APAC
Asia Partnership Conference of Pharmaceutical Associations

# Sustaining and Evolving Regulatory Agilities with Inspiring Partnership

Richard Simon Binos
Sannie Chong
Kanno Masaaki

12th Asia Partnership Conference of Pharmaceutical Associations
RA Session

18 April 2023

Muromachi Mitsui Hall & Conference, Tokyo, Japan

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# Highlights of the APAC Paper

I. Background and Methodology

II. Results

III. Philippines and Malaysia Case Studies

IV. Recommendations & Next Steps

*Therapeutic Innovation & Regulatory Science (2023) 57:12–25*
https://doi.org/10.1007/s43441-022-00435-8

DIA

ORIGINAL RESEARCH

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## Asia Partnership Conference of Pharmaceutical Associations (APAC) Report on Regulatory Agility Implemented During the COVID-19 Pandemic: Inspiring Partnerships and Recommendations for the Way Forward

**Sannie Siaw Foong Chong[1,2] · Masaaki Kanno[3] · Alice Seat Mee Chee[4] · Siew Mei Long[5] · Stephanie Hui Min Ong[6] · Usanee Harnpramukkul[7] · Richard Simon R. Binos[8]**

Received: 7 March 2022 / Accepted: 15 July 2022 / Published online: 29 September 2022


**Abstract**

**Purpose** Asia Partnership Conference of Pharmaceutical Associations (APAC) promote regulatory agility of four important best practices i.e. reliance, digital platform, accepting electronic document and process integration. Dialogues and strong partnership witnessed reforms and efficiencies amidst the pandemic. In tracking the progress of regulatory agility, APAC identifies areas for improvement and recommends prioritizing these areas for change.

**Methods** As one voice, 13 main industry associations under the umbrella of APAC sent joint letters to our National Regulatory Authorities (NRAs) with a call to maintain regulatory agility and consider new ways of working. Consequently, APAC surveyed its member associations to measure regulatory agilities implemented by the NRAs during 2020 and 2021 in view of the pandemic.

**Results** This paper reports progress in implementing regulatory agility, e.g. the number of economies that can accept electronic Certificate of Pharmaceutical Products (eCPP) has reached 100% for the economies that require CPP and more than 90% can waive onsite inspection in the presence of Good Manufacturing Practice (GMP) certificate and/or inspection report. The paper also features the progress made in Malaysia, the Philippines, and the ASEAN (Association of South East Asian Nations) regional reliance initiative to reduce inefficiencies and duplications.

**Conclusions** We have demonstrated the power of working together to enable regulatory agilities and efficiencies. APAC will continue to track the progress of all economies including India within the areas for improvement prioritized and discussed in this paper. APAC is also committed to working with key stakeholders including our NRAs in Asia to sustain and enable a new era of innovation ushered in by COVID-19 to benefit patients.

**Keywords** Partnership · Regulatory agility · COVID-19 · APAC · NRAs

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# Background and Methodology of the APAC Paper

