



Inaugural Roundtable Summit Report

Integrating Patient Engagement into Healthcare and Access to Medicines in the Asia Pacific Region

2 October 2019

Acknowledgements

The views presented in this publication are those of individual contributors and do not represent formal consensus positions of the authors' organisations or CoRE.

We would like to thank our partners, participants and sponsors for supporting the inaugural patient engagement roundtable. We look forward to partnerships and collaborations going forward.

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CoRE-Milken Institute Inaugural Roundtable:

Integrating Patient Engagement into Healthcare & Access to Medicines in the Asia-Pacific Region

The Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School and FasterCures, a Center of the Milken Institute co-hosted an inaugural roundtable on patient engagement in healthcare and access to medicines in the Asia-Pacific region on October 2, 2019 in Singapore. This event brought together 56 participants and observers from 13 countries representing patient groups, ministries of health, national regulatory agencies, clinicians, healthcare administrators, academics and industry. The roundtable launched a regional multi-stakeholder platform for accelerating patient engagement in Asia-Pacific. This is part of the important global conversation happening among health system stakeholders on the value of engaging patients and involving them in medical research, product development throughout the lifecycle and healthcare provision. In Asia, patient group mobilisation and interaction with governments, regulators and companies is in a relatively nascent stage, but at a point ripe for expanding patients' visibility and role.

What is Patient Engagement? : Towards a Shared Understanding and Purpose

A common understanding comes from common language and the participants agreed that when discussing patient engagement, defining what patient engagement means is key to a successful dialogue. Several activities with varying purposes fall under the umbrella of patient engagement. The language and words we use matter. For example, the discussion highlighted the word **advocacy** which has different connotations depending on the cultural context. In some contexts, advocacy means collaboration, education and sharing information to achieve a shared goal. However, in Asia, the word may have negative associations with lobbying which is important to keep in mind.

Following on from this, participants also discussed the difference between advocacy and support. Some groups may have the primary mission to provide psycho-socioeconomic support, such as offering information on centres of excellence, sourcing of products, disease-specific fundraising for treatment/research, while others may focus on advocacy such as patient representation on national committees, pushing for policies, and coordination with global patient groups for engagement with international bodies such as the World Health Organisation (WHO). Given the broad spectrum of possible actions, it is difficult to address all at once, as different skills and competencies are required for the different types of patient engagement.

Currently, there is variation in the words and language used to describe patient engagement activities by different organisations, even within one stakeholder group. For example, in industry, processes, terminology and framing of patient engagement may differ among companies. National or regional guidance on appropriate ways of collaborating could help to create shared meaning and understanding among all the stakeholders. It is important to note that having shared purpose does not equate to stakeholders not having other additional objectives separate to the shared goals. For example, patient groups and industry may have a shared goal of developing an innovative medicine for an unmet need but may diverge when it comes to the pricing conversation. Transparency of objectives from all parties from the outset is key to successful partnerships that can thrive despite areas where stakeholders may disagree.

Why Patient Engagement?

One of the main aims of the roundtable was to assemble diverse stakeholders who would not normally have the opportunity to dialogue with one another and facilitate an enhanced common understanding of the increasing significance of patient engagement across health systems. In broad terms, a range of purposes for patient engagement exist, including the following examples.

1. *Essential Role of Patients in the Health System*

Health care systems are complex and include multiple stakeholders and providers. Patients are the only consistent factor throughout the health system and have an essential role as co-producers of their health. Patients are experts in their illness and in navigating the health system as users but beyond that, they also have a wide range of other skills including leadership, innovation, entrepreneurship, and communication which can be a valuable resource for the health system.

2. *Patient Engagement as a Social Contract*

“Nothing about us without us” is a slogan used to communicate the idea that no policy should be decided without the full and direct participation of members of the group(s) affected by that policy. It is important to consider that the approach to patient engagement at a national level will vary according to the value that the broader society assigns to citizen involvement in the health system.

