

# PMDA's efforts for “Tomorrow's Normal” together ~with everyone around the world~



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# Today's Topics

**1.PMDA new logo and purpose**

2.PMDA's efforts to improve access to  
better innovative products

3.PMDA's international cooperation in Asia

# PMDA established new logo and purpose



**Making everyone's lives brighter together**

We, PMDA, continue to create "Tomorrow's Normal" together,  
as "life Platform" that supports everyday life,  
where everyone can feel peaceful and can lead vibrant and healthy lives  
by PMDA's "Safety Triangle" of review, safety and relief,  
with "intelligence" weaved through science and information, and  
with "human resourcefulness" accompanying  
And bringing the world and the future into harmony.

# Today's Topics

1. PMDA new logo and purpose

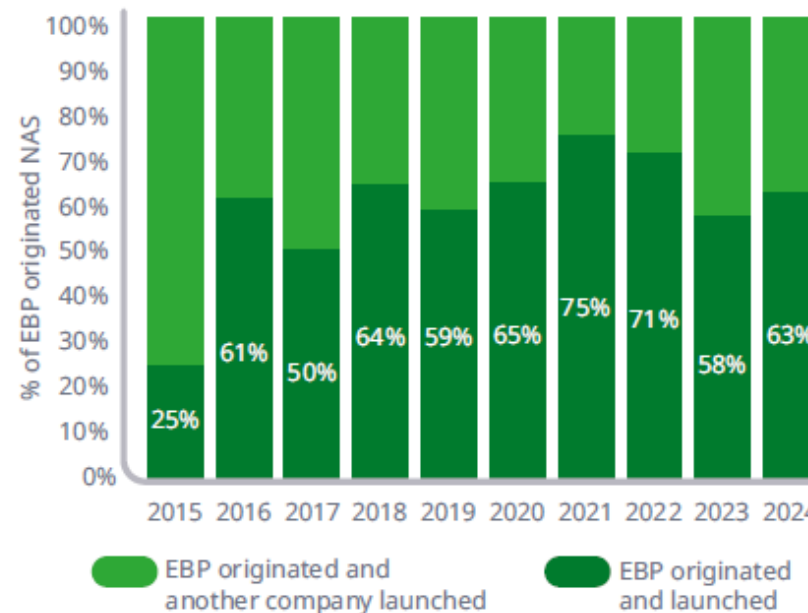
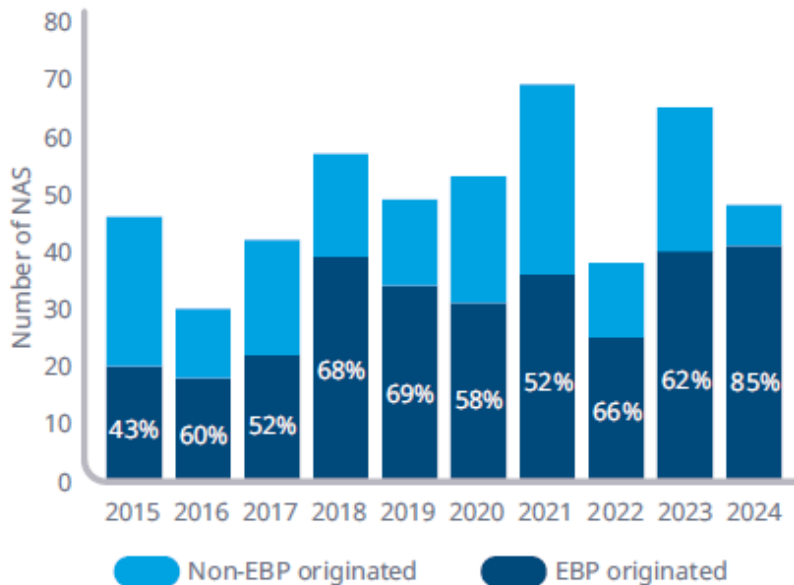
**2. PMDA's efforts to improve access to better innovative products**

3. PMDA's international cooperation in Asia

# Global trend in R&D

Emerging biopharma companies originated 85% of new drugs in 2024 and originated-and-launched 63% of them

Exhibit 37: Companies originating and filing FDA regulatory submissions for NAS and percent of launches by NAS launch year, 2015-2024



