

The 2nd



International Workshop

co-sponsored by

Yokohama City University &

FDA (United States Food and Drug Administration) on

Biomarkers for Development of Biological Products and New Therapy

Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (FDA) and Yokohama City University have worked together to mutually promote their research and education in the field of medical and life sciences on the basis of the mutual agreement in 2006. The first workshop was held on January 29-30, 2008 with the theme of "Scientific Tools to promote Biological Medical Product Success."

The subject we are going to discuss this time is "Biomarkers" which has attracted attentions in improving prevention, diagnosis and treatment, and also in accelerating the processes to develop new drugs including biologic therapeutic products. We are inviting well-known scientists from overseas including FDA as well as from Japan and offer the participants/audiences the opportunity to discuss the feasibility and processes for the application of biomarkers in the areas of medical and life sciences. The workshop also provides a forum to move forward with new ideas and technologies into the 21st Century.

Date: *March 4, 2009*

Venue: *Hepburn Hall, Yokohama City University
(Kanazawa-ku, Yokohama)*

Participation Fee: *Workshop ¥10,000/person
(¥5,000 for person from governmental or academic organizations)*

Organizer: *Yokohama City University/CBER-FDA (USA)*

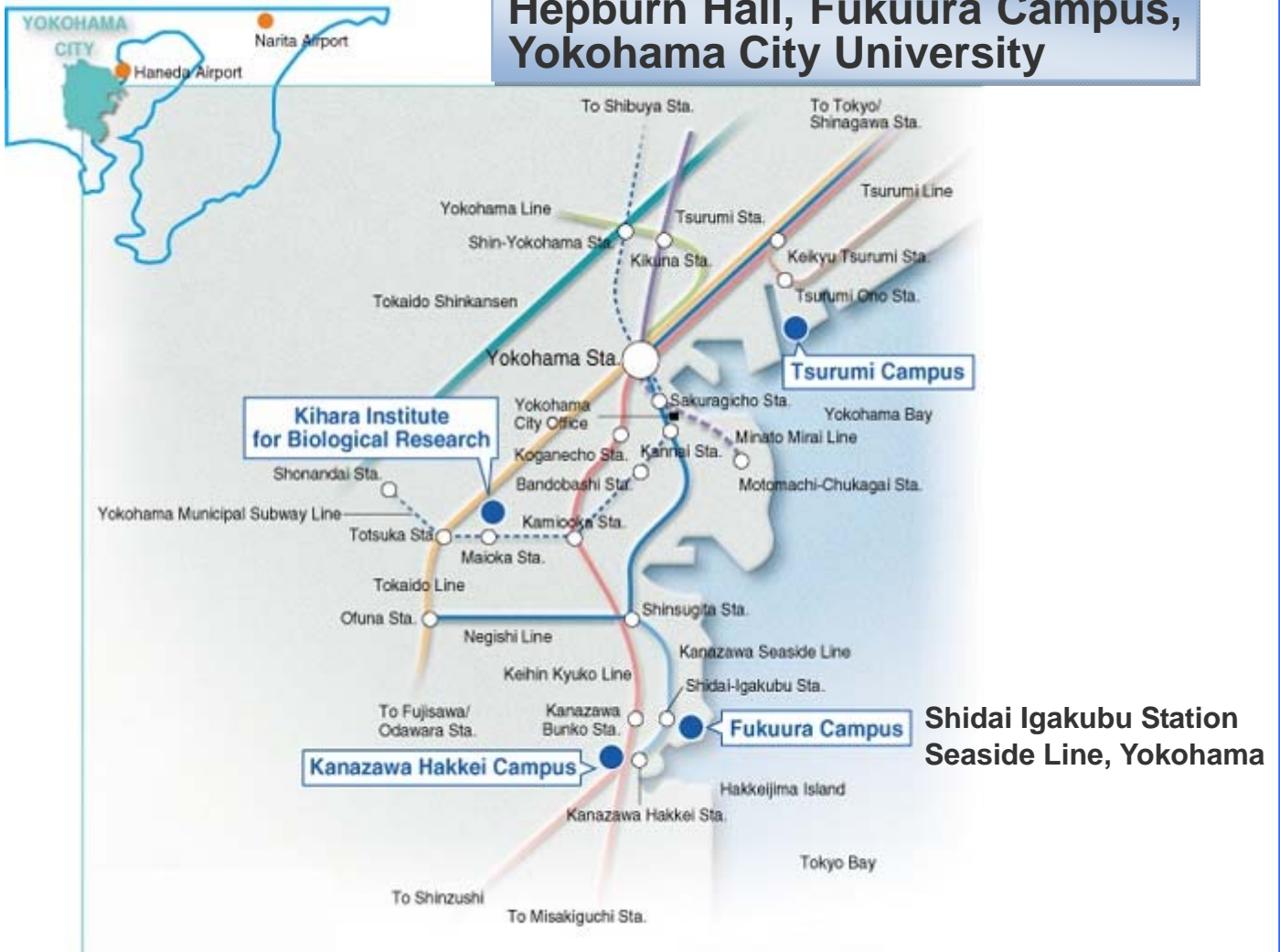
Cooperated by: *Yokohama National University and others*

