

INTRODUCTION

Over the past 10 years, database research has been essential for business strategy in pharma industry globally. In this seminar, we will have 3 speakers describing how to use medical/drug database for the development of new drugs, proper usage of drugs and also pricing strategy.

First of all, I will introduce the future outlook and some actual cases of CER (comparative effectiveness research) in the context of pharmaeconomics, HTA (health technology assessment) and HERO (health economics outcome research).

Then Professor Sato of Keio University will describe the global trend of global clinical trial.

Finally, Mr. Elze, a specialist of drug development and pricing strategy in Europe, will introduce database analysis and the current change of healthcare systems in each country, and R&D strategies required for pharmaceutical industry under the current circumstance.

I do hope this seminar will be valuable for the people involved with business management, R&D, pricing, and lifecycle management of pharmaceutical company.

KOJI KAWAKAMI

Professor and Chairman, School of Medicine and Public Health, Kyoto University

ROI Maximization and Business Innovation in Pharmaceutical Research & Development

Reforming Pharmaceutical R&D Processes of the Future

Date

Fri 13th January, 2012

Location

Hotel New OTANI ACERO (Seminar), AZALEA (Buffet reception)
4-1 Kioi-cho Chiyoda-ku Tokyo 03-3265-1111

Program

14:00 Opening speech

14:10 **Lecture1 : Professor KOJI KAWAKAMI, MD, PhD**

Professor and Chairman, School of Medicine and Public Health, Kyoto University

- "Pharmaceutical marketing, R&D, and pricing strategies and policy Decision making based on pharmacoepidemiology researches utilizing Various database."

14:50 **Lecture2 : Mr. CHRISTIAN ELZE**

Catenion Partners

- "On the Use of Real-World Clinical Data to Inform R&D Project Strategy Development and Pricing & Reimbursement Negotiations"

Break

16:00 **Lecture3 : Professor YUJI SATO, MD, PhD**

Director, Centre for Clinical Research, Keio University School of Medicine, Tokyo, Japan

- "Globalization of clinical research: future challenges"

16:40 Discussion

17:10 Closing speech

17:30 Buffet reception

19:00 Close

Professor KOJI KAWAKAMI, MD, PhD

“Pharmaceutical marketing, R&D, and pricing strategies and policy Decision making based on pharmacoepidemiology researches utilizing Various database.”



Conducting pharmacoepidemiologic research and CER (comparative effectiveness research) using drug database or clinical trial data has been bringing out the disease area to be targeted and the value and appropriate usage of drugs, and cost-benefit performance based on economic values. In this presentation, I will introduce the examples from our database research projects in Kyoto University with related to the global trend of Health Technology Assessment for the R&D strategy and pricing.

Profile

Professor and Chairman, School of Medicine and Public Health, Kyoto University
Deputy Vice President (Research), Kyoto University
Director (acting), Clinical Trial Management, Kyoto Univ. Hospital Translational Research Center
Adjunct Professor, Keio University Clinical Research Center

(Awards)

2004, 2003 Excellence in IND review, FDA-CBER

2003 Scientific Achievement award, FDA-CBER

(International Meetings)

2008- Board Member (Regulatory Science), International Bio-EXPO

2009- Development Committee, Faculty in Regulatory Science, International Society for Biological Therapy of Cancer (ISBTC)

(Domestic Official Activities)

2009- Committee Member, Health Research Advisory Board Committee, Japan Cabinet

2007- Project Member, Science and Technology Project, Life Science Policy Development, Japan Cabinet

2009- Committee Member (R&D), Industrial Structure Advisory Committee, Ministry of Economy, Trade and Industry (METI)

2008- Committee Member, Science and Technology Policy and Innovation, Ministry of Education, Culture, Sports and Technology (MEXT)

2007- Committee Member, Health Science Advisory Committee (Technology), MHLW

Mr. CHRISTIAN ELZE

“On the Use of Real-World Clinical Data to Inform R&D Project Strategy Development and Pricing & Reimbursement Negotiations”



Real-life data for the targeted indication on drug use and associated diagnosis, co-morbidities, patient characteristics, lab values and other medical interventions have proven to be a highly valuable source of information for both drug candidate differentiation in early clinical development and making the case of health economic benefit of drug use by providing the context for the data gleaned from the pivotal trials.

In my presentation, I will show how at Catenion we have adapted our methodologies to reflect the increasing recognition of the usefulness of such data and I will introduce the most important data sources available to companies in Europe and in the US.

Profile

Christian is a founding Senior Partner of Catenion who lives in London. After graduating from the London School of Economics, he sold machine tools in the Soviet Union and Mexico, worked on a development project in North Yemen and held a position in the controller's department of a German bank. After obtaining his MBA in 1984, he started his consulting career in Sao Paulo and eventually ran the European healthcare practice of Mercer Management Consulting out of Paris.

In 2003, he co-founded Catenion.

Christian has helped numerous clients in the pharmaceutical, medical products and other industries.

Professor YUJI SATO, MD, PhD

■ “Globalization of clinical research: future challenges”



Recent years have seen more multinational, complicated trial implementations, with enormous developments in research objectives, methodologies and questions. Given the increasing number of research-assisting functions and specialization aka compartmentalization, a whole picture of these drastic changes is difficult to be drawn. Along with responding to these changes, universal significance and principles inherent in clinical research needs to be maintained. An overview of these changes in clinical research, seen through the research assistance activities at Keio CCR, is given, together with some suggestions for the future.

Profile

Prof Sato received MD degree from Nihon University. After residency in internal medicine at the St. Luke's International Hospital, he specialised in psychiatry at Nihon University along with pharmacokinetic research. This was followed by a clinical fellowship at the Maudsley Hospital, London, then a visiting scholarship at University of Cambridge. Following assistant professorship in neuropsychiatry at Nihon University, he joined Banyu Pharmaceuticals/MSD. In 2007 he was appointed founding professor of the Centre for Clinical Research at Keio University. Prof Sato is Vice Chairperson of the Japan Association of Pharmaceutical Medicine.