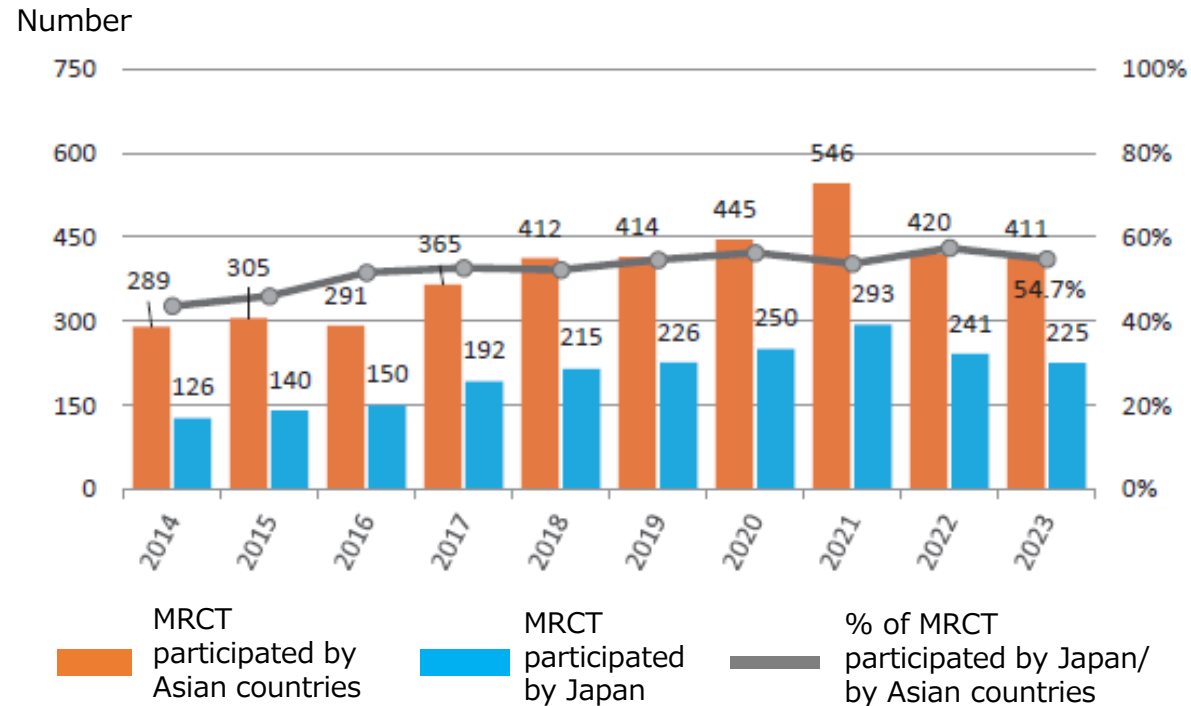
***EBPs :  
a key in R&D***

Source: IQVIA Institute, Jan 2025.

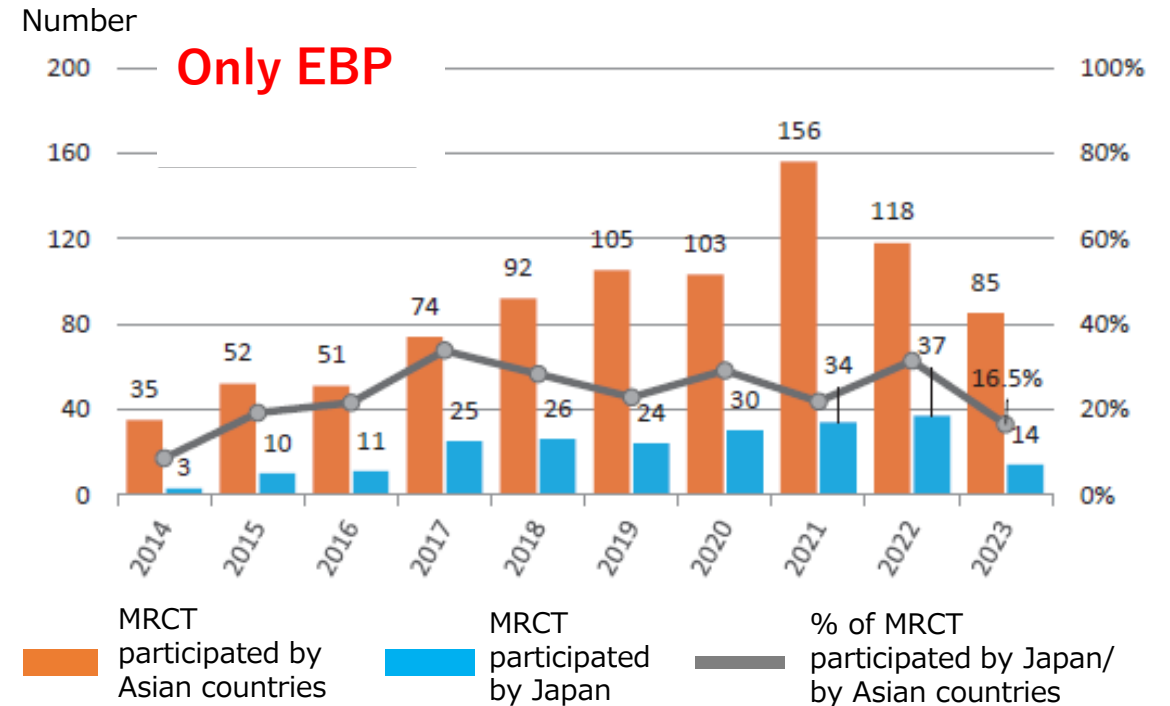
\* **Emerging biopharma (EBP)**: defined as those with R&D spending less than \$200M per year and less than \$500Mn in annual sales

