



EFSPi Statistical Leaders Meeting

20th June 2012

Key Points, Actions and EFSPi Council Response

Executive Summary

The third EFSPi Statistical Leaders meeting was held June 20, 2012, in Weesp, The Netherlands. Representatives from all the European countries and major pharmaceutical companies were in attendance (agenda and full list of attendees, see appendix).

In general, the purpose of the Statistical Leaders Meeting is to develop a network of statistical leaders, shape and influence our professional environment and help to shape the strategy for EFSPi. In this third meeting, feedback was given on previous year's action items such as SIGs, Career Path Initiative, and Risk Benefit. Special attention was given to discuss the clear challenges apparent in the EU pharmaceutical statisticians environment.

An intensive, open-space workshop was set up to find ways to address these and to propose steps to be actioned by the various stakeholders, amongst which, the companies, EFSPi, the Statistical Leaders Forum, and last but not least, the statisticians themselves. The Statistical leaders chose four areas for a deep dive and defined the following goals to be achieved:

- NXT generation Statisticians
 - **to achieve that new graduates have better understanding of the whole drug development process and areas of statistical influence**
- EU differentiators
 - **to maintain collective expertise and strong link between regulators, industry and cooperative group and promote advantages of EU**
- Areas for success now
 - **To educate statisticians in an area such as Benefit/Risk where there is a need for quantitative valid approaches to summarize, present and communicate results across various domains to come to an overall evaluation. An area that would enable statisticians to add value beyond being a “number cruncher” and take a more strategic role while still utilizing their quantitative background.**
- Change Management
 - **To increase awareness and need for change, thereby identifying the skill set needed for statisticians and leaders.**
 - **To define a vision and develop a “support package” that will enable statistical leaders to drive change in companies.**

The group clearly expressed awareness of the present difficult environment and in conjunction with the goals defined above, proposed a rough outline of actions to achieve these goals.

Introduction

Francois Aubin and Stefan Driessen welcomed the attendees and introduced the meeting. The objectives of this meeting were:

- Feedback from last meeting
- Identification of up to 3 priority actions for the strategic direction of EFSPI in
 - Risk Benefit
- Define Goals, Strategies and Follow-Up mechanisms to address the challenges and threats to the EU pharmaceutical statistics environment



2012 EFSPI Stat
Leader Forum Mtg Op

Feedback on the actions taken on the topics discussed at the second EFSPI Statistical Leaders Meeting

Career paths for Statisticians

- After the Statistical Leaders Meeting in 2011 the survey was re-sent to the companies and additional feedback was received. The group led by Hans Ulrich Burger was expanded to further the completion of the reporting of the survey and the paper for publication. The final paper was sent to Pharmaceutical Statistics in June 2012 and is now in the review process. It was also sent as pre-read to the 2012 Statistical Leaders Meeting and Hans Ulrich Burger presented it at the meeting.



Career paths for
statisticians in pharm

SIG Updates

- Stefan Driessen gave an overview of the current SIGs, including updates on last year's action items for the following SIGs:
 - Health Technology Assessment
 - Risk Benefit
 - Modelling & Simulation
 - Epidemiology & Drug Safety

Action Statistical leaders – the forum is further urged to increase awareness on the SIGs within their companies and actively try to engage more people to participate in the SIGs

Actions to EFPSI Council

- define the criteria for setting up a SIG
- get more information on the DIA approach to topics of special interest currently ongoing in US
- get the SIG “Medical Devices” on board of the Statistical Leaders Forum



SIG Update June
2012

Accreditation of Pharmaceutical Statisticians

- No new developments have been reported. The attempt to get more EU countries on board outside of the present set of ten (10) has not been successful.

Actions – none

Risk Benefit – Status of new (EFSP/PSI) SIG

Ian Hirsch introduced this topic (using web-ex) with Sara Hughes as facilitator.



