



# ISPE'S 2<sup>nd</sup> ASIAN MEETING SYMPOSIUM AND WORKSHOP PROGRAM

Tokyo, Japan

October 26<sup>th</sup> and 27<sup>th</sup>, 2007

Further information : <http://www.pharmacoepi.org/>

日本語版の最新情報 : <http://www.jspe.jp/index.html>



## Friday 26th October

Speaker

### PART ONE - Symposium

*Japan's integrated health insurance database: Prospects for significant public health improvement through pharmacoepidemiology*

10 am Opening remarks

Introduction to Japan's integrated health insurance database  
日本のレセプト・データベースについて  
Development of, and progress towards Japan's integrated database データベース構築へ向けて  
Potential of the Japanese claims database  
日本のレセプト・データベースの可能性  
Japan's IT strategy for healthcare  
医療分野における日本のIT戦略

**Prof Shigeru Kageyama**

*JSPE president*

**Japan's Vice-Minister of Health,  
Labour and Welfare**

**Mr Kazuhiro Ooshima**

*IT strategy advocate - MHLW*

**Prof Shigekoto Kaihara**

*Dean, Graduate School, International University  
of Health and Welfare, Japan*

**Mr Toru Yamauchi**

*Counselor, Information Technology Policy Office  
Cabinet Secretariat, Government of Japan*

### BREAK

The problem with intent-to-treat analysis in clinical trials to assess safety  
安全性を評価する臨床試験におけるITT解析に伴う問題  
Challenges and potential for database research  
データベースを用いた研究に関する課題と可能性  
National database experience in Taiwan  
台湾におけるナショナル・データベースの経験  
National database experience in Korea  
韓国におけるナショナル・データベースの経験  
A clinical view and potential population benefits from claims database research  
保険請求データベースを用いた研究から得られるもの: 臨床の立場と公衆の利益  
Closing remarks

**Dr Ken Rothman**

*RTI Health Solutions, Boston University School  
of Public Health, USA*

**Dr Alec Walker**

*i3 Drug Safety, Harvard School of Public Health,  
Boston, USA*

**A/Prof Yea-Huei Kao Yang**

*Institute of Clinical Pharmacy, National Cheng  
Kung University Taiwan*

**Dr Byung Joo Park**

*Dept Preventive Medicine Seoul National  
University College of Medicine, Korea*

**Dr Jerry Avorn**

*Department of Pharmacoepidemiology and  
Pharmacoeconomics, Brigham & Women's  
Hospital, Harvard Medical School, USA*

**Dr Yola Moride**

*ISPE president*

1 pm FINISH

LUNCH - for Workshop registrants (第2部参加者は昼食)

### PART TWO - Educational Workshop

*Fundamentals of epidemiology and pharmacoepidemiology*

2 pm Risk and causal inference  
リスクと因果性の推論

Spontaneous reporting  
自発報告

**Dr Ken Rothman**

*RTI Health Solutions, Boston University School  
of Public Health, USA*

**Dr Alec Walker**

*i3 Drug Safety, Harvard School of Public Health,  
Boston, USA*

### BREAK

Designs of observational studies  
観察研究のデザイン

Confounding by indication  
適応による交絡

**Dr Ken Rothman**

*RTI Health Solutions, Boston University School  
of Public Health, USA*

**Dr Alec Walker**

*i3 Drug Safety, Harvard School of Public Health,  
Boston, USA*

### BREAK

Statistical uncertainty and significance  
統計的不確実性と有意性

**Dr Ken Rothman**

*RTI Health Solutions, Boston University School  
of Public Health, USA*

6:25 pm FINISH

7:15 pm DINNER - for Workshop registrants (懇親会)



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## Saturday 27th October

### Case studies of pharmacoepidemiology

8 am Poster sessions

9 am Case 1: Rota virus vaccine  
ケース1: ロタ・ウイルス・ワクチン

**Dr Alec Walker**

*i3 Drug Safety, Harvard School of Public Health,  
Boston, USA*

### BREAK (Poster session)

Case 2: Avian influenza treatment  
ケース2: 鳥インフルエンザの治療

**Dr Nancy Dreyer**

*Outcome - Boston USA*

11:50 am LUNCH

### Pharmaceutical product risk management: Recent experience and practice developments

0:50 pm Overview: Risk management programs in Japan  
日本におけるリスク管理プログラムの概観

**Dr Kiyoshi Kubota**

*Drug Safety Research Unit Japan, Faculty of  
Medicine, University of Tokyo*

The creation, use and the impact of E2E Guidelines in Japan  
E2Eガイドラインの作成、日本での実装とそのインパクト

**Prof Yusuke Tanigawara**

*Pharmacy Dept, Keio University Hospital, Tokyo*

European experiences in risk management programs  
リスク管理プログラム — ヨーロッパでの実績

**Dr Stella Blackburn**

*The European Medicines Agency, (EMA)  
London UK*

North American experiences in risk management programs  
リスク管理プログラム — 北米での実績

**Dr Yola Moride**

*Faculty of Pharmacy, Université de Montréal  
Canada*

Symposium: Cases for risk management programs  
シンポジウム: リスク管理プログラムの実例

**Moderator: Dr Yola Moride**

**Case Presenters and Speakers:**

**Dr Stella Blackburn, Dr Jerry Avorn,**

**Ms Hiroko Marui,**

*Chugai Pharmaceutical Co, Japan*

**Dr John Knight**

*Johnson & Johnson. Asia Pacific*

### BREAK

Registries as a tool for risk management  
リスク・マネジメントのツールとしての登録制度

**Dr Nancy Dreyer**

*Outcome - Boston USA*

Utility of Japanese claims databases and health screening data in  
the future risk management program  
今後のリスク管理プログラムにおける日本のレセプト・データベースと  
健康診断のデータの有用性

**Mr Shinya Kimura**

*Japan Medical Data Center (JMDC), Tokyo*

Closing remarks

**JSPE Vice President & ISPE President**

5:40 pm FINISH