

Draft agenda

Special Morning Session

(In-Person Only | By Invitation: Regulatory Authority Representatives)

Supported by FIRM

Time (JST)	Duration	Session	Participants
10:00-12:00	120 min	Roundtable Discussion: Efficient and effective development and regulatory review of Cell and Gene Therapies, aiming to accelerate orphan and rare disease treatments and personalized medicine	Health Authority Officers (by invitation only; in-person participation)
12:00-13:00	60 min	Lunch Break (A light lunch will be provided.)	

Hybrid Afternoon Session

(Invited Authorities and Organizations)

Time (JST)	Duration	Session	Chair/Speaker/Panelist
13:00-13:05	5 min	Opening remarks	FIRM
13:05-13:20	Presentation on AAV/CAR-T Report		
	15 min	This session will introduce a report on AAV/CAR-T, prepared based on previous APACRM discussions	FIRM
13:20-14:20	Update on Regenerative Medicine from Participating Industrial Associations		
	60 min	Brief presentations from selected countries/regions to share significant updates on regulations and market developments	ABLE (India) CMBA (China) SAPI (Singapore) TACT (Taiwan) FIRM (Japan)
14:20-14:35	Report on Outcomes of Roundtable Discussion		
	15 min	This session will share conclusions and ensure follow-up for "Roundtable Discussion" held in the morning	PMDA
14:35-14:50	15 min	Break	
14:50-16:10	Overview of CMC Regulations for Cell and Gene Therapies		
	80 min	This session will offer an interactive forum for participants through live questions and a panel discussion covering a broad range of CMC topics including comparability assessment	WG3 members
16:10-16:25	15 min	Break	
16:25-17:05	Post-Launch Regulatory Requirements for Regenerative Medical Products		
	40 min	This session will introduce the current regulatory requirements and practices concerning long-term follow-up in clinical trials/post-launch settings for Cell and Gene Therapies in Asian countries/regions	Clinical Trial WG members
17:05-17:45	Overview of Regulatory Framework for Cell and Gene Therapies as Medical Practices		
	40 min	This session will provide an overview of the regulatory framework for Cell and Gene Therapies delivered as medical practice in Asian countries/regions, Europe and the United States	FIRM
17:45-17:50	5 min	Closing	FIRM
18:00-20:00	Reception (In-person attendees)		