

## ***BENEFIT-RISK SIG***

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Statistics Leaders Meeting Brussels  
July 1<sup>st</sup>, 2015

# BENEFITS VS RISKS



# WHERE CAN STATISTICIAN PLAY A ROLE?

- Facilitate/drive discussion
- Translate medical concepts into valid endpoints
- Analyze favorable/unfavorable effects
- Assess robustness of quantitative models
- Communicate strengths/limitations:
  - clinical trials,
  - observational data,
  - other non-study information
- Leverage methodological rigor/strong technical knowledge with influencing skills



Sound decisions

# THE TEAM

- 17 members
- 12 very active members
- Companies:

1. Abbvie
2. Amgen
3. Astellas
4. AZ
5. Bayer
6. Genentech
7. GSK
8. (Ipsen)

8. ICON
9. Imperial
10. Lilly
11. Mitsubishi Tanabe
12. Mylan
13. Novartis
14. Pfizer
15. Servier

# WORK STREAMS

- Training (David Morgan)
- Literature review (Shahrul Mt-Isa)
- HTA (Susan Talbot)
- Bayes (Maria Costa)
- MCDA/SMAA (Guillemette de La Borderie)
- Points to consider (Veronique Robert)

# Structured Benefit–risk assessment: a review of key publications and initiatives on frameworks and methodologies

Shahrul Mt-Isa,<sup>a\*</sup> Mario Ouwens,<sup>b</sup> Veronique Robert,<sup>c</sup> Martin Gebel,<sup>d</sup> Alexander Schacht,<sup>e</sup> and Ian Hirsch<sup>f</sup>

## NU1: Benefit-Risk Assessment

**Time:** Monday, March 16th, 8:50 – 10:10

**Session Chair:** Frank Langer and Claudia Schmoor


**Room:** M/E 29

- 8:50 – 9:10      Structured Benefit-risk assessment: A review of key publications and initiatives on frameworks and methodologies  
*Alexander Schacht*
- 9:10 – 9:30      Quantitative Methoden zur Risiko-Nutzenbewertung  
*Martin Gebel*
- 9:30 – 9:50      Benefit risk assessment in the drug approval process  
*Norbert Benda*
- 9:50 – 10:10    MCDM im deutschen HTA Umfeld  
*Friedhelm Leverkus and Fabian Volz*



## 61. Biometrisches Kolloquium

15. – 18. März 2015



PSI 2015 – London, UK

- Shahrul Mt-Isa
- Alexander Schacht
- Maria Costa



EFSPi/PSI invites you to attend our webinar

## “Benefit – Risk”

**Tuesday June 16** (2-3.30pm UK / 3pm CEST / 8am EST) &  
**Monday June 29** (2-3.30pm UK / 3pm CEST / 8am EST)

Methodology to weigh Benefit-Risk is complex because it involves the evaluation of large amounts of data and the uncertainty of the data available. This webinar will discuss methodology as well as case studies of B-R assessments. These presentations have also been given at the PSI conference in May 2015

### Presentations:

*From qualitative to fully quantitative approaches to balancing benefits and risks of medicinal products for decision-making - Shahrul Mt-Isa (Imperial College)*

*Structured Benefit-risk assessment: A review of key publications and initiatives on frameworks and methodologies by the EFSPi Benefit-Risk Special Interest Group (SIG) - Alexander Schacht (Eli Lilly)*

*Bayesian Benefit-Risk Assessment - Maria Costa (GSK)*

**Panel discussion after the presentations, opened by Andrew Thompson (MHRA)**

Open to EFSPi & non-EFSPi members – no need to register and free of charge!  
Slides will be made available from the EFSPi website prior to the meeting.

Dial in details and other information are available on the EFSPi website.

( [www.efspi.org](http://www.efspi.org) )



## Resources

Home > Resources > Resources

- Benefit-Risk SIG
  - Benefit-Risk feedback meeting February 2013
    - Benefit-Risk SIG Outputs to share 2013**
- Biomarkers SIG
- Board of Directors
- Careers and Academic Liaison
- Committee Operating Guidelines
- Conference
- Epidemiology SIG
- European Links (EFSP1)
- External Affairs
- Finance
- UTA SIG

TITLE	TYPE	SIZE	DOWNLOAD
<b>Benefit-Risk Current State-literature reviews and initiatives</b>	.PPT	2878976	<a href="#">Download</a>
<b>Benefit-Risk literature and initiatives 2013</b>	.XLS	119296	<a href="#">Download</a>
<b>Benefit-Risk SIG blueprint</b>	.PPTX	167396	<a href="#">Download</a>
<b>Executive Summary-Benefit-Risk Current state</b>	.PPT	620032	<a href="#">Download</a>

### Latest News

#### The IDEAS network

The IDEAS network ([www.ideas-itn.eu](http://www.ideas-itn.eu)), a unique collaboration of major European universities, the pharmaceutical industry, and consulting companies working on statistical methods to improve early stage drug development, is currently seeking applications for early stage researchers to join the network. Network researchers will be based at one of the partner institutions and work closely with other network

[Show all news](#)

### Future Events

**A PSI Training Course on Cross-over trial in Clinical Research - Dates: 04 – 05 Mar, 2015**

**A PSI Training Course: Regulatory Interactions for Statisticians - Dates: 11 – 12 Feb, 2015**

# OPPORTUNITIES



**LEVERAGE** METHODOLOGICAL  
RIGOR/STRONG TECHNICAL  
KNOWLEDGE WITH  
INFLUENCING SKILLS

# BENEFIT-RISK – OPPORTUNITIES FOR STATISTICIANS BEYOND STATISTICS?

# HOW TO MAKE THE SIG MORE ATTRACTIVE?

# IMI BR PROJECT – IMPLICATIONS FOR THE SIG?

MEETINGS, WEBINARS,  
TRAINING, ....  
LOGISTICAL PROBLEMS



# PSI, BIOMETRICAL COLLOQUIUM

– WHAT'S NEXT?

ANY OTHER ADVISE/FEEDBACK?

