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
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.
EFSPPI HISTORY

• Founded 1992
• No individual members
  – A federation of national groups
• Now grown to 11 national groups
• Over 2000 members in total
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<td>Andreas Zipfel</td>
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<td>Karsten Schmidt</td>
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<td>Bernhard Huitfeldt</td>
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<td>Paul Koopman</td>
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<td>2001</td>
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EFSPRI 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
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EFSPi REGULATORY INPUT

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

• Statistical meetings with DIA
  – active participation in European Statistics Advisory Committee of DIA and annual Clinical Statistics workshops

• 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
• EFSPPI has played its part in all of these
EFSP: THE FUTURE

- Core objectives remain relevant
  - Regulatory input is key
- Web-site
- ? Directly-organised EFSP: 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!!
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