

EFSPI

European Federation of Statisticians in the Pharmaceutical Industry

David Morgan
President, EFSPI

SSL meeting: 16 October 2002

CONTENTS

- Objectives of EFSPI
- Member groups
- Activities
- Into the Future

STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY

- Over 2,000 statisticians employed in Europe in
 - pharmaceutical companies
 - Contract Research Organisations
 - drug regulatory authorities
 - chiefly in clinical trials
- Have common requirements

EFSPI OBJECTIVES

- To promote professional standards of statistics and the standing of the statistical profession in the pharmaceutical industry
- To offer a collective expert input on statistical matters to national and international authorities and organisations
- To exchange information on and harmonise attitudes to the practice of statistics in the European Pharma industry and within member groups.

EFSPI HISTORY

- Founded 1992
- No individual members
 - A federation of national groups
- Now grown to 11 national groups
- Over 2000 members in total

EFSPI PRESIDENTS

1990	Alec Vardy	UK/NL
1992	Andreas Zipfel	DE/FR
1994	Karsten Schmidt	DK
1996	Mick Godley	UK
1997	Bernhard Huitfeldt	SW
1999	Paul Koopman	NL
2001	David Morgan	UK

EFSPI MEMBER GROUPS

- Free-standing associations
 - UK, Denmark, Italy, Spain, Finland
- Subgroup of national statistics society
 - France, Sweden, Belgium, Netherlands
- Subgroup of International Biometric Society
 - Germany, Switzerland

EFSPI GROUP NUMBERS

UK (PSI)	1018	Italy	75
Germany	272	Netherlands	75
France	168	Switzerland	75
Sweden	105	Denmark	68
Belgium	82	Finland	47
		Spain	40

EFSPI REGULATORY INPUT

- CPMP Biostatistics guidelines – 1994
 - Consultative meetings held with DIA
- ICH E3: Clinical Trial Reports
- ICH E6: Good Clinical Practice
- ICH E9: Statistical Principles – 1998
- ICH E10: Control Groups – 2000
- CPMP Points to Consider papers

EFSPI MEETINGS INPUT

- Statistical meetings with DIA
 - regulatory consultation 1993, 1994, 1997, 1999
 - active participation in European Statistics Advisory Committee of DIA and annual Clinical Statistics workshops
 - non-clinical meetings 1996, 1998, 2000, 2002
- International Statistical Institute
 - sessions at ISI 1993 and 1999
- Meeting with commercial organiser 2001

PROMOTING PROFESSIONAL STANDARDS

- EFSPI Working Party on qualifications and experience needed to be a statistician in the pharma industry
 - current situation and recommendations
 - paper in Drug Information Journal - 1999
 - presentations in Finland, UK, Sweden, Italy
- Comments on ICH E10
 - paper in Drug Information Journal - 2001

EXCHANGING INFORMATION

- EFSPI web-site has
 - links to all member group web-sites
 - re-launch soon!
 - links to regulatory and other sites of interest
- Activities of one member group open to others
- Links with US and Japanese pharmaceutical statistics groups
- Informal networks of non-clinical and veterinary statisticians

CURRENT ACTIVITIES

- Established permanent office
 - 20 hours per month
- Established budget!
- Re-launch web-site
 - Amateur to professional
- Produced publicity leaflet – launched TODAY
- Comments on regulatory documents
- Scientific Meetings policy

ACHIEVEMENTS OF THE PROFESSION

- Clear regulatory framework established for statistical work in clinical trials
- Statistical role in companies well established
- Statistical role in regulatory authorities established
- Industry/regulatory dialogue in place
- Good programme of international statistical meetings
- EFSPi has played its part in all of these

EFSPI: THE FUTURE

- Core objectives remain relevant
 - Regulatory input is key
- Web-site
- ? Directly-organised EFSPI meetings
 - Or through member groups?
- Better links between “strong” and “weaker” groups
- Update Working Party findings on Qualifications and Experience of Statisticians
 - Recommendations on training
 - Influence on industry

EFSPI: THE FUTURE

- Anything that can be done more effectively on a European level than by individual countries
- It is your society – you decide!!

CONTACTS

david.morgan1@ingenix.com

www.efspi.org

EFSPI@resources.demon.co.uk