



Update

Special Interest Groups (SIGs)

Statistics Leaders Meeting

June 11, 2014

Basel

SIG: Updates

Change of Chairs SIGs:

- **SIG Benefit Risk**
 - New Chair: Alexander Schacht (Lilly, Germany)
 - Previous Chair: Ian Hirsch (AZ, US)

- **SIG Biomarkers**
 - New Chair: Athula Herath (MedImmune)
 - Previous Chair: Martin Jenkins (AZ, UK)



SIG presentations

- Statistics Leaders Meeting 2014
 - SIG Integrated Data Analysis
 - SIG Pharmaco-Epidemiology
- EFSPi Newsletter
 - February Health Technology Assessment
 - March Biomarkers
 - April Medical Devices
 - May Toxicology



SIG of the Month in 2014

- SIG contribution to EFSPI Newsletter in 2014

		2014 EFSPI Newsletter Schedule with SIG input											
SIG	SIG Lead	January	February	March	April	May	June	July	August	September	October	November	December
Modelling & Simulation	Chris Campbell											X	
Health Technology Assessment	Chrissie Fletcher		✓										
Epidemiology & Safety	George Quartey						X						
Benefit/Risk	Alexander Schacht										X		
Biomarkers	Athula Herath			✓									
Medical Devices	Roland Marion-Gallois				✓								
Toxicology	Gareth Thomas					✓							
Integrated Data Analysis	Byron Jones									X			



SIGs at Stats Leaders Mtgs

Core Topics Stats Mtg	2014	2013	2012	2011	2010	Link to SIG
New SIG: Integrated Data Analysis	intro+discuss					Integrated Data Analysis
SIG: Pharmaco-Epidemiology & Safety	present + discuss					Epidemiology & Safety
Risk - Benefit		present + discuss		update	intro+discuss	Benefit-Risk
Assessing Risk Benefit - Roadmap		update	intro+discuss			Benefit-Risk
Model Based Drug Development				intro+discuss		Modeling & Simulation
Totality of Evidence - observational data				intro+discuss		Epidemiology & Safety
Health Technology Assesment (CER)				update	intro+discuss	HTA (CER)
Comparative drug effects - Network meta-analyses				intro+discuss		HTA (CER)
						Biomarkers
Medical Devices		intro+discuss				Medical Devices
						Toxicology
						Professional
EMA Clinical Trial Data Transparency		intro+discuss				Transparency
Adaptive statisticians & the challenges beyond Clinical Trials			intro+discuss			Career Path
Professional development			paper	update	intro+discuss	Career Path
accreditation				intro+discuss		Accreditation



SIG Medical Devices

Stats Leaders Mtg 2013 – request to EFSPI:

- Contribute to comments on upcoming regulatory guidelines changes
- Backing up SIG in promoting good scientific practice as in pharma

Follow-up:

- EFSPI supported SIG in sending a letter to EU Parliament asking for attention to introduce more profound statistical principles in upcoming regulatory framework changes than presently proposed
 - no answer yet from EU deputies
 - Some of SIGs concerns taken into account
 - Yet current regulatory thinking also different from some expectations
 - Role of EMA is not as direct than expected
 - Post-market device surveillance is re-inforced
 - Notified bodies (which are delivering the CE mark) will be less and better controlled.



SIG Benefit Risk

- Stats Leaders Meeting 2013 :
 - SIG can use EFSPi/PSI website for posting of material to be kept under SIG's control such as Position Papers, Presentations, etc.
 - SIG free to investigate more wiki-like environments for triggering more feedback (but without control)
 - Encouraged to collaborate with QSPI (US analogy to EFSPi), but not let that hold up development blue print



SIG B/R follow up

- SIG had EFSPi/PSI one day meeting in September 2014
 - <http://www.efspi.org/index.php?p=EFSPi%20ACTIVITIES&fid=431>
- Submission publication:
 - *“Structured Benefit-risk assessment: A review of key publications and initiatives on frameworks and methodologies”*
- Regular meetings in subgroups
- Involvement in PROTECT
- Collaboration with QSPI:
 - intent to publish a newsletter together with QSPI related to B-R topics
- More information on website:
 - <http://www.psiweb.org/index.php?p=resources&fid=1517#>
- **Planned 2-days Training in 2015**
 - SIG is looking for venue (1 large room, 2 break outs)
 - please let Alexander Schacht know: schacht_alexander@lilly.com

Recent SIG publications

- HTA SIG
 - *Adjusting overall survival for treatment switches: Commonly used methods and practical application*, [Watkins et al](#)
 - Utility values in health technology assessments: a statistician's perspective, [Whately-Smith et al](#)
 - Subgroup Analyses in Cost-Effectiveness Analyses to Support Health Technology Assessments, [Fletcher et al](#)

Meetings planned 2014

- SIG Biomarkers:
 - *Biomarkers Hands-on-workshop/“Biomarker Hackathon”*
 - *Big Data in Biomarker Development*
 - currently scheduled to be held in Cambridge (UK)
- SIG Toxicology
 - Workshop (October)
- SIG Modelling & Simulation
 - ? Meeting planned with EMA
- SIG HTA / EFSPI meeting on HTA: Sept 25, Berlin