



Welcome to

EFSPi's

# 6<sup>th</sup> Statistics Leaders Meeting

July 1, 2015  
MSD facilities  
Brussels, Belgium



# Outline

- Welcome Stefan
- Local Organization William
- EFSPI Chrissie
- Statistics Leaders Meeting Stefan

# Organization

## 6<sup>th</sup> EU Statistics Leaders Meeting

- Organizing Committee
  - Stefan Driessen
  - Uli Burger
  - Chrissie Fletcher
  - William Malbecq
  
- Local Organization Thank You to MSD
  - for Hosting the Meeting

# Welcome to Brussels



- MSD is the international name (ex-US and Canada) for Merck
- Global company with headquarters in US



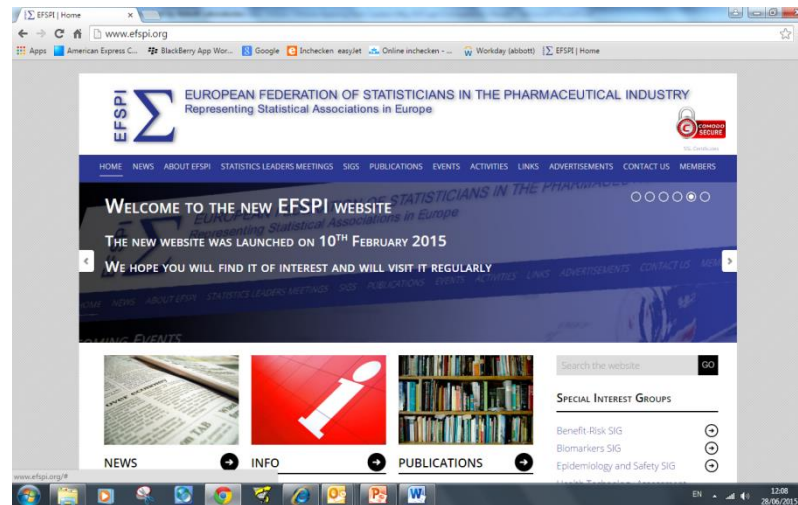
# Biostatistics at MSD

- BARDS: Biostatistics And Research Decision Sciences
- In EU region
  - Statistical and Statistical Programming
  - Global Late Development Projects
  - Center of Excellence for HTA
  - 2 sites: Brussels (since 1979), Hoddesdon (since 2014)



- What is EFSPI?
- Please visit our new website:

[www.efspi.org](http://www.efspi.org)





# EFSPI Goals 2015 - 1

Goal	Description
<b>Strategic Objective 1</b>	<b>Represent the association members of EFSPI and provide a united and respected voice on key scientific, regulatory and statistical issues in drug development</b>
<b>Financial</b>	Manage EFSPI budget and expenses
<b>Scientific meetings</b>	Deliver 3-4 Scientific meetings, including 1 webinar Hold annual EFSPI meeting – moved to 2016
<b>Statistics Leaders meeting</b>	Arrange leaders meeting, agree follow up actions, write article for newsletter
<b>Regulatory</b>	Support PSI/EFSPI Regulatory Committee, including review of new or updated regulatory guidance Support EFSPI/PSI data transparency working group
<b>Communications</b>	Launch new website and use as a resource for sharing information Monthly newsletters to communicate EFSPI activities and latest updates



# EFSPI Goals 2015 – 2

<b>Strategic Objective 2</b>	<b>Enhance the profile of EFSPI in Europe and strengthen alliances and collaborations with other professional bodies within Europe</b>
<b>Enhance profile with EFPIA</b>	Seek opportunities on Clinical Development Committee to engage EFSPI in EFPIA activities Support EFPIA Clinical Trial Design Taskforce
<b>Link to EMA Biostatistics working group</b>	Seek opportunities to engage in development of regulatory guidance documents, including face to face meeting (co-ordinated by Regulatory committee)
<b>Partnerships between Special Interest Groups (SIGs) and other related associations</b>	Support SIGs to establish and/or maintain relationships with other important associations Establish Rare Disease SIG to support ASTERIX

# EFSPI Goals 2015 – 3

<b>Strategic Objective 3</b>	<b>Set and promote professional standards in Europe for the application, understanding and communication of statistics in drug development</b>
<b>Write position papers</b>	Identify topics for further position papers – aim to write at least 1
<b>SIG best practices/manuscripts</b>	Identify best practice papers and/or manuscripts by each SIG Help promote final reports/manuscripts

# Statistical Leaders Meeting - aims

- 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

# Statistics Leaders Meeting

## Membership Statistics Leaders Meeting:

- Extend to wider group of Biostats/Biometrics managers in EU
- Actively pursue on pharmaceutical companies not represented yet
  - 8 new members (using EFPIA member list)
- Allow more members from same company (max 3) in case they represent diversified organizational entities.
  - Statistical Managers in different countries each heading (large) group of statisticians, or
  - Statistical managers responsible for different business (clinical development, epidemiology, late phase/early phase, etc.)

