



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
Martis HERBOLD, EFSPi Council, Hoechst Marion Roussel, Germany
Bernhardt HUITFELDT, EFSPi Council, Astra Arcus AB, Sweden
Paul KOOPMAN, EFSPi Council, U-Gen 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

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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.
