Welcome to EFSPI's

7th Statistics Leaders Meeting

July 5, 2016
Sanofi facilities
Paris, France

Welcome to Paris !

Outline

- Welcome   Stefan

- Local Organization   Sylvain

- EFSPI   Marisa

- Statistics Leaders Meeting   Stefan

Organization

- ## Organizing Committee
  - Stefan Driessen
  - Uli Burger
  - Chrissie Fletcher
  - Marisa Bacchi
  - Sylvain Nicolas
  - Maylis Coste

- ## Local Organization
  - Sylvain Nicolas (Sanofi) & Maylis Coste (Servier)
  - **Thank You** for Hosting the Meeting - Sanofi
  - **Thank You** for great dinner last night – Sanofi & Servier

Sanofi Biostatistics and Programming

- **A global dept in R&D Pharma, present in 3 regions: US (NJ, MA), EU (FR, GE), Asia (CN, JP)**
- **Sciences and Operations**
- **Discovery, Preclin, CMC, Tr Med, Early clin dev, Late dev, M.Affairs**
- **A methodology group + several experts; promote innovations**
- **260 associates**
- **Collaborations with M&S group and Bioinformaticians**
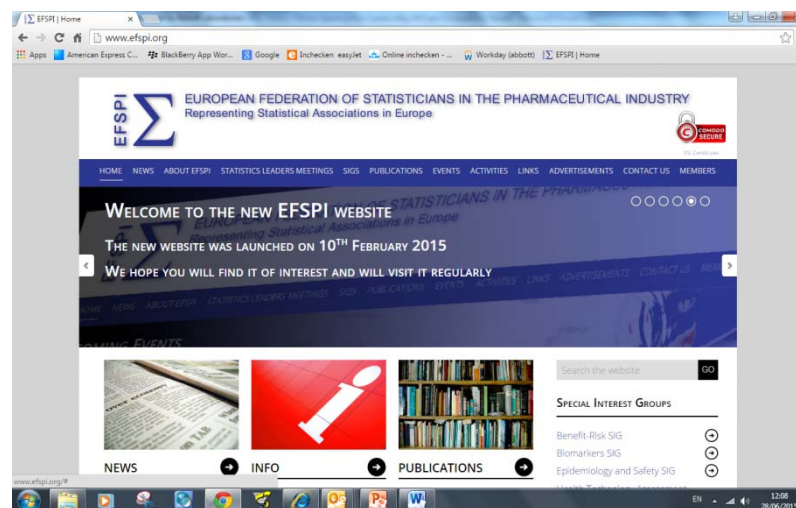- **Collaborations with Sanofi-Pasteur (Vaccines), *and Merial (Animals)***

Common diseases (Diabetes, CV, onco, neurology, immunology) and Rare diseases

This is an EFSPI Meeting

- Please visit our website:

www.efspi.org

EFSPI

SFdS SSL APF DSBS PSDM

BIAS PSI SBS/BVS BBS FMS

- EFSPI = European Federation of Statisticians in the Pharmaceutical Industry
- Founded in 1992
- EFSPI is an "umbrella", non-profit making organisation
- A federation of 10 National European Groups
- No individual members
- Our national organisations collectively represent ~ 2200 members

EFSPI
Strategic Objectives 2016-2018

1. **Represent the association members of EFSPI and provide a united and respected voice on key scientific, regulatory and statistical issues in drug development**

- Develop program of scientific meetings and partner with association members to provide opportunities to discuss and align on key scientific, regulatory and statistical issues (responsible: Scientific Chair)

- Utilise EFSPI Statistics Leaders forum to discuss and align on emerging statistical areas and identify priorities and opportunities for EFSPI to lead/promote these areas in the health care environment (responsible: Statistics Leader Chair)

7th
Statistical Leaders Meeting

Year	Venue	Host	# attendees
2016	**Paris**	***Sanofi***	**35**
2015	Brussels	*MSD*	32
2014	Basel	*Roche*	31
2013	Copenhagen	*Novo Nordisk*	23
2012	Amsterdam	*Abbott*	26
2011	London	*Amgen*	22
2010	Berlin	*Bayer*	26

You have been selected for the Statistical Leaders forum

- **55 Active members**
  - All 10 EFSPI countries
  - Pharma: 40
  - CROs: 10
  - BioTech: 2
  - Med. Devices 2
  - Nutrition: 1

- Agenda's, presentations, and minutes

  of the EU Statistical Leaders Meetings 2010 – 2015

  available on the EFSPI website:

  http://www.efspi.org/EFSPI/Statistics_Leaders_Meetings/Previous_Meetings/EFSPI/Statistics_Leaders_Meetings/Previous_Meetings.aspx?hkey=29eeb7f4-a023-47f2-96e8-046a1a2dd254

Aim Meeting

- ## Set up by EFSPI

- ## Network and share ideas

- ## Shape and influence our environment

  – Education & Continuing Professional Development

  – Methodology Development & Identification of Best Practice

  – Regulatory and Industry policies

  – Effective working with differing resourcing models

- ## Help to shape the strategy for EFSPI

Agenda morning

Time	Topic	Presenter / Facilitator
8:30-9:00	*Registration*	

9:00 - 9:15	• **Welcome address + Intro**
	  o Org. Ctee
	  o EFSPI President
	  o Recap Stats Leaders meeting 2015
		Stefan Driessen + Sylvain Nicolas
		Marisa Bacchi
		Stefan Driessen

