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 ROTH, 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 14, 1996

13:00-
20:00 Registration

MONDAY, April 15, 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. Ruberg
  Hoechst Marion Roussel Inc., USA
- Mick Godley
  Zeneca Pharmaceuticals, UK

Issue 1

Data Monitoring, Continuous Data Quality Control, Data Cleaning and Blind Pre-Analysis Review of Data
L... Mats Lörstad
Astra AB, Sweden

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

Issue 5

Statistical Documentation Requirements
Andreas Zipfel
Synthélabo Recherche, France

15:00 COFFEE-BREAK

15:30 PANEL DISCUSSION 2
with:
- Françoise de Crémiers
  Wyeth-Lederlé, 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

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17:30-
18:30 Workshop Reception

PROGRAMME

TUESDAY, April 16, 1996

09:00 SESSION 2
Theme : A QUALITATIVE APPROACH TO THE ROLE OF STATISTICS
Session Chairperson :
Per Tanghøj
H. Lundbeck A/S, Denmark

The Idea of Statistical Thinking
The Responsibility of the Statistician to Promote a "Wider 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. Björn Andersen
University of Copenhagen, Denmark

11:30 PANEL DISCUSSION with Session Speakers

12:15 LUNCHEON

13:45 SESSION 3
Theme: PLANNING AND ANALYSIS OF DOSE-RESPONSE STUDIES
Session Chairperson :
Dr. Hans Melander
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. Ruberg
Hoechst Marion Roussel, Inc., USA

15:00 COFFEE-BREAK

15:30 SESSION 3 (continued)

Adaptive Dose-Finding
Professor Peter Bauer
University of Vienna, Austria

16:00 PANEL DISCUSSION
with Session Speakers

17:00 End of Tuesday Sessions

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19:00 Optional Workshop Dinner

WEDNESDAY, April 17, 1996

09:00 SESSION 4
Theme : STATISTICAL ISSUES IN MULTICENTRE TRIALS
Session Chairperson :
Dr. Bernhard Huitfeldt
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-Parametic 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

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

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