SIGs

Special Interest Groups

Statistical Leaders Meeting

July 2018

Overview current and new SIGs

SIG	SIG Lead/Chair	SIG Lead e-mail	Founded
Toxicology	Gareth Thomas	thomasg@ukorg.huntingdon.com	2007
Real World Data (former Epidemiology & Safety)	Maurille Feudjo Tepie	maurille@amgen.com	2008
Biomarkers	Athula Herath	heratha@MedImmune.com	2008
Modelling & Simulation	Chris Campbell	ccampbell@mango-solutions.com	2010
Health Technology Assessment	Chrissie Fletcher	fletcher@amgen.com	2010
Medical Devices	Martin Wadepuhl	wadepuhl.m.vsa@t-online.de	2010
Benefit/Risk	Alexander Schacht	schacht_alexander@lilly.com	2012
Integrated Data Analysis	Byron Jones	byron.jones@novartis.com	2013
Small Populations	Egbert Biesheuvel	egbert.biesheuvel@danone.com	2015
Application and Implementation of Methodologies in Statistics (AIMS)	Craig McIlloney/ Lynn Taylor	Craig.McIlloney@ppdi.com; taylor@prahs.com	2016
Decision Making	Gaelle Saint Hillary		2017
Data Transparency	Rebecca Sudlow	rebecca.sudlow@roche.com	2018
NEW Historical Data	Byron Jones	byron.jones@novartis.com	2018
NEW NeuroScience	Nikos Sifkas		2018

SIGs present themselves

- 2014

- Presentation all SIGs at the time in EFSPI Newsletters

Microsoft Word Document

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

SIGs – Statistics Leaders mtg

- Almost all SIGs have been invited to the Statistics Leaders Meetings
- present themselves
- discuss strategic and directional input

Agenda items Stats Mtg	Link to SIG / WG	2018	2017	2016	2015	2014	2013	2012	2011	2010
Management of SIGs	All	strategy SIGs								
New SIG: Decision making	SIG Decision making	intro+discuss	proposal							
New SIG: AIMS	SIG AIMS		written update	intro+discuss						
New SIG: Small Populations	SIG Small Populations			update	intro+discuss					
New SIG: Integrated Data Analysis	SIG Integrated Data Analysis					intro+discuss				
SIG Pharmaco-Epidemiology & Safety	SIG Epidemiology & Safety					present + discuss				
SIG Risk - Benefit	SIG Benefit-Risk				Major Update		present + discuss		update	intro+discuss
- Assessing Risk Benefit - Roadmap	SIG Benefit-Risk						update	intro+discuss		
SIG Modelling & Simulation Model Based Drug Development	SIG Modeling & Simulation			Best Practices Presentation					intro+discuss	
Totality of Evidence - observational data	SIG Epidemiology & Safety								intro+discuss	
Health Technology Assesment (CER)	SIG HTA (CER)				update as F-up action				update	intro+discuss
Comparative drug effects - Network meta-analyses	SIG HTA (CER)								intro+discuss	
	SIG Biomarkers									
	SIG Toxicology									
SIG Medical Devices	SIG Medical Devices						intro+discuss			
New WG: Clinical Trial Data Sharing	WG Data Sharing				update	intro+discuss				

SIG – EFSPI / PSI

- Early SIGs originated from PSI

- Adopted by EFSPI; opened up to statisticians outside PSI

- Became EFSPI/PSI SIG, or PSI/EFSPI SIG

- Contact persons EFSPI Council and PSI Board

SIG Chair EFSPI

- High level role description
  - Oversee the SIGs supported by EFSPI
  - Hold annual SIG leaders teleconference to share news and best practices
  - Share updates with Council and seek input/feedback as needed
  - Keep regular contact with counterpart SIG contact person for PSI Board

- Chair 2012-2018: Stefan Driessen

Starting up SIG

- Develop charter
  - Ask for input EFSPI (Council, Statistics Leaders Meeting)
  - Identify other stakeholders, ask input

- Announce via Newsletter EFSPI
  - Introduce SIG
  - Ask for participants, explain expectations with as starting point:
    - All of the SIGs welcome new members at any time, and individuals who may be interested to join a SIG do not need to be an expert in the topic area(s). Individuals who are motivated to learn about a topic and are keen to actively engage and collaborate with colleagues are very welcome to join a SIG.