# Global trend in R&D

## Total number of MRCT



## The number of MRCT leaded by EBP



**In Japan, The number of MRCT leaded by EBP isn't increasing compared to Total number of MRCT**

# For R&D in Japan (1)

## Support for the Practical Application from PMDA

### ◆ Orphan Drugs: for Expedited Designation

⇒ Early designation of orphan drug  
(initially for non-priority products, for priority designation possible with evidence).

### ◆ Pediatric Drugs: to Promote Development

⇒ Confirmed pediatric drug development during the adult pharmaceuticals development  
(MHLW: *Start pricing incentives for pediatric drug development*)

### ◆ PMDA Pediatric & Orphan Drug Regulatory Consultation Center (From July, 2024)

⇒ New consultation services & financial support for consultation fees

### ◆ Innovative Drugs: for Expedited Review Program

⇒ 6 months: total review period (target)

### ◆ Acceptance: English application (From September, 2024)

⇒ Scope: Foreign companies without a Japanese corporation or office in Japan  
Target: New drugs

# For R&D in Japan (2)

## Strengthening the regulatory response

### ◆Early Implementation: “Clinical Trial Ecosystem”

⇒ Pilot project: clinical trial ecosystem with medical institutions

### ◆Support: Participation to Multi-Regional Clinical Trials (MRCT)

⇒ Clear guidance:

- When Phase I trials in Japanese subjects are not required for participation in MRCTs
- Necessity Case of Japanese patient data when pivotal clinical trials are conducted exclusively overseas for rare diseases

### ◆Outreach and consultation

- ⇒ Outreach activities: Reach overseas start-up companies (through scientific conferences)
- ⇒ Consultation/support services for start-up companies through **PMDA Washington, D.C. Office**