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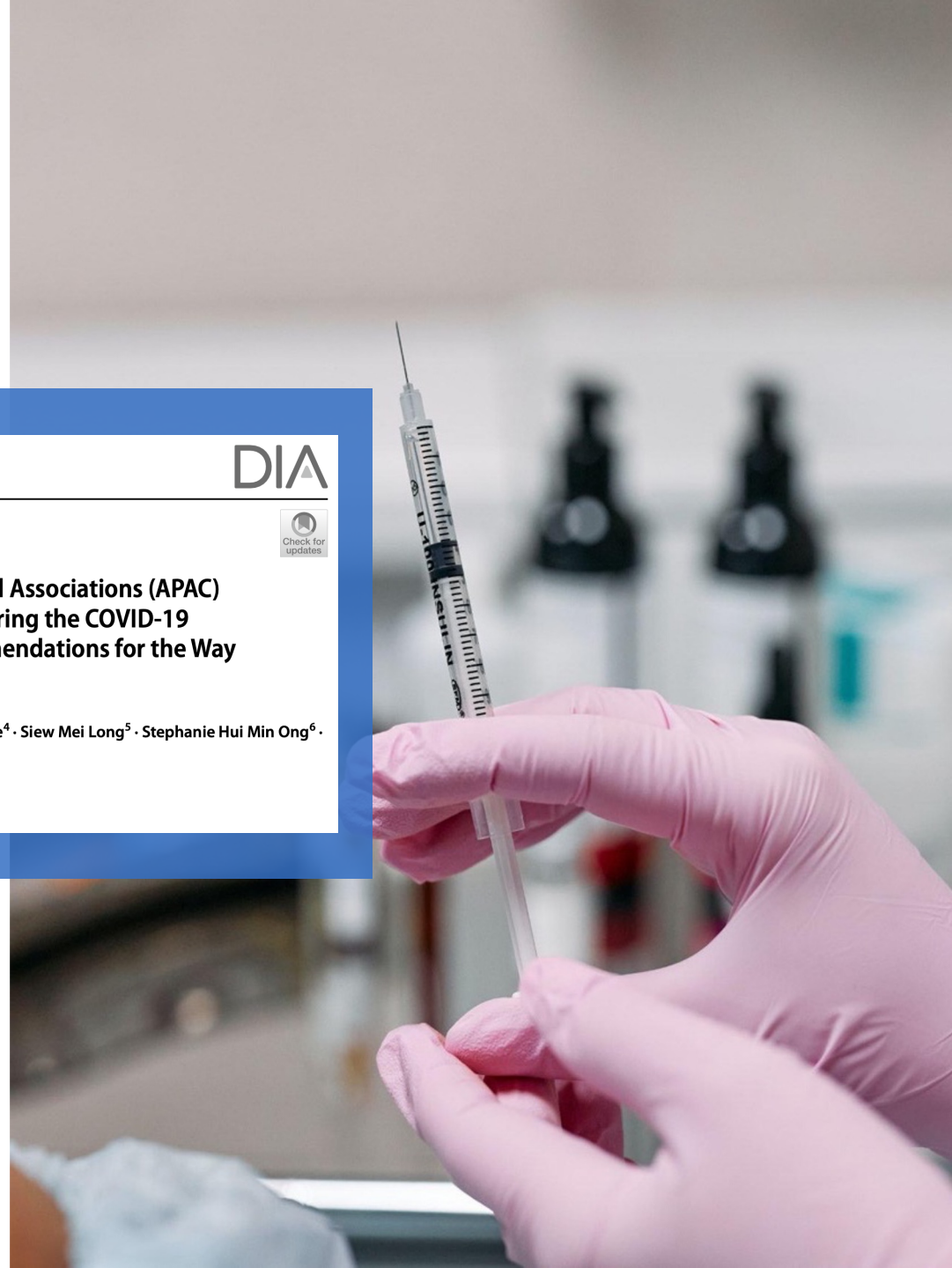

