

# Regulations and Approvals Session

## Introduction of RA-EWG Session

April 5, 2017

APAC RA-EWG

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# *Goal and Approach of APAC RA-EWG*

## *APAC Mission:*

*To Expedite the Launch of Innovative Medicines  
for the Peoples in Asia*

### *Good Registration Management*

- ✓ Introduce **Good Submission Practice**
- ✓ Support promotion of Good Review Practice

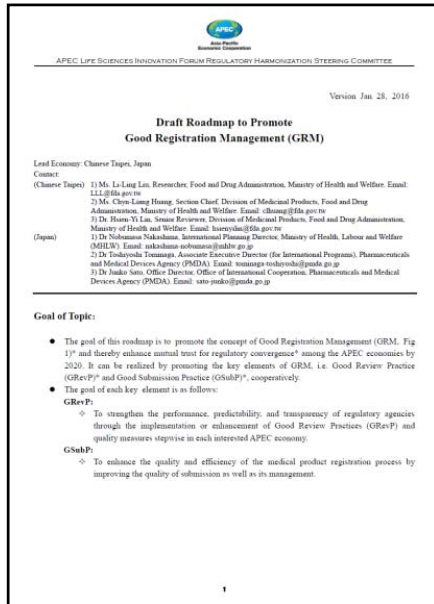
### *Convergence of NDA Requirements*

- ✓ Make proposals to facilitate regulatory convergence of NDA requirements

Efficient and Streamlined NDA Review

Regulatory Convergence

# GRM Roadmap for stepwise implementation



## Obtained endorsement of APEC RHSC Feb 24, 2016

**Step 1 (2011-2012)**

**Gap Analysis Survey for Setting the Foundation for Stepwise GRevP Implementation**

- Set up a technical working group
- Gap analysis survey for APEC economies
- Prioritize needs and strategy for improvement based on result of the gap analysis survey

**Step 2 (2011-2016)**

**Planned Solution to Address Gap in GRM**

- Training: workshops and CoE Pilot Training Program
- Development of normative GRevP/GSubP documents
- Dissemination of GRevP, GSubP and GRM
- Establish a network of GRevP and a network of GSubP

**Assessing the Impact of GRM**

- Assessing the Impact of Training and Implementation of GRevP, GSubP and GRM

of GRevP, GSubP and GRM (continued)

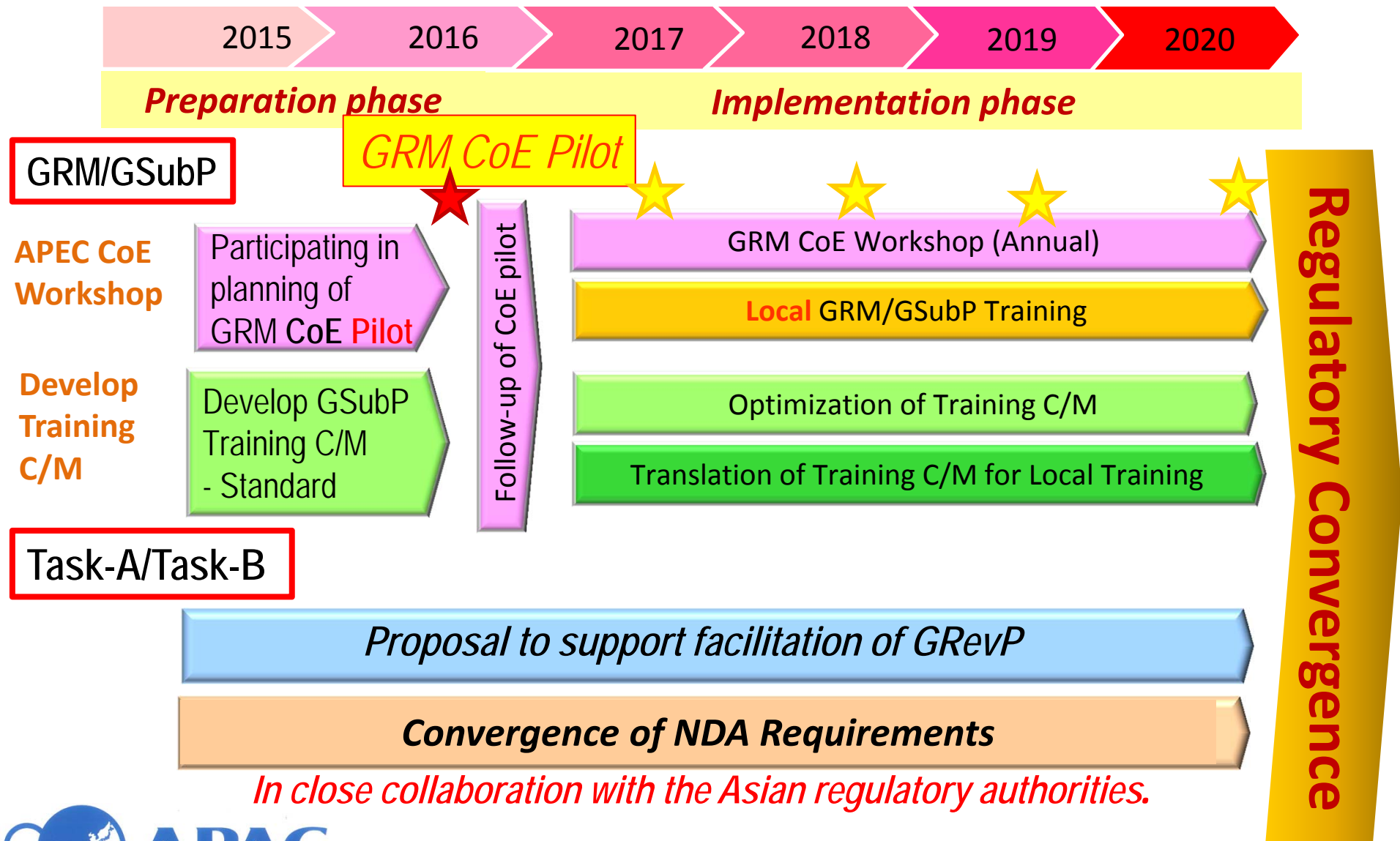
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Reaching the Goal for Implementing GRM  
Follow-up measures and final assessment

To reach the same end: better functioning agency through regulatory convergence by 2020



# Towards Efficient and High-Quality Registration Process





*Thank you !*

