E1506

The *Drug Information Association*
Workshop on

NEW ICH GUIDELINE
on
STATISTICAL PRINCIPLES FOR CLINICAL TRIALS

April 9 & 10, 1997
Hotel LE MERIDIEN
NICE, France

* *PROGRAMME CHAIRPERSON* *

*Karsten **SCHMIDT**, EFSPI Vice President, Spadille Biostatistics ApS, Denmark*

* *FACULTY* *

*Mick **GODLEY**, EFSPI President, Zeneca Pharmaceuticals, UK*
*Marlis **HERBOLD**, EFSPI Council, Hoechst Marion Roussel, Germany*
*Bernhardt **HUITFELDT**, EFSPI Council, Astra Arcus AB, Sweden*
*Paul **KOOPMAN**, EFSPI Council, U-Gene Research BV, The Netherlands*
*Jean-Christophe **LEMARIE**, EFSPI Council, Hoechst Marion Roussel, France*
*Annick **LEROY**, EFSPI Council, Bristol-Myers Squibb Int. Corp. PRI, Belgium*
*John **LEWIS**, Medicines Control Agency, UK*
*Willi **MAURER**, EFSPI Council, Novartis, Switzerland*
*Hans **MELANDER**, Medical Products Agency, Sweden*
*Franck W. **ROCKHOLD**, Merck & Co., Inc., USA*
*Robert **O'NEILL**, Food and Drug Administration, USA*
*Joachim **RÖHMEL**, Federal Institute for Drugs & Medical Devices, Germany*
*Tosiya **SATO**, Institute of Statistical Mathematics, Japan*
*Helmut **SCHÄFER**, Institute of Medical Biometry, University of Marburg, Germany*
*Hiroyuki **UESAKA**, Nippon Hoechst Marion Roussel Ltd., Japan*

PROGRAMME

DRUG INFORMATION ASSOCIATION
European Office
Postfach
4012 - BASEL, Switzerland
Tel.: +41 61 382 90 19
Fax: +41 61 382 90 50
E-Mail: diaeurope@stepnet.de

DRUG INFORMATION ASSOCIATION
321 Norristown Road
Suite 225
AMBLER, PA 19002-2755, USA
Tel.: +1 215 628 2288
Fax : +1 215 641 1229
E-Mail: dia@diahome.org

Visit the DIA Home Page !
http://www.diahome.org

PROGRAMME

WEDNESDAY, April 9, 1997

13:00 **Registration**

14:00 **SESSION 1**
Session Chairperson:
Karsten Schmidt
Spadille Biostatistics ApS, Denmark

Chairperson's Introduction

The Development and Impact of the new ICH E9 Step 3 Draft Guideline on Statistical Principles for Clinical Trials
Bernard Huitfeldt
Astra Arcus AB, Sweden

14:50 **SESSION 2**

Theme: **Most Important Points to Consider from the Perspective of *Regulatory Agencies* and *Academia***
Session Chairperson:
Mick Godley
Zeneca Pharmaceuticals, UK

▷ **The *US* Perspective**
Robert O'Neill
Food & Drug Administration, USA

▷ **The *Japanese* Perspective**
Tosiya Sato
Institute of Statistical Mathematics, Japan

15:30 **COFFEE-BREAK**

16:00 **SESSION 2 (continued)**

▷ **The *EU* Perspective**
John Lewis
Medicines Control Agency, UK

▷ **The *Academia* Perspective**
Helmut Schäfer
Institute of Medical Biometry, Germany

16:40 **Formation of Working Groups**

17:00 **Close of Wednesday Sessions**

18:00-19:00 *** Reception ***

19:00 **Working Group Sessions**

THURSDAY, April 10, 1997

08:30 **SESSION 3**

Theme: **Most Important Points to Consider from the Perspective of the *Pharmaceutical Industry***
Session Chairperson:
Mick Godley
Zeneca Pharmaceuticals, UK

▷ **The *Japanese* Perspective**
Hiroyuki Uesaka
Nippon Hoechst Marion Roussel Ltd., Japan

▷ **The *US* Perspective**
Frank Rockhold
Merck & Co., Inc., USA

▷ **The *EU* Perspective**
Speaker to be announced

09:30 **COFFEE-BREAK**

10:00 **SESSION 4**

Five topics introduced by the Working Group Chairpersons and General Discussion
Session Co-Chairpersons:
Mick Godley
Zeneca Pharmaceuticals, UK
& **Karsten Schmidt**
Spadille Biostatistics ApS, Denmark

PANEL DISCUSSION with:
John LEWIS, Medicines Control Agency, UK
Joachim RÖHMEL, BfArm, Germany
Hans MELANDER, Medical Products Agency, Sweden
Robert O'NEILL, Food & Drug Administration, USA
Tosiya SATO, Institute of Statistical Mathematics, Japan

12:30 **LUNCHEON**

14:00 **SESSION 4 (continued)**

15:45 **Conclusions to be drawn from the Discussion**

16:00 **Close of the Workshop**

Statements made by Speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.