High Level Summary

8th Statistics Leaders Meeting

July 4, 2017

Ludwigshafen, Germany

8th Stats Leaders Meeting 2017

- Venue: Ludwigshafen (AbbVie facilities), Germany
- Date: **Tuesday, July 4, 2017**

- Chair: Stefan Driessen
- Local Org Ctee: Daniele Compagnone
- Program Ctee: Marisa Bacchi, Hans-Ulrich Burger, Daniele Compagnone, Stefan Driessen, Chrissie Fletcher, Maylis Coste

- Attendance: 39
- Topics: Statistics in Decision making, Interaction with Academia, Patented trial designs (invited session by AbbVie), Data Science workshop, EFSPI priorities

8th Statistical Leaders Meeting

Year	Venue	Host	# attendees
2017	**Ludwigshafen**	***AbbVie***	**39**
2016	Paris	*Sanofi*	34
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

Participants
Stats Leaders Meeting 2018

List of Participants

First	Surname	Country	Affiliation
John	Adler	Sweden	AstraZeneca
Jens-Otto	Andreas	Germany	UCB
Marisa	Bacchi	Switzerland	Actelion
Francois	Beckers	Germany	Merck Serono
Egbert	Biesheuvel	Netherlands	Danone
Bruno	Boulanger	Belgium	Arlenda
Janice	Branson	Switzerland	Novartis
Hans Ulrich	Burger	Switzerland	Roche
Simon	Cleall	UK	Biogen
Lisa	Comarella	UK	CROS NT
Daniele	Compagnone	Germany	AbbVie
Maylis	Coste	France	Servier
Stefan	Driessen	Netherlands	Abbott
Cecile	Dubois	Germany	Grünenthal
Andy	Garrett	UK	ICON
Christoph	Gerlinger	Germany	Bayer
Kerry	Gordon	UK	Quintiles
Ingrid Sofie	Harbo	Denmark	Lundbeck
Ray	Harris	UK	Eisai
Jurgen	Hummel	UK	PPD

First	Surname	Country	Affiliation
Delyth	Jones	UK	GSK
Niels Michael	Kamp	Denmark	Novo Nordisk
Olavi	Kilkku	Finland	Orion Pharma
Nelson	Kinnersley	UK	Roche
Martina	Kron	Germany	AbbVie
Frank	Langer	Germany	Lilly
Hans-Jürgen	Lomp	Germany	Boehringer Ingelheim
Nick	Manamley	UK	Amgen
Roland	Marion-Gallois	France	Celgene
Giacomo	Mordenti	Germany	Livanova
Sylvain	Nicolas	France	Sanofi-Aventis
Michael	O'Kelly	Ireland	Quintiles
Emmanuel	Pham	UK	Ipsen
Alan	Philips	UK	ICON
Justine	Rochon	Germany	Boehringer Ingelheim
Christophe	Sauce	France	Danone
Armin	Schueler	Germany	Merck Serono
Jim	Weatherall	UK	AstraZeneca
Josie	Wolfram	Netherlands	Astellas

Agenda

Time	Topic	Presenter / Facilitator
8:30-9:00	*Registration + Coffee*	
9:00 - 9:15	• **Welcome address + Intro** o Org. Ctee o EFSPI President o Recap Stats Leaders meeting 2016 ▪ SIGs (AIMS, …) o Qualification Biostatisticians	**Stefan Driessen, Daniele Compagnone** **Marisa Bacchi** **Stefan Driessen**
9:15 – 9:45	• **Future of Statistical groups – F-up of workshop 2016** o Statistics and Decision making support	**Maylis Coste, Sylvain Nicolas**
9:45 – 10:45	• **Close collaboration with Academia?** o What can they do for us? o What can we (EFSPI) do for them? o What can we (Statistical Leaders) do for them? o How can we support EU supported academic initiatives (ASTERIX, IDEAL, ASPIRE) and how already ongoing collaborations (IMI)	**Uli Burger**
10:45 - 11.15	*Coffee Break*	

Agenda cont.

