Contents of Proceedings of the 33rd Annual Meeting of the Japanese Society of Clinical Pharmacology and Therapeutics

“How Can We Assess Efficacy and Safety of Approved Drugs?”
1. Clinical Epidemiology of Adverse Drug Events Takeshi MORIMOTO 325
2. Evaluation of Safety and Efficacy of Medicine in the Registry after Coronary Revascularization Masahiro NATSUAKI, et al. 329
3. Safety and Efficacy Evaluation of Cardiovascular Drugs after Approval Reiko SATO 334
4. Registry Based Comparative Effectiveness Research Shinichiro UEDA 335

Symposium 5 “Efficient Supply of Post-Marketing Information of Drugs” Summary Masahiro NOMOTO, et al. 339
1. Outline of Risk Management Plan Shinichi WATANABE 341
2. Supply and Utilization of Useful Post Marketing Information in Medical Field -From a Physician’s Viewpoint-- Hideki MOCHIZUKI 343
3. Problem in Post-Marketing Supply of Information --Mainly in Package Leaflet-- Hiroaki ARAKI 345
4. Providing Proactive and Timely Information Resulting from Ongoing Post-Marketing Studies to Medical Institutes Yasuhiko KAI, et al. 347

Symposium 11 “Pharmacokinetics Study on Patients” Summary Yukiko MARUYAMA, et al. 349
1. The Implementation System in Ehime University Hospital for Pharmacokinetic Studies of Patients Risako YAMASHITA, et al. 351
2. Problems in Performing Pharmacokinetic Examinations in Men with Pathological Conditions Kazuhiro HARADA 353
3. PK/PD Study in Patients in Phase 1 Unit Hinako UCHIMARU, et al. 355
4. Request to Japanese Medical Institution to Promote Clinical PK/PD Trial in Patients Shingo MATSUI 357

Symposium 19 “Personalized Medicine Based on Pharmaceutical Care” Summary Hiroki ITO 359
1. An Approach to Personalized Medicine Tomonori NAKAMURA, et al. 361
3. Adverse Event Monitoring Tohru HASHIDA 365
4. Expectation for Clinical Pharmacology from Bed Side

Symposium 20 “What is Needed for Early Phase Clinical Studies in Japan to be Internationally Recognized?” Summary Masako NAKANO, et al. 367
1. FIH Study: In Order to Conduct Successful Global Exploratory Studies Kazuo UMEMURA 369
2. Proof of Concept Trials Masahiro NOMOTO 371
3. Conducting Phase 1 Study in Patient Subjects: Points to Consider Mananari SHIRAMOTO, et al. 373
4. FIH (First-in-Human) Trial of Oncology Drug Products: How to Enhance International Competitiveness of Japanese Academic Hospitals Yasuhiro FUJIWARA 375
5. Promotion of Early Stage Clinical Trials: From the Viewpoint of MHLW Masanobu YAMADA 377