3. *Patient Engagement for Patient Activation/Quality Improvement*

Engaging patients can lead to system-wide improvements in design and delivery of health services and ultimately health outcomes. Through this engagement, patients and their caregivers are more empowered to manage their own health conditions.

4. *Economic Case for Patient Engagement*

In a competitive healthcare market landscape, patient engagement to derive a deeper understanding of consumers may give a competitive edge to organisations in healthcare delivery or product development. Analysis by the Economist Intelligence Unit of patient-centric medicines development has shown that drugs developed using patient centric design had a 20% increased likelihood of being launched compared to drugs developed not using this approach¹. An investment of \$100,000 in patient engagement can generate a Net Present Value (NPV) increase exceeding 500-fold the investment².

It should be noted that these broad purposes for patient engagement may conflict with one another and different purposes may take precedence in different health systems. It is important to consider these different perspectives and motivations as stakeholder partnerships are formed. It was reassuring that the participants in this inaugural roundtable did not need convincing on the importance of patient engagement but instead were keen to hear from one another and learn how they could do more together.

Lessons from other Regions

Two keynote speakers shared on the patient engagement journey in Europe and the United States, where the patient engagement ecosystem is more developed than in the Asia-Pacific region.

¹ <https://druginnovation.eiu.com/patient-centric-trials/>

² Therapeutic Innovation & Regulatory Science 2018, Vol. 52(2) 220-229

Nicholas Brooke, Executive Director at The Synergist and Patient Focused Medicines Development (PFMD) spoke about patient engagement from a drug development perspective. PFMD is an open, independent global coalition of health stakeholders that aims to transform the way in which patients can be engaged globally in the design and development of research and medicines by focusing on unmet patient need.

Key take-aways from the PFMD experience

- Systematic, meaningful patient engagement is still not the norm in most organisations or government agencies in any country or region.
- Fragmentation is the enemy of progress and there is no need to reinvent the wheel. The main challenge that PFMD was set up to tackle was the fragmentation in the patient engagement ecosystem to move towards a global, connected landscape. PFMD has consolidated resources into the Synapse³ library and created a digital registry of patient groups and patient engagement initiatives.
- Evidence-based patient engagement creates more constructive conversations. The European Medicines Agency (EMA) has integrated patient engagement into all their activities which must now include patient representatives. The US Food & Drug Administration (FDA) has shown great initiative in enshrining patient engagement even beyond its own activities and providing practical guidance for how other stakeholders in the health system, outside of FDA, may go about patient engagement in drug development, which EMA will be emulating.
- Regulation of health products has strict evidence requirements to protect patient safety; evidence-based patient engagement principles developed for health products development can be applied to patient engagement in the wider health system.

In a fireside chat and Q&A session, **Dr Margaret Hamburg**, former US FDA Commissioner, shared with participants about the US experience in patient engagement from a public health and regulatory perspective. Prior to her tenure at the FDA, Dr Hamburg served in various roles at the National Institutes of Health (NIH) and as the New York City Health Commissioner during the height of the HIV/AIDS epidemic. She shared her first-hand experience of how HIV patient advocates' aggressive campaign for action culminated in the monumental decision by the National Institute of Allergy and Infectious Disease to engage the advocates - together with researchers, regulators and policy makers - to develop what became the blueprint for the HIV research agenda that eventually resulted in access to life-saving treatment for millions around the world. The institutional changes that the HIV advocacy created at the FDA and the NIH would not have been possible without patient involvement – this shift from the old ways of doing things continues to benefit patient communities to this day.

Dr Hamburg continued to promote patient engagement once she was appointed FDA Commissioner and she offered useful insights on patient engagement from the US/FDA experience.

