Advancing access to diagnostics and therapeutics in Southeast Asia

Workshop report

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The Academy of Medical Sciences

Akademi Sains Malaysia

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Executive summary

The COVID-19 pandemic exposed considerable differences in access to diagnostics and therapies, notably in Southeast Asia (SEA). In response, the UK Academy of Medical Sciences and the Academy of Sciences Malaysia hosted a policy workshop that brought together important regional stakeholders, including policymakers, healthcare professionals, and researchers, to examine ideas about enhancing healthcare access and equity. This report outlines the primary issues, discussions, and recommendations covered during the workshop.

The aim of the workshop was to address the pressing issues surrounding healthcare disparities in SEA by proposing several key objectives. Primarily, it sought to identify and mitigate the gaps in healthcare access that have become evident in recent years. By bringing together a diverse group of stakeholders, the workshop focused on promoting collaboration between governments, healthcare professionals, industries and researchers to discuss strategies for improving healthcare access and equity. Two additional objectives of the workshop were to discuss necessary regulatory reforms to streamline the approval and distribution of new diagnostic and therapeutic tools, ensuring quicker and more equitable access across the region; and to enhance education and training programmes for healthcare professionals, equipping them with the skills needed to address the evolving healthcare landscape. By achieving these goals, the intention was to lay the groundwork for a more resilient and equitable healthcare system in SEA.

The workshop identified the importance of taking a unified approach to healthcare challenges. This can be done by fostering better **collaboration across SEA** by engaging governments and policymakers. The Academy of Medical Sciences and the Academy of Sciences Malaysia can act as 'honest brokers' to ensure continuous communication between stakeholders. Such engagement can facilitate the sharing of resources, knowledge, and best practices, thereby promoting a unified approach to healthcare challenges.

Another key point discussed was **regulatory reform**. Developing an Association of Southeast Asian Nations (ASEAN)-based regulatory platform that is adaptive to the latest advancements in diagnostics and therapeutics is pivotal for accelerating progress in this area. A unified regulatory framework can streamline the approval processes for new diagnostic tools and therapies, ensuring faster and more equitable access across the region. Harmonised regulations can also reduce the complexity and cost associated with bringing new technologies to market to meet current and future needs.

Education reform is another crucial step to equip researchers with the necessary skills and understanding of the healthcare ecosystem. Integrating comprehensive training programmes that focus on diagnostics and therapeutics can better equip future researchers and healthcare professionals to address the region's unique challenges. Continuous education and professional development opportunities are essential for keeping the workforce updated on the latest advancements, regulatory requirements, and best practices.

The **adoption of new technologies** is vital for enhancing diagnostics and therapeutics. Leveraging innovations such as digital health tools, telemedicine, and artificial intelligence (AI) can significantly improve healthcare delivery and accessibility. Using these tools for virtual consultations and research, such as on drug repurposing, may provide new avenues for improving accessibility. These technologies can facilitate remote diagnostics, streamline data management, and support decision-making processes, ultimately benefiting the entire population.

The workshop also featured case studies and presentations that provided real-world examples of successful initiatives. These included the development and use of digital health tools for the early detection of oral lesions and cancer and the implementation of a coordinated product development partnership (PDP) model to meet global health needs.

This workshop highlighted the urgent need for a coordinated regional approach to healthcare. By focusing on collaboration, regulatory reform, education, and technology, as well as strategies to ensure local ecosystem preparedness, the workshop addressed ways to improve healthcare outcomes across SEA. The resulting recommendations are geared at fostering a more equitable healthcare system, ensuring that all populations in the region have access to both essential and advanced diagnostics and therapeutics.

Introduction

The status of diagnostics and therapeutics in SEA is evolving rapidly, driven by technological advancements and increasing healthcare demands. While SEA is making significant strides in improving diagnostics and therapeutics, access to medical products remains inconsistent across the region, with disparities in availability and regulatory frameworks. Addressing regulatory, accessibility, and workforce challenges is crucial for achieving sustained growth and better healthcare outcomes across the region.

This workshop was designed to advance efforts to improve access to diagnostics and therapeutics in SEA. This builds on the Academy of Medical Sciences' previous work, such as the 2018 policy workshop under the Global Challenges Research Fund, which focused on enhancing the development and deployment of diagnostics. The workshop was convened to bring together key stakeholders from the region, including policymakers, healthcare professionals, regulators, and industries and researchers, to discuss strategies and solutions for improving healthcare access and equity.

The primary objectives of the workshop were to: identify and address disparities in healthcare access; promote collaborations among various stakeholders; discuss regulatory reforms to expedite the approval and accessibility of new diagnostic and therapeutic tools; and explore ways to enhance education and training for healthcare professionals. By focusing on these objectives, the workshop aimed to develop actionable strategies that can be implemented across the region to improve healthcare outcomes.

