

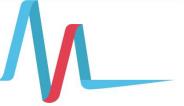


Roundtable on the Value of
Diagnostics in Cardiovascular
Diseases: A Deep Dive into Australia
and Thailand Access Policy

**Output Summary Report** 

March

2024







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# Background to Roundtable and Country Context

- Background
- Overview of Roundtable Session
- Australia's Value Assessment Framework for Tests
- Thailand's Health Technology Evaluation Process





# **Background**

APACMed with ANSEA jointly produced a White Paper that was launched in September 2023, and advocated for a distinct value assessment framework for diagnostics separate from drugs and devices.

Some of the key highlights of the white paper are outlined as below:

#### **Value of Diagnostics**

Diagnostics influence approximately 66% of treatment decisions, but only account for 1-2% of healthcare expenditure (1), suggesting a potential imbalance between the value these diagnostics generate and the amount they are funded. (2) Scholars attribute this imbalance to the lack of an appropriate assessment that can fully capture the value of these technologies, which results in diagnostics being assessed in a rather partial or suboptimal way. This leads to their under-valuation (2) in funding and reimbursement decisions. (3) The contributions of diagnostics to the healthcare system are, therefore, under-recognized and undervalued. (4)

# The critical role of in-vitro diagnostics (IVDs) in Coronary Artery Disease (CAD) and Heart Failure (HF)

IVDs or cardiac biomarkers are an essential part of disease management and therapy, helping physicians to stratify patient cohorts, choose more appropriate drug regimens, avoid adverse events, reduce the amount of uncertainty, facilitate therapeutic monitoring, and define the predisposition to disease. (5)

Diagnostic tests enable improved clinical decision-making and therapy selection, distinct from the value of the underlying therapy intervention itself. (6) Early deployment of an accurate diagnostic test leads to improved patient outcomes and quality of life (QOL) and cost reduction from unnecessary treatment. (4)

Cardiac diagnostic tests have applications throughout the pathway of care. (4) These tests are used to confirm, or rule out a specific diagnosis, monitor the course of a disease, or assess a patient's eligibility for or response to specific treatments. (6) Equipped with this knowledge, providers and health care systems benefit by avoiding ineffective, or wasteful, health care that accompanies less targeted, traditional treatment approaches. (7)

#### The need for a fit-for-purpose value assessment framework for IVDs





To capture the full value potential of an IVD, there is a need for a fit-for-purpose value assessment framework for IVDs that includes a broad set of criteria other than the traditional clinical and safety metrics alone. (8) Value assessments for IVDs should factor in criteria such as indirect costs, spillover costs and non-health outcomes such as the value of knowing and should also consider the numerous potential benefits conferred to the different stakeholders within the healthcare system, including patients.

#### **Policy Recommendations**

Through extensive research and interviews with various stakeholders in the healthcare system, the 5 policy recommendations were proposed, to address the need for a fit-for-purpose value assessment framework across the APAC region for IVDs, separate from drugs and medical devices. These recommendations can be considered by policy makers across different healthcare archetypes, independent of whether the funding decisions are made through a designated HTA agency or not.

Recommendations	Description		
Recommendation 1	Recognise the crucial value IVDs provide throughout the CAD/HF patient care pathway and ensure there is sustainable funding availability for patient access to high quality Diagnostics.		
Recommendation 2	Ensure appropriate value recognition of all intermediate value outcomes IVDs provide to different stakeholders.		
Recommendation 3	Include perspectives of multiple stakeholders such as healthcare professionals, providers, industry experts, academicians, policy advisors, and patients for value assessments.		
Recommendation 4	Include broader value outcomes outside the traditional clinical performance and safety metrics, such as indirect costs, spillover costs and non-health outcomes when assessing the value of Diagnostics.		
Recommendation 5	Support the use of other types of evidence such as real-world evidence when assessing the full value of Diagnostics.		





## **Overview of Roundtable Session**

The 'Roundtable on the Value of Diagnostics in Cardiovascular Diseases (CVDs): A Deep Dive into Australia and Thailand Access Policy' was jointly organized by Asia Pacific Medical Technology Association (APACMed) and ANSEA Consulting on 21<sup>st</sup> November 2023. The closed-door virtual roundtable session was graced by Australian and Thai stakeholders, including policymakers, payors, academics, clinicians, and local trade associations.

#### A step towards implementing White Paper Recommendations m

The Roundtable aimed to serve as an interactive platform for stakeholders to convene and discuss the operational viability of recommendations outlined in a recently launched White Paper on the Value of Diagnostics for CVDs, jointly produced by APACMed and ANSEA. Acute Heart Failure and Coronary Artery Disease were of specific focus due to the huge burden they pose to the healthcare system and society (8). The above-mentioned policy recommendations were centred around the following **2 crucial elements**:

- 1. Holistic value recognition of in-vitro diagnostics (IVDs) beyond conventional outcomes
- 2. Sustainable funding availability for patient access to high value IVDs

#### Overarching Aim of the Roundtable

Discussions revolved around sharing experiences, practices, and exploring potential opportunities and challenges associated with the local implementation of policy recommendations. The focus was on fostering cross-sharing and learning between markets at various stages of their journey towards enhanced funding and accessibility to IVDs.

