F5: Advancing Patient Access to Innovative Health Technologies In Asia – The Role of Real-world Data in the Value Framework

- **Moderator:**
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- **Speakers:**
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Agenda

- **Introduction**
- **Project 1:** Landscape Evaluation of Real World Data in Asia
- **Project 2**: New Trends of HTA Development and Value Evidence Requirement for Access and Reimbursement in Asia
- New Development and updates from Japan and Korea
- Summary

Project 2
New Trends of HTA Development and Value Evidence Requirement for Access and Reimbursement in Asia

- Project Leaders: Larry Liu, Hong Li, Boxiong Tang
- Team Members:
  - Jianwei Xuan, Dong Peng, Ruoyan Gai, Makoto Kobayashi, Sang-Soo Lee, Jun Su, Bruce Wang, Eugene Salole, Hongye Wei

Project 2: Objectives and Approaches

Objectives:

- **Collect information on HTA value evidence requirements for selected countries in Asia-Pacific.**
- **Assess current HTA status in selected countries in Asia-Pacific and the trend in five years.**

Approaches:

- **Conduct a literature review and baseline evaluation**
- **Collaborate with ISPOR regional chapters for researching country-specific HTA status and trend**
- **Partner with organizations such as HTAi Asia Policy Forum and HTAsiaLink.**

Project 2: Methods, Deliverables and Timeline

Methods

- **Define the scope of the work: HTA definition and aspects to be included**
- **Focus on selected countries – group by cluster: countries implemented HTA already, in process (HTA as optional tools), or within five years**
- **To interview and get inputs from some KOLs, government agencies if possible**

Deliverables

- **Summary report, with a brief summary of HTA status in Asia (see Table 1)**
- **One-page summary of HTA in each of the selected countries (See Table 2)**
- **ISPOR Asia Consortium newsletter update, an abstract for a workshop, forum, or a manuscript.**

Timeline

- **Initial literature review completed by May 18, ahead of ISPOR Baltimore**
- **Summary report on detailed findings completed by August 2018, ahead of ISPOR Asia Pacific 2018**
- **Abstract drafted by October 2018**
- **Paper completed by December 2018**

Project 2: Table 1

Country	Current HTA			HTA trend (included in reimbursement decision)	Value evidence requirement- RCT, RWE, ICER
	Clinical effectiveness	Cost-effectiveness	Budget impact		
Australia	Y	Y	Y	Y	RCT, RWE, ICER
South Korea	Y	Y	Y	Y	RCT, RWE, ICER
Taiwan	Y	Y	Y	Y	RCT, RWE, ICER
Japan*	Y	Y	N	N	RCT, ICER
China	Y	Y/N	N	Y/N	RCT
Malaysia					
Philippines			Y		
Thailand					
New Zealand					
Vietnam					

Project 2: Table 2 (Australia as example)

Government Agency	**Pharmaceutical Benefits Advisory Committee (PBAC)**
Assessment process	PBPA pricing based on comparative cost-effectiveness Cost-plus methodology for drugs with incremental benefit Reference pricing for drugs considered “therapeutically similar”
Value Evidence requirements	• Safety, quality, and efficacy by the Australian Drug Evaluation Committee (ADEC) of the Therapeutic Goods Administration (TGA). • Cost and cost-effectiveness evidence
Review committee	PBAC funding recommendation based on input from Economic Sub-Committee (ESC) and Drug Utilization Sub-Committee (DUSC)
Decision process	Pharmaceutical Benefits Scheme (PBS), and the Pharmaceutical Benefits Advisory Committee (PBAC) advisory panel based on cost-effectiveness and budget effects. PBAC also evaluates new vaccines to be included in the National Immunisation Programme. Drugs listed on the PBS fall into three broad categories: unrestricted, restricted, and authority required benefit products
Timeline	Minimal 5 months. Average time to decision 182 days (SD 367 days)
ISPOR contact	