³ SYNAPSE – Patient Focused Medicines Development <https://synapse.pfmd.org/>

Key take-aways from the US/FDA experience

- Patient engagement has been a key driver for several FDA policies existing today, including expedited approval programs, community-based trials, incorporation of real-world evidence in regulatory decision-making and use of surrogate markers.
- Patient groups have been powerful forces for the advancement of science. Besides advocating for awareness of their diseases, groups have been able to shape research agendas, recruit patients to trials, and fund research through philanthropic foundations.
- FDA found there was often misalignment between what they thought was important to measure and what patients highlighted would make the most difference for them in terms of symptoms and concerns for treatments to address.
- It is important to balance expectations and communicate effectively when, despite a strong desire for a treatment to be effective, the evidence does not support approval.
- Engagement of the general public, not just patients, is important for public health, especially in an era of genomics and precision medicine where there are more ethical issues to weigh, requiring greater public understanding of complex science.

Patient engagement in Asia-Pacific

Raj Rajakanth, Executive Director of Rainbow across Borders, an Asia-Pacific focused regional patient group alliance, shared an overview of the patient engagement landscape in Asia. The landscape is highly fragmented with multiple patient groups that do not coordinate and multiple health system stakeholders within countries that do not communicate with each another. There is wide disparity among Asian countries in terms of socioeconomic development as well as level of institutionalisation of patient engagement in healthcare delivery and health policy-making. Importantly, besides their illnesses, patients are also grappling with fundamental socioeconomic challenges such as poverty, limited health literacy, lack of access to health facilities and affordable medicines as well as stigmatisation.

Challenges for Patient Engagement in Asia

Patients, policy makers, regulators and industry participants shared that although they have a genuine desire to collaborate and engage one another they need guidance in the “how to” of patient engagement. Patients and clinicians that have to engage with governments and industry are not confident in their ability to do so. Government, regulators and industry feel similarly ill-equipped to meaningfully incorporate patient outcomes and preferences into their routine decision-making processes. Capacity-building is a common need for all stakeholders.

Challenges for Patient Groups

- **Short term partnership models** – many organisations engage patients for specific purposes e.g., for launch of products or to participate in meetings collecting stakeholder feedback for policy making, but the tendency is not to ask patients the correct questions to find out what they really need and such engagements are not sustained.
- **Lack of resources** – patients lack financial resources but also lack information on their disease conditions and clinical trials conducted around the world. Due to the lack of manpower and

funds, patient groups are not able to collect data on the needs of the patient group members that may be useful for planning support and advocacy.

- **Lack of platforms to voice out their needs** – In most countries, patient involvement is not routine for agency or organisation activities and patients do not know how to access their policy-makers or regulators. In the rare instances when patients are invited to participate in meetings with other health system stakeholders, there is “selective listening” where records tend to reflect items the organisers agree with but ignore what they do not wish to engage on.
- **Paternalistic health system** – patients feel that the broader health system stakeholders do not trust that patients know best what they need for their health and quality of life. The voices of “experts” are prioritised over patient voices. The health system does not always appreciate the value that patient groups can bring to service planning and even clinical care if doctors link their patients to the relevant support groups. These links are especially important for rare conditions where patients may not be able to find each other otherwise.
- **Perception of conflict of interest** – in many countries, patient groups are perceived to be pushing the interests of pharmaceutical companies. For this reason, some groups have avoided industry funding. Participants reported that many of those who do receive some industry funding consciously strive to maintain independence and stay true to their missions. It is important to note that most countries do not have reliable independent funding from government or philanthropy to support patient groups.
- **Lack of capacity to engage with government and industry** - within patient organisations, only a few have any experience participating on government committees or have access to international training to understand the drug development process and how regulations and policies are made. There is a need to create more opportunities to include less visible groups and build the capacity of the current and next generation of patient leaders to be effective partners.

Challenges for Regulators and Government

- Lack of practical guidance and training on how to incorporate patient evidence for regulatory and policy decisions, and the need for case studies of how patient engagement has supported regulatory decision making and policy implementation.
- Fear that patient groups are controlled by industry.
- Balancing between taking a greater leadership role in defining the patient engagement ecosystem and not taking over the space from patients.