The Roundtable served as a pivotal event, aiming to propel dialogues and actions at the country level (focused on Thailand and Australia). Its goal was to advance discussions around increased funding and improved access to high-value diagnostics, marking a significant milestone in the ongoing efforts to enhance healthcare infrastructure.

#### **Key Objectives**

- 1. Understand the current situation related to the value of diagnostics across APAC, with a focus on two key markets Australia and Thailand
- 2. Gather feedback on policy recommendations for proposed framework for diagnostics.





- 3. Assess and understand the key challenges and unmet needs related to adopting the fit for purpose Value Assessment Framework for IVD (in Australia and Thailand)
- 4. Identify necessary steps to improve IVD value recognition, funding, and reimbursement.
- 5. Advise on industry's role in supporting better value recognition and funding of IVDs.

#### **Objectives of Breakout Sessions**

The breakout sessions were designed to dive deeper into the distinct challenges and unmet needs in Australia and Thailand, in adopting a Value Assessment Framework (VAF) for IVDs.

#### Rationale behind Australia and Thailand Deep-Dive

As aforementioned, a mix of mature and advanced HTA markets was selected to facilitate cross-sharing of best practices, challenges, and corresponding remedies. As a key middleincome economy situated in the heart of ASEAN, Thailand was the ideal candidate for a mature HTA market, while Australia was identified as an advanced market globally in terms of having a distinct VAF in place for diagnostics.

#### Australia Thailand

- Represents a fully reimbursed market Represents a semi-reimbursed market with low affordability challenges
- Advanced HTA market archetype: A Mature HTA market: No distinct VAF is distinct VAF is already present for diagnostics
- Enables best practices sharing
- with moderate affordability challenges
- present yet for diagnostics
- Adequate potential for Thailand to adopt a distinct framework, given HTA maturity
- Enables sharing of common access challenges across APAC, with exchange of suggestions to overcome them

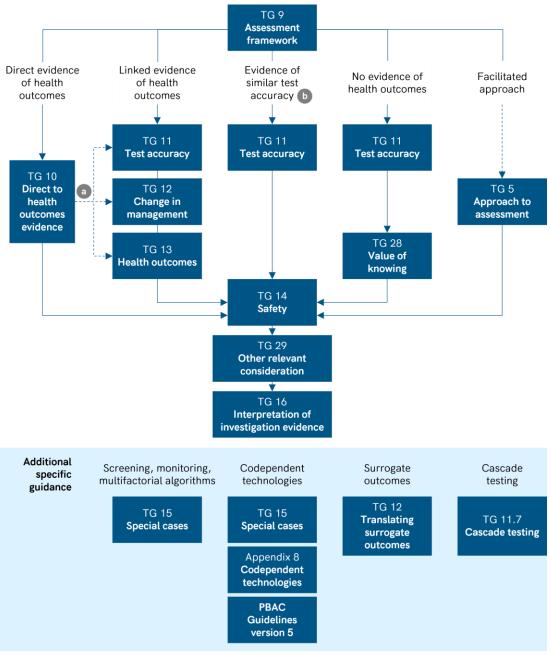
#### Methodology

- Attendees were split into 2 breakout groups for Australia and Thailand respectively.
- Each breakout room was moderated by a moderator and questions were posed to all attendees. Observer insights were sought and captured at relevant junctures.
- Participant, observer responses and insights were captured by dedicated note-takers and consolidated after the Roundtable.
- The key takeaways are outlined in the following section based on responses gathered from and reviewed by attendees present in the 2 breakout sessions.





# Australia's Value Assessment Framework for Tests or 'Investigative Technologies'



Source: (9)

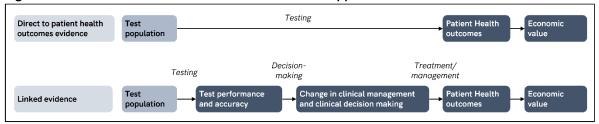
Australia's **Medical Services Advisory Committee (MSAC**) developed its own guidance for assessing tests for reimbursement purposes in 2005, proposing a "linked evidence approach," (9) which has subsequently been recommended in many international guidance documents (**Figure 1**). As direct trial evidence is often absent, this linkage approach maximizes the available information so that the likely impact of the new test on patient health outcomes can be determined. (10) The linked evidence approach factors in the following **3** 





**types of scientific evidence**: Test performance and accuracy, change in clinical management and patient health outcomes.

