

**1st US-Japan Biostatistics Workshop – Final Program –**

date: SEPTEMBER 26, 2003

place: Translational Research Informatics Center

1-5-4 Minatojima Minami-machi, Chuo-ku, Kobe 650-8543, Japan

10:00

- Opening Remarks

Masanori Fukushima, M.D., Ph.D.

Professor, Translational Research Center

Kyoto University Hospital

**Innovative Design and Analysis in Cancer Clinical Trials**

10:20-12:20

- 1) Session Chairperson

Hideki Origasa, Ph. D.

Professor, Biostatistics

Toyama Medical and Pharmaceutical University

10:20

- 2) CRM (Continual Reassessment Method)

Naoki Ishizuka, Ph. D.

Biostatistician, Data Center

Japan Clinical Oncology Group

11:00

- 3) Recent Attempts and Experiences in Design of Cancer Clinical Trials

Yasuo Ohashi, Ph. D.

Professor, Biostatistics/Epidemiology and Preventive Health Sciences

University of Tokyo

Chairman, Japan Clinical Research Support Unit

11:40

4) Some Design Issues in Cancer Clinical Trials

John J. Crowley, Ph.D.

Director, Statistical Center

Southwest Oncology Group

12:20 Lunch

Statistical Analysis on Integrating Gene Expression Profiling into Clinical Trials

13:20–15:20

1) Session Chairperson

Shigeyuki Matsui, Ph. D.

Associate Professor, Pharmacoepidemiology

Kyoto University

13:20

2) Prognostic Prediction using DNA Microarray Gene Expression Data

Shigeyuki Matsui, Ph. D.

14:00

3) Correlation of Gene Expression Profiles with Survival Times

Donna K. Pauler, Ph.D.

Biostatistician, Statistical Center

Southwest Oncology Group

14:40

4) Gene Exploration and Correlation: Applications to Lymphoma

Michael LeBlanc, Ph.D.

Biostatistician, Statistical Center

Southwest Oncology Group

15:20 Break

Statistical Issues in Analysis and Interpretation of Clinical Studies

15:50–17:20

1) Session Chairperson

Masayuki Imamura, M.D., Ph.D.

Professor, Surgery and Surgical Basic Science

Kyoto University

Toshihiko Morikawa, Ph. D.

General Manager, CDM and Biostatistics

Takeda Chemical Industries, Ltd.

15:50

2) Interpretation of Clinical Trials from the Perspective of Clinicians

Shunzo Maetani, M.D., Ph.D.

Director, Statistical Analysis Group

Tenri Institute of Medical Research

16:20

3) Development and Evaluation of Measurement Methods for Clinical Trials

Eisei Oda, Ph.D.

Biostatistician

Translational Research Informatics Center

16:50

4) Individual Patient-Level and Study-Level Meta-Analysis for Investigating Modifiers of Treatment Effect

Satoshi Teramukai, Ph.D.

Assistant Professor, Translational Research Center

Kyoto University Hospital

17:20

5) Final Remarks

Kiyoyuki Furuse, M.D.

Director

The Japan Multinational Trial Organization

17:30 Reception