SIGs

Special Interest Groups

Statistical Leaders Meeting
July 2018
## Overview current and new SIGs

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

- 2014
- Presentation all SIGs at the time in EFSPi Newsletters

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<th>SIG</th>
<th>SIG Lead</th>
<th>January</th>
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<td>Medical Devices</td>
<td>Roland Marion-Galois</td>
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SIGs – Statistics Leaders mtg

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

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<td>present + discuss</td>
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<td>- Assessing Risk Benefit - Roadmap</td>
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<td>SIG Modeling &amp; Simulation Model Based Drug Development</td>
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<td>Best Practices Presentation</td>
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<td>SIG Biomarkers</td>
<td>SIG Toxicology</td>
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<td>WG Data Sharing</td>
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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/](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
SMALL POPULATIONS SIG

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 (IDEA, 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). EFSP/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 EFSP/PSI 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:

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
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<tbody>
<tr>
<td>Francois Aubin</td>
<td>Venn Life Sciences</td>
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<td>Karola Beckmann</td>
<td>Bayer</td>
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<td>Egbert Blesheuev</td>
<td>Danone</td>
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<td>Olivier Imbert</td>
<td>Servier</td>
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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 Blesheuev.
SMALL POPULATIONS SIG

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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)
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](mailto: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
some personal observations …

• SIGs vary strongly
  – From very active to almost dormant
  – 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 >