



Drug Information Association

FORUM on

EUROPEAN BIostatISTICS GUIDELINES

COPTHORNE 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

PROGRAMME

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

12:30 LUNCHEON

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, Synthelabo Recherche, France;

A. Robertson, Zeneca Pharmaceuticals, UK;

M. Girelli, Glaxo SpA, Italy &

K. Schmidt, Spadille Biostatistik Aps, Denmark
Sheraton Hotel, Edinburgh, Scotland