Figure 1: Direct to health outcomes vs linked evidence approach



Source: (9)

#### TYPES OF SCIENTIFIC EVIDENCE

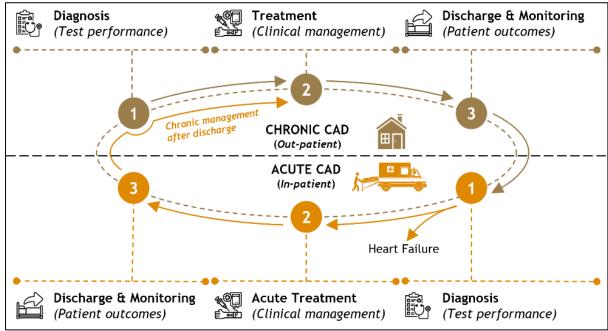
**Evidence 1: Test performance and accuracy** refers to sensitivity, specificity, false positive and false negative rates, positive and negative predictive values, and other measures of test performance, ideally in comparison to a reference standard.

**Evidence 2: Change in clinical management** refers to the interpretation of the test result leading to a change in patient management.

Evidence 3: Patient health outcomes refer to the clinical efficacy of the test and subsequent treatment, including the impact on the patient's survival, functional status, quality of life, and economic outcomes (including direct and indirect medical costs) during decision-making.

The patient populations assessed in evidence 1-3 must be transferrable, that is they should reflect the target population that would be tested and then subsequently treated.

Figure 2: CAD Patient Journey, featuring Evidence Types 1-3

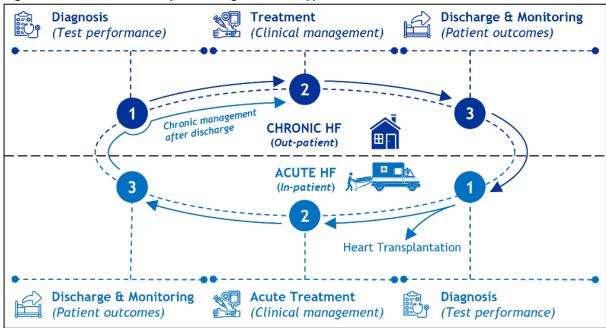


Source: (14)





Figure 3: HF Patient Journey, featuring Evidence Types 1-3



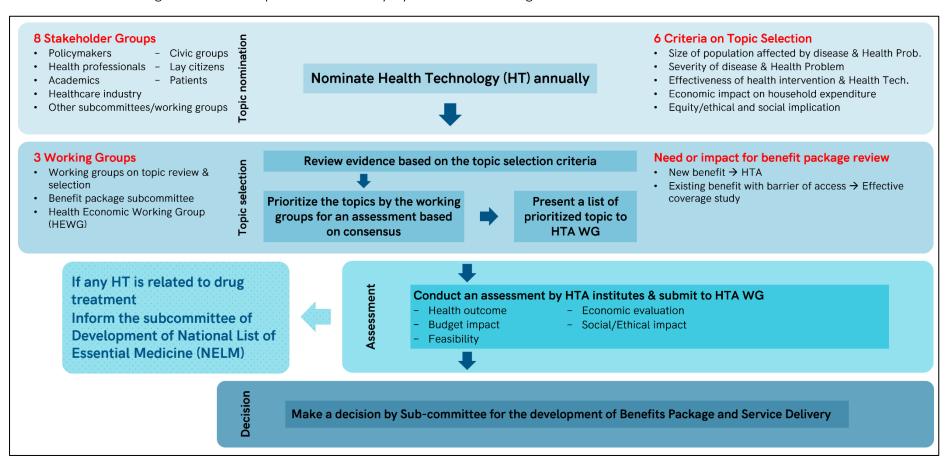
Source: (14)





# Thailand's Health Technology Evaluation Process

While there is no distinct framework for diagnostics evaluation in Thailand, all Health Technologies (HT) are evaluated in the following manner, summarized in the diagram below and presented verbally by Dr. Pattara during the Roundtable session:



Source: (15)



# Key Takeaways

- Highlights of Keynote Speech
- Key Takeaways from Australia Breakout Session
- Key Takeaways from Thailand Breakout Session
- The Path Forward







# Highlights of Keynote speech

The Lancet Commission on Diagnostics was set up to analyze pertinent issues across all aspects of diagnostics and identify solutions to truly transform patient access.(2) Its Commissioner, Datuk Professor Dr. Looi, was invited to inaugurate the Roundtable session by outlining the value derived from nations' commitment to increasing access.