Supported by: *Ministry of Health, Labour and Welfare, Yokohama City*

Application: The Secretariat of International Workshop by YCU & FDA
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Hepburn Hall, Fukuura Campus, Yokohama City University



What are biomarkers?

Biomarkers are substances contained in urine, serum, tissues, etc. in human body which can be used as markers for specific diseases in prevention, diagnosis and treatment, evaluating morbidity, progression and predicting hyper-sensitivity or little response to a specific drug, etc. The quantitative variation of the substance may correlate with progression or recovery of the diseases. Identifying and measuring such biomarkers can be helpful for early diagnosis, evaluating therapeutic efficacy, improving efficiency of clinical development processes, and establishing a new approach for prevention and treatment of

As a tie-up event with our Workshop, the symposium titled “Innovative Integration between Medicine and Engineering based on ICT (Information & Communication Technology)” will be held on March 5, Thursday, at Pacifico Yokohama, aiming at the establishment of a medical/insurance system with innovative ICT. Together with specialists from overseas, the innovation of medical ICT by global co-working will be actively discussed. Please come and join them too.

**Inquiries : GCOE Office, Medical ICT Center, Yokohama National University
TEL&FAX 045-339-4490 mict@ynu.ac.jp**

PROGRAM

- [9:30 – 10:00] **Opening/Introductory Remarks**
Tsutomu Fuse, PhD, President, Yokohama City University (YCU)
Shuichi Kishida, Councillor for Pharmaceutical Safety Minister's Secretariat Ministry of Health, Labour and Welfare
Tatsuya Kondo, MD, PhD, Chief Executive, Pharmaceuticals and Medical Devices Agency
Chintamani D Atreya, PhD, Associate Director for Research, Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER)/United States Food and Drug Administration (FDA)
- [10:00 – 12:00] **Morning Session: Search and Translational Research on Biomarkers**
- 10:00 – 10:25 **Proteomics in the Search for Biomarkers: Current Status and Future Prospects**
Michail Alterman, PhD, Principal Investigator, Division of Cellular and Gene Therapies, Office of Cellular, Tissue and Gene Therapies, CBER/FDA
- 10:25 – 10:50 **Human Proteomes in the Search for Disease-Related Proteins**
Hisashi Hirano, PhD, Department of Supramolecular Biology, International Graduate School of Arts and Sciences/YCU
- 10:50 – 11:15 **Genes Relevant to Cellular Polarity: From Mouse Models to Human Diseases**
Shigeo Ohno, PhD, Department of Molecular Biology, Graduate School of Medicine/YCU
- 11:15 – 11:40 **Translational Research utilizing Imaging Biomarkers**
Tsuneo Yano, Coordinator, Riken Center for Molecular Imaging Science
- 11:40 – 12:00 **Discussion**
- [12:00 – 13:15] **Lunch Break and Poster Session**
- [13:15 – 15:45] **Afternoon Session 1: Biomarkers for Development of Biological Products and New Therapy**
- 13:15 – 13:40 **The Critical Path to Drug/Device (Companion Diagnostics) Co-development**
Sousan Altaie, PhD, Scientific Policy Advisor, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health (CDRH)/FDA
- 13:40 – 14:05 **Biomarkers for Development of Vaccines against Pandemic Influenza Strains**
Hana Golding, PhD, Senior Investigator, Division of Viral Products, Office of Vaccines Research and Review, CBER/FDA
- 14:05 – 14:30 **Towards Development of In Vitro Biomarkers Predictive of In Vivo Quality for Stored Platelets**
Chintamani D Atreya, PhD, Associate Director for Research, Office of Blood Research and Review, CBER/FDA
- 14:30 – 14:55 **Efficient Neuronal Differentiation of Stem Cells with Intracellular Delivery of a Synthetic Peptide and its Application for Regenerative Therapy**
Hiroshi Kanno, MD, PhD, Department of Neurosurgery, Graduate School of Medicine/YCU
- 14:55 – 15:20 **Biomarkers for the Characterization of Stem Cell Products**
Deborah Hursh, PhD, Senior Investigator, Division of Cellular and Gene Therapies, Office of Cellular, Tissue and Gene Therapies, CBER/FDA
- 15:20 – 15:45 **Discussion**
- [15:45 – 16:00] **Break**
- [16:00 – 17:00] **Afternoon Session 2: Biomarkers in Cardiovascular Diseases**
- 16:00 – 16:25 **Advancing Biomarkers and Biomarker Profiling in Clinical and Translational Research**
Kristin Newby, MD, MHS, Cardiovascular Medicine, Duke University Medical Center
- 16:25 – 16:50 **Cardiac Natriuretic Peptides as Biomarkers of Heart Disease**
Heikki Ruskoaho, MD, PhD, Vice-Rector, Institute of Biomedicine, Department of Pharmacology and Toxicology, University of Oulu, Finland
- 16:50 – 17:00 **Discussion**
- [17:00 – 17:30] **Special Lecture: Interdisciplinary Innovation between Medicine and Engineering Promoted by Global COE Program and International Collaboration**
Ryuji Kohno, PhD, Director, Medical ICT Center, and Division of Electrical & Computer Engineering, Graduate School of Engineering, Yokohama National University
- [17:30 – 17:35] **Closing Remarks**
Yoshihiro Ishikawa, MD, PhD, Dean, Cardiovascular Research Institute, Graduate School of Medicine/YCU
- [17:35 – 18:30] **Poster Discussion**

