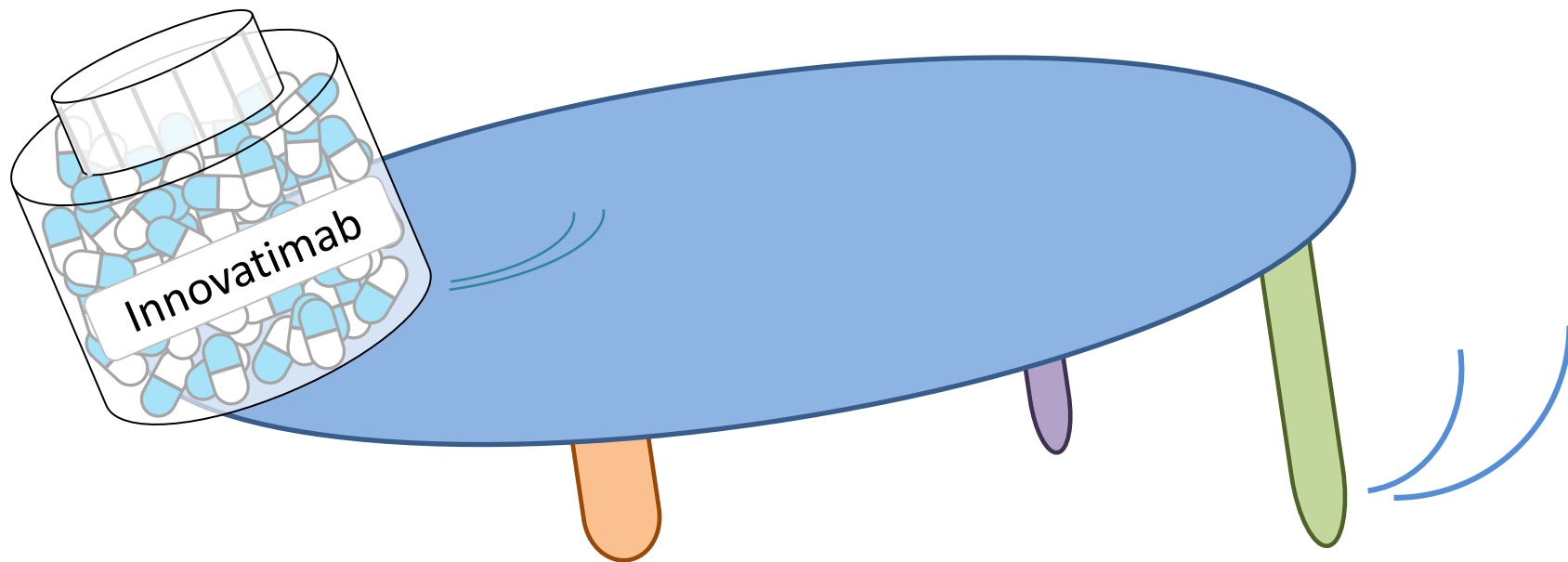


RA Session Opening

Shinji Hatakeyama Ph.D.
Leader, RA-EWG

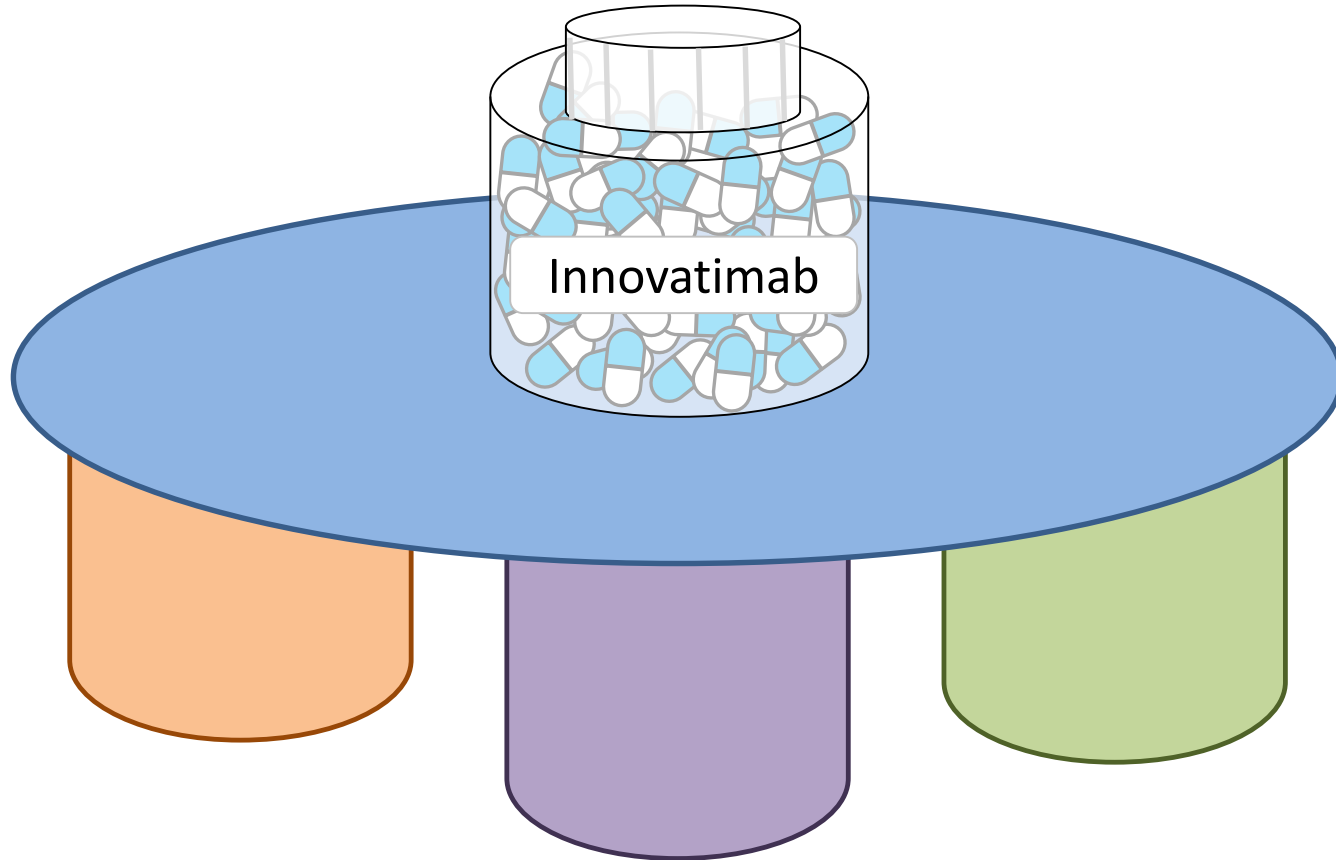
April 9th 2019
8th APAC RA Session

How Establish Sustainable Supply?



**Expedite the launch of innovative medicines
for the peoples in Asia**

Capacity Building & Collaboration



**Expedite the launch of innovative medicines
for the peoples in Asia**

Regulations and Approvals Expert Working Group

Good Registration Management

Regulatory Convergence

Establishment of Regulations and Approvals Expert Working Groups:

- Offering recommendations to realize early submission and approval of NDA for prescription drugs in Asia
- Stable supply of quality drug at global standard

1 st APAC				2012	
2 nd APAC	Concept Paper: <ul style="list-style-type: none"> • Fundamental framework in the activities and outlines a strategic multi-year approach 		Analysis Report	2013	
3 rd APAC	Good Registration Practice Policy Document		Fact Sheet	Analysis Report	2014
4 th APAC	Task A: APAC GRegP Position Paper to GRevP APAC GSubP Guideline		Task B: Convergence of NDA Requirements <ul style="list-style-type: none"> • Brainstorming • ICH implementation questionnaire in APAC Analysis Report		2015
5 th APAC	Progress Report	APEC GRM Roadmap	APEC GSubP Guideline	Analysis Report	2016
6 th APAC	Progress Report	APEC GRM Pilot COE Workshop	Asia Regulatory Conference	Analysis Report	2017
7 th APAC	Interim Report	APEC GRM COE Workshop	Conditional Early Approval	Analysis Report	2018
8 th APAC	Progress Report	APEC GRM Train the Trainer	Reliance Pathway	PMRE	2019
9 th APAC				2020	
10 th APAC				2021	

RA Session Topics

1. Good Registration Management

Success of “Train the Trainers”

- Panel Discussion

2. Regulatory Convergence

Reliance Pathway for Approval of Innovative Medicines in APAC

- Introduction of WHO Activities
- Panel Discussion