What's going on in benefit-risk and what is our role as a statistician?

1st EFSPI Workshop on Regulatory Statistics
September 12-13, 2016 Basel (CH)

Alexander Schacht, PhD

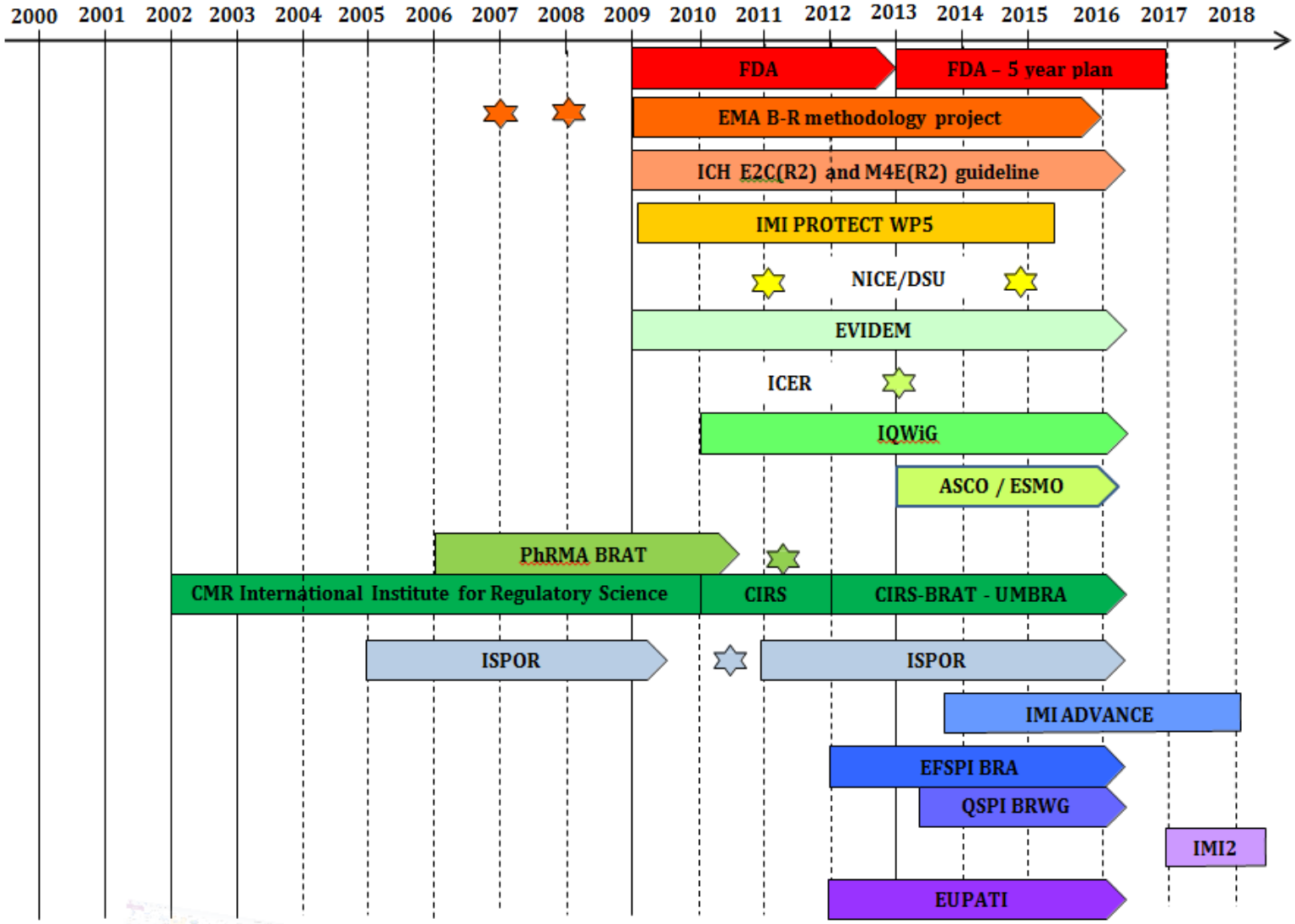
Lilly

Disclaimer

This is my personal view.