#### Advancements and Challenges across the 21st century

Despite numerous advances in healthcare service delivery over the last five decades, advancements and key health challenges that affect certain population segments disproportionately include:

- Rising health and social inequities
- Aging population
- Antimicrobial resistance
- Social and political conflict and displaced populations
- Climate change preparedness and crisis resilience

#### **Focus on UHC Diagnostics**

UHC emerged as a top priority when the 2030 Agenda for Sustainable Development was adopted, as all the Sustainable Development Goals have links to human health.

Diagnostics are expected to bridge gaps in care delivery and health outcomes among populations. Hence the focus is on UHC diagnostics and ease of access.

#### **Global Commitment to increasing Diagnostics Access**

The **76**<sup>th</sup> World Health Assembly has approved a resolution among member nations to ensure that everyone who needs a test can get one.

This has huge implications on national diagnostic strategies including:

- Trading and capacity building
- Research and Innovations
- Alliances to address bottlenecks in service provision

The Lancet Commission of Diagnostics points out that every dollar invested in diagnostics can bring multiple dollars of returns, and millions of lives saved.

"The concept of value must move beyond dollars and cents and look at the positive impacts and ROI."





# **Key Takeaways: Australia Breakout Session**

#### **Discussion Topic 1**



Australia is the only known country with a distinct Value Assessment Framework (VAF) for diagnostics, separate from drugs and devices. Why do you think that is?

- The Australian system values tests and the value it brings
  - Clinically relevant diagnostics with established health outcomes are part of benefits package
- The Linked Evidence Approach and rationale outlined in MSAC guidelines have demonstrated that the same evidentiary rules used for assessing a therapy would not apply to a diagnostic.
  - A diagnostic test will be undervalued if only randomized controlled trial (RCT) outcome data is relied upon, as in evaluation of drugs.
  - MSAC recommends that test performance and accuracy, changes in clinical management, as
     well as patient health outcomes are also considered in evaluating diagnostics
- The political environment, legislation and flexibility of the healthcare system has enabled the separate evaluation of Diagnostics, from drugs and devices.

#### **Discussion Topic 2**



Does the existence of a separate VAF for diagnostics generally improve patient access and funding to innovative diagnostic technologies?

- The existence of the VAF ensures accuracy of funded tests and sustainability of health systems
  - In evaluating test accuracy as one of the key outcomes, the VAF contributes to reducing rates of false positives or false negatives.
  - In the long run, this ensures sustainability of healthcare provision as only patients who are
    correctly diagnosed are referred for follow-up treatments. In this way, payer and provider
    resources are channelled towards those in need, improving patient access.
- Consideration of opportunity costs is crucial. Governments face the pivotal task required to determine the appropriateness of tests, as if the tests are inaccurate and do not lead to better health outcomes, the money could be better spent elsewhere.
- Zooming in on cardiac biomarkers, Australia was cited as 1 of 2 developed countries which were slowest in adopting the uptake of natriuretic peptides (NPs) for HF diagnosis.
  - While N-Terminal pro b-type NP (NT-proBNP) is currently listed in the Medicare Benefits
     Schedule (MBS), it is only reimbursed in the hospital Emergency Department setting.
  - This is noteworthy and impacts clinical practice, as healthcare providers hesitate to offer non-reimbursed devices or diagnostics to patients, (i.e., patients pay 100% out-of-pocket) to avoid imposing a significant financial burden.





- An anecdotal insight surfaced on several patients not being offered a treatment drug for HF
   due to limited access to the preceding diagnostic test
- HTA expert attendees pointed out that NPs were subsumed by the co-dependent technology evaluation framework, and that Australia was 1 of the few countries with a system in place to evaluate the diagnostic and drug together as a unit.
- Patient access and funding is expected to improve as the Australian government is currently conducting a HTA policy and methods review aimed at achieving faster access pathways to medicines including co-dependent tests such as cardiac biomarkers.

#### **Discussion Topic 3**



MSAC has 18 members representing stakeholders with various expertise, contributing to a holistic evaluation process. Why are there no industry representatives?

- Australian stakeholders highlighted the **difficulty in finding a suitable neutral entity representing the industry** that could provide the necessary perspectives.
- As per MTAA's recommendation, it would be ideal for an **individual to have both diagnostic and therapeutic experience** but not actively serving in an industry role. This would enable sufficient distance while providing valuable and deep industry insight.
- The Pharmaceutical Benefits Advisory Committee (PBAC) currently has a neutral industry representative who possesses significant industry experience but is not specifically working in an industry role.
  - An individual with a similar profile could potentially play that role within the MSAC to provide relevant industry perspective.
  - This role (i.e. the appointment and necessary attachments for the representative) can be set up independently under the aegis of the Government of Australia.

#### **Discussion Topic 4**



What are the biggest challenges in Australia, in terms of patient access to diagnostics?