Regional context

Catalysing change in diagnostics across SEA

In his keynote address, Professor Velavan from the University of Tübingen and the Vietnamese German Centre for Medical Research (VG-CARE) provided an insightful analysis of global diagnostic challenges and potential solutions. There is a stark disparity in diagnostic access: 47% of the global population lacks essential diagnostic services, and only 19% of people in low- and middle-income countries (LMICs) have access at the primary care level. Even more concerningly, just 1% of primary care clinics in these regions possess an adequate diagnostic capacity. Additionally, 50% of the top 20 fatal diseases lack suitable diagnostics, while 60% of pathogens on the World Health Organization's (WHO) priority disease list remain undiagnosed.[1] Professor Velavan reflected on the broader value of diagnostics, which not only improve patient outcomes but also support early disease detection, public health efforts, and cost-effectiveness. In ASEAN, diagnostics are a particularly weak link in healthcare, overshadowed by the focus on vaccines and medicines. ASEAN countries face distinct challenges in diagnostics and healthcare delivery. This is driven in part by **demographic shifts** such as ageing populations, which are increasing the demand for diagnostics and pharmaceuticals. Financial barriers remain a major obstacle, with healthcare expenditure across ASEAN member states ranging from 3.1% of gross domestic product in Indonesia to 5.7% in Vietnam—well below the WHO's recommended minimum sustainability threshold. Stark disparities can be seen when it comes to health expenditure per capita, with Laos spending as little as $69 in 2021, compared to $3,970 in Singapore.[2] **High out-of-pocket expenses** further exacerbate these challenges, often pushing families into poverty and creating financial crises. Access to diagnostics and therapies remains highly unequal, especially in rural areas where coordinated laboratory, pathology, and imaging services are lacking. These disparities make achieving universal health coverage difficult, highlighting the need to prioritise robust diagnostic systems.

To enhance access to diagnostics, it is vital to incentivise innovations, implement effective programmes, address knowledge gaps, and develop appropriate policy interventions. Professor Velavan cited VG-CARE as a successful model; located at 108 Hospital in Vietnam, it has established a comprehensive hepatitis diagnostic portfolio through collaboration between the German and Vietnamese governments. The centre not only conducts clinical research and modern diagnostic procedures but also provides ongoing education and training. He also mentioned the PAN ASEAN Coalition for Epidemic and Outbreak Preparedness (PACE-UP), which aims to strengthen health systems across ASEAN through equitable partnerships and multidisciplinary research. In conclusion, Professor Velavan called for the establishment of a regional expert diagnostic network, an advisory group, and training hubs to enhance workforce capabilities and promote the prioritisation of diagnostics in healthcare policies.

Early-phase drug development in Malaysia: Experience sharing from the perspective of a developing country

Cancer is a leading cause of death globally, with nearly 10 million fatalities in 2020.[3] Oncology clinical trials are essential for assessing the safety and efficacy of new treatments. While these trials were historically concentrated in Western Europe and North America thanks to established infrastructure and proximity to pharmaceutical companies, globalisation has shifted the focus towards Asia, making it a key region for oncology trials.[4] Dr Voon Pei Jye, from Sarawak General Hospital and Universiti Malaysia Sarawak,

1. EU-ASEAN Business Council (2022). Transforming Diagnostic Access: A roadmap for ASEAN. http://www.eu-asean.eu/white-papers/transforming-diagnostic-access-asean-roadmap
2. World Health Organization (n.d.). Global Health Observatory data: Indicators. http://www.who.int/data/gho/data/indicators
3. Ferlay J, Ervik M, Lam F, et al. (2020). Global cancer observatory: Cancer today.
4. Murthy S, Mandl K.D. and Bourgeois F.T. (2015). Industry-Sponsored Clinical Research outside High-Income Countries: An Empirical Analysis of Registered Clinical Trials from 2006 to 2013. Health Research Policy and Systems, 13, 28.

highlighted several factors that have contributed to Asia's rise in oncology research. Asia is home to 60% of the global population, providing a large, genetically diverse patient pool, and offering a broad range of cancer types.[5] Streamlined regulatory processes, competitive trial costs, and a growing middle class further enhance the region's attractiveness for clinical trials.[6] Asia also boasts an increasing number of skilled investigators and internationally accredited trial facilities, ensuring high-quality research outcomes. In Malaysia, government support, such as the Economic Transformation Programme, has boosted clinical trials, with a target to complete 1,000 trials and create 1,000 skilled jobs by 2020.[7] The establishment of Clinical Research Malaysia (CRM) has further supported the country's clinical research ecosystem, enabling efficient regulatory processes: Approvals for clinical trial import licences and clinical trial exemptions are processed within 30 days, and ethics approvals within 50 days.[8] Between 2012 and 2023, Malaysia conducted 2,305 industry-sponsored clinical trials, creating 2,753 skilled jobs. Although early-phase oncology trials in Malaysia are still in their infancy, initiatives like the Phase 1 Realisation Project, launched in 2017, have resulted in the establishment of Phase 1 Guidelines and accredited trial sites, such as Sarawak General Hospital. The Clinical Research Centre at Sarawak General Hospital, Malaysia's first fully accredited Phase 1 unit, began with three trials in 2015 and now manages 98 trials, with 61 ongoing and 38 actively recruiting.[9]

Dr Voon outlined several strategies for advancing early-phase oncology trials in Malaysia. He emphasised the need for strong patient advocacy and the importance of involving cancer patient groups in trial design and forging international collaborations for knowledge sharing. Regulatory reforms are crucial to expedite reviews of new therapies, with local regulators actively engaging industry stakeholders. It is essential to develop human capital through training for investigators and the creation of career pathways for clinical scientists. Enhancing both basic and translational research through interdisciplinary collaboration will strengthen drug development. Dr Voon concluded by presenting a vision aligned with the UN's 2030 Agenda, but with a twist: his vision centres on ensuring that where a person lives does not determine their access to promising future drugs via clinical trials.

Pathways to achieve impact across SEA

In SEA, disparities persist in access to healthcare, even though it is considered a fundamental human right. The director of Woodseer Resources, Jean-Michel Piedagnel, discussed the role of non-profit organisations such as the Drugs for Neglected Diseases initiative (DNDi) and Doctors Without Borders/Médecins Sans Frontières (MSF) in advancing research and drug development.