Why should I care?

What‘s going on?



Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle (PREFER)

The main objective of the project is to strengthen patient-centric decision making throughout the life cycle of medicinal products by developing evidence-based recommendations to guide industry, Regulatory Authorities, HTA bodies, reimbursement agencies, academia, and health care professionals on how and when patient-preference studies should be performed and the results used to support and inform decision making.

EFSPI Benefit-Risk Special Interest Group

- Training
- Points to consider
- HTA
- MCDA/SMAA (Multi-Criteria Decision Analysis/Stochastic Multi-criteria Acceptability Analysis)
- Bayes
- Literature review
- BLOG

Manuscripts

LITERATURE REVIEW

Pharmaceutical Statistics

(wileyonlinelibrary.com) DOI: 10.1002/pst.1690

Published online in Wiley Online Library

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

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Introduction
The conductof structured benefit–risk assessment (BRA) of pharmaceutical products is a key area of interest for regulatory agencies and the pharmaceutical industry. However, the acceptance of a standardized approach and implementation are slow. Statisticians play major roles in these organizations, and have a great opportunity to be involved and drive the shaping of future BRA.
Method
We performed a literature search of recent reviews and initiatives assessing BRA methodologies, and grouped them to assist those new to BRA in learning, understanding, and choosing methodologies. We summarized the key points and discussed the impact of this emerging field on various stakeholders, particularly statisticians in the pharmaceutical industry.
Results
We provide introductory, essential, special interest, and further information and initiatives materials that direct readers to the most relevant materials, which were published between 2000 and 2013. Based on recommendations in these materials we supply a toolkit of advocated BRA methodologies.

Webinar

EFSPI

European Federation of Statisticians in the Pharmaceutical Industry

Representing Statistical Associations in Europe

PSI

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)

Conferences

PSI Conference 2016 Session Plan

Tuesday 24th May

08:00 - 09:00	Registration in the Conference Centre Lobby		
09:00 - 10:00	**Methodological Challenges in the (added) Benefit Assessment of Drugs** Room: Basel/Bern/Genf/Zürich Chair: Mark Morris (PSI Chair) Prof. Dr. med. Stefan Lange, Deputy Director at IQWiG		
10:00 - 10:30	**Break** Room: Tessin 1/2/3		
10:30 - 12:00	**Benefit Risk Assessment within Health Technology Assessment: Experiences and Opportunities** Room: Basel/Bern/Genf/Zürich Chair: Alexander Schacht (Eli Lilly and Company) Friedhelm Leverkus (Pfizer) Susan Talbot (Amgen) Fabian Volz (Pfizer)	**Statistical Challenges Relating to Safety** Room: Davos 1/2 Chair: Anna Berglind (AstraZeneca) Elizabeth Merrall (GSK) Arthur Allignol (Universität Ulm) Katie Patel (Roche)	**Translational Biomarkers: from Preclinical to Phase 1** Room: Chur 1/2 Chair: Tony Cornelius (Cmed) Alun Bedding (AstraZeneca) Claire Brittain (Eli Lilly and Company) Thomas Jaki (Uni. of Lancaster)
12:00			

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MONDAY, JULY 25, 2016

Feedback on the EFPSI workshop on regulatory statistics

1 Comment | 0 | Tweet | 0 | +1 | Email | Print

Hi Alexander,

If I were able to attend the workshop, I would be most interested in the topic of the ***Role of Statisticians***. We can be consultants, contributors, collaborators and in some instances leaders, depending on where statisticians are positioned in their companies. We can develop, test and/or apply new methods, depending on our training. Because we carry the stigma of being support staff for clinical trials, a leadership role might require a new frame of mind. Will you telling the audience what role statisticians most often play?

I liked this line from a recent post, "***The understanding of data – its strengths and limitations –is a core competency of statisticians. Thus, they need to play a key role in helping others to understand and interpret the efficacy and safety data correctly.***"

Recent Posts

- Feedback on the EFPSI workshop on regulatory statistics
- What would you like to know about BR as a beginner?
- FDA on further Benefit-Risk framework – an outlook
- ISPOR publishes two reports on the use of MCDA
- Essential learnings: How do I begin...?

