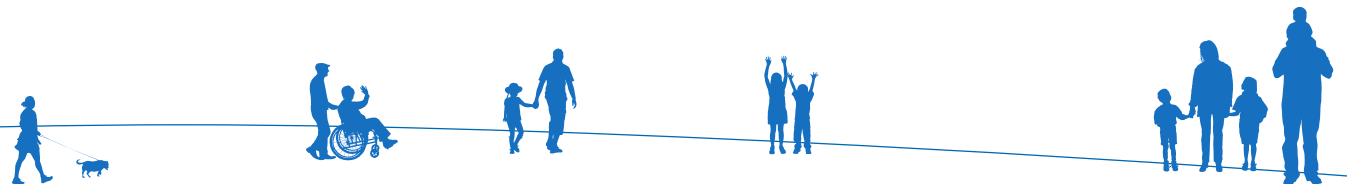


Asia Office's activity to support to facilitate reliance scheme

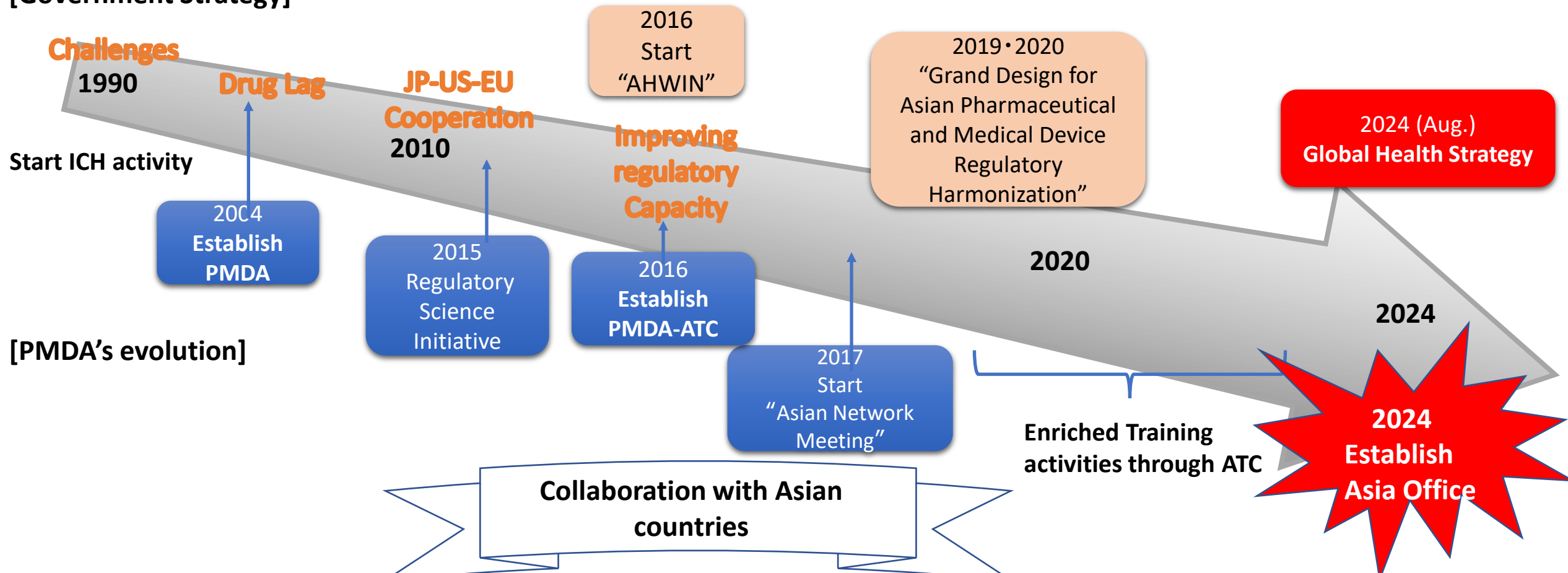
Jun Kitahara, Ph.D.
Head, PMDA Asia Office



Progress of Regulatory Collaboration by Japan

- After the establishment of PMDA (2004), PMDA has promoted regulatory harmonization and regulatory science.
- Based on its experience, PMDA strengthens cooperation with Asian countries (bilateral cooperation; ATC Training)
- Further, PMDA established Asia Office in order to enhance regulatory collaboration

[Government Strategy]



PMDA Asia Training Center



Action Policy of PMDA-ATC

Contribute to universal health coverage in Asia
through regulatory harmonization in the Asian region from capacity building