# Statistics Leaders Forum

- At present:
  - 56 Active members
  - 10 (all) EFSPi countries
  - 32 Pharma companies
  - 8 CROs
- Agenda's, presentations, minutes of the EU Statistics Leaders Meetings held 2010 - 2014 are 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](http://www.efspi.org/EFSPi/Statistics_Leaders_Meetings/Previous_Meetings/EFSPi/Statistics_Leaders_Meetings/Previous_Meetings.aspx?hkey=29eeb7f4-a023-47f2-96e8-046a1a2dd254)

# 6<sup>th</sup> Statistics Leaders Meeting

Year	Venue	Host	# attendees
<b>2015</b>	<b>Brussels</b>	<b>MSD</b>	<b>32</b>
2014	Basel	<i>Roche</i>	31
2013	Copenhagen	<i>Novo Nordisk</i>	23
2012	Amsterdam	<i>Abbott</i>	26
2011	London	<i>Amgen</i>	22
2010	Berlin	<i>Bayer</i>	26

# Recap 5<sup>th</sup> Stats Leaders Mtg

## Main agenda items:

- Clinical Trial Data Transparency
  - Practical issues; different companies' approaches
- SIG Integrated Data Analysis
  - 4 workstreams: Efficacy, Safety, NMA, data transparency
- SIG Pharmaco-Epidemiology
  - Overview 6 yrs with best practice docs, papers, presentations, workshops
- Recent Developments in Data & Data Science
  - Topics: IMI, EFPIAs New Clinical Trial Design Task Force, EMAs guidance on Parallel Scientific Advice Regulators and HTA, EMAs PAES Working Groups, and Big Data – Real World Data
  - Survey showed current engagement in these new areas



# Recent developments Data & Data Science

- Challenges:
  - data quality
  - how to deal with bias and confounding
- Needs:
  - Access to best statistical practices and methodologies developed by experts in the field (e.g., SIGs, working groups),
- Opportunities:
  - statisticians to demonstrate their added value, by collaborating and partnering with other data scientists.
  - New era of electronic health records and access to large databases, big data will bring new opportunities for statisticians.

# F-up on action items

## Statistics Leaders Mtg 2014

- “Data Transparency”
  - again on agenda 2015 as the landscape continues to evolve
  - Data Transparency WG connected with Regulatory Ctee
- PAES working group has been set up
- topic “Big Data” is adopted by SIG Pharmaco-Epidemiology
  - now called SIG Real World Data to cover evidence generation in the real world setting; Subgroup will be set up
  - Over 100 statisticians on distribution list
- HTA SIG will present feedback on how to best champion role of statisticians in HTA

# Meeting 2015 – Agenda morning

Time	Topic	Presenter / Facilitator
8:30-9:00	<i>Registration - Coffee</i>	
9:00 - 9:15	<ul style="list-style-type: none"> <li>• <b>Welcome address + Intro</b> <ul style="list-style-type: none"> <li>○ Org. Ctee</li> <li>○ EFSPI President</li> <li>○ Recap Stats Leaders meeting 2014</li> </ul> </li> </ul>	Stefan Driessen + William Malbecq Chrissie Fletcher Stefan Driessen
9:15 – 9:45	<ul style="list-style-type: none"> <li>• <b>Clinical Trial Data Transparency</b> <ul style="list-style-type: none"> <li>○ Short Follow up 2014</li> <li>○ Role of Statistician</li> <li>○ Role in our Organizations</li> <li>○ Opportunities – Threats</li> </ul> </li> </ul>	Hans Ulrich Burger
9:45 – 10:15	<ul style="list-style-type: none"> <li>• <b>Interaction with Regulators in EU</b> <ul style="list-style-type: none"> <li>○ Short Introduction and Discussion</li> </ul> </li> </ul>	Christoph Gerlinger
10:15 - 10.45	<i>Coffee Break</i>	
10:45 – 11:15	<ul style="list-style-type: none"> <li>• <b>SIGs – Update</b></li> <li>• <b>SIG Rare Diseases</b> <ul style="list-style-type: none"> <li>○ Short Introduction + Discussion</li> </ul> </li> </ul>	Stefan Driessen Egbert Biesheuvel
11:15 – 12:30	<ul style="list-style-type: none"> <li>• <b>Real World Evidence</b> <ul style="list-style-type: none"> <li>○ Follow up 2014 (survey) &amp; Present status</li> <li>○ Business case studies</li> <li>○ Statistician: role and skill set</li> <li>○ Opportunities – Threats</li> </ul> </li> </ul>	Armin Schüler Hans-Ulrich Burger  (table discussions + plenary)

# Meeting 2015 – Agenda afternoon

Time	Topic	Presenter / Facilitator
13:30 – 14:30	<ul style="list-style-type: none"> <li>• <b>SIG Benefit – Risk</b> <ul style="list-style-type: none"> <li>○ Follow-up 2012 - Achievements</li> <li>○ New initiatives: technical and aspirational</li> <li>○ Statistician: role and skill set</li> <li>○ Challenges</li> <li>○ Requests for advice, other issues</li> </ul> </li> </ul>	Alexander Schacht  (table discussions + plenary)
14:30 – 15:00	<i>Refreshments Break</i>	
15:00 – 16:15	<ul style="list-style-type: none"> <li>• <b>Estimands</b> <ul style="list-style-type: none"> <li>○ Problem Statement</li> <li>○ ICH Working Group</li> <li>○ (EFSPI) Position</li> </ul> </li> </ul>	Chrissie Fletcher  (table discussions + plenary)
16:15 – 16.30	<ul style="list-style-type: none"> <li>• <b>Idea Generation Meeting 2016</b></li> </ul>	Stefan Driessen
16:30	<i>2015 Meeting Closure</i>	

# Objectives 2015 meeting

- Be informed, Give your feedback and views
- Interact
- To help EFSPI define strategy &
- To further develop EU pharm. stats community