Time	Topic	Presenter / Facilitator
11:15 – 12:30	• **Invited session by host AbbVie** o Company intro o Discussion topics as determined by Host: • Patented clinical trial designs	**Daniele Compagnone**
12:30 – 12:45	• **Data Science - intro** o Background RSS section on Data Science o Example of Data Science in action (AZ)	**Andy Garrett, Jim Weatherall**
12:45-14:00	*Lunch break*	
14:00 – 15:45	• **Data Science - workshop** o Presentation Survey results o Outline topics for discussion o Break-out groups, present back to main group o Wrap up	**Andy Garrett, Jim Weatherall**
15:00 – 15:15	*Refreshments Break*	
15:45 – 16.15	• **What should be the priorities for EFSPI ?** o Statistics Leaders identify the priorities for EFPSI based on outcome Stats Leaders workshop 2016 (“the bubbles”)	**Marisa Bacchi, Maylis Coste**
16:15 – 16:30	• **Program Statistical Leaders Meeting 2018**	**Stefan Driessen**
16:30	*2017 Meeting Closure*	

High Level Summary (Maylis Coste)

Statistics in Decision Making

- Key Take Aways / Messages:
  - Consensus on the strategic importance to involve Statisticians on that topic (considering also controversies on PoS)
  - Agreement on sharing cases and/or issues and/or methods between Companies
  - Agreement to set-up a Decision making SIG
  - SIG as a support to promote Statisticians involvement within Companies
- Action items for EFSPI:
  - Validation of a new SIG organisation
  - Publication in the EFSPI Newsletter an announcement for a DM SIG for participants and a Leader
- Action items for Stats Leaders group:
  - Identify and mobilise participants for the SIG within companies
  - Elaborate if Study/Drug level and Portfolio strategy level should lead two 2 groups
  - Suggest a Leader for this Decision making SIG
  - Confirm agreement on Cases Sharing , suggesting examples and/or raising specific issues
- Any further comments ?
  - No
- Any recommendations for 2018?
  - Agreement on SIG objectives, identification of the SIG Leader and initiation of Cases sharing
  - First feedback at the 9th EU Statistics Leaders Meeting

High Level Summary (Uli Burger)

Interaction with Academia

Key Take Aways / Messages:

- Deeper interaction with academia is important and we should do it
  - Good academic interactions are important for our success
  - We need to better understand their needs
- Having a specific FP7 project meeting with researchers was not actively supported

Action items for EFSPI?:

  - EFSPI should think about creating a working group like we have today for the interaction with regulators

High Level Summary (@Daniele)

Patented trial designs

- Key Take Aways / Messages:
  - Most participants had not heard before about patented clinical trial designs, and the Sequential Parallel Comparison Design (SPCD) was the only known. Patenting a trial design is possible in US, not in EU.
  - The possibility of patented clinical trial designs was mostly seen critical due to its impact on the ethics and culture of science. It can be a barrier to or prevent important clinical research.
  - The potential for further patented designs was seen; however, the SPCD appeared to be an “outlier”.

High Level Summary (@Daniele)

Patented trial designs (cont'd)

- Action items for EFSPI?:
  - No actions were seen necessary, since the SPCD appeared to be an outlier.
- Action items for Stats Leaders group?:
  - No action items.
- Any further comments?
  - Patented trial designs may also interfere with data transparency.
- Any recommendations for 2018?
  - None, maybe keep an eye on this topic.

High Level Summary (@Jim Weatherall/Andy Garrett)

Data Science

- Key Points / Messages:
  - The Royal Statistical Society in the UK has formed a Data Science Section in order to embrace this emerging, multi-disciplinary area
  - The EFSPI leaders' survey showed: (1) variability in current maturity and activities in data science; (2) a trend to see data science mature further, and focus on areas such as big data and the internet-of things (IoT)
  - The break out groups produced a large amount of ideas around how to proceed in big data, IoT, automation & decision science
- Key Action items for EFSPI:
  - EFSPI should be open minded toward and embrace Data Science, promoting statistical rigor rather than rigidity

High Level Summary (@Jim/Andy)

Data Science

- Action items for Stats Leaders group?:
  - Communicate within own company to raise awareness
  - Find ways to ensure that data science activities are robust, by adding the rigour that high quality statistics brings
- Any further comments?
  - The RSS document on “12 questions” for data science is a great starting point, and can be found here: https://github.com/rssdatascience/industrialisation/blob/master/industrialisation.pdf
- Any recommendations for 2018?
  - Stay connected with the fast-evolving field of data science

High Level Summary (@Marisa)

Priorities EFSPI

Key Take Aways / Messages:

- Accreditation: No real clear need and agreement for a new involvement on that topic, in relation with FENSTAT recent reactivation. The EFSPI will be opened to give its position or review deliverables produced by Fenstat WG (through the French representation in particular)

Recommendations for 2018?

