



EFSPi

Statistical Leaders Meeting

June 20, 2012
Weesp, The Netherlands



Welcome

- 3rd European Statistical Leaders Meeting
- Thank you to organising team
 - Stefan
 - Egbert
 - Uli
 - Ian
 - Sara
 - Kit
- Thank you Abbott
 - for Hosting the Meeting
 - Sponsoring the Dinner

Agenda

Time	Topic	Presenter / Facilitator
9:00-9:20	<ul style="list-style-type: none"> •EFSPI President Welcome address •Organisers welcome 	Francois Aubin Stefan Driessen
9:20-10:30	<ul style="list-style-type: none"> •Risk Benefit (<i>web-ex</i>) 	Ian Hirsch / Sara Hughes
10:30-11:00	<i>Break</i>	
11:00-12:00	<ul style="list-style-type: none"> •Adaptive statisticians & the challenges beyond Clinical Trials 	Kit Roes / Egbert Biesheuvel
12:00-13:00	<i>Lunch break</i>	
13:00-13:20	<ul style="list-style-type: none"> •SIG Update 	Stefan Driessen
13:25-13:45	<ul style="list-style-type: none"> •Career Path 	Hans Ulrich Burger
13:45-15:45	<ul style="list-style-type: none"> •Strategic Do's and Don'ts for the statistical community in EU Pharma 	All
16:15	<ul style="list-style-type: none"> •Meeting summary and actions 	Stefan Driessen
16:30	<i>Meeting adjourn</i>	

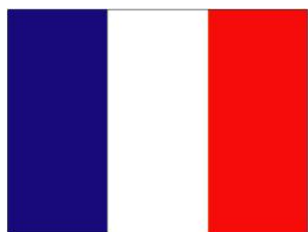


What is EFSPI?

- EFSPI = European Federation of Statisticians in the Pharmaceutical Industry
- Founded in 1992
- EFSPI is an “umbrella”, non-profit making organisation
- A federation of National European Groups
- Now have 10 national groups
- No individual members
- Our national organisations collectively represent 2800 members



EFSPI - Our members



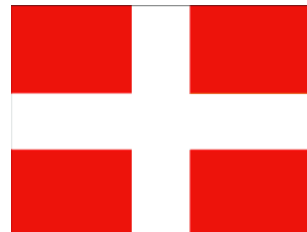
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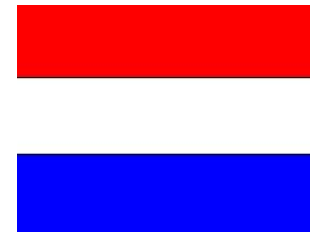
SSL



APF



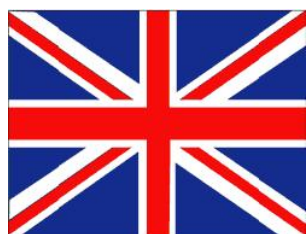
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PSDM



BIAS



PSI



SBS/BVS



BBS



FMS



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 practise of statistics in the European Pharma Industry and within member groups



Key Objectives for 2012

- Build a stronger European platform for statistical interaction
 - Statistical Leaders Meeting
- Use Statistical Leaders Meeting to develop our strategy for the future
- Deliver three quality European Statistical Meetings
 - Benefit-Risk Assessment Methodology 7 June
 - Modelling and Simulation 13 September
 - Subgroup Analyses 30 November
- Provide Cross-industry review of key regulatory documents (Regulatory Committee)
- Make more effective use of the EFSPI website

What we can achieve?

- Successfully supported PSI in lobbying EU Regulators to increase number of statisticians employed by the EU Regulatory Agencies
- Heads of Agencies listened and then commissioned a Strategy Paper to investigate the matter further

OPEN LETTER

European regulatory agencies should employ full time statisticians

Sara Hughes, chair of PSI (professional UK body of statisticians in the pharmaceutical industry) and director of statistics, GlaxoSmithKline chair@psiweb.org
 Nigel Howitt, EFSPi president (European Federation of Statisticians in the Pharmaceutical Industry) and director of analysis and reporting, PRA International;
 Kit Roes, EFSPi vice president and vice president, Global Clinical Information, Orsanon Scherine-Plouah;
 BMJ | 2 FEBRUARY 2008 | VOLUME 336

VIEWPOINT Pharmaceutical Statistics

Received 1 December 2009, Accepted 19 December 2009, Published online 8 February 2010 in Online Library
 (wileyonlinelibrary.com) DOI: 10.1002/pst.416

Statistical resource needs to be increased in the European regulatory agencies

Oliver N. Keene,^a Sara H. Hughes,^{a*} Nigel Howitt,^b on behalf of the PSI and EFSPi Boards of Directors

The following viewpoint from PSI and EFSPi regarding the current level of statistical resource in the European regulatory agencies was first presented as a position paper to a meeting of the EU Heads of Agencies in July 2009, and was endorsed by EFPIA. Copyright © 2010 John Wiley & Sons, Ltd.