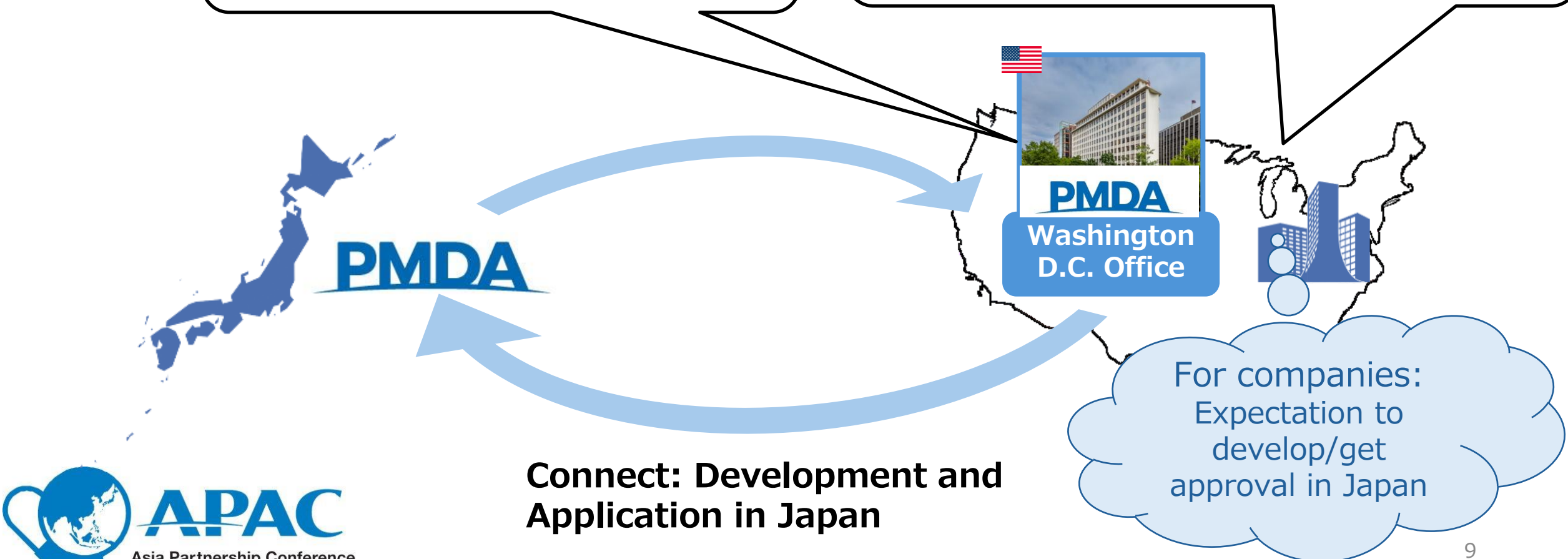


# PMDA Washington, D.C. office

(1) Collaborations with  
US-Gov. Organizations  
(i.e. FDA)

(2) Support Start-up companies  
through

- *Dissemination of relevant information*
- *General-consultation in English*



**Connect: Development and  
Application in Japan**

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# PMDA Asia Training Center



## Action Policy of PMDA-ATC

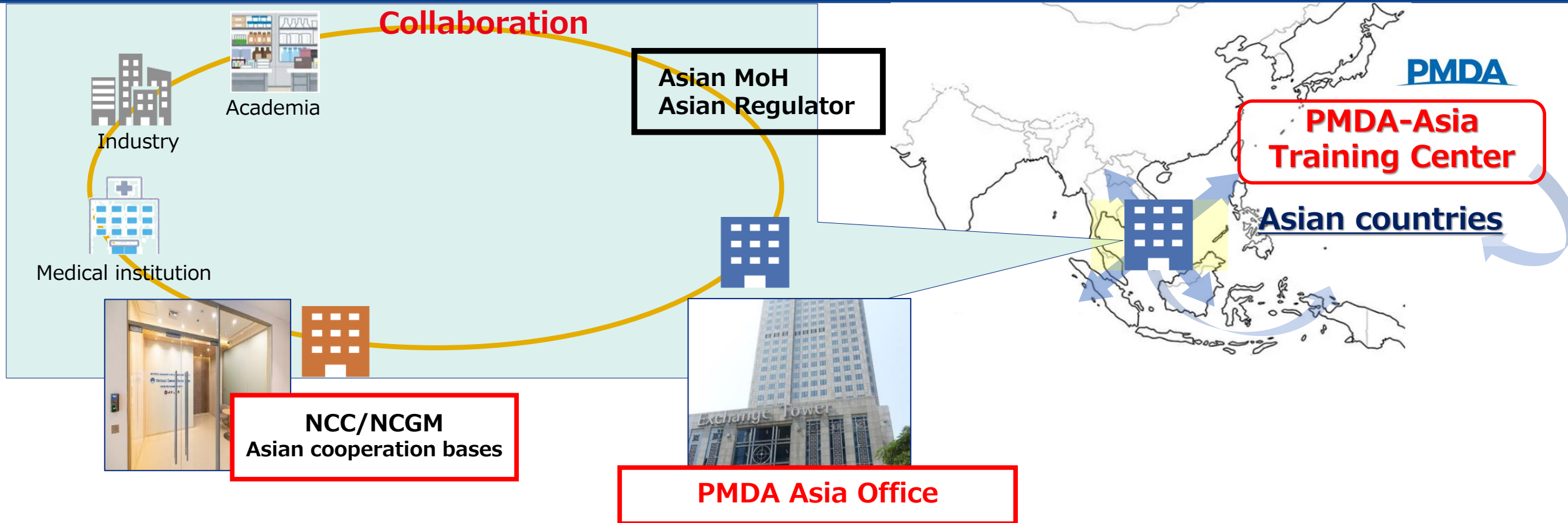
Contribute to universal health coverage in Asia  
through regulatory harmonization in the Asian region from capacity building

