

Diploma Course on Research & Development of Products to Meet Public Health Needs

Sponsored by Nagasaki University

*in cooperation with Thammasat University, Chulalongkorn University,
China Second Military Medical University, Universidad de Antioquia
and The Graduate School of Pharmaceutical Sciences of The University of Tokyo*

*in collaboration with TDR/UNICEF, UNDP, WB, WHO and The Pharmaceutical Society
of Japan (PSJ)*

Nagasaki University, Japan
October 1 - November 3, 2007

Module 1: Course Orientation

1 October, 2007 Monday

- 0900-0915 Welcome address
President, Dr. Hiroshi Saitoh, Nagasaki University, Japan
- 0915-0945 Objective of the course and expectation
*Prof. Dr. Kenji Hirayama, Director of the course, Institute of Tropical
Medicine, Nagasaki University, Japan*
- 0945-1000 Introduction of participants
- 1000-1030 *Tea break*
- 1030-1200 Key medical and public health issues, and the need for new products
Dr. Janis Lazdins, WHO/TDR, Geneva
- 1200-1300 *Lunch*
- 1300-1400 Discovery research and product development and the different
approaches required for each of them
Dr. Janis Lazdins, WHO/TDR, Geneva
- 1400-1500 Stakeholders in Product Research and Development
- Large, medium and small pharmaceutical companies
 - Academic institutions
 - Clinical Research Organization
 - Biotech
 - Regulatory
- Prof. Dr. Eiji Uchida, Showa University, Tokyo, Japan*
- 1500-1530 *Tea break*
- 1530-1600 Stakeholders in Product Research and Development (discussion)
Prof. Dr. Eiji Uchida, Showa University, Tokyo, Japan

Module 2: Drug Development

Drug Discovery

2 October, 2007 Tuesday

- 0900-1100 History and overview of modern drug discovery
Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Japan
- 1100-1130 *Tea Break*
- 1130-1230 From drug target to drug lead
Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Japan
- 1230-1330 *Lunch*
- 1330-1500 Drug targets identification and validation in cardiovascular diseases
Dr. Hisashi Ohta, Tsukuba Research Institute, Banyu Pharmaceutical Co.,LTD, Japan

3 October, 2007 Wednesday

- 0900-1030 Overview of chemistry in drug discovery
Hit/lead generation and optimization
Prof. Dr.Tadashi Yoshimoto, School of Pharmaceutical Sciences, Nagasaki University, Japan
- 1030-1100 *Tea break*
- 1100-1200 Drug discovery for HIV
Prof. Dr.Nobuyuki Kobayashi, Nagasaki University Graduate School of Biomedical Sciences, Nagasaki, Japan
- 1200-1330 *Lunch*
- 1330-1430 Drug discovery for TB
Dr.Hiroshi Ishikawa, Scientific Director, Otsuka Pharmaceutical Co.,Ltd., Osaka, Japan
- 1430-1450 *Tea break*
- 1450-1550 Drug discovery for Trypanosomiasis
Prof. Dr. Kiyoshi Kita, Graduate School of Medicine, The University of Tokyo, Japan
- 1550-1650 Drug targets identification and validation in TB
Assoc. Prof. Dr. Prasit Palittapongarnpim, BIOTEC, Thailand

4 October, 2007 Thursday

- 0900-1000 Publications, IPR and patents in drug discovery
Mr. Kenichi Osawa, Banyu Pharmaceutical Co.,Ltd, Japan
- 1000-1030 *Tea break*
- 1030-1130 Publications, IPR and patents in drug discovery (Cont.)
Mr. Kenichi Osawa, Banyu Pharmaceutical Co.,Ltd, Japan

Chemical Manufacturing and Control (CMC)

5 October, 2007 Friday

- 0900-1000 Introduction to CMC
Director and Prof. Dr. Hitoshi Sasaki, Department of Hospital Pharmacy, Nagasaki University Hospital of Medicine and Dentistry, Japan
- 1000-1100 Formulations
Director and Prof. Dr. Hitoshi Sasaki, Department of Hospital Pharmacy, Nagasaki University Hospital of Medicine and Dentistry, Japan
- 1100-1130 Tea Break
- 1130-1230 Methods for determination of concentrations in various media by means of spectrometric methods, HPLC, and biological methods
Prof. Dr. Masaaki Kai, Nagasaki University Graduate School of Biomedical Sciences Nagasaki University, Japan
- 1230-1330 Lunch
- 1330-1430 Stability for drug substance and drug product
Assoc. Prof. Supornchai Kongpatanakul, Mahidol University, Thailand
- 1430-1500 Tea break
- 1500-1600 Example: Antimalarial drug, dihydroartemisinin
Assoc. Prof. Supornchai Kongpatanakul, Mahidol University, Thailand