9:15 – 10:15	• **Regulatory and Public Interactions**
	  o Results Survey
	  o Estimands, Data Transparency, PRIMES
	  o 1st EFSPI workshop on Regulatory Statistics
	  o GET REAL
		Chrissie Fletcher
		Christoph Gerlinger

10:15 – 10:45	• **SIG Small Populations**
	  o Short update and Q&A
	• **SIG Modeling & Simulation**
	  o Best Practices document
		Egbert Biesheuvel (Chair SIG)
		
		Michael O'Kelly (Member SIG)

10:45 – 11.15	*Coffee Break*	

11:15 – 12:00	• **Precision Medicine & Biomarkers**
	  o R&D is now biomarker-driven;
	    move from broad-spectrum therapies to targeted therapies
	  o Statistician's role and skill set needed
	  o Current support strategies
		Armin Schüler
		Hans Ulrich Burger

12:00 – 12:30	• **SIG AIMS**
	  o Background
	  o Charter, composition, goals
	  o Plans 2016-2018
	  o Interaction with other SIGs
		Craig McIlloney (Chair SIG AIMS)

Agenda afternoon

Time	Topic	Presenter / Facilitator
14:45 – 15:00	*Refreshments Break*	
13:45 – 16:15	• **Present & Future Statistical Depts in EU** o Survey results o Rapidly changing environment o Covering early development to HTA o Top 1-2 Challenges for Stats Manager o Contents (keep up), Operations (keep by) o SME, Big Pharma, CRO	**Maylis Coste** **Sylvain Nicolas** **(table discussions + plenary)**
16:15 – 16.30	• **Idea Generation Meeting 2017**	**Stefan Driessen**
16:30	*2016 Meeting Closure*	

Back Up slides

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2. **Set and promote professional standards in Europe for the development, application, understanding and communication of statistics in drug development and related fields**

- Write 1-2 professional position papers / best practice papers per year in collaboration with representatives from association members and SIGs (responsible: Council representatives, SIG Chairs)

- Hold Annual EFSPI meeting, produce monthly newsletters, and disseminate relevant information (responsible: Communication Office, Scientific Chair)

- Foster collaboration between local organizations to promote relationships and share best practices (responsible: EFSPI president)

3. Enhance the profile of EFSPI and strengthen alliances and collaborations with other bodies within Europe and other regions

Seeking opportunities to collaborate with:

- the EMA Biostatistics Working Group and regulatory statisticians (responsible: Regulatory Chair)
- the EUneHTA Network (responsible: HTA SIG)
- International statistical community and associations important to the Special Interest Groups (SIGs)(responsible: SIG Chair)
- the European Federation of Pharmaceutical Industry Associations (EFPIA) (responsible: President, Scientific Chair)

On the following key activities:

- ❖ Methodology/research and good research practice papers/reports
- ❖ Training opportunities, scientific meetings and discussing mutual areas of interest
- ❖ Development and review of regulatory and payer guidelines
- ❖ Professional development and successfully adapting to changes in the environment

EU Statistical Leaders – key topics discussed in previous meetings

Career Development

Health Technology Assessment

Benefit-Risk   **Medical Devices**

Comparative effectiveness
& network meta-analysis

**Totality of evidence
& observational research**

Integrated
Data
Analysis

Leadership and managing through change

Data transparency   Emerging trends in statistics

Current SIGs*

- Biomarker (leader = Athula Herath, heratha@MedImmune.com)

- Benefit-risk (leader = Alexander Schacht, schacht_alexander@lilly.com)

- Health Technology Assessment, HTA (leader = Chrissie Fletcher, fletcher@amgen.com)

- Integrated Data Analysis (leader = Byron Jones, byron.jones@novartis.com)

- Medical Devices (leader = Roland Marion-Gallois , roland.marion-gallois@medtronic.com)

- Modelling & Simulation (leader = Chris Campbell, ccampbell@mango-solutions.com)

- Real World data (leader = Maurille, maurille@amgen.com)

- Toxicology (leader = Gareth Thomas, ThomasG@UKOrg.Huntingdon.com)

- Small Populations (leader = Egbert Biesheuvel, egbert.biesheuvel@danone.com)

- AIMS (leader = Craig McIlloney, craig.mcilloney@ppdi.com)

* Majority of SIGs formed under leadership of PSI and subsequently expanded to include EFSPI members

EFSPI working group on data sharing

- Lead Sally Hollis (AZ) and Uli Burger (Roche)
- Objectives:
  – To identify and prospectively prioritize statistical issues in data transparency
  – To co-ordinate statistical contributions across Europe to the data transparency debate
  – To disseminate relevant information on the topic across the statistical community
  – To develop and share a vision of the potential longer term impact of data transparency.

EFSPI working group on data sharing

- Five work streams
  - Providing continuous input in EMA/EFPIA (Christoph Gerlinger, Bayer, Chrissie Fletcher, Amgen)
  - Recommendations for re-analysis practices
    (Chrissie Fletcher, Amgen, Sally Hollis, AstraZeneca)
  - Future impact on biostatistics (Nick Manamley , Amgen)
  - Minimal requirements for data sharing (Rebecca Sudlow , Roche, Janice Branson, Novartis)
  - Ensuring patient data confidentiality (Katherine Tucker, Roche)