- Areas for improvement in Australia's current evaluation framework would largely be the challenges around evidence submission for reimbursement
  - Significant time and monetary investment are required to produce and submit the appropriate data required for a satisfactory reimbursement submission
- Citing the relatively measured move towards the reimbursement of NT-proBNP as an example, it was noted that there is **room for Australia's current framework to evolve further.**





# **Key Takeaways: Thailand Breakout Session**

#### **Discussion Topic 1**



What are some considerations on Thailand's current value assessment and reimbursement framework?

- There is a need to holistically adjust the current reimbursement system to ensure better care and access to novel diagnostics and harmonize the 3 insurance schemes
- Diagnostics should be evaluated based on a more fit-for-purpose value assessment framework to enhance population access to more optimised outcomes
- Stronger linkage among diagnostics' downstream clinical impact through adequate treatment, is required
- The subject should be raised among policymakers for it to be prioritized (top 5 or top 10 priorities), with a separate budget to reimburse diagnostics, instead of being lumped with treatment costs
- There is a need to establish a fit for purpose value assessment system for reimbursement of diagnostics, separate from drugs and devices to adequately capture the full value potential of diagnostics
- Many new products or precision medicine need to have a very strong diagnostic capacity to be effective and might be missed from reimbursement due to current system
- **Stronger infrastructure** including the referral system are required to ensure equitable patient access to essential diagnostics

#### **Discussion Topic 2**



What recommendations to improve the evaluation of Dx?

- Diagnostics are currently evaluated by the Health Economic Working Group (HEWG) [(15)]
- For consideration of novel diagnostics for benefits package, **stronger linkage between diagnostics and treatment is required**
- HTA processes for diagnostics should also prioritize evaluation of IVDs/cardiac biomarkers so that incremental improvements can be achieved in patient accessibility

#### **Discussion Topic 3**



How can we increase the awareness of NHSO (payer) around the need to prioritize value assessment and reimbursement of Dx?





- A case should be built around return on investment (ROI) for diagnostics in that health care
  system. Since policymakers may view the cost of treatment as a benchmark especially for
  neglected tropical diseases and high price of novel diagnostics might be a deterrent in getting
  an approval for benefits package. Therefore, if the linkage between the need and value of
  diagnostics and ROI is established, it may motivate a policy change towards better funding
  for high value diagnostics
- Policy makers and payers in Thailand could consider including <u>linked evidence</u> such as test
  performance and accuracy and changes in patient health outcomes, in their pool of data
  sources. This would be similar to Australia where the linked evidence approach is commonly
  used, instead of only relying upon RCT evidence
- More of such dialogue should be organized as there is active appetite for such conversations
- There is a need to holistically adjust the current reimbursement system to ensure better care and access to novel diagnostics and harmonize the 3 insurance schemes





## The Path Forward

The White Paper on "Value of In-Vitro Diagnostics in APAC- Value Assessment Framework with applications for Coronary Artery Disease and Heart Failure" published by APACMed in collaboration with ANSEA, underscores the **imperative for a tailored value assessment framework specifically designed for diagnostics**, such as cardiac biomarkers. This framework stands apart from those applicable to drugs and medical devices. The successful adoption and implementation of this comprehensive framework for In Vitro Diagnostics (IVDs) necessitate a collective effort involving the commitment and engagement of governments, industry stakeholders, payers, and various entities within a country's healthcare system.

The dialogue started in this closed-door roundtable amongst diverse stakeholders from the Australian and Thai healthcare ecosystem marks a positive stride in this direction. Exploration of further avenues for collaboration through such dialogues should continue with a broader set of stakeholders and with other countries. Such dialogue aims to foster collaboration and enhance access pathways for IVDs - acknowledging the varying levels of prioritization within national healthcare programs and differences in the maturity of healthcare systems across the region.

APACMed in collaboration with partner local trade associations in the region aspires to work with the Governments, working collectively towards the common objective of building a more resilient and inclusive healthcare ecosystem. This aligns with the vision outlined in the World Health Assembly's Resolution on "Strengthening Diagnostic Capacity", endorsed in May 2023.

Effecting policy changes is a gradual, effortful process.

Consistent and regular dialogue among stakeholders involved, including the payer, are key to recognizing the value of diagnostics within a healthcare system.