POSTER SESSION

- 1. EVALUATION OF WEIGHT LOSS PROGRAM BY ASSESSMENT OF EATING BEHAVIOR IN OBESE PEOPLE**
N Sakurai, K Ueki, O Tochikubo and S Mizushima - Department of Ubiquitous Preventive Medicine, YCU Graduate School of Medicine
- 2. ASSOCIATION BETWEEN ANGIOTENSIN II TYPE I RECEPTOR (AGTR1) POLYMORPHISMS AND THE OCCURRENCE OF NONALCOHOLIC FATTY LIVER DISEASE (NAFLD)**
M Yoneda, Y Nozaki, K Fujita and A Nakajima - Division of Gastroenterology, YCU Graduate School of Medicine
- 3. DYSFUNCTIONAL VLDL SYNTHESIS AND RELEASE IS A KEY FACTOR IN NON-ALCOHOLIC STEATOHEPATITIS (NASH) PROGRESSION**
K Fujita, Y Nozaki, M Yoneda, H Kirikoshi, S Saito and A Nakajima - Gastroenterology, YCU Hospital
- 4. FUNCTIONAL ANALYSIS OF A NOVEL PEPTIDE FOR PANCREATIC BETA CELL HYPERPLASIA IN PREGNANT MICE**
J Shirakawa, A Nakamura and Y Terauchi - Department of Endocrinology and Metabolism, YCU Graduate School of Medicine
- 5. IDENTIFICATION OF BINDING PROTEINS FOR HUMAN NEDD4L C2 DOMAIN**
N Araki, T Ishigami, M Umemura, H Ushio, T Obana, M Sato, K Tamura, Y Toya, K Uchino and S Umemura - Department of Cardio-Renal Medicine, YCU Graduate School of Medicine
- 6. ASSOCIATION OF VISCERAL FAT ACCUMULATION AND PLASMA ADIPONECTIN WITH ABERRENT CRYPT FOCI**
H Takahashi, T Uchiyama, K Hosono, H Endo, K Yoneda and A Nakajima - Gastroenterology, YCU Hospital
- 7. ROGNOSTIC FACTORS AFTER RESECTION OF PANCREATIC CANCER**
M Ueda,¹ Y Nagano,¹ Y Minami,¹ S Fujii,¹ K Taniguchi,² R Matsuyama,² K Takeda,² K Matsuo,² K Tanaka,² Y Ichikawa,² I Endo² and C Kunisaki¹ – ¹Gastroenterology, YCU Medical Center, ²Gastroenterological Surgery, YCU Hospital
- 8. ASSOCIATION BETWEEN SERUM TRIGLYCERIDE PROFILE IN LIPOPROTEIN SUBFRACTIONS AND THE RESPONSE TO HEPATITIS C TREATMENT IN JAPANESE WITH GENOTYPE 1B**
H Mawatari, S Saito, H Sasaki, Y Shinohara and A Nakajima - Gastroenterology Division, YCU Graduate School of Medicine
- 9. IMAGING AND GENE THERAPY OF GASTRIC CANCER TINY METASTATIC LESIONS WITH COX2-SPECIFIC REPLICATIVE ADENOVIRUS**
T Kosaka, H A Ono, S Hirai, S Ohno, C Kunisaki and M Masuda - Gastroenterological Surgery, YCU Hospital