Benefit Risk June
2012

Key points from the discussion were:

- B/R is cross-functional and statisticians are structured problem solvers, yet statisticians need to get better at safety assessment for adequate B/R
- Quantitative B/R is being piloted in many companies
- Basically B/R exercise is after the fact (the data is there), but B/R should already start early on (even during dose selection)
- B/R area could give opportunities for statisticians to influence the communication and facilitation of this topic within their companies. The quantitative model for B/R could be

the entry for statisticians to play a more strategic role in this rather new and developing field, because they are “on top” of much of the data involved as well as should have most of the expertise needed to display and summarize the data in a well-founded fashion.

- SIG group size is reasonable but not all members do really contribute and foremost listening in

Actions:

- **Statistical leaders:** to ensure that all companies have representation in the new SIG on Benefit Risk and set clear expectations that all members are to contribute actively to the SIG
- **EFSPI** to consider how to support statisticians becoming better at safety assessment as well as at B/R
- **B/R SIG** is to consider how to promote idea of statisticians being leaders in cross-functional effort to look at B/R

Adaptive Statisticians and the Challenges beyond Clinical Trials

Kit Roes was the presenter and Egbert Biesheuvel the facilitator.



Key points from the presentation and the discussion were:

- the analogy of where we are with some of other areas in the past and the analogy with the innovation cycle (following six sigma approach)
- the importance of increasing our strategic role and our capability of communication in cross functional settings that have impact and added value and not just based on detailed statistical contributions; the fact that epidemiologists have an advantage in the communication to the clinical world than the average statistician while not always better equipped from a methodological point of view, but still more influential
- absence of statisticians in projects like IMI Protect and CER research

Messages to Statistical leaders

- **To reconsider current position of the statistician to be better prepared for the future. And to try to take this further in the day-to-day business:**

- need to open up to other areas than Clinical Trials to manage our future
- perception of the statistician as the number cruncher and sample size calculator needs to be changed
- need to become more entrepreneurial, less risk-averse and open to innovation
- reconsider the skill set needed to face the challenges
- re-inforce the need to change (increase awareness and sense of urgency)
- think about exposing the statisticians to other areas and other disciplines more than is being done now
- how are we to position ourselves as statisticians: as professionals involved in day to day 'number crunching' or as innovators?

These considerations were also taken on board into the afternoon workshop.

Action Statistical Leaders:

- support your staff/people to step out their comfort zone into other new area's

Action EFSPi:

- see actions afternoon workshop

Strategic Do's and Don'ts for the EU Pharmaceutical Statistical Community

Stefan Driessen introduced this important strategic item and explained the set up of the open space, brainstorming workshop. Facilitators were Egbert Biesheuvel, Kit Roes, Sara Hughes and Uli Burger.



Strategy Workshop
Set Up JUN 2012



Outcome Strategy
Workshop 20JN2012

During the lunch break all participants were requested to indicate the area of interest where they could see opportunities to influence our future to our best. The topics were then grouped into logical categories and further discussed in focused workshop setting whereby goals, strategies, and follow-up needed to be defined in these selected areas.

The group expressed clear awareness of the present difficult environment and defined goals, strategies, and milestones to jointly undertake for the future. In general, the role of statisticians needs to move away from a very technical oriented scientist to a more strategic partner in drug development. An area where such a role is highly suited and needed would be the Benefit/Risk assessment field. With developing guidelines in EU this area is becoming increasingly important and impactful, where EU statisticians might relate to. For that we will have to go through some changes

to properly manage that, both with respect to individual statisticians as well as for its leadership. The workshop has delivered a rough outline of future steps (see slides).

Proposed Action Items:

1. NXT generation statistician

Goal: new graduates have better understanding of the whole drug development process and areas of statistical influence

Actions: EFSPI to contribute to or organize training program

EFSPI to contact Universities to get this into their curriculum

2. What differentiates EU from the rest

Goal: maintain collective expertise and strong link between regulators, industry and cooperative group and promote advantages of EU

Actions: EFSPI to further links to other EU organizations (regulators, payer organizations, academia)

EFSPI to further organize meetings with these stakeholders in EU

3. Change Management

Goal: Increase awareness and need for change, thereby identifying the skill set needed for statisticians and leaders

Indicate nature of change and come with support model

Actions: Statistical Leaders, EFSPI to set up Working Group to

- define vision, perform benchmarking and gap analysis

- Working Group with external advice

- develop, pilot, and share “support package” that will enable statistical leaders to drive change in companies

- actions, best practices, communication within and across companies

4. Areas of success now

Goal: Educate statisticians in area of Benefit/Risk where there is a need for quantitative valid approaches to summarize, present and communicate results across various domains to come to an overall evaluation.