Case study: Hepatitis C treatment

Jean-Michel shared a success story about how cooperation has lowered the cost of therapies and promoted regional empowerment. The collaboration between MSF, DNDi, Egypt, Malaysia, and Thailand has been essential in making hepatitis C treatment more accessible. As a result, these efforts have significantly decreased treatment costs, upending big pharma's monopoly. As nations like Thailand and Malaysia have demonstrated a significant desire to invest in research and development (R&D), Jean-Michel Piedagnel urged them to take the lead in these projects in the region.

Lessons learned

Jean-Michel highlighted several key lessons for promoting effective healthcare development, emphasising the importance of **intellectual property (IP)** in drug development. Beyond patents, IP knowledge protects innovation and supports researchers and governments in navigating regulatory complexities, with organisations like the Third World Network offering critical guidance in this area. He stressed the need for **efficient legal administration** at regional levels, cautioning that overly stringent regulations could increase costs and delay market access. Balancing innovation with cost-effectiveness, efficiency, and safety is vital for ensuring a

5. Rahman S, et al. (2013). WHO South-East Asia Journal of Public Health. 2(2), 5.
6. Ma B.B.Y. (2019). Trends in phase 1 oncology drug development in East-Asia and Australia, Chinese Clinical Oncology, 8(3), 1.
7. Performance Management and Delivery Unit, Prime Minister's Department. (2013). Economic Transformation Program, Annual Report 2012. https://www.pmo.gov.my/dokumenattached/Eng_ETP2012_Full.pdf
8. Frost & Sullivan. (2020). Asia: Preferred destination for clinical trials
9. Clinical Research Malaysia. (2024). Annual Report 2024.

robust healthcare system. He also highlighted the critical role of **knowledge transfer** and local capacity building, particularly in bioequivalence studies for pharmacokinetics and pharmacodynamics. A shift towards self-reliance is essential since it reduces dependence on external expertise. Countries like Brazil and those in SEA can be instrumental in promoting **South–South collaboration** by decolonising healthcare systems and establishing more equitable power dynamics. Moreover, the effectiveness of Western-led drug development often varies in local contexts, making it necessary to reassess applicability in different regions. By fostering collaboration among Global South countries, shared healthcare challenges can be addressed more effectively, leading to stronger, locally tailored healthcare systems that drive innovation and improve health outcomes. Finally, Jean-Michel emphasised that partnerships must prioritise the needs of endemic countries, with **political leadership** driving these initiatives. These partnerships should allow endemic nations to take the lead while receiving support from non-endemic countries. By aligning national policies and encouraging cross-sector collaboration, the healthcare system can improve resource utilisation, innovation integration, and equitable access to healthcare services.

Malaysia's New Industrial Masterplan 2030: Healthcare solutions for the many, not just the few

Nurul Izzah Anwar, Chairperson of the Social and Economic Research Initiative in Malaysia, delivered a keynote address emphasising health as a fundamental human right. She highlighted that achieving universal healthcare requires scientific research, social justice, and global collaboration. Nurul Izzah highlighted Malaysia's inclusive **"whole of nation" approach** during the COVID-19 pandemic, which ensured that vaccines were made accessible to all, including prisoners, refugees, and stateless individuals. Malaysia, Egypt Thailand and Drugs for Neglected diseases Initative (DNDi) demonstrated affordable access by developing 'Ravidasvir' a Heptatits C antiviral that reduced the cost of treatment from US$80,000 to under US$500. However, challenges remain in making interventions affordable, particularly due to global monopolies and predatory pricing. Nurul Izzah stressed that LMICs face challenges with IP rights and with rapid adoption of advanced technologies to bypass traditional stages of development. **Technological leapfrogging** would enable countries to quickly catch up with and even surpass developed nations in specific areas, providing cutting-edge treatments and diagnostics. **Drug repurposing**, which involves finding new uses for existing drugs with established safety profiles, was also noted as a cost-effective and time- efficient strategy for improving therapeutic accessibility.

Attracting foreign direct investments (FDI) can play an important role for boosting the pharmaceutical and medical sectors. However, Malaysia needs to **build local capacity and preparedness**, infrastructure, and regulatory support to accept such investments. Nurul Izzah discussed national strategies such as:

- The strategic positioning of Malaysia as a central innovation hub for neglected diseases and cancer within ASEAN and Islamic Development Bank (IsDB)-linked countries
- The Phase 1 First-in-Human clinical trials
- The Health White Paper[10]
- The New Industrial Master Plan (NIMP) 2030, which focuses on pharmaceuticals and medical devices as a key sector[11]
- The IA-DATA initiative, which is designed to build strong intersectoral partnerships

Malaysia's efforts align with national policies like the **National Science, Technology, and Innovation Policy**, which emphasises technological development through R&D; local technology-based industries; adaptive science, technology and innovation talent; as well as global prominence. Nurul Izzah also noted the significance of **Malaysia chairing ASEAN in 2025**,[12] as a strategic opportunity to further the agenda of improving accessibility and equitability of diagnostics and therapeutics. This role could be instrumental in addressing regional healthcare disparities, fostering innovation and encouraging the adoption of best practices across ASEAN nations.