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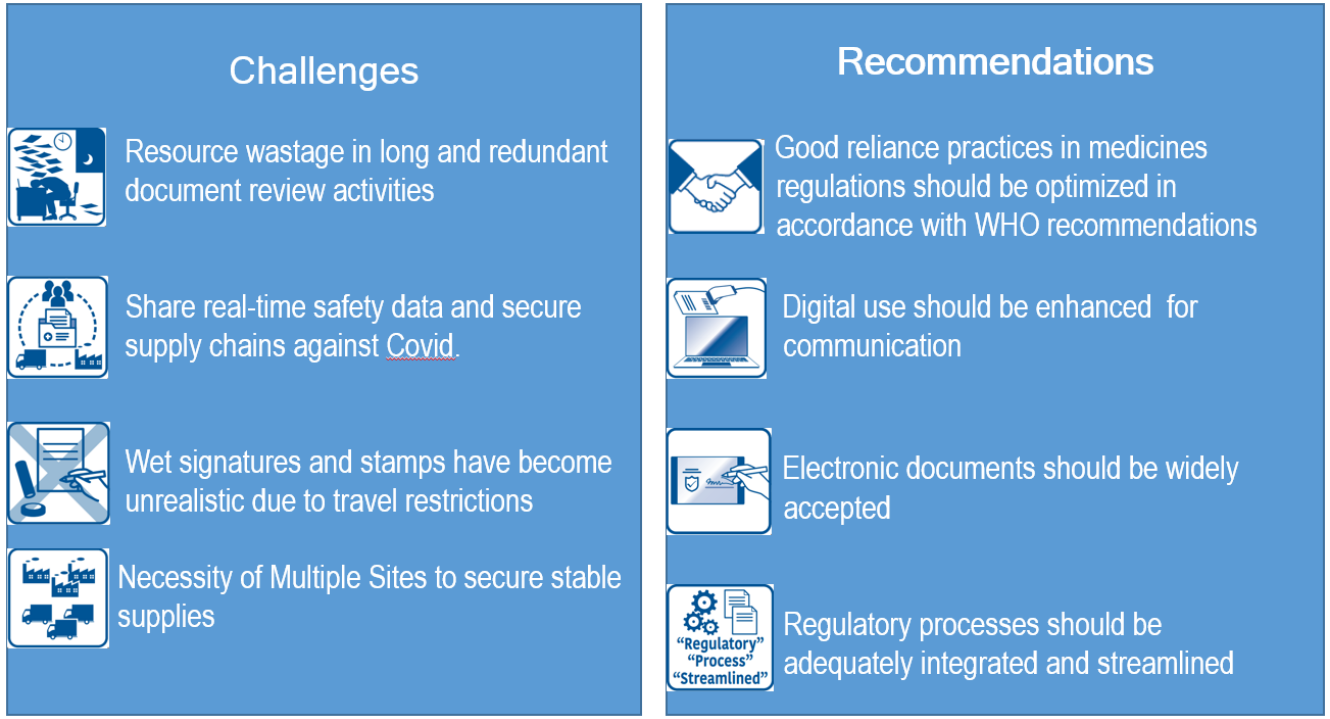
# APAC Paper Published

