

2020



**Centre of Regulatory Excellence
@ Duke-NUS Medical School**

KEY OVERVIEW

Message by Professor John Lim	4
1. CoRE: REALISED	
Our Leadership	6
Our Late Inaugural Chairman	8
Our Journey, Our Future	10
CoRE as an Enabler	12
2020 at a Glance	14
2. COVID-19: RISING UP	16
Strengthened Through Adversity	18
Going Digital: Enabling Education	20
Going Digital: Encouraging Exchange	22
Deepening Local and Global Conversations	24
3. CoRE: REDEFINED	26
Enhancing Expertise for an Evolving World	28
Initiating Change Together	32
Fostering Meaningful Dialogue	34
Promoting Thought Leadership	36
International Partnerships	38
Asia-Pacific Economic Cooperation (APEC) and International Engagements	40
4. CoRE: REACHING OUT	42
Message by Associate Professor Silke Vogel	44
The Year Ahead	46
Sir Alasdair Breckenridge Lecture Series	48
Supporting Tomorrow's Leaders	50
Adjunct Appointments & Visiting Experts	53
Contact Us	57



2020

marked a year of unprecedented challenges.

Thank you for your continued
and unwavering support.



>7000
combined
participants
since 2014



>200
faculty comprising of
local & international
thought leaders



>60
events and
programmes
since 2014



>50
Unique Nationalities Attended our events spanning
from ASEAN & the Asia-Pacific, Europe,
North America, Africa, and the Middle East

Message by Professor John Lim

2020 was a year filled with immense challenges, as healthcare systems around the world were stretched to an unprecedented degree by the COVID-19 pandemic. Singapore was no stranger to this, and experienced similar difficulties with the initial surge in COVID-19 cases. We also witnessed the nation come together and rally around government efforts to contain the pandemic and support frontline workers, not only in healthcare institutions but across all key organisations. Notably, the biomedical research community responded with commendable speed so that locally produced diagnostic kits and vaccine development efforts with key involvement from Duke-NUS researchers made enormous strides within an extraordinarily short timeframe.

As the Centre's resilience and resourcefulness were put to the test, COVID-19 has served to bolster the Centre's efforts and endeavours. Despite being heavily impacted by travel restrictions and having to quickly transition to working from home arrangements, CoRE readily responded by digitally transforming our education programmes and think-tank activities, enabling us to overcome geographical hurdles and allow greater engagement with overseas speakers and participants alike. Furthermore, we actively contributed our voice and perspectives to pertinent COVID-19 discussions alongside regional and international thought leaders, via our webinar series, collaborative thought pieces, and interviews with various news and media providers.

The pandemic has also reinforced the importance of CoRE's mission to strengthen the region's regulatory capabilities. It has also cemented the importance of collaboration amongst regulators, industry players and various stakeholders to ensure that enhanced regulation yields positive outputs and outcomes. Moving forward, CoRE has taken the opportunity to reflect and developed our 2025 Strategy, outlining how we will evolve our education and workstreams to remain future-ready. Some of the year's milestones include the incorporation of medical devices into the Graduate Certificate Programme curriculum, a collaboration with the Diagnostics Development Hub from A*STAR, and patient engagement and digital health roundtable discussions which featured international associations like the World Health Organization in attendance.

In 2021, the Centre looks forward to a year filled with exciting new programmes, initiatives and opportunities, while continuing to address capacity building and think tank activities that support ongoing efforts to manage the pandemic. We greatly appreciate the invaluable guidance of our Advisory Board, Adjunct and Visiting Experts, and other stakeholders who have journeyed with us through these tough times. We look forward to your ongoing partnership as we work towards enhancing health and regulatory systems and promoting regulatory excellence in the Asia-Pacific region.



“

*COVID-19 has served to bolster
our efforts and endeavours as our
resilience and resourcefulness
were put to the test.*

”

CoRE’s success over the past six years would not be possible without the commitment and dedication of the visionary leaders in the Centre’s Advisory Board. We would like to express our appreciation for their indispensable strategic guidance and unceasing support since CoRE’s inception.



Interim Chair
Dr Margaret Hamburg
*Former Commissioner
U.S. Food And Drug Administration*



Prof Guido Rasi
*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
*President &
Chief Executive Officer
Critical Path Institute (C-Path)
Former Senior Vice President
Bayer Pharmaceuticals*



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



Dr Peter Honig
*Senior Vice President
Global Regulatory Affairs
Group Head
China and Japan
Development
Pfizer*



Advisor
Mr Jean-Luc Butel
*President
K8 Global*

We would also like to express our gratitude to Dr Tatsuya Kondo and A/Prof Bruce Burnett, who have stepped down from the Advisory Board, for their invaluable direction, wisdom and support since CoRE was first established. We appreciate the many years of partnership, collaboration, and the positive influence they have made on the Centre to reach our current level of international impact and influence.



Dr Tatsuya Kondo
*Chief Executive Officer
Medical Excellence JAPAN
Former Chief Executive
Medical Devices Agency
Japan*



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



REMEMBERING
PROFESSOR SIR ALASDAIR BRECKENRIDGE
1937 - 2019

Our Late Inaugural Chairman

Professor Sir Alasdair Breckenridge, Inaugural Chairman of the Centre of Regulatory Excellence Advisory Board, passed away peacefully in the United Kingdom on 12th December 2019 at the age of 82.

We owe the late Sir Alasdair a tremendous debt of gratitude for his unparalleled leadership and clear-sighted guidance. Since our inception, Sir Alasdair envisioned CoRE as an influential contributor to regulatory thought leadership and capacity building in Asia-Pacific, and increasingly at a global level. During his tenure, he was instrumental in the formation and implementation of CoRE's strategic objectives, allowing the Centre to serve members from the government, academia, associations and industry. His invaluable encouragement and advocacy has instilled an enterprising and innovative culture within the Centre, and laid a strong foundation for our continuing growth.