10. Ministry of Health, Malaysia. (2023). Health White Paper for Malaysia. https://www.moh.gov.my/moh/resources/Penerbitan/Penerbitan%20Utama/Kertas%20Putih%20Kesihatan/Kertas_Putih_Kesihatan_(ENG)_compressed.pdf
11. Malaysian Investment Development Authority (MIDA). (2023). Launch of the New Industrial Master Plan 2030 (NIMP 2030). http://www.mida.gov.my/launch-of-the-new-industrial-master-plan-2030-nimp-2030/
12. Harinderan K. (2024). Malaysia as ASEAN Chair 2025 aims to achieve significant milestones, Business Today. https://www.businesstoday.com.my/2024/05/06/malaysia-to-helm-asean-next-year-under-aims-to-achieve-significant-milestones-minister/

Opportunities for collaboration in ASEAN

The workshop included an expert panel discussion that provided insightful interventions on critical areas such as access, equity, affordability, clinical research, harmonising regulatory frameworks, infrastructure and capacity, and government ecosystem support.

Chee Yoke Ling, Executive Director of the Third World Network, emphasised the need to move beyond science in addressing public health challenges. She highlighted the importance of sustainable financing for healthcare systems, advocating for public health funding models that prioritise health over revenue. On the topic of innovation, she pointed out that IP plays a key role, and that current monopolies and regulatory barriers are stifling innovation. She also raised concerns about the potential negative impacts of agreements like the Trans-Pacific Partnership on local companies. Yoke Ling argued that public ownership and local investment are crucial for making healthcare affordable and fostering innovation.

Dr Akhmal Yusof, CEO of CRM, discussed the significance of reliable infrastructure in clinical research, emphasising that it affects the reliability and replicability of results. He highlighted the principles of humanity, stability, and sustainability in clinical research, urging the need for Malaysia to expand its clinical trial capabilities. Dr Akhmal called for an increased interest in STEM fields and the training of researchers in Good Clinical Practice to foster regional prosperity and enhance Malaysia's position in clinical research.

Vanessa Daniel, Acting Director of DNDi, discussed the regulatory challenges faced by Malaysia, particularly the dependence on imported medical devices. She pointed out the inconsistent execution of medical device regulations across ASEAN countries and proposed the creation of a common regulatory framework within ASEAN to expedite dossier reviews and incentivise local research and manufacturing. This would improve the capacities of the local research community and help bridge the gap between science and manufacturing.

Teerawat Wiwatpanit, from the Ministry of Public Health in Thailand, highlighted the importance of addressing the gap between science and regulation. He advocated for better forecasting and feedback mechanisms between innovators and regulators to align market and regulatory demands. He suggested that this approach would enhance the capacity for innovation and improve regulatory practices.

Professor Dr Rofina Yasmin Othman, Chairperson of the Malaysian Research Accelerator for Technology & Innovation (MRANTI), reflected on how the COVID-19 pandemic exposed inadequacies in supply chains and capacity. She noted that while there has been a significant investment in research activities since then, there is no one-size-fits-all solution. Dr Rofina emphasised the critical issue of IP and the need for education and communication to address differences. She also discussed the impact of free trade agreements on trade restrictions and called for a balanced approach to IP and innovation.

Breakout sessions and emerging themes

Participants were divided into breakout groups to explore the current state of diagnostics and therapeutics, identify barriers and challenges, and share insights. Participants then pinpointed the key research barriers and challenges faced in addressing these gaps. They worked collaboratively to identify research gaps that could enhance effective interventions and approaches. This included the current research landscape, gaps, and opportunities for collaboration. The findings of the discussions are set out in this section.

Variations in the current state of play across countries in SEA

The COVID-19 pandemic highlighted the crucial role of diagnostics in response strategies, prompting ASEAN member states to improve testing capacities through the increased availability of test kits, laboratories, and resources. However, post-pandemic challenges persist, with disparities in access to diagnostics re-emerging both between and within countries. Regional priorities also remain complex, with different nations focusing on various aspects: India is concentrating on equitable access through Universal Basic Care; Myanmar on reducing import dependency; Vietnam on healthcare costs via screening and prevention; and the Philippines on enhancing diagnostics. Despite initiatives promoting equity and affordability, challenges such as the high costs of cervical cancer drugs and the production complexities of biologics and vaccines remain an issue, particularly for developing nations.

Disparities in technology and innovation for diagnostics and therapeutics were evident among ASEAN countries. Singapore leads with robust talent, funding, infrastructure, and commercialisation capabilities, while Malaysia, Indonesia, and the Philippines face significant challenges with funding, infrastructure, and policy fragmentation. Malaysia struggles with a small market size and fragmented research efforts, and Indonesia lacks demand-driven research and adequate government funding. Thailand has moderate capacity across all metrics. Singapore's national R&D plan, revised every five years, facilitates the transition from research to practical applications through the Industry Alignment Fund, a model less evident in other ASEAN states.

Despite these differences, participants agreed that ASEAN's collective response to the COVID-19 pandemic is a significant success story, with member states enhancing testing capacities and aligning on shared priorities.

Regional initiatives	
ASEAN Diagnostic Development (DxD) Initiative, includes initiatives surrounding genomic surveillance for COVID-19	Co-led by the Philippine Council for Health Research and Singapore's Diagnostics Development Hub (DxD Hub). Open to all ASEAN member states
The ASEAN Joint Assessment Procedure for Pharmaceutical Products has facilitated the approval of various treatments and harmonised regulatory guidelines	Initiated by Malaysia's National Pharmaceutical Regulatory Agency. Open to all ASEAN member states

1. Thailand manufactures colostomy bags using local materials which are widely used worldwide.

2. In the Philippines, interdisciplinary research led to locally tailored prosthetics, while the BALIK Scientist Programme encouraged collaboration with Filipino researchers abroad.

3. **In Singapore:**
   - PRECISE initiative unites stakeholders in implementing precision medicine and developing a diagnostic test for gastroesophageal cancer
   - The Agency for Science, Technology and Research (A*STAR) effectively coordinates efforts within ASEAN and collaborates with partners in North Asia, the EU, and the US for commercialisation.