- 10. SEQUENCE ANALYSIS OF HEPATITIS C VIRUS FROM A PATIENT WITH A RELAPSE AFTER A SUSTAINED VIROLOGICAL RESPONSE TO PEGYLATED-INTERFERON PLUS RIVAVIRIN**
Y Shinohara, S Saitou, Y Tanaka, H Kirikoshi, H Mawatari, M Yoneda, K Fujita, Y Nozaki and A Nakajima - Gastroenterology Division, YCU Graduate School of Medicine
- 11. A THREE-GENE EXPRESSION SIGNATURE MODEL TO PREDICT CLINICAL OUTCOME OF CLEAR CELL RENAL CARCINOMA**
Y Huang,¹ K Shioi,¹ K Hattori,¹ T Murakami,¹ F Sano,¹ M Baba,¹ K Kondo,¹ N Nakaigawa,¹ T Kishida,¹ Y Nagashima,² Y Kubota¹ and M Yao¹ – ¹Departments of Urology and Molecular Genetics, YCU Graduate School of Medicine, ² Department of Molecular Pathology and Oncology, YCU Graduate School of Medicine
- 12. IMMUNOGENIC COMPARISON OF CHIMERIC ADENOVIRUS 5/35 VECTOR CARRYING OPTIMIZED HIV CLADE C GENES AND VARIOUS PROMOTERS**
M Shoji, A Kondo, A Yoshida, K Okuda and M Shimada - Department of Molecular Biodefense Research, YCU Graduate School of Medicine
- 13. DESIGNED RECOMBINANT ADENOVIRUS TYPE 5 VECTOR INDUCED BROADLY NEUTRALIZING ANTIBODIES AGEINST HIV-1**
T Ura, A Yoshida, S Yoshizaki, S Yashima and M Shimada - Department of Molecular Biodefense Research, YCU Graduate School of Medicine
- 14. ADENOVIRUS TYPE 5 WITH MODIFIED HEXONS INDUCES ROBUST IMMUNE RESPONSES IN MICE WITH PRE-EXISTING IMMUNITY AGAINST ADENOVIRUS TYPE 5**
S Abe, T Ura, A Ino, A Yoshida, S Yoshizaki and M Shimada - Department of Molecular Biodefense Research, YCU Graduate School of Medicine
- 15. A SIGNALING POLYPEPTIDE DERIVED FROM AN INNATE IMMUNE ADAPTOR MOLECULE CAN BE HARNESSSED AS A NEW CLASS OF VACCINE ADJUVANT**
F Takeshita and K Kobiyama - Department of Molecular Biodefense Research, YCU Graduate School of Medicine
- 16. SERUM HEME OXYGENASE 1: A POTENTIAL BIOMARKER FOR INFLAMMATORY AND RHEUMATIC DISEASES**
Y Kirino, M Takeno and Y Ishigatsubo - Department of Internal Medicine and Clinical Immunology, YCU Graduate School of Medicine
- 17. EFFICIENT NEURAL-CREST CELL DIFFERENTIATION OF MOUSE EMBRYONIC STEM CELLS WITH A DEFINED SERUM-FREE**