## *Background*

In the second half of 2020, APAC recognized the challenges posed by the COVID-19 pandemic. To ensure faster access and continuity of supply to patients, APAC's 13 main industry associations collectively communicated our objectives as one voice in a form of a joint letter to commend the efforts of our National Regulatory Authorities (NRAs) in practicing regulatory agility and consider new ways of working. APAC promotes regulatory agility of four important best practices: reliance, digital platform, acceptance of electronic documents, and process integration.




*Examples of Challenges and APAC's recommendations in implementing regulatory agilities.*

## *Methodology*

**Step 1: Thank you Letters**

In Jun. 2020 and Jul. 2021, APAC sent a follow-through letter to thank the regulators for taking action and practicing regulatory agility during global crisis.

**Step 2: Survey**

APAC conducted a survey by delivering a progress status form which contained the questions designed to determine the level of regulatory agility practiced by the NRA.

**Step 3: Data Collection**

Data collection commenced with reference to the direct response of the government officials or from the industry associations.

# Results of the APAC Paper

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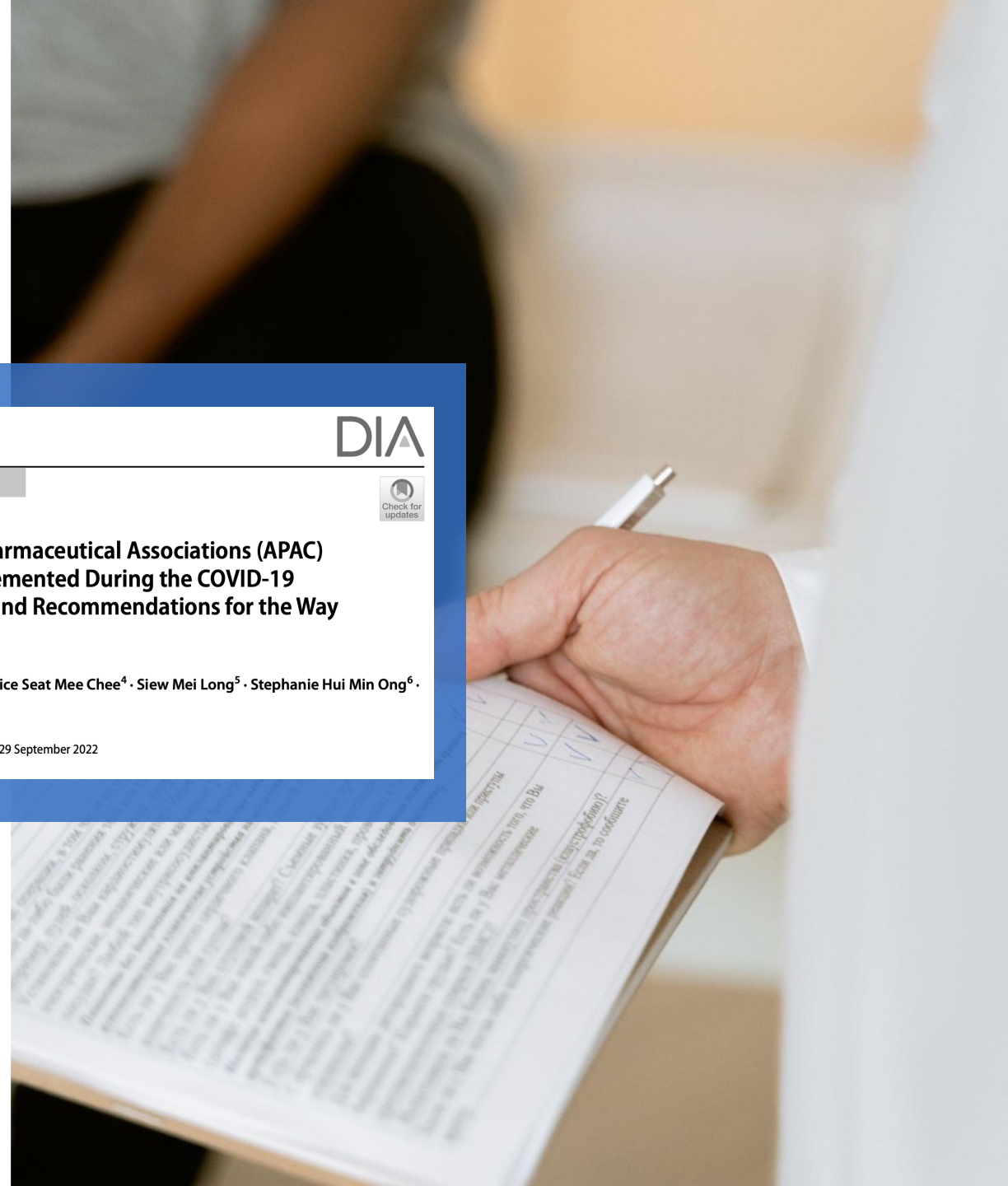
Senior Director, APAC Regional Lead
Merck Sharp & Dohme



