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

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<thead>
<tr>
<th>SIG</th>
<th>SIG Lead</th>
<th>January</th>
<th>February</th>
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<td>Integrated Data Analysis</td>
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### SIGs at Stats Leaders Mtgs

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<th>Core Topics Stats Mtg</th>
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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 blueprint
SIG B/R follow up

- SIG had EFSP/PSI one day meeting in September 2014

- 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:

- 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