2016 – 2024

Participated from **76** countries/regions

All Participants **3,559** / Participants from Asia **3,067**

Work with Asian Countries

Asia's situation

Economic growth

Population growth

Aging of society



- Public interest: **innovative/high-quality** pharmaceuticals and medical devices
- Expansion: **Market** for pharmaceutical and medical device

PMDA's Target (until 2029)

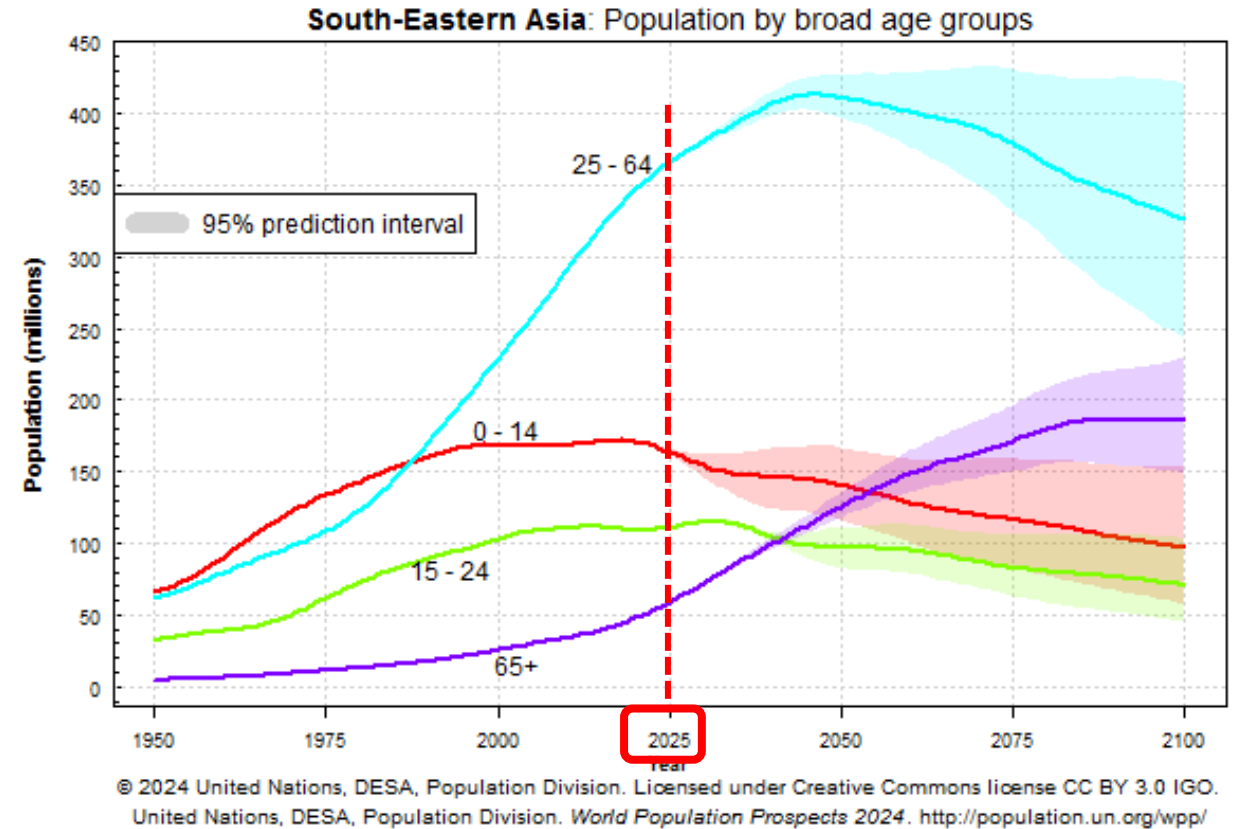
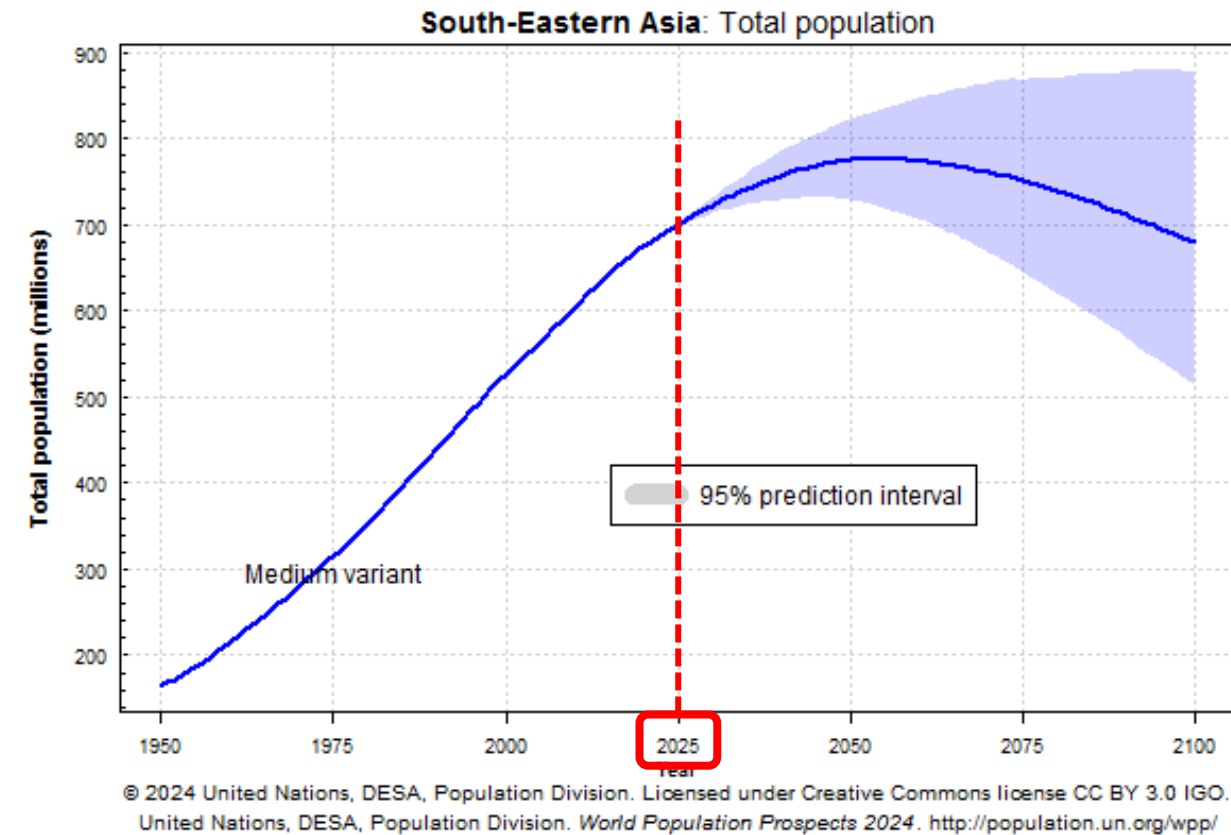
Strengthening the international capability to contribute and make proposal