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# Areas to prioritize Improvements: 1a, 1c, 1d, 2a, 4a, 4b

| | 1) Market Authorization agilities/ reliance including inspection, import re-testing and post approval agilities | | | | 2) Digital Platform (e-labeling, traceability, or serialization | | 3) Electronic-based document | 4) Integrating and streamlining processes (e.g. multiple sites in one license/non site-specific stability data) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Figure 1a Use of CPP | Figure 1b Use of Reliance Pathways | Figure 1c Reliance to waive off redundant re-testing | Figure 1d Reliance to cover new indications and post-approval variations | Figure 2a eLabeling | Figure 2b Serialization | Figure 3 Acceptability of eCPP and eGMP certificates | Figure 4a Multiple DS and DP sites in a single license | Figure 4b Requirement for site-specific stability data | Figure 4c Alignment with ICH Q12 | Figure 4d Substitute for on-site inspection |
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Legend: Emerging Developing Developed

*Note: Tracking India's progress is on-going*

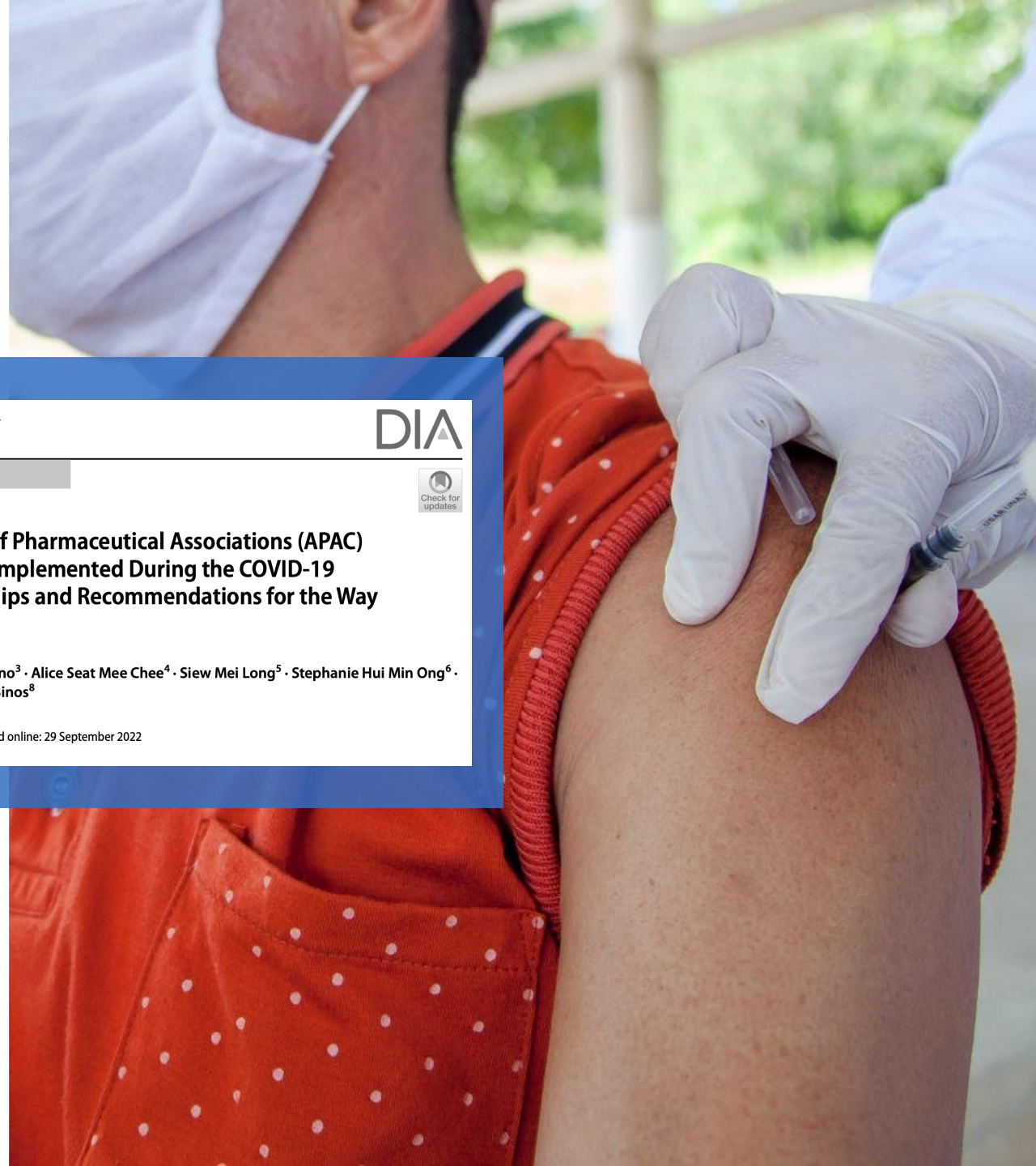
**1(a):** Removal of CPP when using reliance pathway
**1(c):** Utilize reliance to streamline or waive off redundant testing
**1(d):** Extend reliance pathway to new indications and post-approval variations