Sir Alasdair was well-recognised for his tireless dedication to health care, patients and populations. Most notable were his engagement with the administration of the UK National Health Service, as Chairman of the Medicines and Health products Regulatory Agency (MHRA), and his extensive research contributions with publications in many prestigious journals including The Lancet and the British Medical Journal. Sir Alasdair was appointed Commander of the Order of the British Empire in the 1995 Birthday Honours and knighted in the 2004 New Year Honours for his service to UK academic medicine. He was also globally recognised for his involvement with numerous international associations like the World Health Organization and the International Union of Pharmacology, and was awarded the Paul Martini Prize in Clinical Pharmacology and the Poulson Medal of the Norwegian Pharmacological Society. As a highly respected and globally acclaimed clinical pharmacologist, international scientist and visionary regulatory professional, there is much to celebrate about Sir Alasdair's extraordinary achievements, work ethic, and vision, and we wish to honour his memory and continue his mission by launching the Alasdair Breckenridge Lecture Series in 2021.

“ *I would like to specially acknowledge the immense contributions of Professor Sir Alasdair Breckenridge, inaugural Chairman of CoRE's Advisory Board, whose leadership and guidance have been so central in bringing CoRE to where it is today.*

- Mr Gan Kim Yong, Minister for Health,
Singapore at CoRE's 5th Anniversary Dinner, 2 Oct 2019

”

2025 STRATEGY

To meet the evolving needs of our stakeholders, and account for macro-environmental factors, such as COVID-19 and the need to ensure equitable, fair access to treatment and health products, the Centre will create new initiatives, improve operations, and create better efficiencies, as outlined in its 2025 strategy.

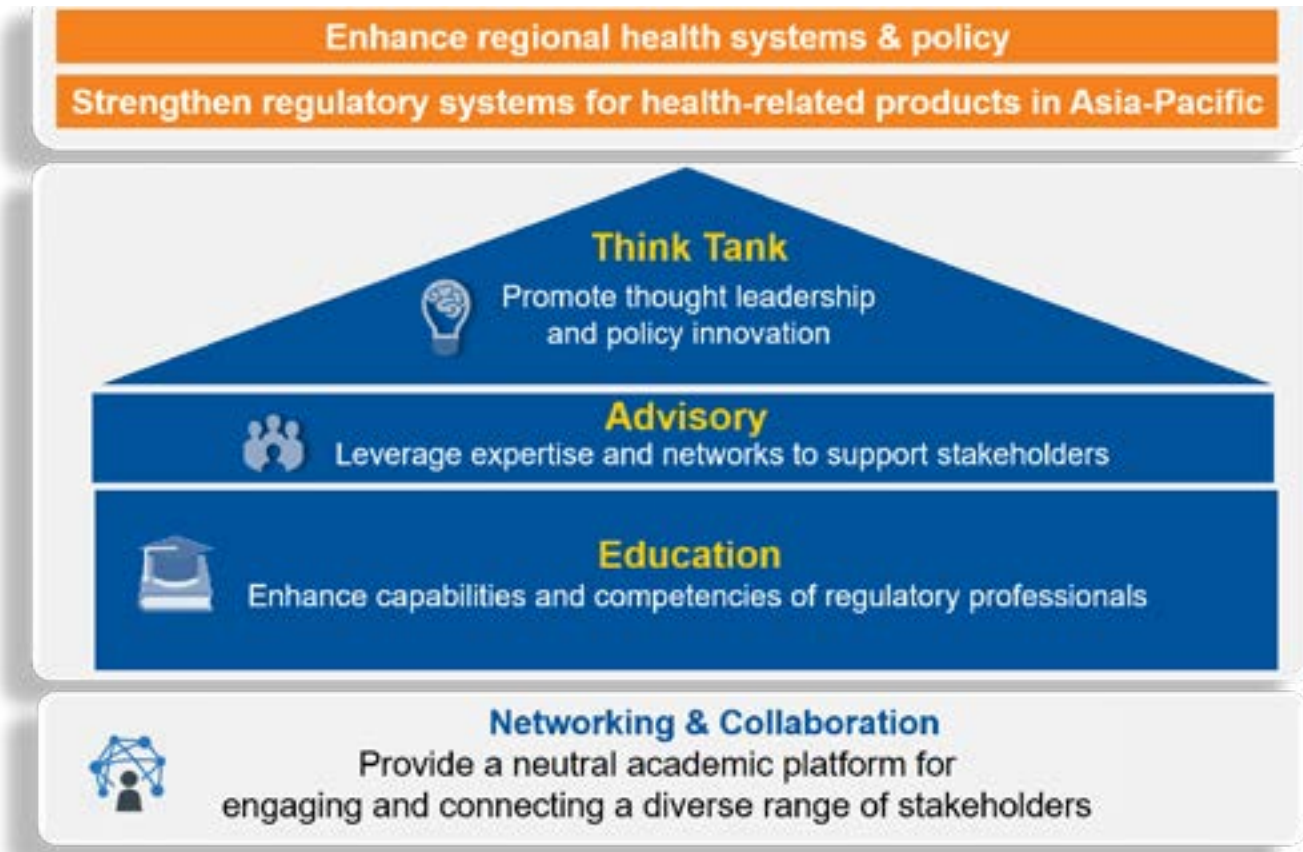
CoRE is centred upon three key approaches to fulfil its vision: **Education**, to develop regulatory talent and enhance the competencies of regulatory professionals; **Think Tank** activities, to promote thought leadership and policy innovation; and **Advisory** services, by leveraging on the Centre's expertise and networks to better support stakeholders.

Bolstered by our extensive networks and collaborations with a diverse range of stakeholders, CoRE provides a neutral academic platform to engage and connect government and regulatory bodies, industry members, academia, and healthcare institutes. The combined expertise and perspectives from various areas of the healthcare and regulatory community enable CoRE to develop well-informed and relevant initiatives in each of our key approaches.

Moving forward, the Centre has outlined a 2025 Strategy to meet the evolving needs of our stakeholders, and account for macro-environmental factors, such as the recent regulatory transformations arising from COVID-19 and the need to ensure equitable, fair access to treatment and health products. Over the next five years, CoRE will channel its efforts and resources into developing Education programmes, Advisory and Think Tank initiatives to build regulatory capacity in six focus areas of burgeoning biomedical and digital innovations. The Centre will continue to build upon its strategic partnerships to support regulatory and health system strengthening.

