BENEFIT-RISK SIG

Alexander Schacht
Lilly
Schacht_Alexander@lilly.com

Statistics Leaders Meeting Brussels
July 1st, 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,⁎ Mario Ouwens, Veronique Robert, Martin Gebel, Alexander Schacht, and Ian Hirsch
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-EFSPAN 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 )
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?