Drug Information Association

announces a Workshop on

A EUROPEAN CONCEPT FOR GOOD STATISTICAL PRACTICE IN GLOBAL DRUG DEVELOPMENT

April 27 & 28, 1994
Sheraton Hotel, EDINBURGH, Scotland, UK

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PROGRAM CO-CHAIRPERSONS

Andreas **Zipfel,** EFSPI President, Synthélabo Recherche, France
Annette **Robertson,** EFSPI Council, Zeneca Pharmaceuticals, UK
Marco **Girelli,** EFSPI Council, Glaxo SpA, Italy
Karsten **Schmidt,** EFSPI Council, Spadille Biostatistik Aps, Denmark

DISCUSSANT PANEL

Deborah **Ashby,** CSM, UK; Sylvain **Durrlemann,** Rhône-Poulenc Rorer, France;
Uwe **Ferner,** F. Hoffmann-La Roche, Switzerland; David **Jones,** University of Leicester, UK;
Willi **Maurer**, Sandoz, Switzerland; Robert **O'Neill,** FDA, USA; Stephen **Senn,** Ciba, Switzerland.

WHO SHOULD ATTEND

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

BACKGROUND

The CPMP Working Party on Efficacy of Medicinal Products has recently released a draft of the "***Note for Guidance on Biostatistical Methodology in Clinical Trials in Drug Licence Applications***" (III/3630/92, Draft 4). This document is widely discussed and many position papers are circulating among expert groups at a national and international level from industry, academia and regulatory agencies.

The final EC Biostatistics guidelines will certainly have a very important impact on European regulatory practice. For this reason there is an urgent need for a general European concept for Good Statistical Practice (GSP) issues comprising the views of professionals with different backgrounds (industry, academia and regulatory agencies), and from the different relevant disciplines, such as statistics, data management, clinical research, and regulatory affairs.

The European concept must also take into account the FDA standards, and other international regulatory requirements, since most pharmaceutical companies operate on a global basis.

It is the objective of this meeting to identify and discuss those aspects of most relevance to the issue of good statistical practice.

DISCUSSION TOPICS

Topics Related to the statistical contents of single reports

1. How many populations must be analyzed and how should they be defined (Intention-to treat; eligible; per protocol population, etc)?
   Discussion Coordinator: Klas Svensson, Astra Draco AB, Sweden

2. How much detail on confirmatory statistics and how much on exploratory statistics must a statistical report contain (e.g: testing of baseline differences and consequences, robustness of statistical methods, etc)?
   Discussion Coordinator: Andreas Zipfel, EFSPI President, Synthelabo Recherche, France

3. Statistical Tests and Estimations (hypothesis tests, equivalence tests, confidence intervals).
   Discussion Coordinator: Karsten Schmidt, EFSPI Council, Spadille Biostatistik Aps, Denmark

4. Placebo controlled trials and alternatives.
   Discussion Coordinator: Horst Nowak, Asta Medica, Germany

Topics Related to statistical procedures in a new drug application

5. Standard operating procedures and quality control of the statistical contents of reports.
   Discussion Coordinator: Annette Robertson, EFSPI Council, Zeneca Pharmaceuticals, UK

6. Interim Analyses
   Discussion Coordinator: Annick Leroy, Bristol Myers Squibb, Belgium

7. Format of overviews (integrated and efficacy reports)
   Discussion Coordinator: Rémy von Frenckell, Bristol Myers Squibb, Belgium

8. The Issue of Multicentre Trials: Can one multicentre trial be an alternative to the concept of "at least two pivotal studies"?
   Discussion Coordinator: Marco Girelli, Glaxo SpA, Italy

WORKSHOP FORMAT

Sessions of this Workshop will be dedicated to discussion of the listed topics. The discussion will be led by the respective Chairperson, and members of the discussant panel. As a discussion basis, a short working document will be mailed to all those registered for the Workshop **two weeks prior to the event**; this document will be available at the registration desk for those who register after this date. All participants will have the opportunity to contribute from the floor.

PROGRAM SCHEDULE

WEDNESDAY, April 27, 1994		THURSDAY, April 28, 1994	
11:00	Registration	08:30	TOPIC 4
14:00	Opening & Introduction	09:30	TOPIC 5
14:30	TOPIC 1	10:30	Coffee-Break
15:30	Coffee-Break	11:00	TOPIC 6
16:00	TOPIC 2	12:00	Luncheon
17:00	TOPIC 3	13:30	TOPIC 7
18:00	End of Wednesday Sessions & Reception	14:30	Coffee-Break
		15:00	TOPIC 8
		16:00	Conclusions & Close of the Workshop