

## Draft agenda

Time (JST)	Duration	Session	Chair/Speaker/Panelist
13:00-13:05	5 min	Opening remarks	FIRM
13:05-13:20	15 min	Tracing the Path of APACRM	FIRM
13:20-13:50	<b>Update on Regenerative Medicine from Participating Industry Association</b>		
	30 min	10-minute presentations from selected countries/regions with significant updates on regulations and market developments to share	China
			Korea
Taiwan			
13:50-14:00	<b>Regulatory Awareness in the APAC Region for Developers</b>		
	10 min	APAC Regulatory Roadmap whitepaper on Cytotherapy	ISCT
14:00-15:00	<b>A-Gene: Case Study Insights on the QbD Approach in Gene Therapy Manufacturing</b>		
	60 min	This session will highlight Project A-Gene, an initiative by ARM showcasing a case study-based approach to integrating Quality by Design (QbD) principles into gene therapy CMC programs.	ARM, FIRM
15:00-15:20	20 min	Break	
15:20-16:00	<b>Non-clinical Data Package for AAV-Based Gene Therapies</b>		
	40 min	Building on last year's discussions, this session highlights the non-clinical data package in the development and regulatory review of AAV-based gene therapies.	WG1 members
16:00-17:20	<b>AAV Gene Therapy: Product Life Cycle and Regulatory Landscape</b>		
	80 min	This session will present a product life cycle map for AAV gene therapies, outlining key development and regulatory considerations from early research and preclinical stages through to post-market activities.	WG3 members
17:20-17:55	<b>Post-Launch Regulatory Requirements for Regenerative Medical Products</b>		
	35 min	This session will focus on compiling and analyzing regulatory requirements for regenerative medical products after their market launch.	Clinical WG members
17:55-18:00	5 min	Closing	FIRM
18:30-20:00	<Reception> in-person only		

### Participating members of the APACRM:

ABLE, Association of Biotechnology Led Enterprises (India);

BPIPO, Biotechnology and Pharmaceutical Industries Promotion Office (Taiwan);

CARM, The Council for Advanced Regenerative Medicine (Korea);

CMBA, China Medicinal Biotech Association (China);

FIRM, Forum for Innovative Regenerative Medicine (Japan);

RMAF, Regenerative Medicine Acceleration Foundation (Korea);

SAPI, Singapore Association of Pharmaceuticals Industries (Singapore)