Challenge for Healthcare Professionals/Healthcare Organisations

- Physicians are not trained in other disciplines relevant to understanding the health system such as economics and public policy.
- Physicians have no training in how to engage industry or government.
- Moving beyond engaging patients for complaints to actively and systematically seeking their input in design and delivery of infrastructure and services.

Challenges for Industry

- Fragmentation of industry definitions and processes - each organisation tends to create its own unique patient engagement structures.
- Lack of frameworks or guidances from regional policymakers or regulators of what patient engagement done right would look like. In Asia-Pacific, Australia is one of the only countries

that has developed a guide⁴ on how industry should work together with patients. Having such guidance emphasises that working together can have a positive, meaningful impact and anchors all stakeholders in standards for appropriate engagement. These standards can be referred to should concerns of conflict of interest arise.

- Lack of clarity on the science of capturing patient preferences and outcomes for clinical trials and outcomes research, and what will be acceptable evidence for regulators and payers in the region. Clarity on evidence required would also help patient groups to calculate how much generating such evidence would cost as they fundraise.

Mind the Gaps in Patient Engagement Initiatives

- Commitment to equity must remain at the heart of patient engagement. It is important to continue to include less visible stakeholders and mentor newer patient organisations.
- Although access to “medicines” was a key focus of the roundtable it is important to think beyond drug development and ensure capacity of patient engagement is also built for medical devices and the safe use of health products. Patients should also be at the forefront of health systems and stakeholders must collaborate to create a more inclusive and caring health system.
- It is important for patients to build their capacity to understand the “rules of the game” but they must not lose their critical thinking. Sometimes the patients are there to highlight issues when the system is not working and to give constructive feedback.
- Shared purpose does not mean that stakeholders do not have other objectives distinct to the shared goals - all organisations must remain true to their missions.
- Patient engagement is not the solution for all the challenges in the health system and it is important to admit that mistakes may be made but still be courageous as a community of stakeholders.

Opportunities for a Multi-stakeholder “Family” to Accelerate Patient Engagement in Asia

Many participants used the analogy of a “family” when describing the wide range of stakeholders in the health system. Currently, communication channels among these family members are not strong and more meetings, such as this inaugural roundtable, that bring the entire family together are a good starting point to advance patient engagement in Asia. However, the hope is that such family meetings would go beyond talking and translate into meaningful multi-stakeholder actions at the country and regional level.

CoRE, the Milken Institute and the partners present do not envision this platform being prescriptive or to duplicate or replace existing groups, but rather to function as a neutral platform facilitating communication and collaboration. Networks of the participants could be leveraged to support capacity-building for all stakeholders. In particular, it is hoped that this type of multi-stakeholder platform could eventually be re-created at country levels and inputs fed back to the regional level platform.

⁴ Medicines Australia Working Together Guide <https://medicinesaustralia.com.au/community/working-together-guide/>

A ground-up and regional multi-stakeholder platform can provide:

- A neutral platform to regularly convene all relevant stakeholders and coordinate fragmented initiatives.
- Platform to share best practices in implementing evidence-based patient engagement.
- Cross-border linkages among stakeholders. This is especially important for rare diseases where the patient populations within countries are small. It would be advantageous to further explore how regional patient engagement platforms can help support creation of a pan-regional infrastructure among regulators, researchers and ministries in different countries to connect all patients in multiple countries to trials and treatments.
- Increased reach of networks to patient groups in other disease areas to address cross-cutting issues and support the work of existing national patient alliance platforms such as the Philippines Alliance of Patients' Organisations (PAPO) and the Taiwan Alliance of Patients' Organisations (TAPO) within countries.
- Wider networks to diversify potential sources of funding for capacity-building through non-product linked collaborative funding mechanisms among industry, philanthropic organisations and governments.