- Use website EFSPI for information exchange
  - Develop presentation for home page (see other SIG pages)
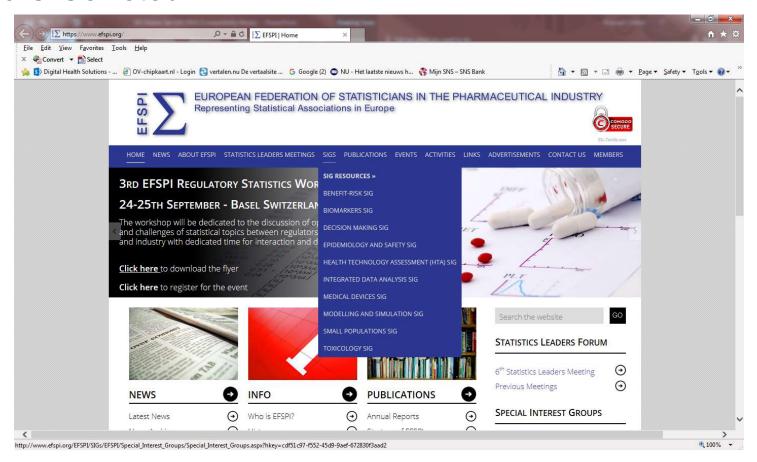 - Use Public area and Private area at SIGs discretion

Charter SIG

Contents:

- Background/Rationale
- Goals/Objectives/Scope:
  - See for generic version separate slide
- Organization
  - Membership
    - Name, company, e-mail address
  - Meetings
    - E.g., t-con/web-ex; monthly 1 hour; Minutes taking
  - Information sharing
    - Website EFSPI
- Communication Plan
  - Newsletter (PSI, EFSPI)
  - Stakeholders identification
  - Collaborations

EFSPI website

- https://www.efspi.org/
- 10 SIGs listed

EFSPI website

- http://www.efspi.org/
- SIGs have their own pages
  - Introduction page
  - Public area
  - Private area
- Webmaster
  - Chrissie Fletcher
    - fletcher@amgen.com

SIG/WORKING GROUP LINKS

Health Technology Assessment →
Modelling and Simulation →
Benefit-Risk →
Epidemiology and Safety →
Biomarkers →

SMALL POPULATIONS SIG

EXAMPLE

MEMBERS CAN ACCESS PRIVATE CONTENT BY CLICKING HERE.

The challenge of generating evidence in small populations is one of the main factors hampering the market authorization of orphan drugs. To enhance the clinical phase of orphan drug development, the European Union funded three consortia *IDeAl* (Integrated Design and AnaLysis of small population group trials), *InSPiRe* (Innovative methodology for small population research) and *Asterix* (Advances in Small Trials dEsign for Regulatory Innovation and eXcellence). EFSPI/PSI is one of the consortium partners in the Asterix project and this generated the idea to set up a Special Interest Group (SIG) for Small Populations.

The **SIG Small Populations** is the most recent Special Interest Group and started in January 2016. The purpose of this SIG is to provide a forum for statisticians working in the Pharmaceutical Industry engaged in the topic of rare diseases cq. small populations.

The main aims of this SIG are the following:

- *To exchange information, share case studies and discuss strategies and methodology being applied in this area of research,*
- *To form a working expert group to interact with the external community, like the FP7 programs (IDEAL, INSPIRE and ASTERIX), and in particular to be in reach for the ASTERIX project in which EFSPI is a partner*
- *Organise and/or participate in workshops and create visibility on biostatistics activities for small populations*

The SIG Steering Committee consists currently of the following 4 members:

Name	Company
Francois Aubin	Venn Life Sciences
Karola Beckmann	Bayer
Egbert Biesheuvel	Danone
Olivier Imbert	Servier

Currently, the SIG Small Populations is working through monthly teleconferences on the last Friday of the month.

