

Agenda for APACRM 2024 (7th APACRM)

As of February 14th, 2024

Brief Overview of APACRM 2024

Date of the Meeting:

Thursday, April 25th, 2024

Venue (or Zoom):

TOKYO MIDTOWN YAESU CONFERENCE (Please note the change in venue)

4F Main Conference Room

2-2-1 Yaesu, Chuo-ku, Tokyo 104-0028

<https://www.yaesu.tokyo-midtown.com/en/conference>

Past Participants:

Presenter/Discussant

Industrial Association: China, India, Japan, Korea, Singapore, Taiwan

Regulatory Authority: India, Japan, Korea, Singapore, Taiwan

Observer

Regulatory Authority: Indonesia, Malaysia, Myanmar, Philippines, Thailand, Vietnam

Time (JST)	Duration	Session	Chair/Speaker/Panelist
13:00-13:03	3 min	Opening remarks	FIRM
13:03-13:10	7 min	Introduction	FIRM
13:10-14:10	Update on Regenerative Medicine from each Participating Industrial Association		
	60 min	10-min presentations from each country/region (Pre-recorded)	FIRM (Japan)
			CMBA (China)
			CARM & RMAF (Korea)
			SAPI (Singapore)
			ABLE (India)
			BPIPO (Taiwan)
14:10-14:40	Educational Lecture		
	30 min	Points to Consider for Cellular Therapy CMC toward New Drug Application (NDA)	FIRM
14:40-15:10	Topics for future activities		
	30 min	Considerations for Conducting Clinical Trials of Regenerative Medicinal Products	FIRM
15:10-15:20	10 min	Break	
15:20-16:40	Considerations for Preparing an NDA for AAV-based Gene Therapies		
	80 min	Presentation and Panel Discussion	WG3 member & ALL
16:40-17:10	Non-clinical data package for AAV-based Gene Therapies		
	30 min	Presentation and Discussion	WG1 member & ALL
17:10-17:55	Compilation of Case Studies on Cell and Gene Technology provided to the Patients as Medical Care or Medical Practice without Market Authorization		
	45 min	Presentation and Discussion	FIRM & ALL
17:55-18:00	5 min	Closing	FIRM
18:30-20:00	<Reception> in-person only		

Abbreviations: ABLE, Association of Biotechnology Led Enterprises in India; BPIPO, Biotechnology and Pharmaceutical Industries Promotion Office in Taiwan; CARM, Council for Advanced Regenerative Medicine in Korea; CMBA, China Medical Biotech Association in China; RMAF, Regenerative Medicine Acceleration Foundation in Korea; SAPI, Singapore Association of Pharmaceuticals Industries in Singapore.