Next Steps

1. Coordination of Activities by a Steering Committee

The Steering Committee will comprise the organisers of the first roundtable and relevant stakeholders

2. Establish Working Groups to Start Work in Initial Priority Areas:

- **Priority Area 1:** Conduct landscape mapping on the state of patient engagement, from the perspective of multiple stakeholder groups, in research, product development, regulatory approval, financing, healthcare delivery and health system policy-making in a few selected countries as a start.
- **Priority Area 2 :** Create country Action Plans and host multi-stakeholder meetings within countries for feedback
- **Priority Area 3 :** Initiate adaptation of training resources and share best practices for evidence-based patient engagement

The working groups will provide updates on their activities at the next roundtable

3. Plan for Regional Roundtable on Patient Engagement 2020

The second regional roundtable on patient engagement will be held in October 2020. The date and location are to be confirmed. Suggestions and ideas for the scope of the next meeting are welcome.

4. Create and maintain a Community of Practice

All organisations involved in patient engagement are encouraged to join the digital global registry of patient organisations and patient engagement initiatives at PFMD Synapse [<https://synapse.pfmd.org/>], where you can also browse and add to resources on patient-

focused drug development. The hope is to see more Asian organisations added to the PFMD database while the creation of a regional level digital community for curating selected resources and sharing training opportunities is explored.

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Annex

Attendees

Name	Role	Organisation	Region
Prof John Lim	Executive Director	Centre of Regulatory Excellence (CoRE)	Singapore
Dr Tanisha Carino	Executive Director	FasterCures, a Center of the Milken Institute	USA
Mr Nicholas Brooke	Executive Director	Patient Focused Medicines Development; The Synergist	Belgium
Mr Rajakanth R	Executive Director	Rainbow Across Borders	Singapore
Dr Margaret Hamburg	Foreign Secretary, National Academy of Medicine; Former Commissioner of the U.S. Food & Drug Administration (U.S. FDA)	National Academy of Medicine Interim Chairman, CoRE Advisory Board	USA
Dr Brenda Huneycutt	Director	FasterCures, a Center of the Milken Institute	USA
Ms Laura Deal Lacey	Managing Director	Milken Institute Asia Center	Singapore
Ms Melissa Kirwin	Consultant	Milken Institute Asia Center	Singapore
Dr Nikki Kitikiti	Senior Resident	Centre of Regulatory Excellence	Singapore
Ms Mary Wong	Chairman	Global Chinese Breast Cancer Organisations Alliance	Hong Kong
Ms Aryanthi Putri	Founder & CEO	Indonesian Cancer Information and Support Center Association (CISC)	Indonesia
Ms Naomi Sakurai	President	Cansol Cancer Solutions	Japan
Ms Fatima "Girlye" Lorenzo	Head	Philippines Association of Patient Organisations (PAPO)	Philippines
Mr Chris Knight	Senior Advisor	Alliance for Safe Medicines	Singapore