VISION

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



MISSION

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

6 Key Focus Areas



Digital Health

To help define the domain and relevant follow-through, primarily in regulation



Patient Engagement

Accelerate systematic and meaningful patient involvement in health systems in the Asia-Pacific



Innovative Therapies

Build competencies in the region and facilitate access



Medical Devices

Build competencies in Medical Devices regulations for the region



Clinical Trials

Build competencies in the region and contribute to enhancement of Clinical Trials ecosystem in Singapore



Vaccines

Promote vaccine access and support pandemic preparedness

Amalgamate efforts to achieve targeted outcomes

Impact health outcomes

Address strong demand and interest from stakeholders

Play an enabling role with tangible outcomes

Create synergy between education programmes & think tank initiatives

For the next five years, CoRE will work towards enhancing well-established and quality education programmes to incorporate six focus areas, to provide a strong anchor for continued growth. These areas are: digital health, patient engagement, innovative therapies, medical devices, clinical trials, and vaccines. Similarly, the Centre will grow its Think Tank and Advisory functions in these new areas to raise awareness and promote thought leadership and policy innovation for up-and-coming biomedical and healthcare issues, acting as a compass to help steer the direction of healthcare and regulatory development in Asia-Pacific.

By amalgamating our efforts in these six areas, CoRE has the potential to impact health outcomes, address the strong demand and interest from stakeholders, play an enabling role with tangible outcomes, and create synergy through educational programmes and think tank activities.

While the COVID-19 pandemic posed significant challenges, CoRE was able to leverage this as an opportunity to introduce and integrate digital and remote work schemes to continue our education and think tank activities. The successful digital transition of our Graduate Certificate modules, workshops and seminars has been well received by our participants and allowed us to reach new audiences around the world. Going digital gave us the opportunity to become involved in a myriad of dialogues, joint publications and articles, and share our South East Asian perspective on a global platform.

CoRE Team

- Worked from Home since March
- Going Digital



Education Activities

- From face to face to remote learning
- Restriction to class size
- Rerun of modules

3

brand new Medical Devices Workshops implemented in collaboration with DxH Hub

90%

of Graduate Certificate workshops conducted via Synchronous Learning

2nd Run

for 3 courses of our Graduate Certificate Programme due to overwhelming response

Think-Tank Activities

- Convening stakeholders to raise awareness and facilitate discussion on pressing regulatory issues arising from COVID-19

100%

of seminars successfully conducted as webinars

15

articles, dialogues and publications on COVID-19 shared in a worldwide effort to end the virus

Despite COVID-19, 2020 has been a year of growth and evolution for the Centre, with the enhancement of our Graduate Certificate Programme, initiation of new workstreams in line with our 2025 Strategy, and new local and international partnerships to further regulatory capacity building in the region, all the while being actively engaged in global activities and discussions to progress the regulatory environment.

New Initiatives

- Incorporated Medical Devices
- Redesigned the curriculum to Graduate Certificate in Health Products Regulation

New Workstreams

- 3 new workstreams including Medical Devices, Digital Health and Patient Engagement

New Partnerships

- Diagnostics Development Hub (DxD)
- JUMPStart
- Centre for Innovation in Regulatory Science (CIRS)

Global Engagements

- Regulatory Harmonization Steering Committee Life Sciences Innovation Forum (RHSC LSIF)
- Council for International Organizations of Medical Sciences (CIOMS)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- Drug Information Association (DIA)

Stakeholder Engagements

- Webinars
- Publications
- Articles
- Dialogues

COVID-19: Rising Up

A YEAR OF TRANSFORMATION



Strengthened Through Adversity



Going Digital: Enabling Education



Going Digital: Encouraging Exchange



Deepening Local and Global Conversations



Doing our part to bring some joy to the CoRE community amidst the loneliness and stress of circuit breaker, the Centre’s in-house designer created a series of uplifting cartoons, illustrating how to stay safe, healthy and positive by sharing kindness with one another.



Settled into a new rhythm and established workflows to ensure smooth operations for the Centre and participants

Working from home, and transitioning from face-to-face classes and in-person think-tank activities, to an online mode of delivery instead



Singapore was affected by COVID-19, as early as January 2020 and as the cases surged, the country entered into its “Circuit Breaker” period to curb local transmission of the virus. Amidst fear and uncertainty for the nation’s wellbeing, Singapore’s people and the government promptly responded and partnered with each other to practice a high degree of social awareness and compliance to strict public health measures.

At CoRE, this meant quickly adapting to working from home, and transitioning from face-to-face classes and in-person think-tank activities, to an online mode of delivery. To bring some joy to the CoRE community amidst the loneliness and stress of circuit breaker, the Centre’s in-house designer created a series of uplifting cartoons, illustrating how to stay safe, healthy and positive by sharing kindness with one another.

After the partial lockdown, Singapore progressively re-opened through a series of planned phases, and by the mid-year, the situation had stabilised with low spread in the community. By then, CoRE was no stranger to the challenge of adjusting to a “new normal” resulting from COVID-19, as we settled into a new rhythm and established workflows to ensure smooth operations for the Centre and participants.

Throughout this year of adversity, CoRE kept a spirit of resourcefulness, resilience and compassion alive among us, and translated it into our work towards regulatory capacity building and systems strengthening at both the individual level and on the international stage. Despite the disruptions and setbacks resulting from COVID-19, CoRE remained undeterred in engaging healthcare systems, regulators, industry players and patients in discussions that truly matter.



Going Digital: Enabling Education

Measures and restrictions implemented due to COVID-19 led to operational challenges for the Graduate Certificate Programme. As overseas speakers and participants were prevented from entering Singapore, and social distancing practices were implemented, face-to-face lessons were no longer possible. Despite these challenges, the team adapted Duke-NUS' well-established TeamLEAD pedagogy to suit a virtual classroom setting that provided an optimal learning experience. With the successful transition of all Graduate Certificate modules to full online

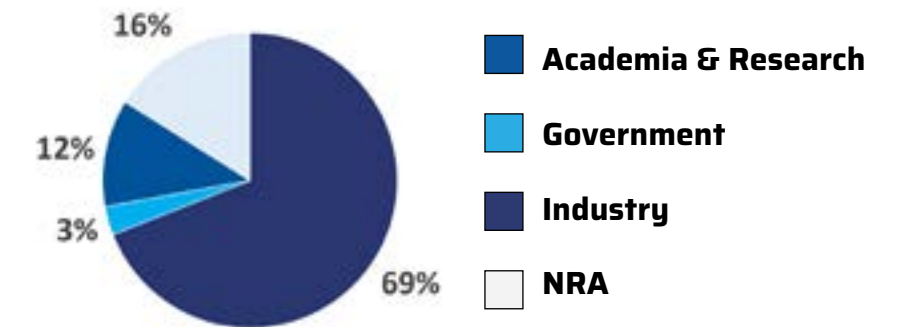
delivery via Synchronous Learning and through the NUS' Learning Management System, the team ensured that Duke-NUS' pedagogy was extended from face-to-face to online workshops as well.