4. **Malaysia's success stories:**
   - The National Essential Medicines List
   - The Institute for Medical Research developed orthopaedic innovations that are now used in Ministry of Health hospitals
   - The US government's investment in Biogenes Technologies for COVID-19 diagnostics
   - CRM and the Institute of Clinical Research have achieved success in developing a clinical trial ecosystem.

5. Indonesia's Omnibus Health Law prioritises healthcare innovation, focusing on domestic pharmaceuticals and medical devices.

Evidence gaps, barriers, and challenges

Participants identified several challenges concerning healthcare infrastructure and capacity and proposed solutions to address the gaps, as outlined in the table below:

Challenges	Proposed solutions
Lack of comprehensive data on drug use, treatment patterns, and best practices	Strengthen the evidence base through national data collection and baseline assessments for future interventions and the evaluation of healthcare strategies
Geographical barriers to healthcare access	Implement digital tools such as telemedicine, AI, and electronic health records to overcome these barriers and improve efficiency
Inefficient resource distribution	Conduct localised cost–benefit analyses to optimise resource allocation and ensure high returns on investments
Fragmented healthcare systems with poor digital infrastructure	Invest in digital infrastructure and policies supporting Findability, Accessibility, Interoperability, Reusability (FAIR)-compliant electronic medical records and laboratory networks for diagnostics
High costs and lack of equity in healthcare access	Focus on localised strategies, South–South collaboration, and regulatory reforms to foster competition, lower costs, and improve affordability
Inconsistent regulatory frameworks and inadequate IP protection	Develop comprehensive IP guidelines, reform regulatory frameworks, and create incentives for innovation while addressing affordability
Insufficient patient-centric research and stakeholder engagement	Involve patient advocacy groups to ensure policies reflect patient needs, promoting more patient-centric R&D
Gaps in technology readiness, funding, and research site coordination	Tailor initiatives to local needs, such as technology readiness in Malaysia and improving research site coordination in Indonesia and the Philippines
Limited bilateral and regional collaboration in diagnostics and therapeutics	Advance diagnostics and therapeutics through bilateral partnerships, joint funding schemes, and knowledge exchange across countries
Regulatory barriers slowing market access and innovation	Streamline regulatory processes, encourage public–private partnerships, and harmonise regulations to create a competitive regional market
Underutilisation of advanced technologies like AI and biomarker discovery	Invest in AI, biomarker discovery, and clinical diagnostics to drive innovation and improve healthcare outcomes
Challenges in translating research into clinical practice	Support translational research, with bodies like the Academy of Sciences Malaysia playing a key role in ensuring research leads to impactful healthcare solutions

Case study spotlight session: regional exemplars of success

During the workshop, speakers gave presentations on local initiatives to develop diagnostics and therapeutics. Summaries of these presentations are given below.

Affordable treatments for acute myeloid leukaemia and access to CAR-T cell therapy

Achieving a balance between low-cost solutions and high-end therapies requires a shift from profit-driven models to socially responsible healthcare, prioritising patient wellbeing and ensuring accessible technologies. Professor Vikram Mathews, Head of Haematology at Christian Medical College Vellore, highlighted the success of arsenic trioxide in treating acute promyelocytic leukaemia (APML), showcasing it as an example of effective translational research that leverages indigenous knowledge. Prior to the availability of all-trans retinoic acid (ATRA), treatments were less effective and more toxic, and although ATRA improved outcomes, its high cost remained prohibitive.[13] Ayurvedic treatments with arsenic offered potential but posed risks of secondary tumours, necessitating dose optimisation. When properly administered, arsenic trioxide achieved up to 70% success rates with no long-term side effects and was significantly cheaper, costing only one-fourth of the cost of conventional therapies.[14]

Professor Mathews presented cases of sustained remission with arsenic trioxide, highlighting its affordability, outpatient applicability, and minimal side effects, such as no hepatotoxicity or second malignancies. This treatment model exemplifies the potential of low-cost, locally sourced solutions for APML and other diseases. In contrast, he discussed the high costs and limited accessibility of CAR-T cell therapy in India,[15] where many patients seek treatment abroad, with costs ranging from $373,000 to over a million dollars. The limited options and logistical barriers underscore the need for enhanced research capabilities, local reagent production, decentralised manufacturing,[16] and improved facilities to make CAR-T therapy more accessible. The ongoing VELCART study is an initiative aimed at optimising CAR-T cell therapy for relapsed and refractory diffuse large B-cell lymphoma.

13. Philip C, et al. (2014). Blood. 124(21), 3685. Chepsy C.P, Geoge B, Ganapule A, et al. (2014). Acute Myeloid Leukemia: Challenges and Real World Data from India, *Blood*, 124(21), 3685. https://doi.org/10.1182/blood.V124.21.3685.3685
14. Mathews V, George B, Chendamarai E, et al. (2010). Single-agent arsenic trioxide in the treatment of newly diagnosed acute promyelocytic leukemia: long-term follow-up data, *Journal of Clinical Oncology*, 28(24), 3866–3871.
15. Hosen N. (2020) CAR T cell therapy, *Immunological Medicine*, 44(2), 69–73. https://doi.org/10.1080/25785826.2020.1796063
16. Palani H. K, Arunachalam A. K, Yasar M et al. (2023). Decentralized manufacturing of anti CD19 CAR-T cells using CliniMACS Prodigy®: real-world experience and cost analysis in India. *Bone marrow transplantation*, 58(2), 160–167. https://doi.org/10.1038/s41409-022-01866-5

Navigating technology transfer – Duopharma's journey: The Malaysian experience

Priya Darshini Asokan from Duopharma shared that, from 2016 to 2022, the company invested over RM400 million (US$90.2 million) in plants and equipment, highlighting its commitment to producing high-quality pharmaceuticals and expanding into the biologics sector. A key achievement is the co-development and commercialisation of **Malaysia's first Erythropoietin (EPO) biosimilar, Erysaa**. ASEAN is an emerging market for biosimilars,[17] but Malaysia's pharmaceutical industry remains reliant on imports, with only eight out of 69 approved biologics locally manufactured, including Erysaa.