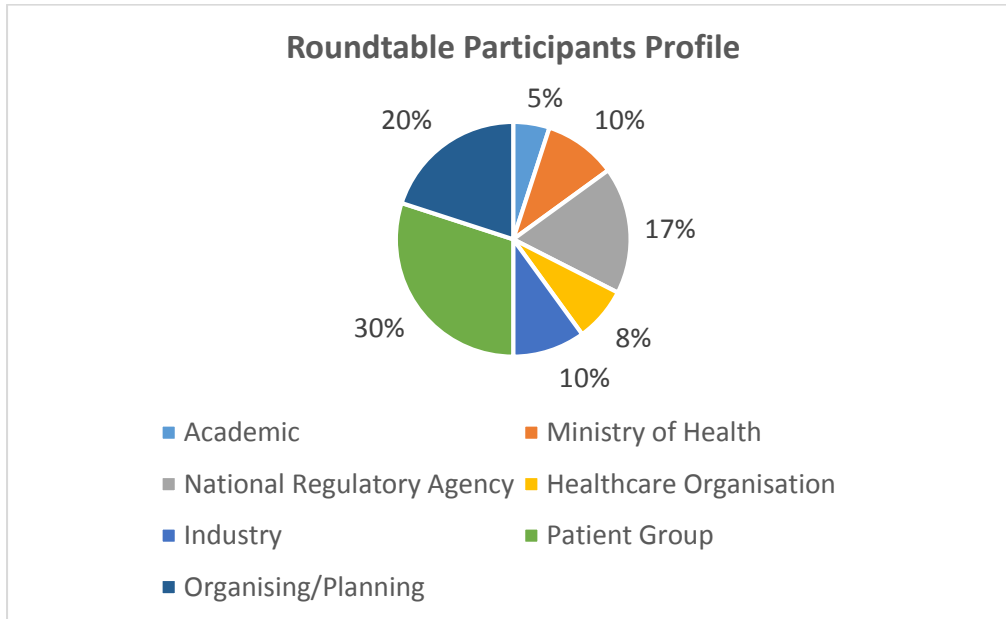
Name	Role	Organisation	Region
Dr Ritu Jain	President	Asia Pacific Alliance of Rare Disease Organisations (APARDO)	Singapore
Ms Melissa Lim	President	Brain Tumour Society of Singapore	Singapore
Mr Kenneth Mah	Executive Director	Rare Disease Society (Singapore)	Singapore
Mr Albert Ching	CEO	Singapore Cancer Society	Singapore
Ms Ya Hsin Wang	Executive Director	Psoriasis Association of Taiwan	Taiwan
Mr Harry Ko Yi-Mou	Director	Taiwan Alliance of Patient Organizations (TAPO)	Taiwan
Mr Ekawat Suwataroj	Director	Hemophilia Foundation of Thailand	Thailand
Mr Sea Thol	Director Chief of Essential Drug Bureau, Department of Drugs and Food (DDF)	Department of Drugs and Food, Cambodia	Cambodia
Ms. Dwiana Andayani	Head of Subdirectorate of Biologicals Production Control	National Agency of Drug and Food Control, Indonesia	Indonesia
Dr Bounxou Keohavong	Deputy Director General	Food and Drug Department, Ministry of Health	Laos
Datin Dr Faridah Aryani Mohd Yusof	Director	National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia	Malaysia
Prof Khin Zaw	Director General	Food and Drug Administration (FDA)	Myanmar
Ms Adena Lim	Deputy Director, Vigilance & Compliance Branch	Health Sciences Authority (HSA)	Singapore
Mrs Nguyen Minh Hoai	Director of Center for Training and Supporting Pharmaceutical and Cosmetics Companies	Drug Administration of Vietnam	Vietnam

Name	Role	Organisation	Region
Ibu Lucky Slamet	Visiting Expert; Former Head of National Drug and Food Control Indonesia	CoRE	Indonesia
Mrs Dita Novianti Sugandi Argadiredja	Director for Pharmaceutical Services	Ministry of Health	Indonesia
Dr Mohd Aminuddin Bin Mohd Yusof	Senior Principal Assistant Director	Malaysian HTA Section (MaHTAS), Medical Development Division, Ministry of Health	Malaysia
Dr Kelvin Bryan Tan	Director, Policy, Research and Evaluation Division	Ministry of Health	Singapore
Dr Tan Ee Shien	Senior Consultant Head, Medical Genetics	KK Women's and Children's Hospital (KKH)	Singapore
Dr Saumya Jamuar	Senior Consultant, Medical Genetics	KK Women's and Children's Hospital (KKH)	Singapore
Mrs Tan-Huang Shuo Mei	Senior Director, Special Projects	SingHealth	Singapore
Prof Vikki Entwistle	Director, Prof of Bioethics	NUS Centre for Biomedical Ethics	Singapore
Dr Yupin Patara	Assistant Professor	Chulalongkorn University	Thailand
Ms Kylie Park	Director, Advocacy and Government Relations, Japan Asia Pacific (JAPAC)	Amgen	Australia
Dr Shamiram Feinglass	Executive, Global Government and Medical Affairs	Danaher Corporation	USA
Mr Michael Alzona	Asia Pacific Patient Engagement Lead	Merck Sharp & Dohme (MSD)	Philippines
Ms Rumana Haque-Ahmed	Regulatory Affairs Head, Asia	Sanofi	Singapore
Ms Syamsidar Thamrin	Head of Human Resources Development Center	National Agency of Drug and Food Control, Indonesia	Indonesia
Mrs Helsy Pahlemy	Head of Sub Directorate for Pharmacoeconomic Analysis	Ministry of Health, Indonesia	Indonesia