*Promotion of **the strategic international activities** including **strengthening the ability to communicate services and achievement of PMDA to the world and setup of the Asian and US offices***

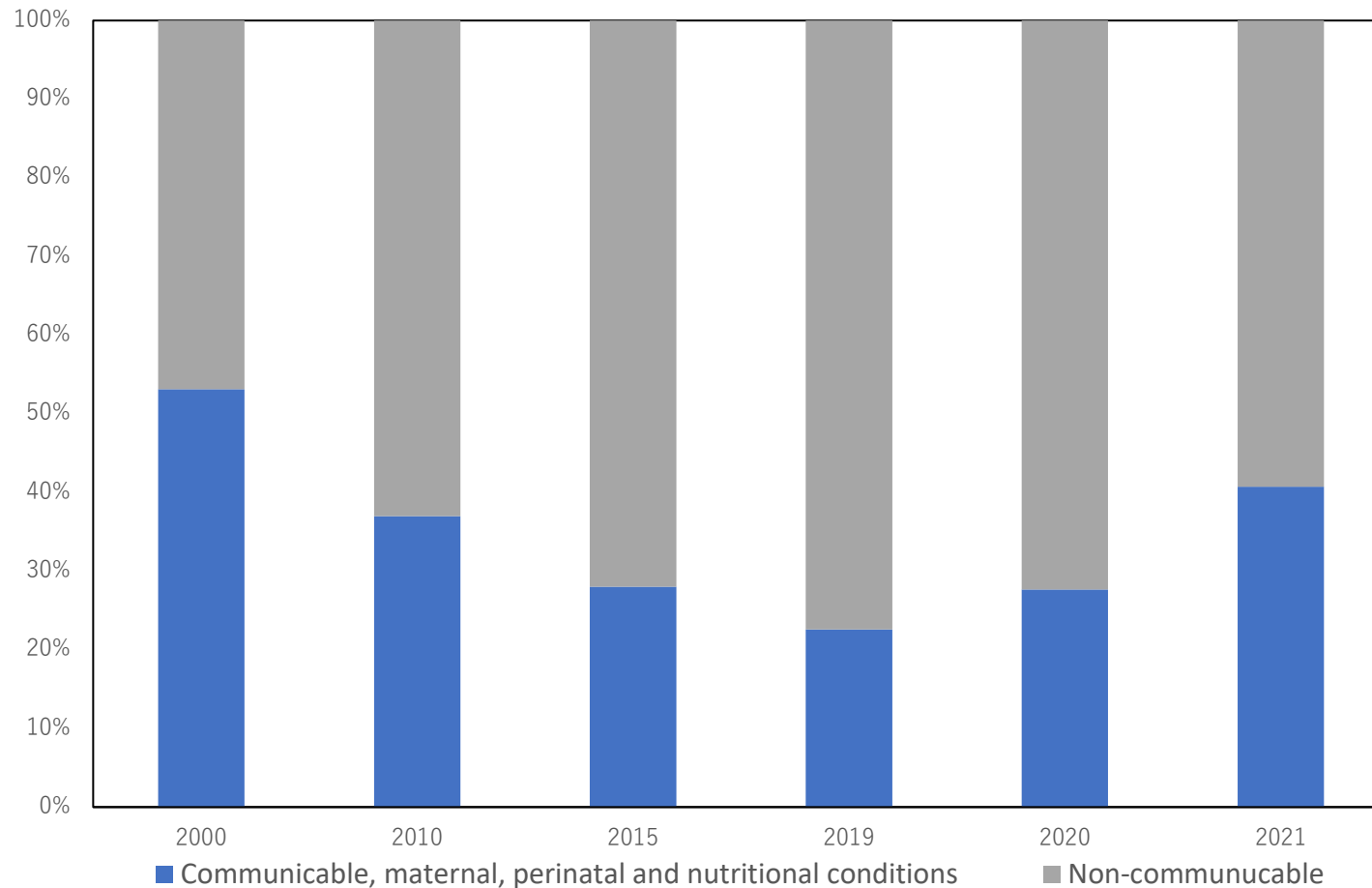


- ☐ Establish an Asian office
- ☐ Work with the counterpart authorities directly

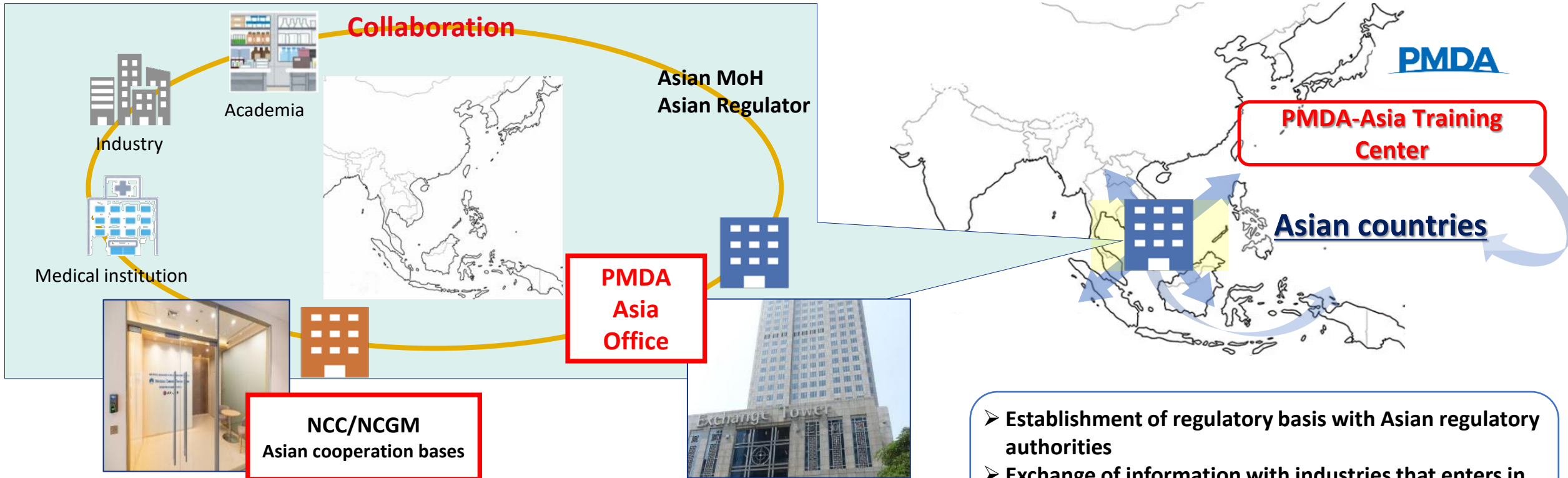
Population Estimates in South-Eastern Asia in comparison to Japan



