



# EU Statistical Leaders 2017-

What should be the priorities for EFPSI?

Marisa Bacchi, Maylis Coste

Statistical Leaders to identify the priorities for EFPSI based on outcome Stats Leaders workshop 2016 (“the bubbles”)

EFSPi  $\Sigma$  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



## Discussion topics, for Round 1 and Round 2

Portfolio strategy:  
-Portfolio management  
-Decision making support  
(need for –good- POS methodology)

Product Global Life cycle  
-from discovery to M.A.  
-translational approach  
- model-informed development plan

More complex development plan  
-Use innovative designs and methods  
(Adaptive, bayesian)  
-Biomarkers

New focus:  
-Real World Evidence  
-PharmacoEpidemiology  
-Evidence synthesis  
-Comparative effectiveness -  
PharmacoEconomy

Organizational strategy:  
-Re-organization/ engineering  
-Transversal /multidisciplinary activities

Capacity & Resources  
-Collaborators: nb & skills  
-Productivity & timelines  
-Project teams vs methodo teams (&exploratory)  
-Outsourcing

Interaction with Regulators  
- Marketing Authorization  
- HTA  
- Europe, US and worldwide

New mindset to generate knowledge  
- 2ndary use of Database  
- Multidisciplinary collaboration  
- Data Mining

Structure & mindset:  
-Europe vs US  
-Joint devlpt with partner  
-Clinical project vs methodology work

New operational activities:  
-Transparency: disclosure, anonymisation  
-DSUR, PBRER  
-CDISC

New data sources  
-Connected objects  
-Longitudinal data  
Health records  
-Digital  
- Big Data

New technics and softwares:  
- Advanced analytics,  
-Modélisation/Simulation  
-Decision making calculations



## Round 2: adjustment of our organization and models ?

### **Groups of ~5-6 participants**

Discuss a domain where adaptation or evolution of the organisation of our statistical groups should be relevant as well as new commitments for Statistical leaders in our Company

Try to answer the following questions as applicable

- What is the benefit for us to be involved in each theme ?
- What is the benefit for the Company to involve Statistical skills?
- What are the risks for our discipline not to be included in these areas ?
- What do we need to be ready and proficient ?
- Do we identify opportunities and/or needs to develop new internal or external partnerships ?
- Do we need to develop other skills to be influential ?
- Could we identify new opportunities for professional careers of Statisticians ?



# Round 1: new/future activities

## **Groups of ~5-6 participants**

Discuss a topic about the new activities or upcoming changes.

Try to answer the following questions as applicable

- Which extent of involvement should Biostatistics groups have ?
  - Initiate, develop and produce / R.A.C.I
  - internalize or externalize, partially or totally
- What do we need to be ready for and proficient: methodology, know-how, development, production, interpretation, robustness, ...
- What expertise shall we need? what profile/background/training for Statisticians ?
- Should we have more input in Statistical education programs?
- Should we support multidisciplinary skills?
- Which role for the external experts ?
- Should we consider new collaborations with academic groups ?



## EU Statistical Leaders 2017-

What should be the priorities for EFSPi?

Identified Priorities (summary of the meeting discussion)



## Professional accreditation (ISI, 07/2017)

Working group: M. Pettersson (SE), A. Bathke (AT), D. Rozkrut (PL), F. Turkman (PT), G. Sanz Sáiz (ES), L. Pieri (IT), P. Koopman (NL), S. Marque (FR)

---



- **Criteria** (based on the systems applied by ASA and RSS)
  - ✓ MSc degree in statistics or education deemed equivalent
  - ✓ Five years of documented working experience as statistician
  - ✓ Continual Professional development after graduation
  - ✓ Communication and pedagogical skills
  - ✓ Comply to FenStats ethical standards and other relevant standards
  - ✓ Member of national statistical association
- **Roles**
  - ✓ **FenStatS**: set the criteria and standard for accreditation
    - keep a register of accreditations
    - evaluate the accreditation process
  - ✓ **National Associations**: receive applications
    - evaluate the applications
    - issue credentials to successful applicants
- **Points under discussion**: Fenstat and national associations, Recruitment of auditors, Utility of extensions (eg biostatistics), Continuous application terms or fixed dates, Application fees



## Accreditation Statisticians

---

Heavily discussed within EFSPi in 2011

- Accreditation on European level for 'Pharmaceutical' Statisticians
- Should cover statistician mentioned within GCP
- One Professional Level (PSTAT)
- Combination of relevant education and number of years of experience
- Low registration fee, renewal every 5 years
- Should recognize the existing national accreditation systems
- RSS and ASA were reconsidering their admin part
- FENStatS mention to start with EU level
- Due to other EFSPi priorities & new external initiatives - postponed

Proposal to introduce an accreditation on European level

Target group

Level

Criteria for registration

Fee

Renewal

European registration board

How should it work



## Accreditation Statisticians:

### next steps

---

#### Points to be discussed

- Agreement to reinvest in this topic ?  
depending on speciality : Pharma ? Agro? Academics ? Others ?
- Agreement to participate to Fenstat initiative ?  
interaction with S. Marque (Société française de Statistique, Fr) ? And/or other national representatives ?
- Topic to be considered by Statistical Leaders ? or within EFSPi council ?
- Working or Reference group to be set up ?  
to consider speciality, level of experience/responsability, junior/senior, fees, renewal, auditors .....
- Interested Statistical Leaders ? Companies ?



# European ITIT

- Introduction to Industry Training (ITIT) consists of 6 x 1.5 day courses running from October – June
- To describe the drug development process from research right through to marketing
- Each course is given at a different host company
- Aimed at statisticians/programmers with 1-3 years experience
- Currently run within UK, extremely popular course (max 25 delegates with ~20% from mainland Europe)
- PSI would like to make this course available to more European delegates



# Questions for EFSPI leaders

1. How many new graduates does your company employ each year?
2. Would you be able to send your new graduates on this course?
  - Course fees ~£1000, includes hotel and food costs for all sessions
  - Would need to travel to 6 different European cities between October-June

3. Would your company be willing to host a session in mainland Europe?

Current sessions: Drug discovery/research; Toxicology; Data management & CRO; Clinical trials; Health Technology Assessment; Marketing