Drug Information Association

FORUM on

EUROPEAN BIOSTATISTICS GUIDELINES

COPITHORNE TARA Hotel
LONDON, UK, 6-7 October, 1993

PROGRAM CO-CHAIRPERSONS
Dr. Jørgen Seldrup
ITEM, France
Professor John Lewis
University of Kent, UK

This Forum is intended to facilitate free discussion about the CPMP Note for Guidance: Biostatistical Methodology in Clinical Trials in Applications for Marketing Authorisations for Medicinal Products.

There will be six Sessions:
* **Session 1** will concentrate on the intended purpose, format and general approach of the Guidelines.
* **Sessions 2 to 5** will each examine in sequence approximately one quarter of the Guidelines.
* **Session 6** will attempt to evaluate the relative importance and degree of agreement attached to the points raised.

Each Session will have a Panel of Experts to assist the Chairperson in stimulating and directing discussion.

Delegates who have indicated an interest in raising a topic will be provided with an opportunity to do so during the relevant Session.

The following programme indicates some of the topics likely to be raised in each Session.

Delegates are strongly encouraged to indicate their interest in contributing to the discussion on these or other topics by completing and returning the attached Questionnaire to the

DIA Registration Desk, by Wednesday, October 6 - 12:00 h
WEDNESDAY, October 6, 1993

09:30 Registration

11:00 INTRODUCTION TO THE FORUM
Dr. Jørgen Seldrup
ITEM, France
&
Professor John Lewis
University of Kent, UK

INTRODUCTION TO THE DRAFT GUIDELINE
Professor David Jones
University of Leicester, UK
&
Professor Joachim Röhmel
Bundesgesundheitsamt, Germany

11:30 SESSION I
Theme: The Guidelines - Is the General Approach Right?
Session Chairperson:
Dr. Jørgen Seldrup
ITEM, France

SECTIONS covered: 1

TOPICS raised:
* Relationship to other Guidelines
* Intended purpose and audience
* Role of statistician
* Scatter of protocol issues
* Philosophy: frequentist, Bayesian, other?

PANEL with:
Professor David Jones, University of Leicester, UK
Professor John Lewis, University of Kent, UK
Professor Joachim Röhmel, Bundesgesundheitsamt, Germany

14:00 SESSION II
Theme: Planning and Special Designs
Session Chairperson:
Professor John Lewis
University of Kent, UK

SECTIONS covered: 2 and 3

TOPICS raised:
* Multicentre trials
* Equivalence trials
* Crossover trials
* Distributional problems

PANEL with:
Dr. Sylvain Durrleman, Rhône-Poulenc Rorer, France
Dr. Sheila Gore, Institute of Public Health, UK
Professor Peter Freeman, University of Exeter, UK

15:30 COFFEE-BREAK

16:00 SESSION III
Theme: Further Protocol Issues
Session Chairperson:
Dr. Jørgen Seldrup
ITEM, France

SECTIONS covered: 4, 5, 6, 7 & 8

TOPICS raised:
* Randomisation
* Documentation of excluded patients
* Blinding
* Sample size

PANEL with:
Dr. Karsten Schmidt, Spadille Biostatistik, Denmark
Dr. Alan Ebbutt, Glaxo Group Research, UK
Professor Helmut Schäfer, Philipps-Universität Marburg, Germany

17:30 End of the Wednesday Sessions

17:30 - 18:30 Reception
THURSDAY, October 7, 1993

09:00 SESSION IV
Theme: Pre-specified Data Analysis
Session Chairperson:
Professor John Lewis
University of Kent, UK

SECTIONS covered: 9

TOPICS raised:
  * Intention-to-treat
  * Multiplicity
  * Interactions
  * Missing data

PANEL with:
Dr. Deborah Ashby, University of Liverpool, UK
Dr. Manfred Wargenau, Focus, Germany
Dr. Andrew Grieve, Zeneca Pharmaceuticals, UK

10:30 COFFEE-BREAK

11:00 SESSION V
Theme: Conduct, Analysis and Overview
Session Chairperson:
Dr. Jørgen Seldrup
ITEM, France

SECTIONS covered: 10, 11, 12, 13 & 14

TOPICS raised:
  * Replication of trials
  * Overviews
  * Safety

PANEL with:
Dr. Hans Melander, Medical Products Agency, Sweden
Dr. Trevor Lewis, Pfizer Central Research, UK
Dr. Gerhard Dietlein, Ciba, Germany

12:30 LUNCHEON

14:00 SESSION VI
Theme: Summary & Evaluation
Session Chairperson:
Professor John Lewis
University of Kent, UK

QUESTIONS
  * What must stay in the Guidelines?
  * What are the key areas for change?

PANEL with:
Dr. Jørgen Seldrup, ITEM, France
Professor Joachim Röhmel,
Bundesgesundheitsamt, Germany
Professor David Jones, University of Leicester, UK

15:30 Close of the Workshop & Farewell Coffee

Key Workshops of interest to our Statistician Colleagues:

April 25-27, 1994
STATISTICAL METHODOLOGY IN CLINICAL RESEARCH AND DEVELOPMENT
5th European Workshop
Chairperson: Dr. Stephen Senn, CIBA, Switzerland
Sheraton Hotel, Edinburgh, Scotland

April 27 & 28, 1994
EUROPEAN CONSENSUS ON STATISTICAL PRACTICE IN GLOBAL DRUG DEVELOPMENT
Chairpersons:
A. Zipfel, Syntheilabo Recherche, France;
A. Robertson, Zeneca Pharmaceuticals, UK;
M. Girelli, Glaxo SpA, Italy &
K. Schmidt, Spadilie Biostatistik Aps, Denmark
Sheraton Hotel, Edinburgh, Scotland