For further information, or to join our Small Populations SIG, please contact Egbert Biesheuvel

Search the website   GO

 SIG Resources »

Benefit-Risk SIG

Biomarkers SIG

Epidemiology and Safety SIG

Health Technology Assessment (HTA) SIG
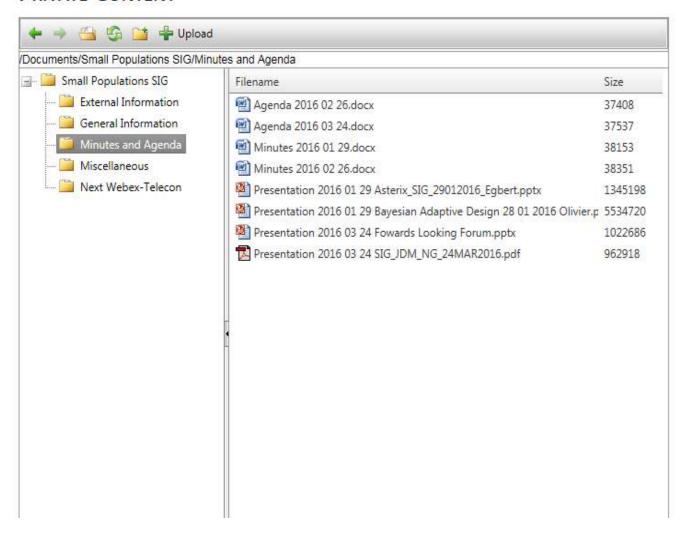
Integrated Data Analysis SIG

Medical Devices SIG

Modelling and Simulation SIG

Small Populations SIG

Toxicology SIG

SMALL POPULATIONS SIG

Search the website   GO

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Biomarkers SIG

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Epidemiology and Safety SIG

Health Technology Assessment
(HTA) SIG

The main aims of this SIG are the following:

Integrated Data Analysis SIG

Medical Devices SIG

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Modelling and Simulation SIG

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Small Populations SIG

Toxicology SIG

- *Organise and/or participate in workshops and create visibility on biostatistics activities for small populations*

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SMALL POPULATIONS SIG

PRIVATE CONTENT

SIG Data Transparency

- NEW SIG (2018)

- "group of cross-pharma statisticians working together on topics addressing the challenges and opportunities of patient level data sharing. As the data transparency environment continues to evolve and with the move to quantification of risk of re-identification, there is a need for statisticians (both from industry and academia) to have an awareness and understanding of these issues and techniques. A current area of focus is practicalities in the delivery of clinical trial documents and their associated risk quantification via EMA Policy 70.

- Outputs from this SIG will be used to inform, educate and pass on learnings to this within EFSPI, its affiliations and beyond.

Lead: Rebecca Sudlow (rebecca.sudlow@roche.com)   14

New SIG Historical Data

- proposed as new SIG (2018)

- Scope:
    - *What is the state of the art regarding approaches to incorporate historical data?*
    - *Which statistical methods should we use to make historical and current data comparable?*
    - *What are the regulatory requirements necessary for the acceptance of historical data in drug approval?*

- Approach:
    - Publishing reviews of the available methods, sources of historical data and case studies.
    - Collaborating with experts to refine and possibly extend the available methods.
    - Interacting with regulators to obtain a better understanding of their requirements.
    - Providing trainings, workshops and talks.
    - Promoting good practice through templates for study protocols and statistical analysis plans.

- Chair: Byron Jones (byron.jones@novartis.com)

New SIG Neuroscience

- proposed as new SIG (2018)

- Objectives:
  - To support/strengthen the role of biostatistics in the development of new medicine for CNS
  - To identify areas where collaboration makes sense

- Approach:
  - Open to large and small pharmaceutical industry
  - Exchange methodological information
  - Do not exchange molecule/project specific information
  - Can initiate working groups for working on CNS specific methodological issues together where it makes sense to do it together
    - E.g., estimands in Neuroscience and the use of MMRM

- Chair: Nikos Sifkas

16

some personal observations …

- SIGs vary strongly
  - From very active to almost dorment
  - Very responsive to not responding at all
  - Very communicative using new technology to silent
- Success of SIGs is very much in drive members
- EFSPI was supportive, did not drive their agenda (unlike working group)
- SIG was connected to Stats Leaders Mtg but deserves track on its own
- SIGs can add to Stats Leaders, Scientific Ctee, Communication & Training (best practices)
- SIGs can be very supportive to EFSPI strategy and vice versa

- How to get Win-Win?
- How does success look like for EFSPI?
- How to get there?

New SIG Chair EFSPI

- Stefan Driessen: 2012-2018

- Maylis Coste & Anne Daniau: 2018 >