PHARMACEUTICAL STATISTICS
 Pharmaceut. Statist. (2009)
 Published online in Wiley InterScience
 (www.interscience.wiley.com) DOI: 10.1002/pst.367

Statisticians in European regulatory agencies

Eva Skovlund^{1,2,*}

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What we can achieve?

Main Paper

Pharmaceutical
Statistics

(wileyonlinelibrary.com) DOI: 10.1002/pst.508

Published online in Wiley Online Library

The draft FDA guideline on non-inferiority clinical trials: a critical review from European pharmaceutical industry statisticians

Bernhard Huitfeldt,^{a*} and Jürgen Hummel,^b on behalf of European Federation of Statisticians in the Pharmaceutical Industry (EFSPI)

The European Federation of Statisticians in the Pharmaceutical Industry (EFSPI) engages more than 2000 statisticians through its ten national organizations. Amongst other things, EFSPI is involved in reviewing regulatory guidelines under development, including the draft FDA guideline on non-inferiority clinical trials. This review resulted in several critical comments relating to as follows: (i) the lack of one single standard for proving efficacy of new drugs implied by the guideline; (ii) the problems with the suggested 'fraction of effect to be preserved'; (iii) the formulation of the primary hypothesis in a non-inferiority trial aiming at indirectly demonstrating a new drug is superior to placebo; and (iv) the preference in the guideline for the fixed-margin method over the synthesis method in the analysis. The presumed implications of this guideline, if implemented as is, are (i) increased confusion of how efficacy could be demonstrated when placebo control is not available, (ii) more complicated communication between pharmaceutical industry and FDA because of the apparent disagreements on fundamental statistical matters, and (iii) illogical consequences in the approval process because of which order drugs are approved rather than how they fulfill the regulatory requirements. We believe that the area is not yet ready for such a prescriptive regulatory guidance and that further research and experience are required until the methodology can be finally agreed. A strategy needs to be developed by regulatory agencies together with drug industry and academia for a long term solution for this topic. Copyright © 2011 John Wiley & Sons, Ltd.

Keywords: FDA guideline; non-inferiority; synthesis method; fixed-margin method; EFSPI

September 2011



www.efspi.org



European Federation of Statisticians in the Pharmaceutical Industry
Promoting Professional Standards in Europe

HOME	European Statistical Meetings 2012: Benefit-Risk Assessment Methodology Workshop 7 June – Programme - Register *** NEW *** Modelling and Simulation Workshop 13 September – Programme - Register *** NEW *** Subgroup Analyses 30 November – Programme - Register		
NEWS	  		
INFORMATION ON EFSPI	news latest news news archive newsletters	information on EFSPI ***New*** Who's EFPSI? ***New*** general information history member groups working parties officers more...	advertisements job postings **New** services CROs providing statistical services statistical consultants/contractors other products
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PUBLICATIONS	publications annual reports status reports position papers regulatory comments	calendar of events meetings ***NEW*** Benefit-Risk Assessment Methodology Workshop - 7 June 2012 courses	EFSPI activities Statistics Leaders Meetings EFSPI international events member group events member group training history of EFSPI events *** new *** Special Interest Groups *** new ***
CALENDAR OF EVENTS	JOB POSTINGS SERVICES PRODUCTS		
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2013

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Year of Statistics

2013 Year of Statistics



The screenshot shows the website for the International Year of Statistics (Statistics2013). The header features a red bar with a Twitter link on the left and the text "Math of Planet Earth 2013" on the right. The main logo is a stylized bar chart with a red arc, labeled "STATISTICS2013.ORG" and "INTERNATIONAL YEAR OF STATISTICS". A navigation menu includes links for "Announcements", "View Participants", "Join Participants", "Activities", "Steering Committee", "Resources", and "Home".

The International Year of Statistics (Statistics2013)

The International Year of Statistics ("Statistics2013") is a worldwide celebration and recognition of the contributions of statistical science. Through the combined energies of organizations worldwide, Statistics2013 will promote the importance of Statistics to the broader scientific community, business and government data users, the media, policy makers, employers, students, and the general public.