MONOLAYER CULTURE SYSTEM

Y Aihara,¹ Y Hayashi,² N Arika,³ K Ohnuma,² M Nakanishi,² M Warashina,⁴ H Uchiyama,¹ M Asashima^{2,3,5} and M Kusuda-Furue^{5,6,7} – ¹ International Graduate School of Arts and Sciences, YCU, ² Department of Life Sciences (Biology), Graduate School of Arts and Sciences, University of Tokyo, ³ Department of Biochemistry and Molecular Biology, and Biological Science, Graduate School of Science, University of Tokyo, ⁴ Genome Research Laboratories, Wako Pure Chemical Industries, Ltd., Hyogo, ⁵ International Cooperative Research Project/Japan Science and Technology Agency, Tokyo, ⁶ Japanese Collection of Research Bioresources (JCRB) Cell Bank, National Institute of Biomedical Innovation, Osaka, ⁷ Laboratory of Cell Processing, Stem Cell Research Center, Institute of Frontier Medical Sciences, Kyoto University

18. INDUCING FUNCTIONAL HEPATOCYTES FROM HUMAN HEPATIC STEM CELLS WITH A NOVEL CULTURE SYSTEM

B Li, Y Zheng, Y Miyabe, Y Ueno and H Taniguchi - Department of Regenerative Medicine, YCU Graduate School of Medicine

19. A TRIAL SURVEY FOR SAFETY BIOMARKERS USING CLINICALTRIALS.GOV E-LEARNING SYSTEM (CLINQ)

Y Yamaguchi, PhD,^{1,2} S Haneda² and Y Natsumeda, MD, PhD¹ – ¹ Clinical Research, YCU Graduate School of Medicine, ² Jikko Data Science, Co., Ltd.

20. TRIPLE RULE-OUT” CT ANGIOGRAPHY FOR ACUTE CHEST PAIN: DEVELOPMENT OF A NOVEL COMPUTER-AIDED DIAGNOSIS SYSTEM

K Yoshida, M Gayhart and T Inoue - Radiology, YCU Graduate School of Medicine

21. NEW MOUSE MODEL OF FOCAL SEGMENTAL GLOMERULOSCLEROSIS WITH DEFECTIVE CELL POLARITY IN PODOCYTES

T Hirose, D Satoh, H Kurihara, C Kusaka, H Hirose, K Akimoto, T Matsusaka, I Ichikawa, T Noda and S Ohno - Department of Molecular Biology, YCU Graduate School of Medicine

22. FRONTAL AFFINITY CHROMATOGRAPHY TECHNOLOGY PROVIDES GLYCAN-BINDING PROFILES AND BIOMARKERS OF ANIMAL LECTINS

Y Fujii, S M A Kawsar, R Matsumoto, H Yasumitsu and Y Ozeki - Laboratory of Marine Biochemistry, Department of Environmental Biosciences, International Graduate School of Arts and Sciences, YCU

23. SEROTONIN MEDIATES CROSS MODAL REORGANIZATION OF CORTICAL CIRCUIT

S Jitsuki, H Tada and T Takahashi - Department of Physiology, YCU Graduate School of Medicine

24. EXPRESSION PATTERN OF LOTUS, A NOVEL MOLECULE SERVING FOR NEURAL CIRCUIT FORMATION

M Iketani,¹ Y Sato,^{1,2,3} M Yamaguchi,¹ Y Arie,¹ H Kaneko-Sekiguchi,¹ F Nakamura,¹ Y Goshima,^{1,3} and K Takei^{1,3} – ¹ Department of Molecular Pharmacology and Neurobiology, YCU Graduate School of Medicine, ² Brain Stroke Research Group, Mitsubishi Kagaku Institute of Life Sciences, Tokyo, ³ CREST, Japan Science and Technology Agency, Kawaguchi

25. INVOLVEMENT OF CDK5/GSK3 β /CRMP SIGNALING IN SEMA3A-INDUCED FACILITATION OF AXONAL TRANSPORT

T Hida, K Takeuchi, H Usui and Y Goshima - Department of Molecular Pharmacology and Neurobiology, YCU Graduate School of Medicine

26. MAPPING AND IDENTIFICATION OF DNA DAMAGE IN HUMAN ORGANS BY THE ADDUCTOME APPROACH

RA Kanaly,^{1,3} T Hanaoka² and T Matsuda³ – ¹ Department of Environmental Biosciences, International Graduate School of Arts and Sciences, YCU, ² Department of Pathology, Hamamatsu University School of Medicine, ³ Graduate School of Global Environmental Sciences, Kyoto University