Duopharma's strategic plan includes building a biologics facility to boost local manufacturing, reduce reliance on imports, and create skilled jobs. These in-house capability improvements offer numerous benefits, such as enhancing the accessibility and affordability of generic and biosimilar products, reducing reliance on imports, and creating skilled job opportunities. Conducting phase-III trials locally allowed Duopharma to tailor the treatment to the specific needs of Malaysian patients while adhering to international standards, resulting in a reduced cost per injection of EPO from RM100 (US$23) to RM15–20 (US$3.50–$5). Despite these advances, Duopharma faces challenges such as Malaysia's small population, reliance on global partners, high regulatory barriers, and foreign exchange volatility.

To address these challenges, increased support for industry–academia collaborations is crucial for researching and developing platform technologies and pushing towards commercialisation. Incentives for high-tech investments leveraging new technologies are needed to develop infrastructure for self-sufficiency. A stable policy and procurement environment supported by government commitments can further facilitate technology transfers and local manufacturing initiatives. Transparent reporting of both successes and challenges, including poor outcomes and deaths, is crucial for maintaining trust and improving practices.

Local solutions and community-based interventions to dengue

Dr Ami Fazlin Syed Mohamed, from the Institute of Medical Research, Ministry of Health Malaysia, introduced the ***Wolbachia* strategy**, an innovative method to combat dengue by using *Wolbachia*-infected mosquitoes to control and suppress the wild mosquito population. *Wolbachia* naturally infects other insects but not *Aedes aegypti*, the mosquito species carrying dengue, chikungunya, and zika viruses. The strategy consists of two primary strategies: the replacement strategy, which involves the release of female *Wolbachia*-infected mosquitoes, and the suppression strategy, which involves the release of male *Wolbachia*-infected mosquitoes.

Dr Ami's *Wolbachia* strategy is a comprehensive approach to combat dengue. The strategy involves selecting suitable trial sites, identifying dengue hotspots, ensuring public cooperation through surveys and informed consent, and confirming the presence and high population of *Aedes aegypti* mosquitoes. The trial sites must be located at a distance of a least 0.6 km² and

17. Future Market Insights. (2024). Biosimilars and follow-on biologics market. http://www.futuremarketinsights.com/reports/biosimilars-and-follow-on-biologics-market

accessible by road for efficient release and monitoring processes. The release of *Wolbachia*-infected Aedes aegypti reduced dengue transmission by 40–60% in research localities.[18,19] To increase the impact of the *Wolbachia*-infected mosquito release programme, collaboration in production, release, and monitoring will enhance the programme's overall efficacy. Dr Ami emphasised four key principles: trust, transparency, accountability, and listening. Building trust involves conveying information in a jargon-free manner without compromising scientific accuracy. To ensure transparency, it is essential to provide the community with clear information about ongoing activities, known facts, and uncertainties. Accountability involves keeping the community informed about actions taken and outcomes, and making promises that can be fulfilled. Listening means respecting and addressing community concerns, perceptions, and beliefs.

Technology transfer through collaborative partnerships

Dr Ruifen Weng introduced the DxD Hub, a national platform managed by A*STAR, Singapore's foremost public-sector agency for economic-oriented R&D. Established in 2014, the DxD Hub aims to bridge the diagnostics productisation gap in Singapore and facilitate the transition of translational research IP into validated registered diagnostic products. Furthermore, it seeks to enhance the diagnostic medical technology ecosystem by attracting both research and private investment. Fit-for-purpose diagnostics are essential for addressing national health priorities, particularly in preventive and precision care, as well as community-based decentralised testing. The Hub collaborates with industry partners to develop medical devices and digital solutions that integrate novel diagnostics into healthcare systems while fostering the creation of prototypes based on health impact and commercial feasibility.

Dr Weng highlighted the shift from technology transfer to solution transfer through collaborative partnerships, as exemplified by the UNITED 500™ test for pan-cancer genetic aberrations. Other initiatives include clinical decision support systems for breast cancer risk prediction and antenatal risk assessment. These innovations have gained considerable traction, with 95% of public and private hospitals in Singapore utilising domestically developed polymerase chain reaction (PCR) assays instead of those from multinational corporations. The effectiveness of the productisation engine was particularly evident during the COVID-19 pandemic, as A*STAR's Fortitude PCR kits were ready for clinical use within 17 days of Singapore's first reported case, underscoring the vital role of novel diagnostics in managing public health crises.