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# **Appendix**

- Program Flow
- Attendees
- Attendee Profiles
- Acknowledgements







# **Program Flow**

	Duration	Session	Responsible
1	10mins	<ul><li>Welcome</li><li>Agenda and housekeeping rules</li><li>Brief Introduction of Attendees</li></ul>	<ul> <li>Benish Aslam, Manager, Diagnostic Projects, APACMed</li> <li>Anh Bourcet, Strategic Advisor, APACMed</li> </ul>
2	10mins	Keynote Speech	<ul> <li>Dr. Looi Lai Meng, Commissioner, Lancet Commission on Diagnostics</li> </ul>
3	15mins	Brief review of White Paper Policy Recommendations  Facilitated sharing on Australia's distinct VAF for diagnostics	<ul> <li>David Champion, Senior Director,         ANSEA Consulting</li> <li>Prof Tracy Merlin, Director, Adelaide         Health Technology Assessment         (AHTA); Head, School of Public         Health, University of Adelaide</li> </ul>
4	5mins	Brief sharing on Thailand's current diagnostics evaluation and reimbursement situation	<ul> <li>Dr. Pattara Leelahawarong, Senior Researcher, Siriraj Health Policy Unit, Faculty of Medicine Siriraj Hospital, Mahidol University</li> </ul>
5	40mins	<ul> <li>Break-out Sessions</li> <li>2 parallel sessions</li> <li>Facilitation of discussion around discussion topics identified</li> </ul>	<ul> <li>David Champion (Australia)</li> <li>Anh Bourcet (Thailand)</li> <li>Note-takers (x2)</li> </ul>
6	5mins	BREAK (Attendees) Consolidation of key takeaways and next steps discussed.	<ul><li>David Champion</li><li>Anh Bourcet</li><li>Note-takers</li></ul>
7	10mins	<ul><li>Presentation of breakout discussions</li><li>Australia (5 mins)</li><li>Thailand (5 mins)</li></ul>	<ul><li>David Champion</li><li>Anh Bourcet</li></ul>
8	15mins	Audience inputs and questions	<ul><li>David Champion</li><li>Anh Bourcet</li></ul>
9	5mins	Overall Summary and Perspectives	<ul><li>Anh Bourcet</li><li>Anand Jha, Managing Director, ANSEA Consulting</li></ul>
10	5mins	Next Steps and Closing Remarks	Benish Aslam, Manager, Diagnostic Projects, APACMed





# **Attendees**

Name	Designation	Role	
Dr. Looi Lai Meng	Distinguished Professor, University of Malaya, Malaysia Commissioner, Lancet Commissioner on Diagnostics	Chairperson	
Professor Tracy	Director, Adelaide Health Technology Assessment (AHTA)	Australia	
Merlin	Head, School of Public Health, University of Adelaide	Representative	
Mr. Blaise Agresta	HTA Lead, NHMRC Clinical Trials Center, University of Sydney, Australia	Australia Representative	
Professor Andrew Coats	Scientific Director and CEO, Heart Research Institute, Sydney, Australia	Australia Representative	
Professor	Professor in the Department of Pharmacotherapy at the University of Utah College of Pharmacy, Utah	Thailand	
Nathorn Chaiyakunapruk	Former Member, Health Economic Working Group of Benefit Package Selection Committee of National Health Security Office (NHSO), Thailand	representative	
Dr. Netnapis Suchonwanich	Information and Technology Management Advisor to the ThaiHealth Promotion Foundation (ThaiHealth)	Thailand representative	
	Former Deputy Secretary-General of NHSO, Thailand	. sp. cocmative	
Dr. Pattara Leelahawarong	Senior Researcher, Siriraj Health Policy Unit, Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand	Thailand representative	
Dr. Sittiluck Wongwatanee	Head of the Cardiology Department, Rayong Hospital Member of Health Administration Division, Ministry of Public Health Thailand	Thailand representative	
Madeline O'Donoghue	Communications and Government Affairs Lead, Pathology Technology Australia (PTA), Australia	Participants in the Australia Breakout Session	
Dr. Toby Hodgson	Digital Health Senior Manager, Medical Technology Association of Australia (MTAA), Australia		
Preecha Bhandtivej	President, Thai Medical Device Technology Industry Association (ThaiMed), Thailand	Participant in the Thailand Breakout Session	
Industry Represe	Observers		
Representatives f	Organizers		





# **Chairperson Profile**



Datuk Professor Dr. Looi Lai Meng, MBBS, MD, FRCPA, FRCPath, FAMM, FASc

Distinguished Professor, University of Malaya, Malaysia Commissioner, Lancet Commissioner on Diagnostics

Academician Datuk Professor Dr Looi Lai Meng is Malaysia's inaugural National Distinguished Professor (Profesor Ulung), and consultant histopathologist at the University Malaya Medical Centre (UMMC). She co-chaired the InterAcademy Partnership for Health (2010-2016) when this global network of National Sciences and Medical Academies extended initiatives into global health, the social determinants of health, urban health, and young physician leadership capacity-building. She is the Founding President of the College of Pathologists, Academy of Medicine Malaysia (CPath-AMM) and former President of the World Association of Societies of Pathology and Laboratory Medicine (WASPaLM), with a specific interest in laboratory accreditation and capacity-building in countries-in-need. She is a Founding Fellow and Senior Fellow (Academician) of the Academy of Sciences Malaysia (ASM). She chaired the ASM Newton-Ungku Omar Fund Committee for Bilateral Research Programmes with the MRC, UK. (2015-2018) and the 2019 MRC-Malaysia Joint Panel on Non-Communicable Diseases. Accolades for her contributions include the CPath-AMM Lifetime Achievement Award, WASPaLM gold headed cane, ASEAN Outstanding Scientist Award, the Merdeka Award 2016 (Health, Science and Technology category) and Honorary Professor of the Chinese Academy of Medical Sciences-Peking Union Medical College. Current engagements include the Lancet Commission on Diagnostics, International Regional Advisor (Western Pacific) of the Royal College of Pathologists UK, First Vice-President of the World Pathology Foundation, Chair of the UMMC-Medical Research Ethics Committee and the MRC (UK) Applied Global Health Research Board.