6 October, 2007 Saturday

- 0900-1000 Development of specification
Prof. Dr. Hiroaki Nagaoka, Faculty of Health Management, Nagasaki International University, Japan
- 1000-1100 Quality assurance/quality control
Prof. Dr. Hiroaki Nagaoka, Faculty of Health Management, Nagasaki International University, Japan
- 1100-1115 Tea break
- 1115-1230 Regulatory (with an example of a drug CMC requirement)
Prof. Dr. Hiroaki Nagaoka, Faculty of Health Management, Nagasaki International University, Japan
- 1230-1300 Naming the New Chemical Entity (NCE)
Prof. Dr. Hiroaki Nagaoka, Faculty of Health Management, Nagasaki International University, Japan
- 1400-1530 Synthesis of active pharmaceutical ingredient
Prof. Dr. Masakatsu Shibasaki, Graduate School of Pharmaceutical Sciences, University of Tokyo, Japan

Pre-clinical Development

Pharmacological development

8 October, 2007 Monday

- 0900-1100 Pharmacological data in new drug application
Assoc. Prof. Dr. Shunsuke Ono, University of Tokyo, Graduate School of Pharmaceutical Sciences, Japan
- 1100-1130 *Tea break*
- 1130-1230 Methods in pharmacological R&D (1)
Dr. Hiroyuki Itoh, Astellas Pharma Inc, Japan
- 1230-1330 *Lunch*
- 1330-1430 Methods in pharmacological R&D (2)
Dr. Hiroyuki Itoh, Astellas Pharma Inc, Japan
- 1430-1500 Discussion
Drs. Shunsuke Ono and Hiroyuki Itoh
- 1500-1530 *Tea break*
- 1530-1700 R&D for Medical Devices and Alternative to Animal Experiments
Assoc. Prof. Dr. Tsutomu Kurosawa, The Institute of Experimental Animal Sciences, Osaka University, Japan

Toxicology

9 October, 2007 Tuesday

- 0900-1000 Principles of toxicology
Assoc. Prof. Dr. Wongwiwat Tassaneeyakul, Khon Kaen University, Thailand
- 1000-1100 Toxicological tests: *in vitro* & *in vivo*: acute, subacute, chronic, special organ toxicology, reproduction toxicology, teratogenicity, mutagenicity, carcinogenicity studies
Assoc. Prof. Dr. Wongwiwat Tassaneeyakul, Khon Kaen University, Thailand
- 1100-1130 *Tea break*
- 1130-1300 Principles of pharmacokinetics: ADME processes
Assoc. Prof. Dr. Wongwiwat Tassaneeyakul, Khon Kaen University, Thailand,
- 1300-1400 *Lunch*
- 1400-1530 Pharmacokinetic data analysis & pharmacokinetic parameters
Assoc. Prof. Dr. Wongwiwat Tassaneeyakul, Khon Kaen University, Thailand

Pre-clinical Pharmacokinetics

10 October, 2007 Wednesday

- 0900-1030 Scheduling of toxicological studies in the development plan, the registration requirements, human & animal pharmacology, the proposed clinical application and the forms of administration.
Dr. Soisungwan Satarug, Thammasat University, Thailand and Sendai,
- 1030-1100 *Tea break*
- 1100-1230 Continuous monitoring of the correlation between new toxicological findings and the unwanted events observed in humans up till now.
Dr. Soisungwan Satarug, Thammasat University, Thailand and Sendai, Japan
- 1230-1330 *Lunch break*
- 1330-1530 Transferability of the pharmacokinetic findings in animals to humans
Investigating toxicological problems - practices and pitfalls
Dr. Soisungwan Satarug, Thammasat University, Thailand and Sendai, Japan

11 October, 2007 Thursday

- 900-1000** **Participants' Report on Drug discovery**
- 1000-1200 Visit animal facility for medical research
Assoc. Prof, Dr. Kazutaka Osawa, Laboratory Animal Center for Biomedical Research, Nagasaki University, Japan
- 1500-1630 Evaluation of viability (risk and benefit) for further development (case study)
Dr. Tadaaki Taniguchi, Banyu Pharmaceutical Co., Ltd.