To enable statisticians to add value beyond being a “number cruncher” and take a more strategic role while still utilizing their quantitative background.

Actions Statistical Leaders:

Get (more) acquainted with regulatory background and framework of Benefit/Risk (not only the techniques)

Start projects/pilots on Benefit/Risk within your company, and encourage your statisticians to also concentrate on graphical presentation and sensitivity analyses

Share EMA pilots on this area and best practices with other companies

Develop experts within your company

Actions EFSPI:

To request from and support SIG with developing a B/R toolkit and a plan/process to support companies to take this on.

Organize more meetings/workshops to get statisticians exposed to topic.

Action Statistical leaders:

- Review and “approve” minutes of meeting, including outcome of workshop.
- Define proposals to EFSPI Council for follow up
- Contribute to design and implementation defined strategy track

Wednesday June 20, 2012

Weesp, The Netherlands Abbott facilities

AGENDA: Statistical Leaders Meeting 2012

Time	Topic	Presenter / Facilitator
9:00-9:20	<ul style="list-style-type: none">• EFSPI President Welcome address• Organisers welcome	Francois Aubin Stefan Driessen
9:20-10:30	<ul style="list-style-type: none">• Risk Benefit (<u>web-ex</u>)	Ian Hirsch / Sara Hughes
10:30-11:00	<i>Break</i>	
11:00-12:00	<ul style="list-style-type: none">• Adaptive statisticians & the challenges beyond Clinical Trials	Kit Roes / Egbert Biesheuvel
12:00-13:00	<i>Lunch break</i>	
13:00-13:20	<ul style="list-style-type: none">• SIG Update	Stefan Driessen
13:25-13:45	<ul style="list-style-type: none">• Career Path	Hans Ulrich Burger
13:45-15:45	<ul style="list-style-type: none">• Strategic Do's and Don'ts for the statistical community in EU Pharma	All
16:15	<ul style="list-style-type: none">• Meeting summary and actions	Stefan Driessen
16:30	<i>Meeting adjourn</i>	

List of Participants

First	Surname	Country	Company
François	Aubin	France	Cardinal Systems
John	Adler	Sweden	AstraZeneca
Egbert	Biesheuvel	The Netherlands	Merck
Bruno	Boulanger	Belgium	Arlenda S.A.
Frank	Bretz	Switzerland	Novartis
Hans Ulrich	Burger	Switzerland	Hoffmann-La Roche
Maylis	Coste	France	Institut de Recherches Internationales Servier
Stefan	Driessen	The Netherlands	Abbott Healthcare Products B.V.
Chrissie	Fletcher	United Kingdom	Amgen Ltd
Birgit Gaschler	Gaschle	Germany	Boehringer Ingelheim Pharma GmbH & Co. KG
Sara	Hughes	United Kingdom	VIIV Healthcare
Neils Michael	Kamp	Denmark	Novo Nordisk A/C
Olavi	Kilkku	Finnland	ORION PHARMA
Juergen	Kuebler	Germany	CSL Behring
Pasi	Korhonen	Finnland	StatFinn
Frank	Langer	Germany	Lilly Deutschland GmbH
David	Morgan	United Kingdom	Ipsen Biopharm Ltd
Thorkild	Nielsen	Germany	Bayer Schering
Michael	O'Kelly	Ireland	Quintiles
Martin	Struijs	The Netherlands	Genzyme
Kit	Roes PhD	The Netherlands	Julius Center for Health Sciences and Primary Care
Herve	Salomon	France	Laboratoires Fournier S.A
John	Whittaker	United Kingdom	GSK
Josie	Wolfram	The Netherlands	Astellas
Kerry	Gordon	United Kingdom	Quintiles
Paolo	Morelli	Italy	Cros