**2 (a):** Implement e-labelling
**4 (a):** Multiple DS+DP sites in a single license
**4 (b):** Waive site-specific stability data

# Discussion of the APAC Paper: *Philippines & Malaysia Case Studies*


**Richard Simon Binos**

Health Systems and Market Access Manager
Pharmaceutical & Healthcare Association of the Philippines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# The Importance of Inspiring Partnership

*PFDA's Reforms amidst the Pandemic*

## Pre-pandemic

***Collaborative mindset***

- ✓ Presentation of reform plans and gather industry concerns and suggestions through the reinstitution of the quarterly dialogue
- ✓ Consultative and/or pre-submission meetings,
- ✓ Opportunities for discourse on regulatory findings
- ✓ Participated in conferences and fora

## Pandemic

***Partnership continued and grew stronger***

- ✓ Risk management plans and global PMS
- ✓ limiting lot release certification requirements to vaccines, toxoids, and immunoglobulins
- ✓ Acceptance of electronic signatures and eCPP
- ✓ Digitalization of certain regulatory processes
- ✓ introduction of facilitated registration procedures

## Post-Pandemic

***Explored other agilities***

- ✓ Multiple sites under a single license
- ✓ Non-site-specific stability reports
- ✓ Smart or electronic labeling

# The Outcome of Partnership in Advancing Regulatory Transformation in Asia

*NPRA at the Forefront of Digitalization and Modernization*

## RECOMMENDATIONS

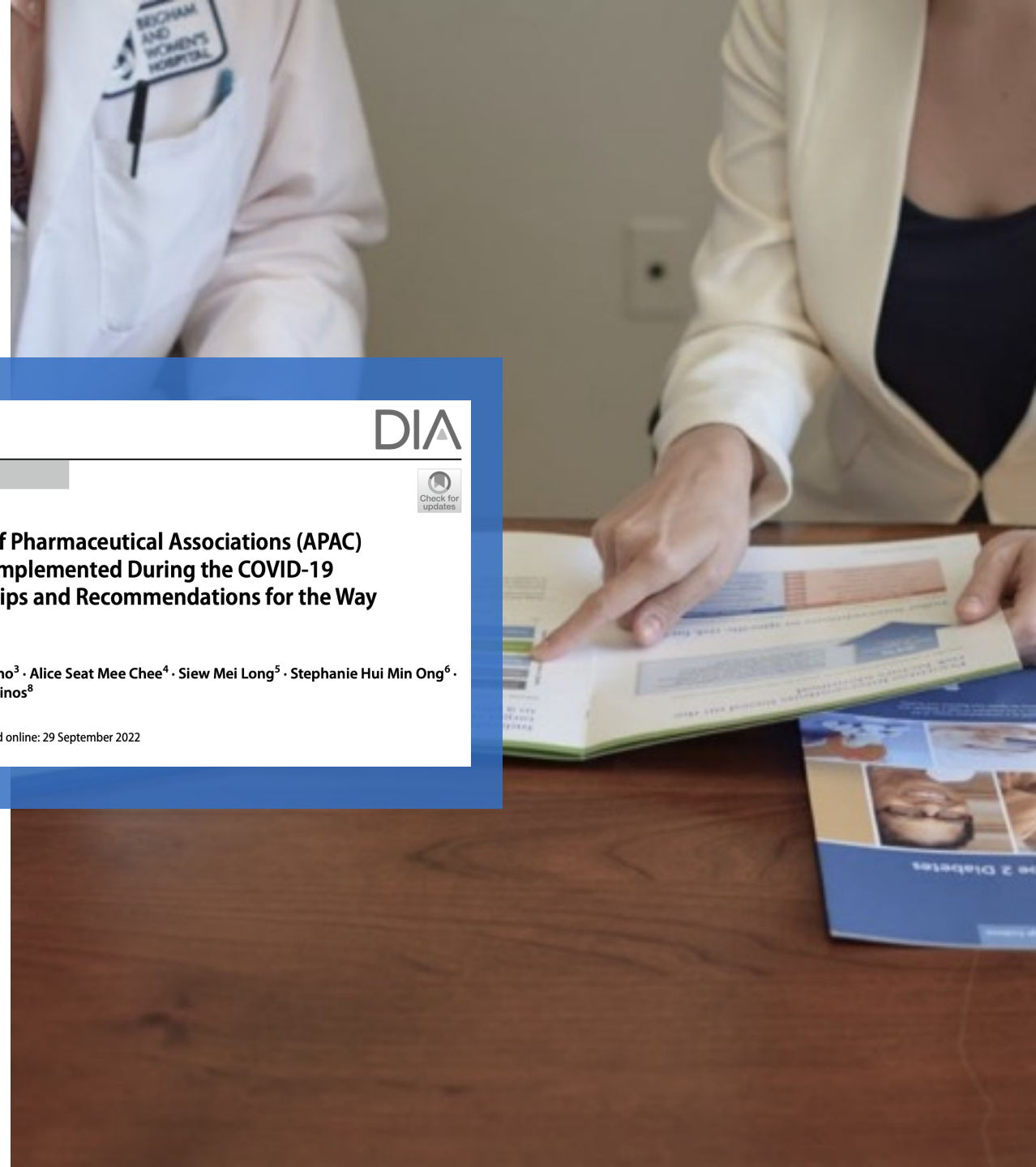
- ✓ *Improve and optimize the ASEAN Joint Assessment Procedure:*
  - ✓ *expanding the eligibility list to all diseases and product types*
  - ✓ *Streamlining the administrative procedures*
- ✓ *Expanding the scope of facilitate review pathway including post-approval product quality lifecycle management*
- ✓ *Adoption of e-labeling*
- ✓ *Optimization of online system QUEST*
- ✓ *Use of RWD/E to facilitate regulatory decisions*

## OUTCOME

- ➢ *It has been agreed to enhance the AJA procedure; expand the list of priority products*
- ➢ *Exploring and considering concepts of reliance for post-approval product quality lifecycle*
- ➢ *Joint industry-Ministry of Health working group led by MOH has been formed*
- ➢ *Commitment to prioritize the optimization of the online system QUEST*
- ➢ *RWD/E capacity building*