Clinical Development

Clinical Trial

12 October, 2007 Friday

- 0900-1100 Overview of clinical development
- Assessment of pre-clinical information
 - Clinical development plan
 - Application of pharmacokinetics and pharmacodynamics in drug development
 - Dose selection and regimen
- Dr. Tadaaki Taniguchi, Banyu Pharmaceutical Co., Ltd.*
- 1100-1130 *Tea break*

- 1130-1200 The various investigational phases of clinical research (Phases I-IV)
Dr. Tadaaki Taniguchi, Banyu Pharmaceutical Co., Ltd.
- 1200-1300 *Lunch*
- 1500-1530 *Tea break*
- 1530-1630 Pharmacogenomics
Dr. Shyh-Yuh Liou, Takeda Pharmaceutical Company Limited, Japan

13 October, 2007 Saturday

- 0900-1000 Therapeutic exploratory (with example)
Dr. Kenji Nonaka, Banyu Pharmaceutical Co., Ltd.
- 1000-1100 Therapeutic confirmatory (with example)
Dr. Kenji Nonaka, Banyu Pharmaceutical Co., Ltd.
- 1100-1130 *Tea Break*
- 1130-1230 Therapeutic use (with example)
Dr. Kimihiro Kasamo, Banyu Pharmaceutical Co., Ltd.
- 1230-1330 *Lunch*
- 1330-1500 Safety monitoring and reporting in clinical trials
- Basic principles and evaluation of investigational results (Phase-I and early Phase-II), with a view to further Development
 - Basic principles for decisions regarding further development or discontinuation of a development project
- Dr. Kimihiro Kasamo, Banyu Pharmaceutical Co., Ltd.*
- 1500-1520 *Tea Break*
- 1520-1620 Role of CRO in global drug development
- 1620-1830 Human pharmacokinetics:
- Clinical Application of PKs
 - Special human-pharmacokinetic studies e.g. bioavailability studies of multiple-dose, interaction studies, pregnancy, liver disease *etc.*
- Prof. Dr. Kesara Na-Bangchang, Thammasat University, Thailand*

Study design

15 October, 2007 Monday

- 0900-1030 Study design
- Possible study designs taking into account ethical aspects, indication, controls, patient population, location of the trial centers
 - Trial design (parallel group design, cross over design, factorial design, group sequential design)
 - Design techniques to avoid bias (blinding, randomization)
- Prof. Dr. L. Jeyaseelan, Christian Medical University, Vellore, India*
- 1030-1100 *Tea break*

- 1100-1230 Study design (Cont.)
- Multi centers trials
 - Type of comparison
 - Outcome measurements
- Prof. Dr. L. Jeyaseelan, Christian Medical University, Vellore, India*
- 1230-1330 *Lunch*
- 1330-1500 Statistical considerations
- Biostatistics in the planning phase (estimate of number of cases, randomization, statistical models, definition of end-points, planning of the subsequent evaluation)
 - Statistical analysis plan
 - Analysis sets: full analysis set, per protocol set, missing values and outliers
- Prof. Dr. L. Jeyaseelan, Christian Medical University, Vellore, India*
- 1500-1530 *Tea break*
- 1530-1700 Statistical considerations (Cont.)
- Data transformation
 - Method of statistical analysis (estimation, confidence intervals, hypothesis testing, evaluation of safety and tolerability)
 - Statistical analysis report
- Prof. Dr. L. Jeyaseelan, Christian Medical University, Vellore, India*

Regulatory Issues

16 October, 2007 Tuesday

- 0900-1030 Regulatory aspects of clinical development
Prof. Dr. Koji Kawakami, Graduate School of Medicine and Public Health, Kyoto University, Kyoto, Japan
- 1030-1100 *Tea break*
- 1100-1230 Special topics:
- Genetic engineer product
 - Gene therapy and stem cells
- Prof. Dr. Koji Kawakami, Graduate School of Medicine and Public Health, Kyoto University, Kyoto, Japan*
- 1230-1430 *Lunch & Break*
- 1430-1530 Visiting the Nagasaki University Hospital of Medicine and Dentistry
Director and Prof. Dr. Hitoshi Sasaki, Department of Hospital Pharmacy, Nagasaki University Hospital of Medicine and Dentistry, Japan