2016 – 2024

Participated from **76** countries/regions

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

# PMDA Asia office



- Regulatory collaboration through direct communication
- Communication with industries in Asian regions/harmonization of regulatory issues
- Working together with related Stakeholders (including Clinical Trial Network)

# “Reliance”

## Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization

*“When a regulatory authority of one country region conducts approval reviews or inspections, they consider, attach importance to, and utilize in their regulatory activities, the outcomes of assessments made by their counterparts in other countries/regions.”*

Headquarters for Healthcare Policy of Japan (20 June 2019)

## Draft Good regulatory practices for regulatory oversight of medical products

*“The act whereby the NRA (National Regulatory Authority) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision.”*

WHO (August 2020)

## Statement from Global Medicines Regulators on the Value of Regulatory Reliance

*“Regulatory reliance, which is a mechanism to strengthen regulatory capacity, to improve health systems nationally and internationally, to increase the availability of medicines, to save financial resources and to use human resources more strategically.”*

ICMRA (27 November 2020)



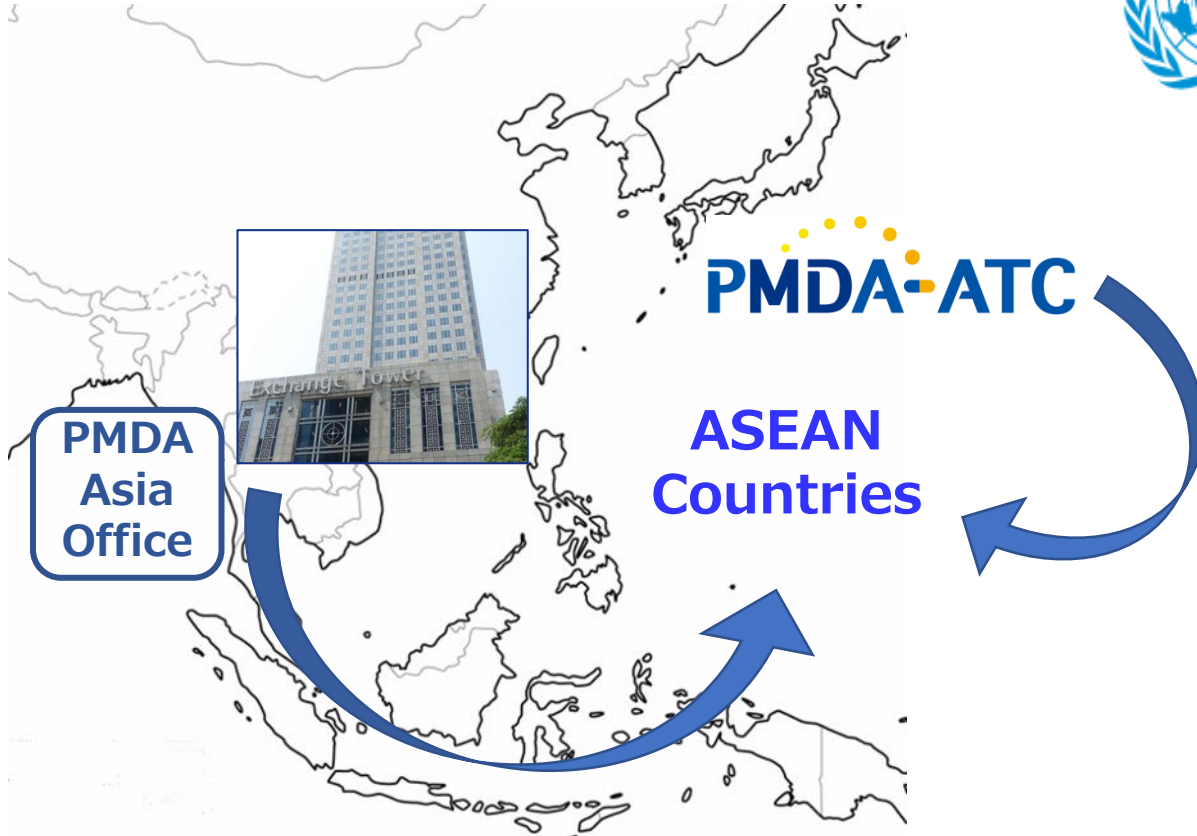
# Cooperation between WHO and PMDA



World Health  
Organization



PMDA-ATC



**Strengthening collaboration**  
- *Capacity building in Asian Region*

+

**Promoting "Reliance"**  
- *ASEAN Joint Assessment*  
- *Bilateral Reliance Scheme*

# Thank you for your attention