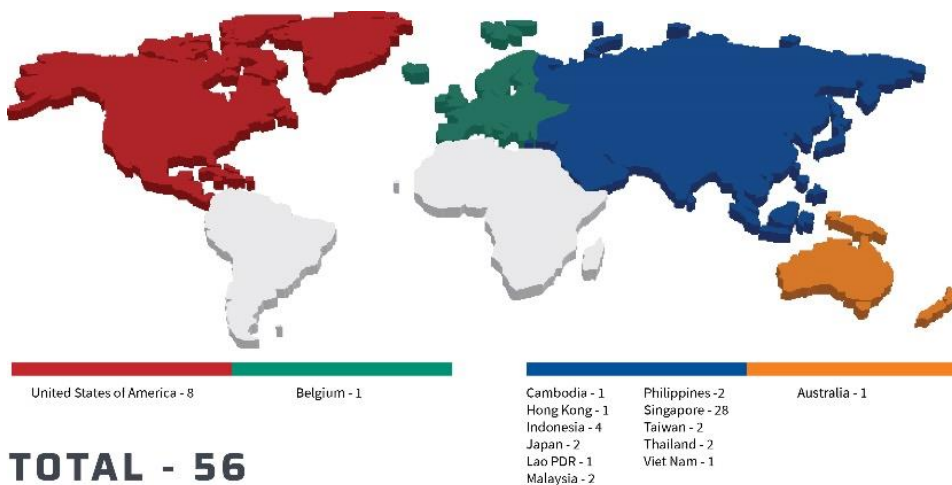
Name	Role	Organisation	Region
Dr Tatsuya Kondo	Former Chief Executive, Pharmaceutical and Medical Device Association (PMDA)	CoRE Advisory Board	Japan
Dr Joseph Scheeren	CEO, Critical Path Institute (C-Path)	CoRE Advisory Board	USA
Mr Michael Gropp	Former Chair, RAPS Global Advisory Council	CoRE Advisory Board	USA
A/Prof Bruce Burnett	Director, Regulatory Affairs, Duke Translational Medicine Institute, Duke University	CoRE Advisory Board	USA
Ms Tallin Ang	SingHealth Group Office of Patient Experience	SingHealth	Singapore
Ms Ai Ling Sim-Devadas	Co-Chair, SingHealth Patient Advocacy Network (SPAN)	SingHealth	Singapore
Mr Ellil Mathiyan	Co-Chair, SingHealth Patient Advocacy Network (SPAN)	SingHealth	Singapore
Ms Amina Mahmood Islam	Head, Programme Development	SingHealth Duke-NUS Global Health Institute (SDGHI)	Singapore
Ms Sunniva Bloem	Programme Manager	SingHealth Duke-NUS Global Health Institute (SDGHI)	Singapore
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Mr Quintus Lim	Research Associate	Milken Institute Asia Center	Singapore
Mr Dene Grindal	Director, Global Market Access	Cepheid, Danaher Corporation	Singapore
Ms Joyce Lim	Business Unit Lead, Pharmaceuticals	Johnson & Johnson (J&J)	Singapore
Mr Carmel Spiteri	Director Oncology CORE Asia Pacific Regional Team	Merck Sharp & Dohme (MSD)	Australia
Ms Ruth Kuguru	Head, Communications and Patient Advocacy	Novartis	Singapore

Name	Role	Organisation	Region
Mr Ariosto Matus	Regional Policy & Public Affairs Lead, Asia-Pacific	Roche	Singapore
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Profile of Participants



Origin of Participants





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