## **Moderator Profiles**

#### Main Moderator and Thailand Breakout Session Facilitator



Anh Bourcet (Nguyen), PhD Strategic Advisor, APACMed Global Market Access Leader, ex-J&J and Abbott

Seasoned Global Healthcare Leader, Anh Bourcet (Nguyen) has a 15-year track record of driving excellence and transformation in Market Access for pharmaceuticals, medical devices and diagnostics. Known for establishing strategic multi-stakeholder partnerships, Anh has shaped access policies, built the Market Access function from the ground up, transforming clinical practices, for optimised patient access to innovations. Her various roles in Medical Affairs, Health Economics & Market Access and Regulatory Policy, across diagnostics, medical devices and pharmaceutical industries, enable her to have a broad perspective on different levers of market access. In particular, she has played a key role in shaping market access policies for Public Health and Digital Health in Asia-Pacific for a more sustainable care.

Anh held leadership positions in Abbott and Johnson & Johnson in APAC, and at the French Health Safety Agency (ANSM). She is currently Strategic Advisor for APACMed (Asia-Pacific Medical Technology Association).

Her contributions to the field have been widely recognized, and she has been a regular speaker at major international conferences, providing valuable insights on topics such as digital health, health data, access, and reimbursement.

#### Australia Breakout Session Facilitator



**David Champion, MPH**Senior Director - ANSEA Consultants Pte. Ltd.

David Champion has 17 years' experience in healthcare and has held a variety of country, regional and global roles in pricing, market access & health economics across Australia, Thailand, Singapore, Hong Kong & UK, in companies such as Pfizer, Novartis, and Amgen. He has worked directly with HTA bodies including Australian PBAC and MSAC, Thailand HiTAP and UK NICE. Most recently, he has co-authored the Value of Diagnostics White Paper highlighting the importance of a distinct value assessment framework for cardiovascular IVDs across APAC.

David has a Master of Public Health degree from the University of Sydney and a degree in Clinical Epidemiology and Economics from the University of Newcastle.





# **Australia Attendee Profiles**



Prof Tracy Merlin, PhD, MPH
Director, Adelaide Health Technology Assessment (AHTA); Head, School of
Public Health, University of Adelaide

Professor Merlin is the first Professor of HTA in Australia, having worked in this relatively new field for over 20 years as a methodologist and clinical epidemiologist. She has written over 200 systematic literature reviews, clinical practice guidelines, methods publications and HTA reports. She is the Managing Director and co-founder of Adelaide Health Technology Assessment (AHTA) at the University of Adelaide. In this role she leads a large and experienced team of researchers undertaking multi-million dollar applied research and evaluation activities on behalf of government and non-government agencies, which directly informs health policy and clinical practice, including the 2023 Australian HTA Policy and Methods Review. Her other roles are as Head of the School of Public Health and Deputy Executive Dean of the Faculty of Health and Medical Sciences, University of Adelaide.



Blaise Agresta, MBA, MPH, MAppFin
HTA Lead, NHMRC Clinical Trials Center, University of Sydney

Blaise Agresta has over 15 years of experience in the field of HTA in Australia and the UK. Blaise has been involved with MSAC evaluations over those 15 years, along with PBAC evaluations, developing global health economic models for pharmaceutical companies, developing model adaptations for various markets, developing budget impact tools and models for various markets, as well as reimbursement strategies, evidence evaluation and biostatistics. Blaise's career started with systematic reviews and critiquing and evaluating clinical evidence, and over his career, he has focused more on health economics and modelling methodologies, and statistics. Blaise's previous appointment lead the HTA evaluation unit at the University of Sydney and recently moved back into consultancy advising pharmaceutical and medical device companies with HTA.



