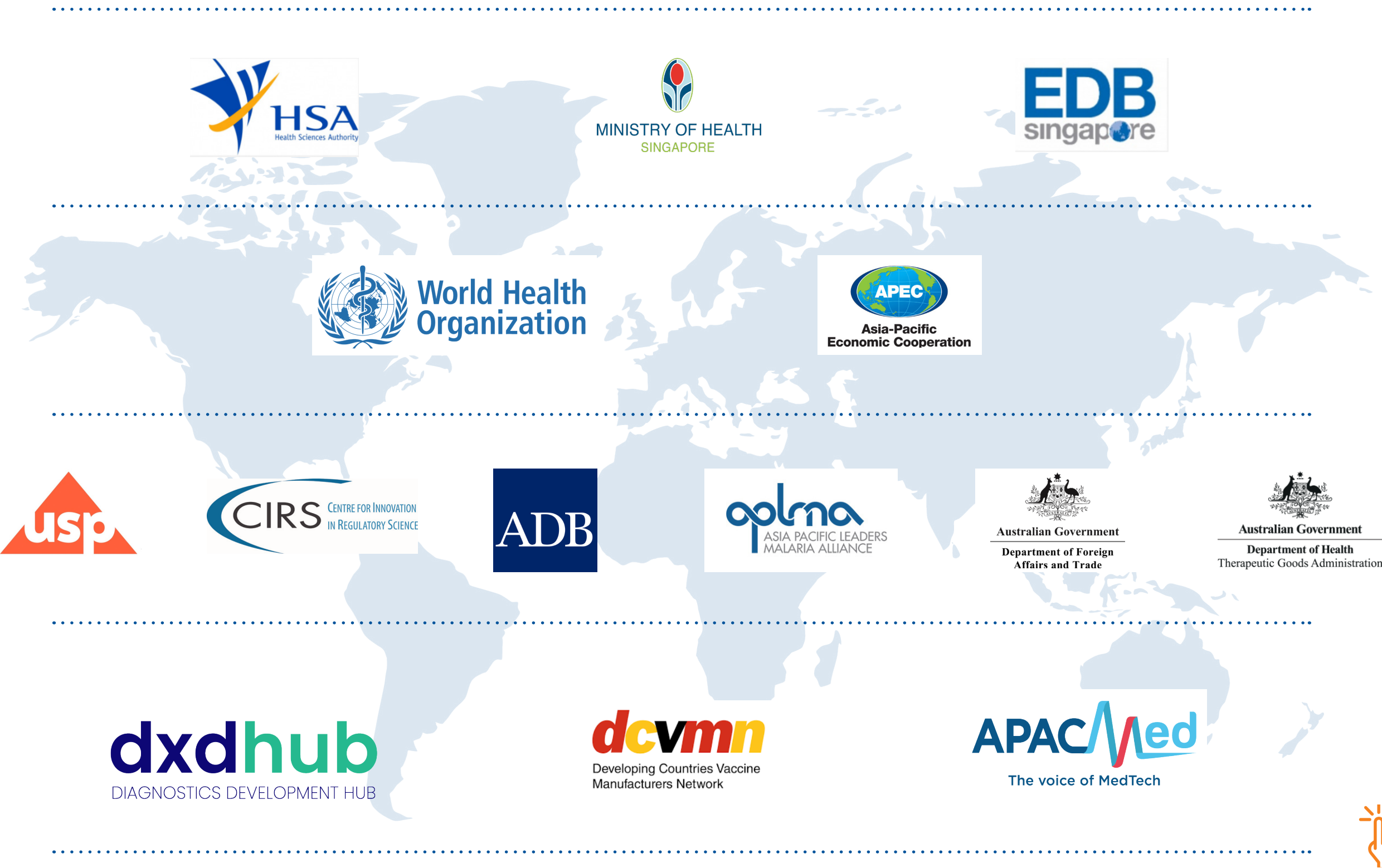
While CoRE convened a series of regional roundtables on Patient Engagement in the past years, this year there is a country specific initiative to host a Singapore centred roundtable meeting for a deeper engagement beyond our regional approach, as part of the multi-stakeholder partnership CAPE.

Digital Health Webinars & Symposium

A series of webinars, symposium and publication on Digital Health topics is in the pipeline for 2022, deep diving into and raising awareness on issues related to data collection, quality, validation, and security that were highlighted as key to progressing the use of digital health initiatives in the APAC region.