The goals of Statistics2013 include:

- increasing public awareness of the power and impact of Statistics on all aspects of society;
- nurturing Statistics as a profession, especially among young people; and
- promoting creativity and development in the sciences of Probability and Statistics

Would your organization like to be a part of this celebration? [Click here](#) to indicate your interest and join the list of supporters of Statistics2013. [Click here](#) to view a list of groups that have expressed interest thus far.

Remember: Signing up as a participating organization creates no obligation for your organization. It simply indicates that you support the goals of the International Year of Statistics.

Of course, your organization might choose to have special activities during 2013, or to shine a special light on Statistics through some of your regularly scheduled activities.

We hope many groups will place special emphasis on activities to engage students and potential students of statistics, helping them to become more aware of statistics as a key scientific discipline. Some organizations might consider special foci, such as a broad statistical literacy outreach or promoting the ways in which statistics advances science and improves the human condition.

The bottom right of the screenshot features a word cloud of the word "statistics" in various languages and scripts, including English, Greek, Arabic, Hindi, Chinese, and Hebrew. The browser's address bar shows "Internet" and a 100% zoom level.

<http://www.statistics2013.org/>



2013 Year of Statistics

- EFSPI is participating

Participants

Professional societies

- (Australia) [Statistical Society of Australia](#)
- (Austria) [Austrian Statistical Society](#)
- (Belgium) [Belgian Statistical Society](#)
- (Botswana) Botswana Statistical Association
- (Brazil) [Brazilian Statistical Association](#)
- (Canada) [Southern Ontario Regional Association of the Statistical Society of Canada](#)
- (Canada) [Statistical Society of Canada](#)
- (Congo) [Association des Statisticiens du Congo \(DRC\), ASTACO](#)
- (Croatia) [Teachers Association "Suradnici u ucenju"](#)
- (Czech Republic) [Czech Statistical Society](#)
- (Denmark) [Danish Society of Theoretical Statistics](#)
- (Estonia) [Estonian Statistical Society](#)
- (Estonia) [Statistics Estonia](#)
- (Ethiopia) [Ethiopian Statistical Association](#)
- (Europe) [European Federation of Statisticians in the Pharmaceutical Industry \(EFSPI\)](#)





Statistical Leaders Meeting

- Develop a forum for Statistical Leaders to
 - Network and share ideas
 - Shape and influence our environment
 - Education & Continuing Professional Development
 - Methodology Development & Identification of Best Practice
 - Regulatory and Industry policies
 - Effective working with differing resourcing models
 - Help to shape the strategy for EFSPI



Objectives 2012 meeting

1. To identify priorities for the strategic direction of EFSPI in
 - Evaluation of Risk Benefit
 - Challenges to statisticians beyond Clinical trials

 - SIGs
 - Career Path

Format

- First two topics will be presented followed by:
 - Facilitated discussion to identify 3 priority actions
 - Facilitators will summarise key actions at the end of each discussion
- The other two presentations will be updates from previous Statistical Leaders Meetings and also will contribute to 2nd objective



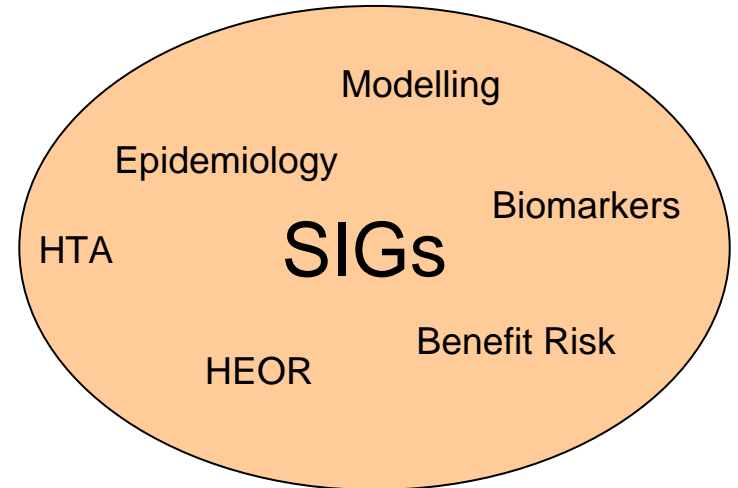
Objectives 2012 meeting

2. To define goals and a road map to help the individual EU pharmaceutical statistician to best influence their future, and thus ourselves, in order to secure and grow the statistical community in EU in the pharmaceutical/life sciences industry

Format

- Open Space workshop
 - 4 areas of interest to be identified
 - One facilitator per table
 - Per topic/area/item:
 - 3 Outcomes to describe on flip charts
 - Present back outcomes
 - Plenary session

Areas as pre-read



?
**Coming
from
LUNCH
BREAK**

