The Drug Information Association announces its
7th Annual European Workshop on

STATISTICAL METHODOLOGY
IN CLINICAL RESEARCH & DEVELOPMENT

April 15-17, 1996
Hotel SHERATON
COPENHAGEN, Denmark
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PROGRAMME COMMITTEE

Dr. Bernhard HUITFELDT
Astra Arcus AB, Sweden
Dr. Hans MELANDER
Medical Products Agency, Sweden
Karsten SCHMIDT
Spadille Biostatistics ApS, Denmark
Per TANGHØJ
H. Lundbeck A/S, Denmark
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WORKSHOP OBJECTIVES

The goal of the Workshop is to provide an open forum for statisticians from the pharmaceutical industry, academia, and regulatory bodies involved in drug development for discussion of important statistical issues of current interest. The various sessions will allow ample time for discussion and sharing of experience between Speakers and Participants.

WHO SHOULD ATTEND?

Statisticians, and those with a keen interest in the application of statistics to drug development, from the pharmaceutical industry, academia and regulatory bodies, and elsewhere.

WORKSHOP PROFILE

This will be the seventh Workshop of its kind in Europe. It will be comprised of four sessions. Two of them will be dealing with statistical methodology issues of current interest, viz. planning and analysis of dose-response studies and multicentre trials. One session will deal with issues concerning the regulatory review process, and one with a qualitative approach to the role of statistics. The format will allow plenty of time for discussion with contributions from invited discussants and from the audience.

EXHIBITION

The DIA will provide the opportunity for Pharmaceutical Industry Support Organizations to exhibit their materials and services at this meeting. To obtain details on exhibition space and facilities, interested Exhibitors should contact:
Ms. Eileen KOTEL, DIA, P.O.Box 3113, MAPLE GLEN, PA 19002, USA
Tel.: +1 215 628 22 88 or Fax: +1 215 641 1229
**PROGRAMME**

**SUNDAY, April 13, 1996**

13:00-20:00 Registration

**MONDAY, April 14, 1996**

09:00 WELCOME & INTRODUCTION

**SESSION 1**
Theme: REGULATORY REVIEW OF STATISTICS, STATISTICAL HARMONIZATION, AND THE ICH PROCESS
Session Chairperson: Karsten Schmidt
Spadille Biostatistik ApS, Denmark

How is the Review Done?
Which are the Major Points to Consider by the Applicant?
Do the Agencies offer Consultations?

- Professor John Lewis
  Medicines Control Agency, UK
- Dr. Hans Melander
  Medical Products Agency, Sweden
- Professor Joachim Röhmel
  Federal Institute for Drugs & Medical Devices, Germany
- Dr. Robert O’Neill
  Food and Drug Administration, USA

10:30 COFFEE-BREAK

11:00 PANEL DISCUSSION 1
with:
- Professor John Lewis
  Medicines Control Agency, UK
- Dr. Hans Melander
  Medical Products Agency, Sweden
- Professor Joachim Röhmel
  Federal Institute for Drugs & Medical Devices, Germany
- Dr. Robert O’Neill
  Food and Drug Administration, USA
- Dr. Stephen J. Rubarg
  Hoechst Marion Roussel Inc., USA
- Nick Godley
  Zeneca Pharmaceuticals, UK

**ISSUE 2**
Baseline Comparisons of Patient Characteristics and the Use of Covariates, Stratification and Sub-Group Analysis
Simon Day
Leo Laboratories Ltd., UK

**ISSUE 3**
Multiplicity Issues in Repeated Measurements and Multiple Efficacy Outcome Variables
Lennart Claesson
Astra Arcus AB, Sweden

12:30 LUNCHEON

14:00 PANEL DISCUSSION 1 (continued)

**ISSUE 4**
Statistical Analysis of Safety Data from Efficacy Trials
Joachim Vollmar
Pharmaceutical Research Associates, Germany

15:00 COFFEE-BREAK

15:30 PANEL DISCUSSION 2
with:
- Françoise de Crémiers
  Wyeth-Lederle, France
- Professor John Lewis
  Medicines Control Agency, UK
- Dr. Robert O’Neill
  Food and Drug Administration, USA

**ISSUE 1**
The ICH Process and the Guideline "Content and Structure of Clinical Study Reports"
John Shelton
Wyeth Research, UK

**ISSUE 2**
The new ICH Topic on Biostatistical Methodology
Professor Joachim Röhmel
Federal Institute for Drugs & Medical Devices, Germany

17:30 End of Monday Sessions

17:30-18:30 Workshop Reception
TUESDAY, April 16, 1996

09:00 SESSION 2
Theme: A QUALITATIVE APPROACH TO THE ROLE OF STATISTICS
Session Chairperson:
Per Tønnesen
H. Lundbeck A/S, Denmark
The Idea of Statistical Thinking
The Responsibility of the Statistician to Promote a "Water View" of Statistics
Professor Chris J. Wild
University of Auckland, New Zealand
Support and Illumination
How does Statistical Modelling and Modification of Data fit into the Overall Objective: to Facilitate the Human Understanding of Data?
Professor David J. Finney
University of Edinburgh, Scotland
10:30 COFFEE-BREAK
11:00 SESSION 2 (continued)
The Communication of Statistical Results
Dialogue rather than Monologue, in the Language of the Non-Statistician
Dr. Bjørn Andersen
University of Copenhagen, Denmark
11:30 PANEL DISCUSSION with Session Speakers
12:15 LUNCH

13:45 SESSION 3
Theme: PLANNING AND ANALYSIS OF DOSE-RESPONSE STUDIES
Session Chairperson:
Dr. Hans Wiedenhaefer
Medical Products Agency, Sweden
Clinical and Regulatory Needs for Dose-Response Information
Dr. John Warren
Medicines Control Agency, UK
Design and Analysis of Dose-Response Studies
Dr. Stephen J. Rubberg
Hoechst Marion Roussel, Inc., USA
16:00 COFFEE-BREAK

15:30 SESSION 3 (continued)
Adaptive Dose-Finding
Professor Peter Buehr
University of Vienna, Austria
16:00 PANEL DISCUSSION
with Session Speakers
17:00 End of Tuesday Sessions
18:00 Optional Workshop Dinner

WEDNESDAY, April 17, 1996

09:00 SESSION 4
Theme: STATISTICAL ISSUES IN MULTICENTRE TRIALS
Session Chairperson:
Dr. Bernhard Huffeldt
Astra Arcus AB, Sweden
Interpreting Interaction: The Classical Approach
Dr. Steve Snapinn
Merck Research Laboratories, USA
Treatment by Centre Interaction: What is the Issue?
Dr. Anders Källén
Astra Draco AB, Sweden
10:30 COFFEE BREAK
11:00 SESSION 4 (continued)
A Non-Parametric Approach to Addressing the Role of Centres in a Multi-Centre Trial
Professor Gary G. Koch
University of North Carolina, USA
11:45 PANEL DISCUSSION
with Session Speakers and:
Professor Joachim Röhmel
Federal Institute for Drugs & Medical Devices, Germany
12:30 Close of the Workshop

For any additional information, please contact your nearest DIA Office:

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