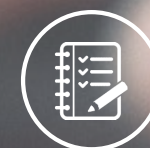
INTERNATIONAL PARTNERSHIPS

Working towards regulatory excellence is never an individual endeavour, nor can it be achieved alone. CoRE is honoured to have the opportunity to collaborate and journey with like-minded and mission-driven academic, regulatory and health organisations locally and across the globe. As we collectively set our sights on strengthening systems and building competency through regulatory cooperation and reliance, together, we can realise a world where everyone has access to safe, quality and effective health care.





CoRE:People



Year Ahead



Faculty Appointments
and Visiting Experts



CoRE Team



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YEAR AHEAD

2022 will be an exciting year, not just for the Centre, but for all who participate in CoRE’s initiatives as well. Guided by our forward-looking 2025 Strategy, we have launched new and improved Graduate Certificate modules and collaborative workshops to look forward to, in addition to opportunities to assemble even more policy makers, regulators, industry members and healthcare providers at our roundtable discussions and think-tank activities.

We look forward to meeting you at our upcoming events in 2022!

CoRE Scientific Conference

Sir Alasdair Breckenridge Lecture
2022 Lecturer: Dr Penny Heaton

DIA-CoRE Conference

CoRE Conversation

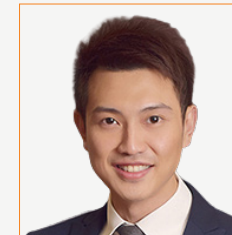
Launch of Online Programme in collaboration with DxD

FACULTY APPOINTMENTS

The Centre would like to show our appreciation to our adjunct faculty, visiting experts, and workshop faculty from NRAs, government agencies, international companies, and industry associations around the world. They collectively bring together an extraordinary wealth of wisdom and real-world experience as they continue to be extensively involved through their contributions and dedication to building regulatory and healthcare excellence across the region and globally.



A/Prof Hsu Li Yang
Vice Dean (Global Health) & Programme Leader
(Infectious Diseases)
NUS Saw Swee Hock School of Public Health



A/Prof Daniel Ting
Director
Cluster AI Program
Singapore Health Service (SingHealth)



Adj A/Prof Chan Cheng Leng
Group Director
Health Products Regulation Group
Health Sciences Authority Singapore



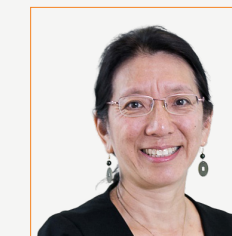
Adj A/Prof Sidney Yee
Founding Chief Executive Officer
Diagnostics Development Hub
Inaugural Co-Chair
ASEAN DxI Initiative



Adj A/Prof Raymond Chua
Deputy Director
Medical Services
Health Regulation Group
Assistant Commissioner
Cybersecurity
Ministry of Health, Singapore



Adj A/Prof Kelvin Bryan Tan
Director
Policy, Research and Evaluation Division
Ministry of Health, Singapore



Adj A/Prof Cynthia Sung
Portfolio & Platform Lead
Translational Sciences
Global Health
Bill & Melinda Gates Medical Research Institute



Adj A/Prof Teoh Yee Leong
Chief Scientific Advisor
Consortium for Clinical Research & Innovation Singapore (CRIS)



Adj Asst Prof Danny Soon
Chief Executive Officer
Consortium for Clinical Research and Innovation, Singapore
Executive Director
Singapore Clinical Research Institute



Adj Asst Prof Kellathur Srinivasan
Director
Advanced Therapy Products Branch
Medicinal Products Pre-market Cluster
Health Products Regulation Group
Health Sciences Authority Singapore

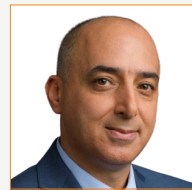


Adj Asst Prof Pengiran Hishamuddin Bin Pengiran Badaruddin
Chief Medical Officer
Practice Innovators International & GPNOW



Adj Asst Prof Clive Tan
Adjunct Assistant Professor
Saw Swee Hock School of Public Health

VISITING EXPERTS



Dr Fouad Atouf
Vice President
Global Biologics
The United States
Pharmaceutical Convention
(USP)



A/Prof Bruce Burnett
Director
Regulatory Affairs
Duke Translational Medicine
Institute
Duke University



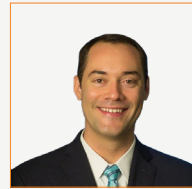
A/Prof Edwin Chan Shih-Yen
Chief Scientific Officer
Singapore Clinical Research
Institute
Director
Cochrane Singapore