Participants's report on Drug Development

Traditional Medicine

17 October, 2007 Wednesday

- 0900-1030 Introduction of Traditional Medicine: Alternative but rational approach
Prof. Dr. Kiichiro Tsutani, Graduate School of Pharmaceutical Sciences, The University of Tokyo, Japan
- 1030-1100 *Tea break*
- 1100-1200 Guidance on herbal medicine
Prof. Dr. Kiichiro Tsutani, Graduate School of Pharmaceutical Sciences, The University of Tokyo, Japan
- 1200-1300 *Lunch*
- 1300-1400 Regulation for traditional medicine development
Dr. Ichiro Arai, Manager, Tsumura Drug Information Library, Tsumura & Co.
- 1500-1530 *Tea break*
- 1530-1700 Example of Clinical Drug development
Dr. Chihiro Takayama, Director, Eisai Co., Ltd., Tokyo, Japan

Module 3: Vaccine Development

Vaccine Discovery

18 October, 2007 Thursday

- 0900-0930 Historical of vaccine Discovery
Dr. Howard Engers, AHRI, Ethiopia
- 0930-1030 Overview of modern vaccine discovery
Dr. Howard Engers, AHRI, Ethiopia
- 1030-1100 *Tea break*
- 1100-1200 Screening for antigens
Prof. Dr. Kenji Hirayama, Director of the course, Institute of Tropical Medicine, Nagasaki University, Japan
- 1200-1330 *Lunch*
- 1330-1430 Evaluating antigens
Prof. Dr. Kenji Hirayama, Director of the course, Institute of Tropical Medicine, Nagasaki University, Japan
- 1430-1500 *Tea break*
- 1500-1600 Visiting Vaccine Discovery Laboratory Institute of Tropical Medicine, Nagasaki University

19 October, 2007 Friday

- 0900-1030 Adjuvant
Dr. Howard Engers, AHRI, Ethiopia
- 1030-1100 *Tea break*
- 1100-1200 Alternatives to antigens: DNA vaccine, Live or attenuated pathogen
Dr. Howard Engers, AHRI, Ethiopia
- 1200-1330 *Lunch*
- 1330-1430 Selection of development candidate and back-ups
Dr. Howard Engers, AHRI, Ethiopia
- 1430-1500 *Tea break*
- 1500-1630 Efficacy, toxicity, route of immunization, price, stability, cold chain,
Dr. Howard Engers, AHRI, Ethiopia

20 October, 2007 Saturday

- 0900-1030 Example: Herbal medicine to modern medicine
Dr. Nasir Shuaibu, COE Resercher, Institute of Tropical Medicine, Nagasaki University, Japan, Nagasaki University
- 1030-1100 *Tea break*

- 1100-1200 Cholera vaccine discovery
Dr. Masahiko Ehara, Nagasaki University, Japan
- 1200-1300 *Lunch*
- 1300-1400 Oral vaccine discovery
*Dr. Takeshi Arakawa, Center of Molecular Biosciences,
University of the Ryukyus, Japan*

Antigen Development

22 October, 2007 Monday

- 1030-1200 Example: Leishmaniasis vaccine discovery and clinical trials
Prof. Dr.Ivan Velez, Universidad de Antioquia, Colombia
- 1200-1300 *Lunch*
- 1300-1415 **Quality Assurance of Vaccine**
Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Tokyo, Japan
- 1415-1430 *Tea break*
- 1430-1600 **Quality Assurance of Vaccine (Continued)**
Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Tokyo, Japan
- 1600-1730 Safety assessment
Toxicity test for animal: regional complications, systemic toxicity such
as fever, anaphylactic shock
Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Tokyo, Japan

Pre-Clinical Development

23 October, 2007 Tuesday

- 0900-1030 Immunogenicity assessment
Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Tokyo, Japan
- 1030-1100 *Tea break*
- 1100-1230 Regulatory
Dr. Yasushi Yoshino, J-Pharma.Co.ltd., Japan
- 1230-1330 *Lunch*

Clinical Development

Overview

- 1330-1430 Assessment of pre-clinical information
Dr. Howard Engers, AHRI, Ethiopia
- 1430-1445 *Tea break*