In spite of the need to accommodate to this new mode of delivery, as well as the restrictions to class sizes which meant fewer could attend, very positive feedback from participants were received. For some, working in smaller class sizes enhanced their learning with greater individual attention and guidance, while for others, going digital meant more flexibility to learn

at their own pace. Additionally, going digital has enabled the programme to overcome geographical boundaries, allowing us to expand our reach and engage a larger pool of overseas speakers and participants, wherever they may be situated.

CoRE continues to experience an overwhelming demand for its education programmes, keeping the team busy well into 2021 as a second run of popular modules have been scheduled and are being conducted.

Student Profile



Internationally Recognised Faculty

>70

Culturally diverse internationally recognised expert faculty

40+

Organisations partner with CoRE to provide real-world practice and application



CoRE taps into an international community of active practitioners of regulatory affairs and biomedical science who can provide comprehensive perspectives of the environment. From governments and NRAs, 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.

Going Digital: Encouraging Exchange

As the pandemic gave rise to more 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: Mr Food Yang Tong (Acting Assistant Group Director, Health Sciences Authority Singapore), Dr Sidney Yee (Chief Executive Officer, Diagnostics Development Hub); Middle row from left: A/Prof Jenny Low (Senior Consultant, Singapore General Hospital); Bottom row from: Dr Tippi Mak (Board Member, International Vaccine Centre), Dr Sethuraman Rama (Director, Health Sciences Authority Singapore)



Top row from left: Prof Guido Rasi (Executive Director, European Medicines Agency), Prof John Skerritt (Deputy Secretary, Department of Health Australia); Bottom row from left: Dr Mimi Choong (Chief Executive Officer, Health Sciences Authority Singapore), Dr Murray Lumpkin (Deputy Director, Bill & Melinda Gates Foundation)



Top row from left: Mr Ellil Mathiyon (President, Ostomy Association of Singapore); Mr Kenneth Mah (Co-founder and Vice President, Rare Disorders Society (Singapore)); Ms Fatima Lorenzo (President, Philippine Alliance of Patient Organisations); Mr Ekawat Suwataroj (Vice President, Thai Hemophilia Patient Club); Ms Peni Utami (Chairman, Indonesia Rare Disease Foundation); Bottom row from left: Prof John Lim (Executive Director, CoRE), Mr Rajakanth R (Executive Director, Rainbow Across Borders), Mr Nicholas Brooks (Executive Director, Patient Focused Medicines Development), Ms Kristin Scheeman (Program Director, FasterCures)

Improving Access: Singapore's Innovations for COVID-19 Diagnostics and Therapeutics

16 APRIL 2020

As the rapid spread of COVID-19 challenges capacities of healthcare systems around the world, global scientific research into potential therapeutics advanced at an unprecedented rate. This webinar discussed how to facilitate access to such therapeutics, and showcased Singapore's innovations.

Global Regulatory Coordination to Facilitate Access to COVID-19 Diagnostics and Therapies

11 MAY 2020

The development of COVID-19 diagnostics, therapeutics and vaccines reached extraordinary speed globally, rendering global regulatory coordination more critical than ever. This webinar tackled the conundrum of providing equitable access to all and how regulators around the world are working to make it happen.

COVID-19's Impact on Patient Engagement in East Asia

29 JUNE 2020

As healthcare resources were over-stretched by the crisis and consequently changed priorities, patients, especially those with rare diseases, are concerned with continued healthcare access in the coming days. This webinar gathered patient group leaders across ASEAN to share challenges and discuss solutions to bolster patient engagement as an approach to address the concern.

1075
Combined participants



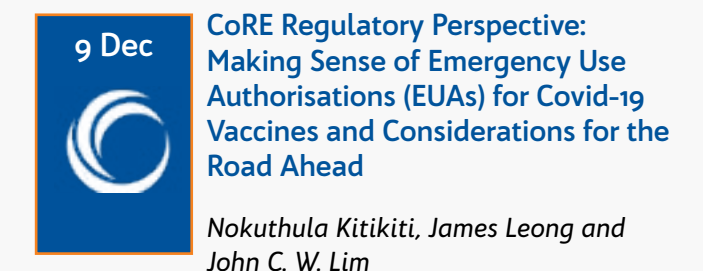
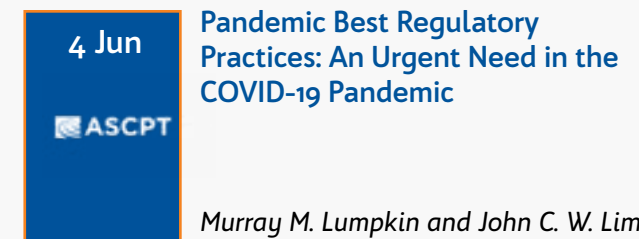
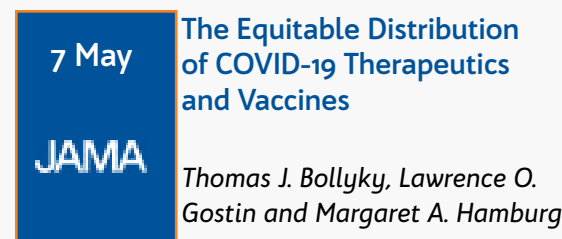
55%
Global attendance
from more than
30
economies

Deepening Local and Global Conversations

Apart from utilising the Centre's presence as a regional platform to stir conversations and prompt thinking on diagnostic devices and patient engagement issues arising from COVID-19, CoRE lent our regulatory expertise to various news pieces, informing the public on current regulatory processes and vaccine development.

Similarly, CoRE authored and co-authored numerous commentaries and journal articles with fellow academics and regulatory scientists, on issues critical to the immediate pandemic and beyond.