Dr Sannie Chong
Head
Asia Pacific Technical Regulatory
Policy
Global Regulatory Policy Group
Roche Singapore Technical
Operations Pte Ltd



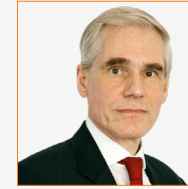
Dr Anne Cook
Expert Quality Assessor
UK Medicines & Healthcare
products Regulatory Agency



Dr Gregory Daniel
Global Head of Public Policy
Global Corporate Affairs
Eli Lilly and Company



Dr Jean-Christophe Delumeau
Head
Pharmacovigilance Policy Strategy
(Global)
Bayer



Prof Hans-Georg Eichler
Professor
Medical University of Vienna
Austria
Consultant Physician
Association of Austrian Social
Insurance Institutions



Mr Michael Gropp
Former Chair
RAPS
Global Advisory Council



Prof Kenneth Hartigan-Go
Head
Stephen Zuellig
School of Development
Management
Asian Institute of Management



Dr Nikki Kitikiti
Associate Visiting Expert
CoRE



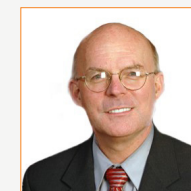
Dr Lam Siu Ping
Director
Licensing Division
UK Medicines and Healthcare
products Regulatory Agency



Dr Leung Pak-yin
Former Chief Executive
Hospital Authority
Hong Kong Special
Administrative Region



Dr Kerwin Low
Vice President
Regulatory Affairs
Emerging Markets
Takeda Pharmaceuticals
International



Dr Murray Lumpkin
Deputy Director
Integrated Development
Lead
Global Regulatory Systems
Initiatives
Bill & Melinda Gates Foundation



Dr Tippi Mak
Board Member
Vaccine & Infectious Disease
Organization - International
Vaccine Centre, University of
Saskatchewan Canada
Medical Affairs Lead
Infectious Diseases & Vaccines
Janssen



Dr Wassim Nashabeh
Vice President & Global Head
Policy & International Operations
Pharma Technical Regulatory
Roche



Dr Moheb Nasr
Principal
Nasr Pharma Regulatory
Consulting (NPRC)



Dr Poh Weijie
Global Project Manager
Healint Pte. Ltd



Mr Rajakanth R
Principal Consultant
Manifeste LLP
Executive Director
Rainbow Across Borders Ltd



Dr Lembit Rago
Secretary-General
Council for International
Organizations of Medical
Sciences (CIOMS)



Dr Sethuraman Rama
Director
Medical Devices Branch
Health Sciences Authority
Singapore



Dr Valerio Reggi
Consultant
Drug Regulatory Matters &
Pharmaceutical Policy



Dr.-ing Stephan Roenninger
Adjunct Assistant Professor
George Washington University
Director
Quality External Affairs
Amgen (Europe)



Dr Tomas Salmonsan
Partner
Consilium Salmonson &
Hemmings
Former Chair
Committee for Medicinal
Products for Human Use
European Medicines Agency



Dr Adelheid Schneider
Head
Regulatory and Quality Asia
Pacific
Roche Diagnostics Asia Pacific



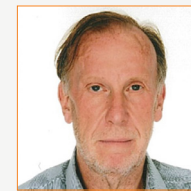
Dr Rominder Singh
Head
Regulatory Affairs, Asia
Global Regulatory Affairs
International
Pfizer



Dra Lucky Slamet
Former Head
National Agency of Food & Drug
Control
Indonesia



Mr Teo Cher Hwa
Director
National Health Innovation
Centre
Singapore



Dr John Thornback
Senior Advisor
Diagnostics Development Hub



Prof Stuart Walker
Founder
Centre for Medicines Research
International Limited
Professor
Pharmaceutical Medicine
University of Wales, Cardiff



Mr John Wilkinson
Chair
Global Medical Devices Nomen-
clature Agency
Former Director of Devices
UK Medicines & Health Products
Regulatory Agency



Mr Wong Kum Cheun
Head Asia Pacific
Regulatory & Development Policy
Novartis Asia Pacific
Pharmaceuticals Pte Ltd

CoRE TEAM

CoRE's success over the past years would not be possible without the commitment and dedication of our CoRE Team and we look forward to working with you in 2022.





Contact Us

Find us

Duke-NUS Medical School
8 College Road
Singapore 169857

Call us

+65 6601 5147

Email us

core@duke-nus.edu.sg

Browse us

www.duke-nus.edu.sg/core

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