18. Nazni W.A, Hoffmann A.A, NoorAfizah A, et al. (2019). Establishment of Wolbachia Strain wAlbB in Malaysian Populations of Aedes aegypti for Dengue Control, Current Biology, 29(24), 4241–4248. https://doi.org/10.1016/j.cub.2019.11.007
19. Hoffmann A.A, Ahmad- N.W, Keong W.K, et al. (2024). Introduction of Aedes aegypti mosquitoes carrying wAlbB Wolbachia sharply decreases dengue incidence in disease hotspots, *iScience.* 27(2). https://doi.org/10.1016/j.isci.2024.108942

The development and use of digital health for the early detection of oral lesions and cancer

The early detection of oral cancer is paramount as Asia accounts for 64% of global oral cancer cases and 74% of related deaths.[20] Within ASEAN, oral cancer is among the top five cancers, highlighting the critical need for effective screening tools. The national goal, as outlined in Malaysia's National Oral Health Plan (NOHP) 2021–2030, aims to increase stage-1 detection from 15% to 30%,[21] aligned with the broader objective of the 12th Malaysian Plan to enhance equitable access to healthcare.[22] Professor Cheong Sok Ching illustrated the transformative potential of telemedicine in oral cancer detection. She shared that the MeMoSA® Mobile Mouth Screening Anywhere application, an initiative by Cancer Research Malaysia, which allows for mobile-based mouth screening, providing a practical and scalable solution for the early detection of oral cancers both in clinical settings and within communities. The app's capabilities include the ability to capture images of oral lesions, facilitate remote communication between healthcare volunteers in villages and clinicians for preliminary diagnosis, and aid in referral decisions. This process ensures that patients enter the care pathway as swiftly as possible, addressing a significant gap in early diagnosis. Professor Cheong detailed the objectives of the MeMoSA® initiative, which include screening adults in high-risk communities, conducting opportunistic screenings at dental clinics and community programmes, and ensuring necessary referrals and compliance monitoring. The app's functionality empowers communities to better manage their oral health and significantly broadens the reach of oral cancer screening.

The development of AI for object detection and disease classification within the MeMoSA® app represents a leap forward in leveraging technology for public health. Professor Cheong shared the app's success, demonstrating its effectiveness in real-world settings. The implementation of MeMoSA® also highlighted the importance of understanding gaps and working towards national goals, securing early buy-in from stakeholders, and grounding efforts in scientific data. Despite its successes, the MeMoSA® initiative has faced challenges such as limited baseline data, expertise gaps in AI development and implementation science, and the need for clear IP and regulatory pathways. Guidelines for the use of AI in most developing countries are still lacking, which poses an additional hurdle. Professor Cheong stressed the benefits of international funding for equitable partnerships, the national drive for home-grown technologies, and learning from other countries facing similar challenges.

Global PDPs – Meeting unmet global health needs

In the design and development of Global Access Diagnostics (GADx), Dr Mark Street-Docherty emphasised the importance of adhering to the REASSURED principles: real-time connectivity; ease of specimen collection; affordable; sensitive; specific; user-friendly; rapid and robust; equipment-free; and deliverable to end users. These principles ensure that high-quality diagnostic technologies effectively reach and benefit their intended users. He identified

20. Kimman M, Norman R, Jan S, et al. (2012). The burden of cancer in member countries of the Association of Southeast Asian Nations (ASEAN), Asian Pacific Journal of Cancer Prevention, 13(2), 411–420. https://doi.org/10.7314/apjcp.2012.13.2.411
21. Ministry of Health Malaysia. (2021). National Oral Health Plan 2021–2030.
22. Government of Malaysia. (2021). 12th Malaysian Plan 2021–2025.

several key challenges in global health, such as low profit margins for leading diagnostic companies and the complexities of initial design due to the need for high-quality, annotated clinical samples and user-specific requirements. The presentation also highlighted the benefits of PDPs, which GADx leverages through a robust network of collaborators. These partnerships provide access to well-annotated clinical samples, aiding in the development and validation of superior tests. Global funding partners play a crucial role, strategically supporting the design, development, and deployment stages based on their priorities. This model promotes open access to IP and the creation of patent pools under limited licensing agreements, facilitating broader access to critical technologies.

Dr Street-Docherty discussed strategic engagements with global health organisations, particularly in regulatory conversations with entities like WHO, the Emergency Response and Preparedness Department, and local regulatory bodies. A significant case study involved the design, development, and technical transfer of an epidemic portfolio to DIATROPIX in Dakar, Senegal, which now operates as the first ISO-accredited manufacturing unit in West Africa. GADx is also working to address disparities in access to diagnostic technologies through ongoing PDPs with partners such as the Saudi Health Agency, MRANTI, the Ministry of Science, Technology and Innovation, and Universiti Malaya. A proposal is currently in preparation for submission to the IsDB, the African Development Bank, and the European Investment Bank, all of which have established partnerships with WHO in primary healthcare initiatives as of 2023.

Conclusion

This policy workshop concluded with a strong emphasis on the need for a coordinated approach to healthcare in SEA. One of the primary takeaways was the importance of addressing IP issues and regulatory challenges that hinder the development and deployment of new diagnostic and therapeutic tools. By fostering South–South collaboration, countries in the region can share resources and expertise, ensuring that healthcare advancements benefit all populations. South–South collaborations can bring together different geopolitical configurations to tackle the issues arising in healthcare by extending from ASEAN+ nations to include partners in Brazil, Russia, India, China, and South Africa. Countries such as Malaysia that boast noteworthy medical R&D potential and skill sets can harness and advance their collective capabilities. This underscores the notion that the successful development of innovative approaches to treatments can be achieved through collaborations rooted within LMICs without the customary dependence on large pharmaceutical corporations.

Political leadership was identified as a crucial component for driving these changes. Leaders must be committed to breaking down silos and fostering collaboration among various stakeholders. Knowledge transfer and capacity building were also highlighted as essential components for ensuring that healthcare professionals and researchers in the region are equipped with the necessary skills and knowledge to address healthcare challenges effectively. To implement effective policies delivering these goals, several approaches have been advocated.