CoRE had the opportunity to offer a unique South East Asian perspective and experience in dialogue sessions discussing issues arising from and catalysed by the pandemic, namely regulatory reliance and the building of resilient health systems in the digital age.



Micaela Leong Hui Jin, Silke Vogel, Nokuthula Kitikiti, Ananda Padmanabhan



Alexander R. Giaquinto, Alberto Grignolo, Lawrence Liberti, John C. W. Lim, Tomas Salmonson, Fernand Sauer and Henrietta Ukwu



Uttara Soumyanarayanan, Mimi Choong, James Leong, Murray M. Lumpkin, Guido Rasi, John H. Skerritt, Silke Vogel and John C.W. Lim



Click to read

CoRE: Redefined

Coming Together and Collaborating



Enhancing Expertise for an Evolving World



Initiating Change Together



Fostering Meaningful Dialogue



Promoting Thought Leadership



International Partnerships



**Asia-Pacific Economic Cooperation (APEC)
and International Engagements**



ENHANCING FOR AN EVOLVING WORLD



Participants can choose a wider and diverse range from the Graduate Certificate Programme



Choose from 11 Modules



Increased flexibility to obtaining Certificate



Expanded scope to include medical devices



Flexible curriculum to accommodate latest regulatory science

Graduate Certificate in Health Products Regulations

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

While the existing programme has gained 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. After taking this and our stakeholders’ feedback into consideration, CoRE has enhanced and redesigned the curriculum to feature three brand-new modules on the topic of medical devices, the post-market processes for medical technologies, the regulation of digital health products, and in vitro diagnostic devices and precision medicines.

With a wider selection of modules and increased flexibility to attain the Graduate Certificate, CoRE offers participants a comprehensive and well-rounded education that facilitates learning, networking, collaboration, and encourages the growth of a community committed to health and regulatory excellence. In doing so, we aim to nurture a generation of future-ready regulatory professionals, and better prepare them for their careers.



Graduate Certificate in Health Products Regulation

3 new Medical Technology Topics incorporated:

1. Post-Market for Medical Technologies
2. Regulation of Digital Health Products
3. In Vitro Diagnostic Devices and Precision Medicines

Graduate Certificate in Pharmaceutical Regulation

2018

2020

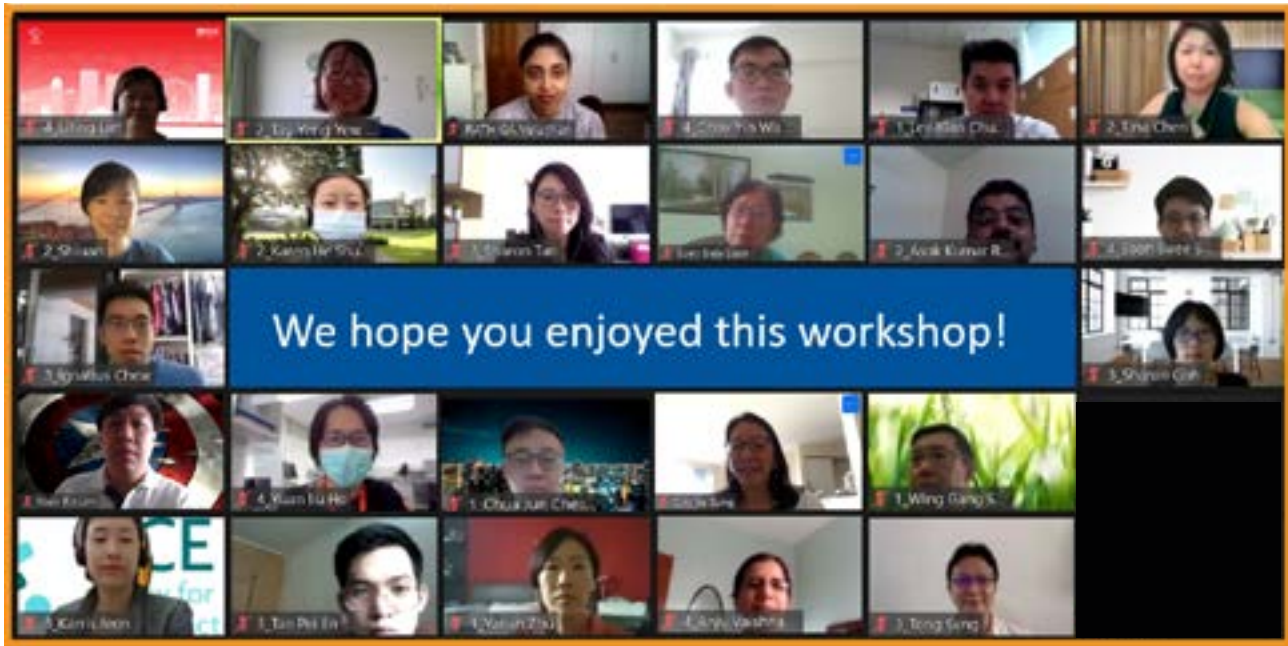
While medical devices (MD) form key health products alongside medicines and drugs, regulations addressing its unique and broad spectrum of risks and challenges have yet to be fully implemented throughout the Asia-Pacific region. To respond to this need for competency and capacity building for both regulators and the industry, CoRE launched its first-ever MD workshops to lay the foundational understanding of regulating such medical innovations.



Regulation of In Vitro Diagnostic Devices

1 - 2 SEPTEMBER 2020

Organised in response to the growing significance and role of IVDs in the patient healthcare journey, the 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 Yingao (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

1 - 2 DECEMBER 2020

As the emergence of digital health technology calls for regulatory oversight specific to SaMD that existing medical device regulations cannot provide, this workshop presented the fundamentals of software standards and guidelines as a crucial tool for effective governance of such devices.



“To enhance my knowledge in this growing field, I participated in both medical device workshops. It was enlightening to hear diverse experts share key insights and provide real-life examples on the development and regulatory requirements of such technologies. These workshops have encouraged me to enrol in CoRE’s Graduate Certificate Programme, and I look forward to gaining a wider exposure on the regulatory landscape.

Tina Chen, Regulatory Affairs Manager

”

INITIATING CHANGE TOGETHER

Building on prior engagements and collaborations, CoRE cemented our partnerships with various stakeholders who share a common vision to promote capacity building, thought leadership and excellence in regulatory science in the Asia-Pacific and beyond. By exchanging regulatory insight and experience with fellow academic institutions and hubs of regulatory science, and actively cooperating in endeavours of regulatory innovation, change for the better is made possible.

