SIGs

Special Interest Groups

Update

Statistical Leader Meeting

20 JUN 2012

What is a SIG ?

- comprise (usually) small groups of statisticians (and sometimes others) with a shared interest in a specific topic that is less furnished within the usual (statistical) societies, communities, etc.
- given the sufficient attention to clinical trial statistics, SIGs were set up in "new" areas like:
  - Benefit Risk
  - Health Technology Assessment (HTA)
  - Modeling & Simulation
- Used to be PSI SIGs and EFSPI SIGs but now all are open to both

SIG's purpose

Generally:

- To learn about, share and understand best practices in area of interest
- To discuss and make recommendations on key methodological issues
- To comment on or contribute to the development of guidelines
- To inform, share, and educate

SIG practically

- Largely self-sufficient
- No formal organization
- Most interactions by telecons, mails, but also (few) life meetings at site of participating company
- Often invited to co-organize scientific events
- produce papers (e.g., special issue of Pharmaceutical Statistics)

SIGs
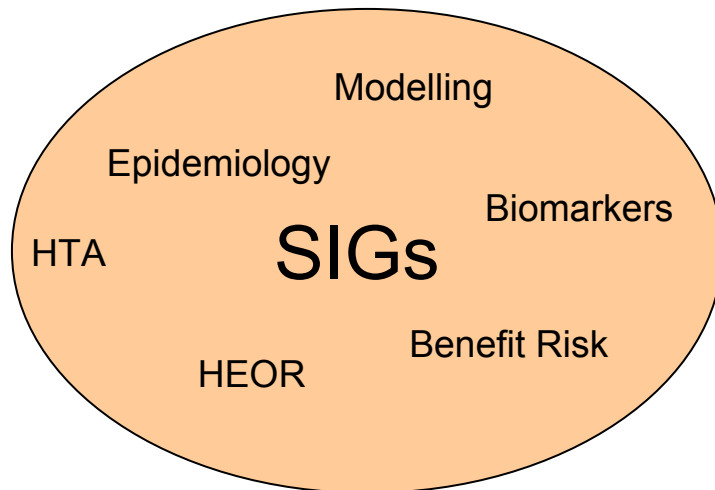
SIGs - Stats Leaders Mtgs

Core Topics Stats Mtg	2012	2011	2010	Link to SIG
Risk - Benefit		update	intro+discuss	Benefit-Risk
Assessing Risk Benefit	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
				Toxicology
SIGs	update			all
Adaptive statisticians & the challenges beyond Clinical Trials	intro+discuss			Epidemiology & Safety; Career Path
				Professional
Professional development	paper	update	intro+discuss	Career Path
accreditation		intro+discuss		Accreditation

SIG:
Stat. Leaders Mtg – EFPSI/PSI

Feedback previous meeting(s):

- SLM to increase awareness within their companies on SIGs
- SLM action to promote active membership into SIGs
- EFSPI action to set up links to SIGs on EFSPI website
- EFSPI action to include news from SIGs in EFSPI Newsletter

- SLM request to set up new SIG for Risk- Benefit
- EFSPI action to organize meeting on Modelling & Simulation
- EFSPI action to identify modelling & simulation methods to be made available through website
- EFSPI action to organize meeting on CER (or webinar)
- EFSPI action to expand PSI SIG Epidemiology & Drug Safety to EFSPI SIG

Good reference to the work by SIGs:

- *Pharmaceutical Statistics, Volume 10, Issue 6, dedicated to SIGs*

SIG: Benefit - Risk

- Newly formed
- Kick off 16 FEB 2012

Membership:

Ian Hirsch	AstraZeneca; Chair of SIG
Susan Shepherd	Amgen
Martin Gebel	Bayer
Rebecca Sudlow	Roche
George Quartey	Roche; link to SIG Epi/Safety
Guenter Heimann	Novartis
Ekkehard Glimm	Novartis
Maylis Coste	IRIServier
Veronique Robert	IRIServier
Carl-Fredrik Burman	AstraZeneca
Rick Herman	AstraZeneca; link to BRAT initiative
Dan Evans	Pfizer

SIG: Benefit - Risk

Plan 2012:

– Finalize charter

– Finalize key topics to prgress

– Sollicit feedback from:

- PSI Board Meeting May 2012

- EFSPI Statistical Leaders Meeting (and subsequent EFSPI Council mtg)

SIG: Biomarkers

- Became joint PSI-EFSPI SIG in 2011

Membership (SIG committee):