An alliance that shares these goals and contains the necessary expertise to engage with policymakers can accelerate delivery. The overall aims are to focus on a return on impact and not focus solely on returns on investment, such that, although impacts may be harder to assess, they include the broader maintenance of wellbeing in society, environmental welfare, and the inclusivity of societal benefits. With support from learned societies such as the Academy of Medical Sciences and the Academy of Sciences Malaysia, regulatory bodies, industry and academia, a more ambitious product development partnership (PDP) can be conceptualised. This PDP should be based in the SEA region with the aim of defining mechanisms to lower barriers that currently add to high costs and impede the accessibility of healthcare interventions. To achieve the maximum impact, this PDP should be positioned at arm's length from for-profit concerns so that its scientific and policy outputs remain credible. As synergies develop between partners working with the PDP, alliances could catalyse synergies between regional programmes to maximise the speed of developing drugs, diagnostics, and vaccines that are relevant to addressing local challenges. Capacity strengthening in laboratory-based studies, clinical trials, and implementation science will contribute to the value of regional programmes.

Mapping existing expertise in different sectors, for example an ASEAN Joint Assessment Procedure Initiative, the regional collaboration to Improve ASEAN Drug Security and Self-Reliance, or the ASEAN Diagnostics Initiative, will help promote best practices more widely. Different configurations of ASEAN countries can also be catalytic for wider regional and wider South–South collaborations. As this workshop has illustrated, regions have very valuable experiences in different disciplines. When this expertise is allied with manufacturing capacity to support healthcare interventions, such as in relation to diagnostics, regional needs can be met through investments in technology sharing and technology transfer, fostering regional self-reliance. This is particularly important in a world that is displaying continued susceptibility to pandemics.

The workshop concluded with a commitment by the participants to continue their efforts to address these issues and work towards a future where all individuals in the region have access to the diagnostics and therapeutics they need. By focusing on a coordinated approach and leveraging the strengths of each country, SEA can make significant strides in improving healthcare access and equity. This commitment to collaboration, innovation, and continuous improvement will be essential for achieving the workshop's goals and ensuring better healthcare outcomes for all.

Annexes

Annexe one: Steering committee

Co-chairs

Academician Professor Datuk Dr Looi Lai Meng FASc, Vice President, Academy of Sciences Malaysia; National Distinguished Professor, University of Malaya

Professor Sanjeev Krishna FMedSci, Professor of Molecular Parasitology and Medicine, St George's, University of London

Members

Professor Dr Abhimanyu Veerakumarasivam, Provost, Sunway University

Jean-Michel Piedagnel, Director, Woodseer Resources

Professor Dr Rofina Yasmin Othman FASc, Chairperson, MRANTI

Dr Ruth March OBE FMedSci, Senior Vice President Precision Medicine, AstraZeneca

Professor Sharon Yvette Angelina M. Villanueva, Professor and Associate Dean for Research, Department of Medical Microbiology, University of the Philippines Manila

Dr Sidney Yee, Founding CEO of Diagnostics Development (DxD) Hub, Singapore's Agency for Science, Technology and Research (A*STAR)

Professor Datin Paduka Dr Teo Soo Hwang FASc, Chairperson of the Medical and Health Sciences Discipline, Academy of Sciences Malaysia

Dr Yolanda Augustin, Oncologist, St George's, University of London

Annexe two: Participant list

Aaron Kual, British High Commission Malaysia
Achal Prabhala, Access IBSA
Adrian Joseph, Biogenes Technologies
Dr Akhmal Yusof, Clinical Research Malaysia
Dr Ami Fazlin Syed Mohamed, Institute for Medical Research (IMR)
Dr Audrey Teh, St George's, University of London
Dr Cheah Phaik Leng FASc, Genomic Medical Science (GEMS) Laboratory, University of Malaya
Chee Yoke Ling, Third World Network
Professor Cheong Sok Ching FASc, Cancer Research Malaysia
Associate Professor Elaine Chan Wan Ling, Vidanex, Malaysia
Dr Fresthel Climacosa, University of the Philippines Manila
Hajnalka Kovacsevics, St George's University of London
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Professor Ivy Chung, University Malaya
Professor Jaime Montoya, University of the Philippines College of Medicine, Chair of the Health Sciences Division and Secretary, National Academy of Science and Technology
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Professor Dr Le Huu Song, 108 Military Central Hospital; VG-CARE
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Madihah Ahmad Razae, Malaysian Global Innovation & Creativity Centre.
Dr Mark Street-Docherty, Global Access Diagnostics
Dr Melissa Lim, University Sarawak Malaysia
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Dr Nafeesa Mat Ali, St George's University of London
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Annexe three: List of acronyms

AI Artificial intelligence
APML Acute promyelocytic leukaemia
ASEAN Association of Southeast Asian Nations
ATRA All-trans retinoic acid
CRM Clinical Research Malaysia
DND*i* Drugs for Neglected Diseases initiative
EPO Erythropoietin
GADx Global Access Diagnostics
GEMS Genomic Medical Science Laboratory
HITAP Health Intervention and Technology Assessment Program Foundation
IP Intellectual property
IMR Institute for Medical Research
IsDB Islamic Development Bank
LMICs Low- and middle-income countries
MDA Medical Device Authority

MIDAS Medical Innovation Development and Assessment Support
MRANTI Malaysian Research Accelerator for Technology & Innovation
MSF Médecins Sans Frontières (Doctors Without Borders)
NIMP New Industrial Master Plan
NOHP National Oral Health Plan
PCR Polymerase chain reaction
PDP Product development partnership
R&D Research and development
SEA Southeast Asia
VG-CARE Vietnamese German Centre for Medical Research
WHO World Health Organization

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