DIAGNOSTICS DEVELOPMENT HUB



From left: Prof John Lim (Executive Director, CoRE), Prof Thomas Coffman (Dean, Duke-NUS Medical School), Dr Sidney Yee (Chief Executive Officer, DxH), Dr John Thornback (Chief Operating Officer, DxH)

Collaborative Agreement with Diagnostics Development (DxD) Hub

15 OCTOBER 2020

CoRE signed a collaborative agreement with the DxH Hub of Singapore's Agency for Science, Technology and Research (A*STAR) to develop a joint training programme for IVD and SaMD developers. By combining CoRE's regulatory expertise and DxH Hub's technical capabilities and resources, the partnership seeks to enable IVD and SaMD developers' transformation of ideas into game changing innovations safely and effectively. The joint training programme integrates product development and regulation by incorporating hands-on product development experience with regulatory recommendation and expertise, building the business and regulatory capacities of up-and-coming start-ups.

ASEAN Medical Devices Workshop with JUMPstart

16 OCTOBER 2020



CoRE became a part of many up-and-coming bio-entrepreneurs' development journey at the exclusive ASEAN Medical Device Regulatory Workshop organised by JUMPstart (Joint University Medtech Programme). Designed to help aspiring medtech innovators bridge the gap from laboratory research to clinical use, CoRE shared the fundamentals of medical device regulation in ASEAN and provided the necessary skills to navigate the region's complex regulatory landscape.

Memorandum of Understanding with Centre for Innovation in Regulatory Science (CIRS)

17 DECEMBER 2020

CoRE and CIRS signed a Memorandum of Understanding to reinforce our common interest in promoting thought leadership and excellence in regulatory science in the Asia-Pacific and other regions, covering areas such as regulatory reliance, benchmarking and incorporation of stakeholder perspectives in decision making.



As a neutral academic platform, CoRE played a key role in convening a diverse range of stakeholders to address challenging, innovative and meaningful issues through robust and open dialogue. The Centre gathered policy makers, regulators, industry members, healthcare professionals and patients across the globe to explore emerging issues and hot topics that need attention. Through virtual solutions, CoRE overcame challenges posed by COVID-19 and ensured the continuation of the conversations.

Digital Health Roundtable: Enabling Digital Health Adoption in Asia-Pacific

18 - 19 NOVEMBER 2020



Digital Health is a fast-developing field that holds great promise to strengthen healthcare systems and improve patient care. However, it is a very wide area with many challenges and uncertainties that need to be addressed before its value can be realised. CoRE convened its first virtual Digital Health Roundtable, bringing together 34 health policy makers, regulators, academics, researchers and industry players from ASEAN, Asia-Pacific and Europe, to identify the current landscape of digital health in the region and key opportunities for aligning digital health policy and regulation. Opened with a keynote address by Mr Bernardo Mariano Jr, the World Health Organisation's Chief Information Officer and Director, Digital Health Innovation, the conversations that arose proved to be very fruitful in understanding the region's perspectives on the role and impact of digital technology in healthcare. These discussions continue to be expanded upon, as the Centre commences on drafting a paper centred on the roundtable findings. As we advance collective understanding and define potential solutions in this fast-evolving field, we aim to support faster and appropriate Digital Health adoption for the benefit of patients.

Regional Multi-Stakeholder Roundtable: Accelerating Patient Engagement for more Resilient Health Systems

23 - 24 NOVEMBER 2020



CoRE, in partnership with Rainbow Across Borders, Milken Institute, Patient Focused Medicines Development and the SingHealth Duke-NUS Global Health Institute, convened 58 participants at the second regional multi-stakeholder roundtable on Patient Engagement, themed "Accelerating Patient Engagement for Resilient Health Systems". This year's discussion built on 2019's inaugural roundtable, and explored how to support and empower patients and increase capacity for engagement, especially amidst uncertainties of the COVID-19 pandemic and beyond. This Roundtable launched the Coalition to Accelerate Patient Engagement (CAPE), a multi-stakeholder partnership to accelerate systematic and meaningful patient involvement in health systems across the Asia-Pacific. CAPE aims to be a hub to share best practices for evidence-based patient engagement and increase coordination and collaboration among stakeholders to build strong and people-centred health systems in Asia-Pacific.

PROMOTING THOUGHT LEADERSHIP

Drawing on our expertise, strong education foundation and a wide network, CoRE played an important role in promoting thought leadership based on science and facts. With our unique presence in the global arena, CoRE also collaborated with partners and acted as a platform to promulgate pertinent issues impacting the regulatory and health systems. Regulators, industry members and healthcare providers learnt the perspectives of fellow professionals and discovered how they can respond to the world's healthcare challenges.



Drug Information Association (DIA) and CoRE Virtual Conference

6 - 7 JULY 2020 & 13 - 14 JULY 2020



Top row from left: Prof John Lim (Executive Director, CoRE), Ms Finny Liu (APAC Regional Regulatory Policy Lead, Roche, Singapore), Agnes Chan (Director, HSA); Middle row from left: Dr Adelheid Schneider (Head Quality and Regulatory Asia Pacific, Roche, Singapore), Dr Samvel Azatyan (Group Lead, WHO), Ms Siti Hidayah Kasbon (Senior Principal Assistant Director, National Pharmaceutical Regulatory Agency, Malaysia); Bottom row from left: Ms Jesusa Joyce N Cirunay (Director, Food & Drug Administration, Philippines), Mr Thean Soo Lo (Regulatory Affairs Management Consultant, Singapore), Dr Sethuraman Rama (Director, HSA)

DIA and CoRE jointly organised the third Conference in Singapore, on the theme of “Driving Healthcare Innovation and Collaboration in Asia. Alongside global thought leaders across the healthcare continuum, we presented the latest developments in medical technology and healthcare management, showcased opportunities to advance patient care as well as discussed hurdles and potential solutions to optimise regulatory efficiency and effectiveness.