•	Martin Jenkins	AstraZeneca; Chair of SIG
•	Nigel Dallow	GSK
•	Paul Delmar	Roche
•	Aiden Flynn	Exploristics
•	Chris Harbron	AstraZeneca
•	Athula Herath	MedImmune
•	Jayantha Ratnayake	Roche
•	Tony Sabin	Amgen
•	Trevor Smart	Lilly
•	Charlotte Vignal	Roche
•	David Wille	GSK

SIG: Biomarkers

Recent achievements (2011):

- LinkedIn group
- 100 others on mailing list
- Delivery of review paper for Pharmaceutical Statistics
    - Covering many current issues in statistical biomarker work
- Organized session at PSI Annual conference in 2011 on:
    - Diagnostic development
    - Genetic biomarkers
    - Safety biomarkers development
- Organized one-day meeting November 2011 (host Amgen)
    - Incorporation of biomarkers into clinical trial designs

Plan for 2012:

- Organize 1-2 one-day meetings
    - Meeting on "the statistical validation of biomarkers" soon to be announced
- Developing training materials on biomarkers
    - Putting together plans for a training course (with PSI) for 2013
    - Developing a webpage of resources

SIG: Toxicology

- Exists already 6 years

Membership:

- Jim Saul   Covance; Chair of SIG
- Mike Aylott   GSK
- Simon Bate   Huntingdon Life Sciences
- Sarah Kirk   AstraZeneca
- Helena Geys   Johnson & Johnson

SIG: Toxicology

Achievements:

- Organized 2-day workshop (UK)
    - Genetic toxicology
    - Comet assay
    - Analysis of behavioural and Censored Data
    - Statistics in pathology
    - Translation from pre-clinical to clinical
    - (presentation slides on website)
- 2 publications in Pharmacuetical Statistics on
    - statistical analysis of comet assay
    - Statistical analysis in toxicology studies

Plan 2012:

- Organize 2 day workshop in 2012/2013

SIG: Epidemiology and Drug Safety

Membership:

•	George Quartey	Genentech
•	Maurille Feudjo-Tepie	Amgen
•	Joseph Kim	Quintiles
•	Nilani Liyanage	Ipsen
•	Jason Wang	Novartis
•	Jonathan Alsop	Numerus
•	Volker Hosel	StatSciConsult
•	David Prieto-Merino	LSHTM
•	Alex Thompson	Roche
•	Arlene Gallagher	MHRA
•	Athula Herath	MedImmune
•	Gerry Downy	Amgen
•	Charles Warne	Amgen
•	Guiyuan Lei	Roche

SIG: Epidemiology and Drug Safety

Achievements:

- Published 3 articles in Pharmaceutical Statistics on
    - Minimization of confounding in observation research
    - Review of risk measures in pharmaco-epidemiology
    - Bayesian approach to safety analysis in pharmaco-vigilance

Plan 2012:

- Organizing parallel session for PSI Annual Conference with MHRA

- Planning for One-day meeting on "Safety Signal Detection and Evaluation methods" early 2013

SIG: Modelling and Simulation

Membership:

• Chris Campbell	Mango Solutions; Chair
• Ad Theeuwes	Astellas
• Alun Bedding	GSK
• Athula Herath	MedImmune
• Benoit Beck	Axiosis
• Carl-Frederik Burman	AstraZeneca
• Martin Scott	Numerus
• Michael O'Kelly	Quintiles
• Michelle Jones	Covance
• Nilani Liyanage	Ipsen
• Rich Pugh	Mango Solutions
• Stig Johan Wiklund	AstraZeneca
• Tom Parke	Tessella
• Vincent Haddad	Amgen
• Vladimir Anisimov	Univ. Glasgow

SIG: Modelling and Simulation

Achievements:

- Hosted mini-conferences
- Organized sessions at conferences (e.g., PSI Annual)
- Contributed to EMA/IFPIA workshop on Modelling and Simulation in 2011
- Published articles in Pharmaceutical Statistics on
    - Predictive event modelling in multicentre clinical trials with wiating time to response
    - Reflections on use of modelling and simualtino in pharma industry

Plan 2012:

- Practical course on Modelling and Simulation, 24-25 October, 2012
- Working on "Best Practices" document
- Organizing with EFSPI meeting on Modelling and Simulation

SIG: Medical Devices

Membership:

Group Leader: Roland MARION-GALLOIS

	Affiliation	Country
Abdallah ABOUIHIA	Medtronic	Switzerland
Mikael ASTROM	Telia	Sweden
François AUBIN	Cardinal Systems	France
Hubert BEAUMONT	Median Technologies	
Gilles BERDEAUX		France
Julie BESTEL	Advance Bionics	France
Pascal CANDOLFI		
Javier CASTANEDA	Medtronic	Netherland
Tiziana De SANTO	Medtronic	Italy
Julie DOREY	Creativ'Ceutical	France
Marie-Christine FALCOU	Institut Curie	France
Claudio GARUTTI	Medtronic	Netherland
Bart GERRITSE	Medtronic	Netherland
Sophie GROSZ	Biomerieux	France
Florent GUELFUCCI	Creativ'Ceutical	France
Khaled MAMAN	Creativ'Ceutical	France
Roland MARION-GALLOIS	Medtronic	Switzerland
Nicolas MOLINARI		France
Jonas RANSTAM	National Musculoskeletal competence	Sweden
Gérard TAP		France
Rod TAYLOR		UK
Françoise TONDU		France
Mondher TOUMI	Creativ'Ceutical	France
Peter TREASURE	Free-lance	UK
Anne-Lise VATAIRE	Creativ'Ceutical	France

SIG: Medical Devices

- Formed End 2010.

- <u>Objectives</u>
  - Create visibility on biostatistics activities for Medical Device
  - Strengthen methodological aspects in the development of Medical Devices
  - Create an expert group identified by authorities
  - Share Good Statistical practice

- Monthly meeting by teleconference
  - Odd month: every 3rd Wednesday 16:00-17:00
  - Even month: every 3rd Thursday 17:00-18:00

SIG: Medical Devices

- ## Activity in 2011:
  - Review the environment context
  - Place of post-approval registries
  - Is there a place for statistical methodology in the recast of the Medical Device EU Directive?

- ## Plan for 2012:
  - Categorize Medical Devices according to clinical research needs
  - Technological watch on methodological aspects for Medical Devices (guidelines, regulation…)

SIG: HTA

- formed in 2010

Membership:
- Chrissie Fletcher   Amgen; Chair of SIG
- Marie-Laure Bravo   Celgene
- Christy Chuang-Stein   Pfizer
- John Davies   GSK
- Christoph Dierig   Bayer
- Pierre Ducournau   Amgen
- Christoph Gerlinger   Bayer
- Byron Jones   Pfizer/Novartis
- Andy Lawton   GSK
- Patrick Moneuse   Takeda/Vifor Pharma
- Marie-Ange Paget   Eli Lilly
- Carol Reid   Roche
- Fred Sorenson   Quintiles
- Helen Tate   consultant
- Claire Watkins   AstraZeneca
- Caroline Whately-Smith   consultant

SIG: HTA

Achievements 2011:

- 4 meetings and several submeetings
- Round table discussions with "opinion leaders"
- Helped organize and contributed to plenary "Mock HTA" and parallel sessions at PSI annual conference
- update the HTA Handbook (on psi website)
- Published 2 manuscripts in 10th anniversary Pharmaceutical Statistics journal on:
  - Network Meta-Analyses
  - Sub-Group Analyses

SIG: HTA

2012 plans:

- Continue to foster collaboration, share case studies, discuss and debate statistical issues pertaining to HTA

- Maintain HTA handbook

- Publish papers on subgroup analyses in cost-effectiveness, evidence synthesis, utilities

- Continue to meet with external experts in the HTA field e.g. Mark Sculpher (ISPOR President)

- Contribute to 2012 PSI conference (pre-conference course on Network Meta-Analysis, HTA parallel sessions)

- Contribute to 1-day PSI HTA Scientific meeting

- Review and provide comments on Industry and/or regulatory guidelines relating to HTA, e.g. updated NICE methods guide, EUnetHTA relative effectiveness methods guide

- Share materials on PSI website

- Write articles for PSI and EFSPI newsletters keeping members abreast of HTA developments and raise awareness of training materials relating to HTA

- Seek to collaborate with other interested parties, e.g. ISPOR

How can EFSPI support the HTA SIG?

- Support SIG members to participate in SIG activities

- Review the SIG materials on the website, e.g. HTA handbook, and give feedback

- Let the SIG know if there are specific activities which would be useful for the wider statistical community

SIGs - Questions

- What do we expect from SIGs?
- What can SIGs expect from us?
- Should there be a less "voluntary" participation?
- Do we expect contributions from each company?
- Which SIGs should be "standard" to our community rather than "special interest"?
- What role can SIGs play to enhance our resiliance?