Changes in Cause of Death in South-East Asia



Pharmaceuticals and Medical Devices Development Ecosystem in Asia



- Establish parallel and circulating support system
- Improve clinical development environment / strengthen regulatory capacity

- Establishment of regulatory basis with Asian regulatory authorities
- Exchange of information with industries that enters in Asian regions and Identification of issues
- Collaboration with related Stakeholders

→ **Establish Pharmaceuticals and Medical Devices Development Ecosystem in Asia**

Facilitated/Abridged/Abbreviated Assessment/Evaluation



ASEAN Countries which Recognize Japan as Reference Country for Pharmaceuticals [As of Jan 2024]

Country/ region	System
Indonesia	<ul style="list-style-type: none">• Abridged assessment
Malaysia	<ul style="list-style-type: none">• Verification process of additional indications• Abridged review
Philippines	<ul style="list-style-type: none">• Abridged and Verification review pathways
Thailand	<ul style="list-style-type: none">• Abridged review
	<ul style="list-style-type: none">• Japanese Pharmacopoeia (JP) as a reference pharmacopoeia
Vietnam	<ul style="list-style-type: none">• JP as a reference pharmacopoeia• Abridged review (to be implemented near future)

Activities in PMDA Asia Office

1. Enhance collaboration between ASEAN regulators in person
2. Contribute regulatory cooperation
3. Collaboration with academia in clinical study in Asia
4. Close communication with industry representatives in each Asia country

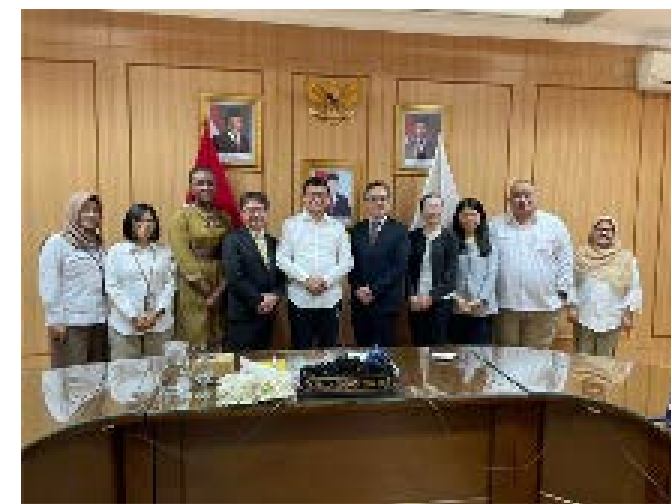


Conducted about 40 meetings

Courtesy visit, introduction of their business activities, concerns on regulation in specific country etc.,

Visit to Regulatory Authorities

Thai FDA, Vietnamese DAV (with NCC), Philippine FDA and Indonesia BPOM (with NCGM)



Visit to Hospitals and Academia

Thailand: Siriraj Hospital (with NCC),

Indonesia: Gadjah Mada University, Sardito Hospital, Sulianti Saroso Hospital, University of Indonesia and Cipto Hospital (with NCGM)

Vietnam: Ho Chi Ming City Oncology Hospital and K3 Hospital (with NCC)



Other Visit etc.,

Economic Research Institute for ASEAN and East Asia (with NCGM)
Attending International Health Seminar (with NCGM)



While keeping transparency and predictability,

PMDA Asia Office strives

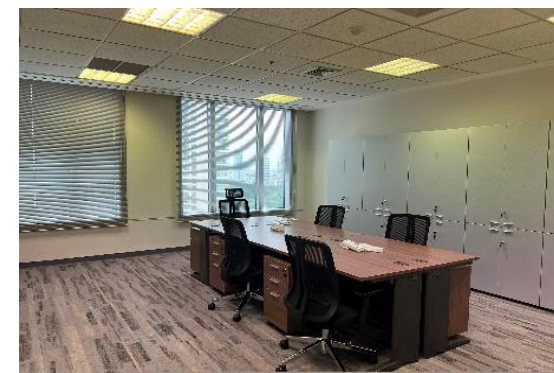
to communicate with regulatory authorities in ASEAN
to introduce pharmaceuticals to Asia from Japan!



Thank you for listening!
Please visit PMDA Asia Office.



Contact: kitahara-jun@pmda.go.jp



PMDA Asia Office web page:

<https://www.pmda.go.jp/english/int-activities/overseas-office/asia/0001.html>