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President
International Medical Center of Japan

(Alphabetical order)

PROGRAM

Global Drug Development Techniques: Bridging Strategies

Thursday, October 5 (14:00 - 18:00)

14:00-14:20	Opening Remarks and Welcoming Address	Prof. Toshiro Sato <i>Kitasato University</i> Dr. Declan P. Doogan <i>Pfizer Inc.</i>
	GLOBAL HARMONIZATION	<i>chaired by</i> Prof. James H. Ware <i>Harvard School of Public Health</i>
14:20-14:50		Dr. Elaine C. Esber <i>US Food and Drug Administration</i>
14:50-15:20		Dr. Keiji Ueda <i>Tokyo Metropolitan Tama Geriatric Hospital</i>
15:20-15:35	Discussion	
15:35-15:50	Break	
	ETHNIC DIFFERENCES	<i>chaired by</i> Prof. Yoshio Yazaki <i>International Medical Center of Japan</i>
15:50-16:20	Drug Metabolism	Prof. Takashi Ishizaki <i>Kumamoto University</i>
16:20-16:50	Disease Presentation West vs East	Dr. Jiang He <i>Tulane University</i>
16:50-17:20	Dose Setting	Dr. Chikayuki Naito <i>The Organization for Pharmaceutical Safety and Research</i>
17:20-18:00	Discussion	<i>chaired by</i> Prof. Yoshio Yazaki <i>International Medical Center of Japan</i> Prof. Mitsukuni Murasaki <i>Yutaka Clinic</i> <i>discussants</i> Prof. Shigeto Yamawaki <i>Hiroshima University</i>

Friday, October 6 (9:00 - 17:30)

	BRIDGING STRATEGIES	<i>chaired by</i> Prof. Hiroo Imura <i>Council for Science and Technology</i>
9:00-9:30	Bridging : Efficacy and Safety	Prof. Shinichi Kawai <i>St. Marianna University School of Medicine</i>
9:30-10:15	Bridging : Methods and Special Populations	Prof. James H. Ware <i>Harvard School of Public Health</i>
10:15-10:30	Break	
10:30-11:15	Bridging: Statistical Considerations	Prof. Masahiro Takeuchi <i>Kitasato University Graduate School</i> Dr. Robert O'Neill <i>US Food and Drug Administration</i>
11:15-12:00	Bridging Guidance	Mr. Mamoru Narukawa (TBC)
12:00-12:45	Summary and Panel Discussion	<i>chaired by</i> Prof. Hiroo Imura <i>Council for Science and Technology</i> Dr. Akiyoshi Uchiyama <i>Eisai Co., Ltd.</i>
12:45-13:45	Lunch	
	FUTURE STRATEGIES AND CHALLENGES	<i>chaired by</i> Prof. Lee-Jen Wei <i>Harvard School of Public Health</i>
13:45-14:15	Bridging Western Data to Japan	Prof. Fumihiko Sakai <i>Kitasato University</i>
14:15-14:45	Bridging Japanese Data to the West	Dr. Richard Pazdur <i>US Food and Drug Administration</i>
14:45-15:15	Depression: Western and Japanese Differences	Prof. Kunitoshi Kamijima <i>Showa University</i>
15:15-15:30	Break	
15:30-17:00	Discussion	<i>discussants</i> Dr. Yasuhiro Fujiwara <i>Pharmaceuticals & Medical Devices Evaluation Center</i> Mr. Katsuyoshi Shimatani <i>Pfizer Pharmaceuticals Inc.</i>
17:00-17:30	Summary and Conclusions	Prof. Stephen W. Lagakos <i>Harvard School of Public Health</i> Prof. Masahiro Takeuchi <i>Kitasato University Graduate School</i>