- 1445-1600 Example: Animal model used in pre-clinical studies
Dr. Shigeyuki Kano, Research Institute, International Medical Center of Japan, Tokyo
- 1600-1700 Clinical development plan
Dr. Howard Engers, AHRI, Ethiopia

Clinical Development

24 October, 2007 Wednesday

Overview

0900-1200 Report on Vaccine R&D

1200-1300 *Lunch*

1300-1430 Application of immunogenicity for vaccine development
Dr. Shigeharu Ueda, The Research Foundation for Microbial Diseases of Osaka University (BIKEN), Japan

1430-1500 *Tea break*

1500-1600 Dose selection and regimen
Dr. Shigeharu Ueda, The Research Foundation for Microbial Diseases of Osaka University (BIKEN), Japan

1600-1730 Participants's report on Vaccine R&D

Module 4: Diagnostic Development

25 October, 2007 Thursday

- 0900- 1530 Discovery and development of diagnostic tools:
Necessity assessment, Principles and technology selection
Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan
- Prototype production and assessment
Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan
- Scale-up, manufacture and control
Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan
- Scale-up, manufacture and control (Cont.)
- Development of kits
Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan
- Quality assurance/quality control: evaluation of efficacy after
application
Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan
- Clinical development: validate prototype, manufacture pilot lot, initiate
clinical trial
Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan
- Clinical development: Supply chain logistics and production, Statistical
consideration, regulatory issues
Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan
- 1600-1700 Herbal medicine to modern medicine in China
*Dr. Luping Qin, School of Pharmacy, Second Military Medical
University, Shanghai, China*

Module 5: Good Clinical Practice

Ethics in research and Ethics Committee

26 October, 2007 Friday

- 1500-1600 Principles of Research Ethics
Prof. Dr. Kenji Hirayama, Director of the course, Institute of Tropical Medicine, Nagasaki University, Japan
- 1600-1730 Research methodology and ethical issues International study -Case studies
Prof. Dr. Kenji Hirayama, Director of the course, Institute of Tropical Medicine, Nagasaki University, Japan

27 October, 2007 Saturday

- 0900-1030 Human Subject Protection and Ethics Committees
Dr. Allan Johansen, Roche Products Pty limited, Australia
- 1030-1100 *Tea break*
- 1100-1230 Human Subject Protection and Ethics Committees Cont.
Dr. Allan Johansen, Roche Products Pty limited, Australia
- 1230-1330 *Lunch*
- 1330-1430 Monitoring and Auditing Ethics Committee
Dr. Allan Johansen, Roche Products Pty limited, Australia
- 1430-1530 Data and Safety Monitoring Board (DSMB)
Dr. Allan Johansen, Roche Products Pty limited, Australia
- 1530-1545 *Tea Break*
- 1545-1630 Case studies
Dr. Allan Johansen, Roche Products Pty limited, Australia

29 October, 2007 Monday

Quality Standards

- 0900-0930 Concept of Good Clinical Practice
Prof. Dr. Juntra Karbwang, WHO/TDR, Geneva, Switzerland
- 0930-1230 Responsibilities
Sponsor (*Dr. Allan Johansen*)
Investigators (*Prof. Dr. Kenji Hirayama*)
IRB (*Prof. Dr. Juntra Karbwang*)
Monitors (*Prof. Dr. Juntra Karbwang*)
DSMB (*Dr. Allan Johansen*)

1230-1330 *Lunch*
1330-1530 *Audit and Inspection*
Dr. Allan Johansen, Roche Products Pty limited, Australia

30 October, 2007 Tuesday

Field Trip to Hisamitsu Pharmaceutical Co.,Inc. by Bus:

at Hisamitsu Kyushu Head Office, Tosu

Contents:

13:00-14:00 Tour the Nakatomi Memorial Medicine Museum
14:30-14:45 Introduction of Hisamitsu
Mr. Hideki Nakano, Manager, Clinical Development Dpt.
14:45-15:45 Tour the Factory
Mr. Shigehiro Osawa, Factory Director
16:00-16:20 Good Manufacturing Practice (GMP)
Mr. Shigeru Makizaki, Manager, Quality Assurance Unit
16:20-16:40 Good Laboratory Practice (GLP)
Mr. Shigeru Makizaki, Manager, Quality Assurance Unit
16:40-17:00 Topics for Research Technology
Dr. Takaaki Terahara, Director of TDDS Laboratory

Operation Manager of all the Tour;

Mr. Takuya Fuchigami, Manager, Clinical Development Dpt.

