



# Update

## Special Interest Groups (SIGs)

Statistics Leaders Meeting

July 1, 2015

Brussels

# SIGs in Stats Leaders Mtg

SIG / WG	2015	2014	2013	2012	2011	2010
SIG Rare Diseases	intro new SIG					
SIG Integrated Data Analysis		intro new SIG				
SIG Epidemiology & Safety		SIG status+plans			observational data	
SIG Benefit-Risk	SIG status+plans		SIG status+plans	B/R Roadmap	SIG status+plans	intro+discuss
SIG Modeling & Simulation					intro+discuss	
SIG HTA (CER)	Follow up				SIG status+plans	intro+discuss
SIG Biomarkers						
SIG Toxicology						
SIG Medical Devices			intro new SIG			
WG Data Sharing	WG status+plans	intro+discuss	main agenda item			

# SIGs - 2014



Microsoft Word Document

## Series SIG of the Month 2014 completed

- All SIGs have presented themselves in EFSPIs Newsletter
- Collation included

		2014 EFSPI Newsletter Schedule with SIG input											
SIG	SIG Lead	January	February	March	April	May	June	July	August	September	October	November	December
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									✓			

# New SIGs

- EFSPi/PSI SIG **Rare Diseases**
  - Will present itself at Stats Leaders Mtg
- SIG Application and Implementation of Methodologies in Statistics (**AIMS**)
  - Set up out of PSI
  - Very much willing to convert into EFSPi/PSI SIG
    - in discussion

# SIG AIMS – charter (draft)

## Aims:

- To support PSI Committees and Special Interest Groups (SIGs) with the **technological application and implementation of statistics**. To develop understanding of new analytical tools and approaches to share with PSI members via appropriate forums. To ensure PSI members are supported with understanding the requirements for the implementation of industry data standards.

## Anticipated Outputs:

- There is a need for all statisticians and programmers to continue to develop their technology toolkit and support industry enhancements. These may cover:
  - **New analytical tools**
  - Enhancement of existing **analysis software packages**
  - Evolution of industry data standards and guidelines

## Chair SIG:

- Craig McIloney (PPD) & Lyn Taylor (Parexel)
- + 4 to 6 additional members needed

# SIGs - 2015

## **SIG Modelling and Simulation**

- organized one-day workshop, London, March 20, 2015
- Drafted Best Practice document

## **SIG Benefit-Risk**

- Presented at APF, Germany, 2015, and PSI conference, UK, 2015
- Organizes two webinars June 16, and 29, 2015 with PSI/EFSPi

## **SIG IDA**

- Paper on Product Safety Labelling soon to be submitted to journal

## **SIG Toxicology**

- two-day workshop, October 13-14, 2015, near Heathrow Airport