Professor Andrew Coats, AO, MA, MB B CHIR, DM, DSC, FRACP, FRCP, FESC, FACC, FAHA, FHFA, FHFSA, FCSANZ, FSCWD, FAICD, MIOD, MBA Scientific Director and CEO, Heart Research Institute, Sydney, Australia

Professor Coats is the Scientific Director and CEO of the Heart Research Institute based in Sydney, Australia. Andrew is a fully accredited physician and cardiologist in the UK and Australia, a qualified company director with more than 60 board years of experience, and a trained and experienced fundraiser with an excess of \$500M raised. He has held senior offices in five major Professional Societies and is President of the largest specialist society in his field (the Heart Failure Association). He has launched two successful spin-out biotechnology companies with capital raises. He has over 750 career full papers, 160,000 citations and an H-index of 157. Andrew was recently recognised as Australia's top researcher in cardiology for the second year running. The accolade was given by The Australian newspaper in its annual special report, the 2024 Research Magazine.





### **Thailand Attendee Profiles**



**Prof Nathorn Chaiyakunapruk, PharmD, PhD**Professor in the Department of Pharmacotherapy at the University of Utah College of Pharmacy

Dr.Chaiyakunapruk's expertise is in HTA and Health Policy. He has applied health economics, real world data analysis, and evidence synthesis to support national and global policy, especially his contributions to the WHO and CDC. His current research works have been focused on health equity and health economics. He is a coauthor of CHEERS 2022 (Consolidated Health Economic Evaluation Reporting Standards Statement) and WHO guide for standardization of economic evaluations of immunization programmes. He was a co-founder of the ISPOR Asia Consortium, an adviser of National Essential Drug List Selection Subcommittee and a member of Health Economic Working Group (HEWG) of Benefit Package Selection Committee of NHSO.



Dr. Netnapis Suchonwanich

Information and Technology Management Advisor to the ThaiHealth Promotion Foundation (ThaiHealth)

Former Deputy Secretary-General of National Health Security Office (NHSO), Thailand

Mrs. Netnapis Suchonwanich is former Deputy Secretary General of NHSO. She is holding an Honorary Doctorate Degree in Pharmacy along with over 25 years of working experience in the field of pharmaceutical procurement and pricing policy. During these years, she introduced a highly beneficial 'Pricing and Access Tool' for National medicines price negotiation. Additionally, she has been nominated as Advisor for multiple National Medicine Management Policy Committees such as Committee of Central Procurement for medicines and medical supplies and the Advisor for Price Negotiation Working Group. Currently, she is a member of the WHO Technical Advisory Group on Pricing Policies for Medicines.



**Dr. Pattara Leelahawarong, PhD**Senior Researcher, Siriraj Health Policy Unit, Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand

Pattara Leelahavarong, a researcher at Siriraj Health Policy Unit, graduated with a Ph.D. in health economics from the University of Glasgow, United Kingdom, a Master's degree of science in pharmacy, and a Bachelor's degree of science in pharmacy from Mahidol University. She has vast experience in HTA using economic modelling in pharmaceutical, medical devices, and health promotion programs for a wide range of health policy process since 2008. She is involved in the national policy decision-making process as a member of the HEWG and Price Negotiation Working Group under the Subcommittee of National List of Essential Medicine.



**Dr. Sittiluck Wongwatanee**Head of the Cardiology Department, Rayong Hospital
Member of Health Administration Division, Ministry of Public Health, Thailand

Having graduated from the Faculty of Medicine, Siriraj hospital, Mahidol University, Dr. Sittiluck is Head of the Cardiology Department at Rayong Hospital, and Deputy Director of Health Administration Division, Ministry of Public Health in Thailand. He is personally and professionally focused on effective health systems management and quality healthcare service standards.





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Stakeholder Group	Name(s)	Designation(s)*			
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	Anand Jha David Champion	Managing Director Senior Director (Moderator and co- author of White Paper)			
ANSEA	S Bhuvaneswari	Senior Analyst (Roundtable I/C)			
YOUR ACCESS PARTNER	Varun Kakkar Sheena Suthen	Analyst (Design & Formatting) Senior Analyst (Note-taker and co-author of White Paper)			
	Monica Verma	Senior Consultant (Note-taker)			
	Prof Tracy Merlin	Director, Adelaide Health Technology Assessment (AHTA); Head, School of Public Health, University of Adelaide			
Australian Expert Panel	Prof Andrew Coats	Scientific Director and CEO, Heart Research Institute, Australia			
	Mr. Blaise Agresta	HTA Lead, NHMRC Clinical Trials Center (Sydney) Australia			
	Dr. Netnapis Suchonwanich	Information & Technology Management Advisor, ThaiHealth			
Thai Expert Panel	Dr. Pattara Leelahawarong	Senior Researcher, Siriraj Health Policy Unit, Mahidol University, Thailand			
	Prof Nathorn	Professor, University of Utah's			
	Chaiyakunapruk	Department of Pharmacotherapy, USA			
Industry Stakeholders					

<sup>\*</sup>Designations are as at the date of the Roundtable session (i.e. 21 November 2023).