Council for International Organizations of Medical Sciences (CIOMS) Consensus report on Drug-Induced Liver Injury

20 JULY 2020



The incidence of Drug-Induced Liver Injury (DILI) grows with the ever-increasing usage of drugs in medical care. Collaborating with CIOMS, CoRE hosted a webinar targeting global pharmaceutical professionals, regulators and healthcare providers, to share the challenges and best practices to detect, manage and communicate DILI risks.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

4 NOVEMBER 2020



[Click here to read Brochure](#)

IFPMA commissioned CoRE to develop a brochure on “Regulatory Systems Strengthening for Health Products in Asia-Pacific”. This, alongside a video summary of the brochure, was unveiled at the 10th Asia Regulatory Conference. The key takeaway from the brochure is that regulatory agility, convergence, reliance and capacity building are integral to strengthening regulatory systems.

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.



The Asia-Pacific Economic Cooperation (APEC) encompasses twenty-one economies in the Asia-Pacific and CoRE participates in the Life Sciences Innovation Forum (LSIF) and its sub-fora the Regulatory Harmonisation Steering Committee (RHSC) and the APEC Rare Disease Network.



Life Sciences Innovation Forum (LSIF)
18 SEPTEMBER & 1 DECEMBER 2020

Beyond Prof John Lim's participation as a LSIF Executive Board member in the biannual Senior Official Meetings (SOMs), CoRE facilitated discussions on accelerating regulatory convergence in the Asia-Pacific at the Policy Dialogue in September 2020, integrating impact and insights from COVID-19, shared insights on building resilient and sustainable systems for vaccination and supply chains at the High Level Meeting on Health & the Economy in September 2020, and shared insights at the Virtual workshop on Facilitated Regulatory Pathways in December 2020.

Participation in the Regulatory Harmonisation Steering Committee (RHSC)
15 JUNE & 1 DECEMBER 2020

As host of the RHSC Secretariat, CoRE supported the organisation of the biannual SOMs and took part in it as a Centre of Excellence. Significantly, CoRE contributed to the drafting of the "RHSC Vision 2030" which sets out the strategic framework RHSC will adopt in the next decade as it continues its efforts to accelerate regulatory convergence for medical products in the APEC region as much as possible by 2030.

Travel restrictions did not curb the Centre's participation on the international scene as CoRE had the opportunity to participate in a variety of overseas virtual engagements. From South Korea to the United States, the Centre's voice and South East Asian perspective was shared with regulators around the world.

<div>14 Sep</div> <div>APACMed</div> <div>South Korea</div>	<div>Use of Real-World Endpoints to Drive Next Generation Healthcare – Viewpoints of Regulators, Payors, Clinicians and Patients in Asia-Pacific Region</div> <div>Virtual ISPOR Asia Pacific conference</div> <div>Moderator</div>	<div>23 Sep</div> <div>APEC</div> <div>Malaysia</div>	<div>Building Resilient and Sustainable Systems - Vaccination and Supply Chains</div> <div>Virtual APEC 10th High-Level Meeting on Health & the Economy</div> <div>Intervention Panel</div>
<div>24 Sep</div> <div>APACMed</div> <div>South Korea</div>	<div>Why is it Critical to Build Regulatory Agility?</div> <div>APACMed Virtual Conference</div> <div>Moderator</div>	<div>24 Sep</div> <div>APACMed</div> <div>South Korea</div>	<div>The Future of Regulatory Policies for Digital Health in APAC</div> <div>APACMed Virtual Conference</div> <div>Panelist</div>
<div>21 Oct</div> <div>Boston USA</div>	<div>The Regulatory Response to COVID-19 in APEC: Perspectives from Singapore</div> <div>Virtual Global Conference on Regulatory Science</div> <div>Speaker</div>	<div>4 Nov</div> <div>IFPMA</div> <div>Malaysia</div>	<div>Regulatory Reliance in Asia</div> <div>Virtual 10th Asia Regulatory Conference</div> <div>Moderator</div>
<div>4 Nov</div> <div>IFPMA</div> <div>Malaysia</div>	<div>Regulatory System Strengthening for Health Products in Asia</div> <div>Virtual 10th Asia Regulatory Conference</div> <div>Speaker</div>	<div>11 Nov</div> <div>ADB</div> <div>Manila</div>	<div>COVID-19 Vaccine Procurement and Distribution in Asia: Gaps and Opportunities</div> <div>Virtual discussion with Board of Directors and senior staff of the Asian Development Bank</div> <div>Panelist on Milken Institute Session</div>

CoRE: Reaching Out



Message by Associate Professor Silke Vogel



The Year Ahead



Sir Alasdair Breckenridge Lecture Series



Supporting Tomorrow's Leaders



Adjunct Appointments and Visiting Experts



Contact Us



Message by Associate Professor Silke Vogel

2021 will be an exciting year for the Centre, as well as for all who participate in CoRE's programmes and initiatives. With the launch of our 2025 strategy, and a renewed focus on developing, supporting and guiding health and regulatory systems for future-preparedness, the CoRE community has plenty to look forward to.

Learning never stops at CoRE, as 2021 will feature new and improved Graduate Certificate modules and collaborative workshops that will broaden the horizon of the region's regulatory and healthcare professionals. The new year will also feature more opportunities for policy makers, regulators, industry members and healthcare providers to come together and outline how they can advance healthcare together. Participants can look forward to a new series of webinars too, exploring how the regulatory landscape can evolve for the better in a post-COVID-19 world.

2021 will also be a year for the Centre to reaffirm our mission and dedication to advancing healthcare with our new funding initiative, The CoRE Campaign #thankstoyou, as well as the Sir Alasdair Breckenridge Lecture Series. Looking back over the years, we recognise how integral your support is in enabling us to do what we do today, especially during this year of hardship and crisis. 2021 will be the year we give back, as the Centre translates your contributions and investment in the future of healthcare into meaningful and actionable change for the region and its people.

Thank you once again for journeying and growing with us. Regardless of whether you were here from our humble beginnings or just year ago, we hope you continue to work with us all the same, as we collectively work towards a healthier, brighter future for Asia-Pacific.



“

2021 will be an exciting year for the Centre, as well as for all who participate in CoRE's programmes and initiatives.

”

The Year Ahead

2021 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. Similarly, we will also remember the Centre's origins and recommit ourselves to our mission with the launch of the Alasdair Breckenridge Lecture Series in honour of our late inaugural Chairman as we emerge stronger from the pandemic.

We look forward to meeting you at our upcoming events in 2021!



