

2011 APEC MULTI-REGIONAL CLINICAL TRIALS TOKYO WORKSHOP
highlighting KOREA, CHINA AND JAPAN TRIPARTITE SYMPOSIUM

Day 1, November 1

10:00-10:10	Welcoming Remarks			
	<i>Speakers:</i>	Dr. Yoshinobu Hirayama (MHLW) Dr. Tatsuya Kondo (PMDA)	10min.	10:00-10:10
10:10-10:30	MRCT Roadmap and Recommendation from Last Year's Workshop			
	<i>Speaker:</i>	 Dr. Justina Molzon (APEC RHSC Training Subcommittee)	20min.	10:10-10:30
10:30-12:30	Session 1:DG meeting report symposium I			
	<i>Chair :</i> Mr.Naoyuki Yasuda (MHLW)			
	<i>3 Speakers:</i>	 Japan : Mr. Naoyuki Yasuda (MHLW)	25 min.	10:30-10:55
		 Korea : Dr. Sun-Hee Lee (KFDA)	25 min.	10:55-11:20
		 China : Mr. Zhang Wei (SFDA)	25 min.	11:20-11:45
	<i>Discussant</i>	 USA : Dr. Justina Molzon (FDA)	25 min.	11:45-12:10
	Discussion & Summary of the session		20 min.	12:10-12:30
12:30-13:30	Lunch		60 min.	12:30-13:30
13:30-15:00	Session 2:DG meeting report symposium II			
	<i>Chair :</i>  Dr.Masahiro Tohkin (Nagoya City University)			
	<i>3 Speakers:</i>	 Dr. Masahiro Tohkin (Nagoya City University)	25 min.	13:30-13:55
		 Prof. Cui Yimin (Peking University First Hospital)	25 min.	13:55-14:20
		 Dr. In-Jin Jang (Seoul National University)	25 min.	14:20-14:45
	Discussion & Summary of the session		15 min.	14:45-15:00
15:00-15:30	Intermission		30 min.	15:00-15:30
15:30-17:50	Session 3:Importance of Asia in global development strategy			
	<i>Chair :</i> Dr. Ling Su (Novartis)			
	<i>5 Speakers:</i>	 Dr. Jerry Stewart (Pfizer)	25 min.	15:30-15:55
		 Dr. Yoshiaki Uyama (PMDA)	25 min.	15:55-16:20
		 Dr. Tomas Salmonson (EMA)	25 min.	16:20-16:45
		 Mr. Haruhisa Hirosaki (Astellas)	25 min.	16:45-17:10
		 Dr. Thomas R. Verhoeven (Eli Lilly)	25 min.	17:10-17:35
	Discussion & Summary of the session		15 min.	17:35-17:50

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Day 2, November 2

9:30-12:00	Session 4:Study Design				
	Chair : Dr. Masahiro Takeuchi (Kitasato University)				
	Chair's Report	 2010MRCT Workshop&Introduction	10 min.	9:30-9:40	
	5 Speakers:	 Ms. Madoka Takeuchi (Harvard School of Medicine), presenting on behalf of Dr. Lee-Jen Wei (Harvard School of Public Health)	25 min.	9:40-10:05	
		 Dr. Jim Hung (FDA)	25 min.	10:05-10:30	
		 Ms. Yuki Ando (PMDA)	25 min.	10:30-10:55	
		 Dr. Yao Chen (Beijing University)	25 min.	10:55-11:20	
		 Dr. Kihito Takahashi (GSK)	25 min.	11:20-11:45	
	Discussion & Summary of the session			15 min.	11:45-12:00
12:00-13:00	Lunch		60 min.	12:00-13:00	
13:00-15:05	Session 5:Case Studies				
	Chair : Dr. Yasuhiro Fujiwara (National Cancer Center Hospital)				
	Chair's Report	 2010 MRCT Workshop & Introduction Topic: Oncology	10 min.	13:00-13:10	
	4 Speakers:	 Ms. Yang Zhimin (CDE, SFDA)	25 min.	13:10-13:35	
		 Dr. Hanlim Moon (GSK)	25 min.	13:35-14:00	
		 Dr. Junichi Hashimoto (Pfizer)	25 min.	14:00-14:25	
		 Dr. Chih-Hsin James Yang (National Taiwan University)	25 min.	14:25-14:50	
	Discussion & Summary of the session			15 min.	14:50-15:05
15:05-15:30	Intermission		25 min.	15:05-15:30	
15:30-17:00	Session 6:Panel Discussion				
	Chairs: Dr. Toshiyoshi Tominaga (PMDA) and Dr. Masaru Iwasaki (Yamanashi University)				
	Part I :Session Report				
	Speakers:	 Dr. Toshiyoshi Tominaga (PMDA)  Dr. Masaru Iwasaki (Yamanashi University)	20 min.	15:30-15:50	
	Part II :Panel Discussion				
	Panelists:	Dr. Masahiro Takeuchi (Kitasato University) Dr. Yasuhiro Fujiwara (National Cancer Center Hospital) Dr. Yoshiaki Uyama (PMDA) Dr. Wen Chang (BMS) Dr. Gyu-Han Chae (KFDA) Ms. Dong Jiangping (CDE, SFDA)	70 min.	15:50-17:00	
17:00-17:10	Concluding Remarks:Direction found in this WS				
	Speaker:	Dr. Hideo Utsumi (PMDA)	10 min.	17:00-17:10	
17:10-17:20	Closing Remarks				
	Speaker:	Dr. Yutaka Kirino (Society for Regulatory Science of Medical Products)	10 min.	17:10-17:20	
	Meeting Adjourned				