# Recommendations & Next Steps of the APAC Paper


**Sannie Chong**
Senior Director, APAC Regional Lead
Merck Sharp & Dohme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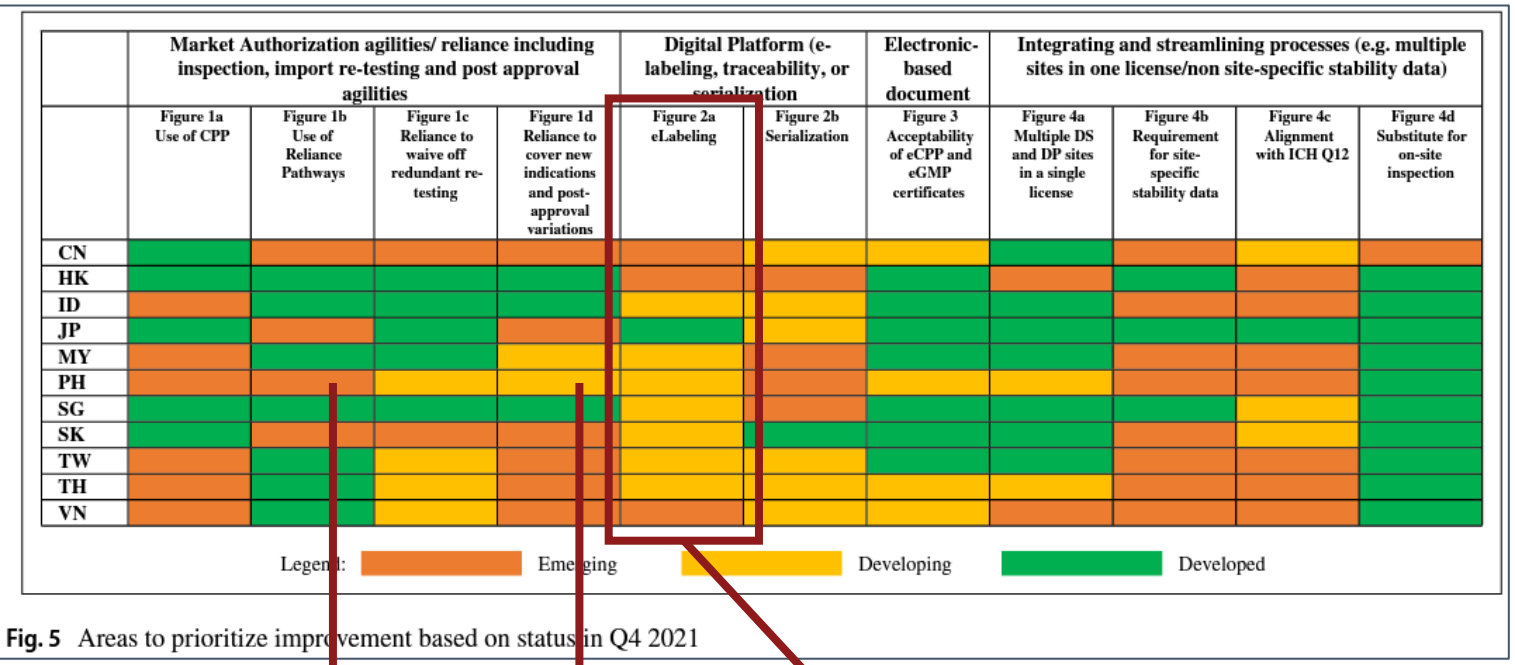
# Good progress made after APAC paper in sustaining agility

## Next Step #1: *APAC to re-survey to validate current agility status areas*



| | Market Authorization agilities/ reliance including inspection, import re-testing and post approval agilities | | | | Digital Platform (e-labeling, traceability, or serialization | | Electronic-based document | Integrating and streamlining processes (e.g. multiple sites in one license/non site-specific stability data) | | | |
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Legend: Emerging Developing Developed

**Fig. 5** Areas to prioritize improvement based on status in Q4 2021

## Progress noted from Q4 2021 to Q2 2023

**Thailand FDA:** full implementation of e-submission, multiple manufacturing sites per one license, reliance pathways, and GMP site clearance streamlined

**Vietnam DAV:** Simplifies CPP requirement to align with WHO; Active discussion on e-labeling and reliance pathways

**Singapore HSA:** Utilize reliance pathway approac in lot release/vaccine testing requirement
A streamlined yet robust approach

**Philippine FDA:** Implemented reliance pathways for both NDAs and post-approval variations

**Singapore HSA:** Paperless e-labelling in addition to Japan
E-labelling pilots for ALL products by **Malaysia NPRA, Philippine FDA, Taiwan FDA, Thailand FDA, and Indonesia BPOM.** South Korea MFDS' pilot is for hospital injectable products

After paper publication, **we have observed great improvements** made in areas identified by APAC in Thailand, Vietnam, Philippines, Malaysia, Taiwan, Indonesia and more! The **greatest progress made is in e-labelling**.

# Good progress made after APAC paper in sustaining agility

## Next Step 2: *APAC to explore ways to evolve the practices implemented*

### FEATURE ON REGIONAL RELIANCE PATHWAY:

**Citing best practices** including works of Australia TGA; and recommendations on a good model of regional programs.

**Feature ASEAN Joint Assessment** and explore ways for APAC to  to support the regional reliance pathways.

### FEATURE ON DIGITAL TRANSFORMATION:

**Practices evolved**, e.g. paperless e-labelling

**Practices evolved**, e.g. Thailand FDA's full e-submission, eCTD readiness in Singapore, e-submission upgrade in Malaysia

**APAC to partner** with key stakeholders including our National Regulatory Authorities in Asia to enable a new era of innovation powered by Real World Data/Evidence, De-centralised CTs, and more.

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# Acknowledgments for the APAC Paper


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- **Mika Niboshi** for assisting in the APAC letters
- **All the 13 APAC member associations** for responding to the survey and funding the publication of the paper.
- **George Nakayama**, President of the JPMA for leading in signing our APAC letters to all regulators in Asia.