Digital Health

Graduate Certificate:
Digital Health
Products

NIHA Future Leaders
Programme and Seminar

Health Technology
Assessment & the Art of
Decision Making Workshop



Patient Engagement

Patient Engagement
Webinar

Patient Engagement
Roundtable

Launch of Coalition
to Accelerate Patient
Engagement in Asia-
Pacific (CAPE)



Innovative Therapies

Graduate Certificate:
Regulation of Cell, Tissue
and Gene Therapies

Advanced Therapies Virtual
Roundtable & Webinar



Medical Devices

Graduate Certificate:
In Vitro Diagnostic Devices
and Precision Medicine

Medical Device Workshop:
Design and Development

Medical Devices Workshop:
Verification and Validation

Medical Devices Workshop:
Manufacturing and QMS



Clinical Trials

Graduate Certificate:
Clinical Trial Design and
Data Analytics

Regulatory Cooperation and
Innovative Clinical Trials

CoRE-CIRS SAPI Roundtable



Vaccines

Webinar: COVID-19 Vaccines
- Global solidarity to enable
access to vaccines during a
pandemic

More Modules of the Graduate Certificate in Health Products Regulation

Chemistry, Manufacturing
and Controls

Fundamentals of
Pharmaceutical Regulation

Post-market Surveillance
and Enforcement

Pharmacovigilance:
Principles & Frameworks

More Upcoming Events

Webinar: Regulatory Changes
Arising from COVID-19

DIA-CoRE Conference 2021

Sir Alasdair Breckenridge
Lecture Series 2021

Pharmacovigilance Workshop
with Health Sciences Authority,
World Health Organization &
Uppsala Monitoring Centre



To commemorate Prof Sir Alasdair Breckenridge and continue his mission of promoting excellence in health regulatory and policy systems, CoRE will launch the Sir Alasdair Breckenridge Lecture Series on 8th April 2021, with Sir Jeremy Farrar, the Director of the Wellcome Trust, as the inaugural lecturer.

This series will take place annually and present and foster dialogue on issues, challenges and fast-evolving biomedical and regulatory trends, with a forward-looking perspective on the themes of improving health systems, enhancing biomedical innovation and promoting access to good, safe and effective health products.

In keeping with Sir Alasdair's interest in promoting capacity building and professional excellence, the Lecture Series will be held in conjunction with the graduation ceremony of our Graduate Certificate participants, to celebrate their achievements and affirm their commitment to pursuing regulatory excellence.

In addition, our Interim Chairperson, Dr Margaret Hamburg, will officially launch the CoRE Campaign #Thankstoyou, in recognition of our community's support in enabling the Centre to enact meaningful changes in the region.

Through these initiatives, Sir Alasdair's legacy continues to make a lasting impact on future generations of regulatory science and health professionals, in and around the Asia-Pacific.

Funding support provided to

408

students with scholarships for
our modules and workshops

62

Students granted scholarships
for our Graduate
Certificate modules

10

Countries represented



Brunei



Indonesia



Malaysia



Philippines



Thailand



Cambodia



Lao PDR



Myanmar



Papua New Guinea



Viet Nam

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

ASEAN Regulators Tuition Support Scholarship Scheme



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

Australian Indo-Pacific Regulatory Strengthening Program (RSP)



The RSP seeks to improve partner countries' regulatory capacity and hence lead to access of 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)



The 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 Programme.

“

I would like to extend my sincerest gratitude for the funding support provided by the Duke-NUS CoRE ASEAN Regulators Tuition Support Scholarship. CoRE truly values nurturing the talents of regulatory professionals, and I believe that such opportunities, which support continuous education and professional development will positively impact our overall health care system, which in turn will benefit patients in my country.

”



Mr Sea Thol

Deputy Director
Department of Drugs and Food (DDF)
Ministry of Health, Cambodia

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.



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



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



Adj A/Prof Cynthia Sung
Research Program Manager
Translational Sciences
Global Health
Bill & Melinda Gates Medical
Research Institute



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



Adj A/Prof Teoh Yee Leong
Chief Scientific Advisor
Consortium for Clinical Research
& Innovation Singapore (CRIS)
Director
Solutions Technology Evaluation
and Piloting
MOH Office of Healthcare
Transformation
Joint Associate Professor
Saw Swee Hock School of Public Health,
NUS and Centre of Regulatory Excellence
Duke-NUS Medical School



Adj Asst Prof Pengiran Hishamuddin Bin Pengiran Badaruddin
Director
Healthcare
Deloitte Consulting South East Asia



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

CoRE Visiting Experts



Prof Hans-Georg Eichler
Senior Medical Officer
European Medicines Agency
United Kingdom



Mr Michael Gropp
Former Chair
RAPS
Global Advisory Council



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



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



Dr Danny Soon
Chief Executive Officer
Consortium for Clinical
Research & Innovation
Singapore (CRIS)
Executive Director
Singapore Clinical Research
Institute



Dr Moheb Nasr
Principal
Nasr Pharma Regulatory Consul-
ting (NPRC)



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



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



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



Dr Fouad Atouf
Vice President
Global Biologi cs
The United States
Pharmacopeial Convention
(USP)



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



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



Dr Gregory Daniel
Head
U.S. Healthcare Policy
Edwards Lifesciences



Dr Sethuraman Rama
Director
Medical Devices Branch
Health Sciences Authority



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



Dr Anne Cook
Expert Quality Assessor
UK Medicines & Healthcare pro-
ducts Regulatory Agency



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



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



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



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



Dr Poh Weijie
Global Project Manager
Healint Pte. Ltd



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



Mr Alok Mishra
Chief Executive Officer
Value Addition



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



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



Dr Valerio Reggi
Consultant
Drug Regulatory Matters &
Pharmaceutical Policy



A/Prof Edwin Chan Shih-Yen
Chief Scientific Officer
Singapore Clinical Research
Institute
Director
Cochrane Singapore
Associate Professor
Centre for Quantitative Medicine
Office of Clinical Sciences
Duke-NUS Medical School



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



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



Prof Kisantha Weerasuriya
Independant Consultant



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

Follow us



facebook.com/CoREDukeNUS



linkedin.com/company/centre-of-regulatory-excellence



<https://www.instagram.com/coredukenus/>



<https://tinyurl.com/watchCoREhere>

Scan us