Recent Comments

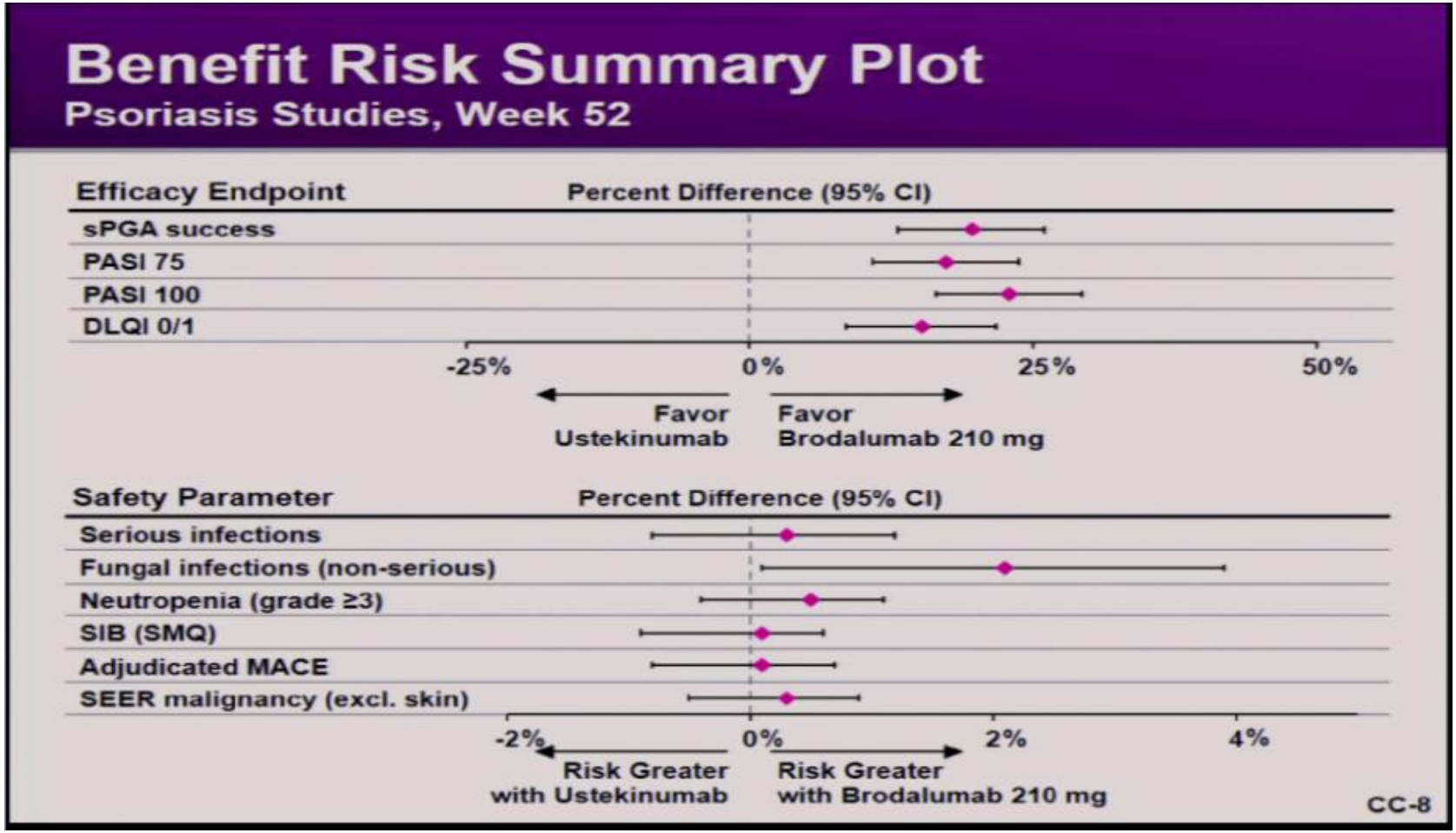
schachtalexander on What would you like to know about BR as a beginner?

What is my role?

Next steps – some thoughts

Next steps – some thoughts

Next steps – some thoughts



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