*Sample APAC Letter to Regulators, 18 May 2021*

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18 May 2021

Mr. Frank Chan, Drug Office, Department of Health, Hong Kong SAR
Dr. Roshayati Mohamad Sani, Acting Director of National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia.
Dr Ir. Penny K Lukito, MCP, Head of National Agency of Drug and Food Control, Indonesia
Minister Jiao Hong, Commissioner of China's National Medical Products Administration, China
Minister Kim Kang-lip, Ministry of Food and Drug Safety, South Korea
Dr Mimi May Ling Choong, Chief Executive Officer of Health Sciences Authority, Singapore
Dr Paisarn Dunkum, Secretary General, Food and Drug Administration, Thailand
Dr Rolando Enrique D. Domingo, Director General of FDA, the Philippines
Ms. Shou-Mei Wu, Director General, Taiwan FDA
Mr Vu Tuan Cuong, Director General, Drug Administration of Vietnam
Dr. Yasuhiro Fujiwara, Chief Executive, Pharmaceuticals and Medical Devices Agency, Japan

Dear Mr Frank Chan, Dr. Roshayati Mohamad Sani, Dr Ir. Penny Lukito, Minister Jiao Hong, Minister Kim Kang-lip, Dr Mimi Choong, Dr Paisarn Dunkum, Dr Rolando Domingo, Ms. Shou-Mei Wu, DAV Director General Vu Tuan Cuong and Dr Yasuhiro Fujiwara,

*Signatories to the APAC Letter to Regulators, 18 May 2021*

PharmaGroup Innovation. Quality. Health.
HKAPI 香港科研製藥聯會
IPMG International Pharmeceutical Manufacturers Group
IRPMA
JPMA
KPBMA Korea Pharmaceutical and Bio-Pharma Manufacturers Association
KRPIA Korean Research-based Pharma Industry Association
PhAMA 'Innovative Medicines for Malaysia'
PHAP PHARMACEUTICAL & HEALTHCARE ASSOCIATION OF THE PHILIPPINES
PhIRDA 中国药促会
PReMA Pharmaceutical Research & Manufacturers Association
RDPAC
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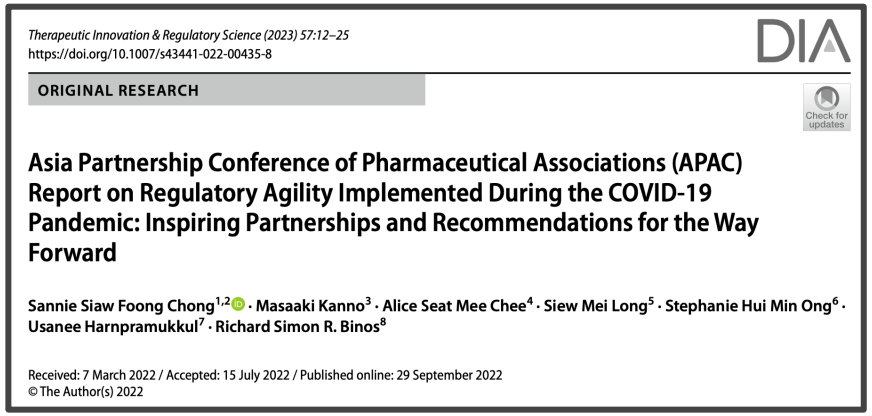

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# CONCLUSION

***Need to sustain regulatory agility even in a "normal" environment, and to explore ways to evolve the practices implemented.***

## Next step (1)

- ✓ To validate and confirm that we are sustaining regulatory agilities – APAC to conduct a re-survey including India in Q4 2023
- ✓ Based on the output from above #2, identify/prioritise potential "KPIs" to track together with recommendations.
- ✓ identifies countries to showcase as best practices

## Next Step (2)

To explore ways to evolve the practices implemented

- ✓ Feature on regional reliance pathway:
  - ➢ Citing best practices including works of Australia TGA; and recommendations on a good model of regional programs.
  - ➢ Feature ASEAN Joint Assessment; and explore ways for APAC to to support the regional reliance pathways.
- ✓ Feature on digital transformation:
  - ➢ Practices evolved, e.g. paperless e-labelling
  - ➢ Practices evolved, e.g. Thailand FDA's full e-submission, eCTD readiness in Singapore, e-submission upgrade in Malaysia
  - ➢ APAC to partner with key stakeholders including our National Regulatory Authorities in Asia to enable a new era of innovation powered by Real World Data/Evidence, De-centralised CTs, and more.

***FOLLOW-UP PAPER TO BEGIN DRAFTING IN 2024***

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