Module 6: Clinical Data Management

31 October, 2007 Wednesday

- 0900-1000 Overview of clinical data management
Data management plan
Dr. Sangkae Chamnanvanakij, TU-CDMC, Thailand
- 1000-1030 Protocol and CRF
Prof. Dr. Kesara Na-Bangchang, TU-CDMC, Thailand
- 1030-1100 Tea break
- 1100-1145 Development of database using StudyBuilder
Dr. Sangkae Chamnanvanakij & Panida Kongjam, TU-CDMC, Thailand
- 1145-1230 Practical session on Protocol and CRF
Prof. Dr. Kesara Na-Bangchang, TU-CDMC, Thailand
- 1230-1330 Lunch
- 1330-1430 Statistical Analysis Plan (SAP)
Data: primary & secondary data
Prof. Dr. Jia He, Department of Health Statistics, Second military Medical University, China

1 November, 2007 Thursday

- 900-930 Standard Operating Procedures (SOPs)
Prof. Dr. Kesara Na-Bangchang, TU-CDMC, Thailand
- 930-1030 Data coding (demonstration)
 - Adverse Event Dictionary
 - Drug Dictionary*Dr. Sangkae Chamnanvanakij, TU-CDMC, Thailand*
- 1030-1100 Tea Break
- 1100-1230 Quality Control & Assurance (QC & QA)
Prof. Dr. Jia He, Department of Health Statistics, Second military Medical University, China
- 1230-1330 Lunch
- 1330-1400 Development of database using StudyBuilder (Demonstration)
Dr. Sangkae Chamnanvanakij & Panida Kongjam, TU-CDMC, Thailand
- 1400-1530 Practical session on: data verification, entry, validation, audit trail clarification process, data query and resolution and data extraction
Prof. Dr. Kesara Na-Bangchang, Dr. Sangkae Chamnanvanakij and Panida Kongjam, TU-CDMC, Thailand

Module 7: Post-registration Activities

2 November, 2007 Friday

- 0900-1200 Stakeholders to be involved in making product development work for the intended beneficiaries
Prof. Dr. Chitr Sitthi-amorn, Chulalongkorn University, Thailand
Dr. Kihito Takahashi, Japanese Association of Pharmaceutical Medicine (JAPHMED), Merck Banyu Pharma, Japan
- 1200-1300 Lunch
- 1300-1400 Public private partnership
Prof. Dr. Chitr Sitthi-amorn, Chulalongkorn University, Thailand
- 1400-1430 Tea break
- 1430-1530 Medicine Access Problems and PPP
Mr. Kenji Toda, Senior Vice President, Government Relations, Tokyo, Eisai Co., Ltd,

3 November, 2007 Saturday

- 0900-1030 Improving the quality of new products in health systems: International network of rational use of drugs
Prof. Dr. Chitr Sitthi-amorn, Chulalongkorn University
- 1030-1045 Tea break
- 1045-1230 Post-marketing product vigilance
Dr. Yong Huang, Global Pharmacovigilance Otsuka Pharmaceutical Co. Ltd.
Prof. Dr. Yupin Lawanprasert, Principal Scientific Advisor on Safety, Efficacy And Use of Medicines and Health Products, Thailand
- 1230-1330 Lunch
- 1330-1500 Intellectual Property Rights Protection in Developing Countries
Prof. Dr. Hiroko Yamane, Graduate Institute for Policy Studies, Japan

1500-1630 Participants's report on post registration activities

- 1630 Closing Ceremony
Prof. Dr. Hiroshi Saito, President, Nagasaki University
Prof. Dr. Kenji Hirayama, Dean, Institute of Tropical Medicine, and Course Director, Nagasaki University
Prof. Dr. Masao Tomonaga, Dean, Graduate School of Biomedical Sciences, Nagasaki University, Japan
Prof. Dr. Shigeru Kohno, Dean, Faculty of Medicine, Nagasaki University
Prof. Dr. Susumi Hatakeyama, Dean, School of Pharmaceutical Sciences, Nagasaki University

1700-1900 Farewell party