- Promote Data Science with different stakeholders as Pharma and , Health Authorities as well as Statisticians and Academics
- Continue to interact and partner with Health Authorities (BSWG, MHRA, …) as a professional organisation with a trusted voice
- Plan a Capacity Survey and share resources metrics solutions
- Organise a Forum for sharing experiences in a non competitive way
- Stimulate Knowledge and reference sharing
- Follow the evolution of Interactions with Academics
- Develop interactions with other professional groups as CROs, Startups, …

Back Ups

Detailed feedback from break out groups

Interaction with Academia - Questions to the break out groups

- Here are a number of questions for us
  - Do we want a closer relationship with academia?
  - Do we know what academia needs from us? Did we ask them?
  - What do we know about their wishes?
  - Are there things we can do differently?
  - Do we want to help academia for publicly funded initiatives beyond IMI?
  - How could such help look like?
  - Are we interested in the outcome of such initiatives? Do we implement those (e.g. Get Real initiative)?
- What do we think about the proposal to support current FP7 projects?

Interaction with Academia

Feedback from the break out 1st table

- It's worth doing it – to work with universities / trial units (*what we had in mind – at lest my understanding - are the centres like the KKS - see http://www.zafes.de/partner/neu/index-kks.php*)
- Stay focused on contacts you can manage / you are interested in
- Company gains
- - reputation
- - networking
- - hiring
- - scientific support (difficult topics, tasks we don't have time for)
- University gains
- - topics for research
- - internship / PhD support
- - funding
- - to attract students if they see the job opportunities

Interaction with Academia

Feedback from the break out 2nd table

- Collaboration mandatory
- Academia needs the big question
- Do things differently
  - Support conferences for students (e.g. Bayer, NCS)
  - Networking meetings
- Identify and sponsor funding opportunities

Interaction with Academia

Feedback from the break out 3th table

- Academia = universities + MRC
  - Already a lot going on at many companies in supporting master and PhD students
- Academic needs
  - Data
  - Support for PhD students (where to go)
- Do differently
  - Apprenticeship (growing importance for study)
  - Academic courses for industry and vice versa (already happening)
  - Some involvement with research initiatives, more important
- Threat of data science on both sides

Interaction with Academia

Feedback from the break out 4th table

- It is not academia but academicians
  - What they need ? Money ? Publications?
- Find out what they need
  - What is their goal?
  - What do they try to achieve?
- What to do differently?
  - Consult with academics
  - Support internships
  - Closer relationship like with regulators?

Interaction with Academia

Feedback from the break out 5th table

- Just additional points:
- It is important to find out what is required by law in each country
- In Denmark for example University advisory boards are required to have industry representation

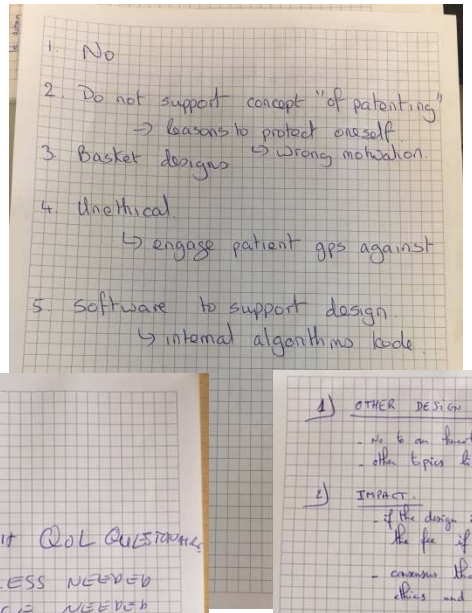
Patented trial designs

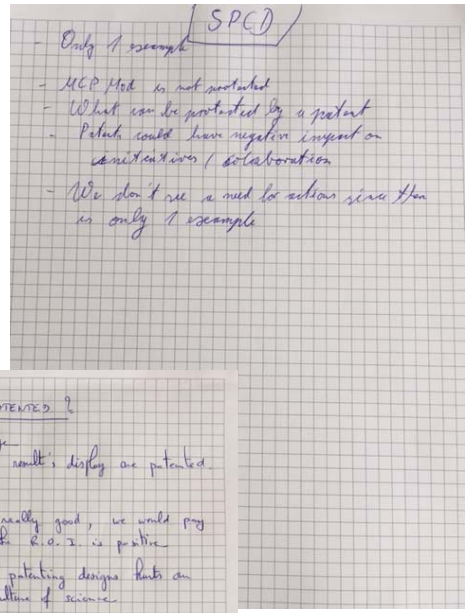
- Breakout groups – questions

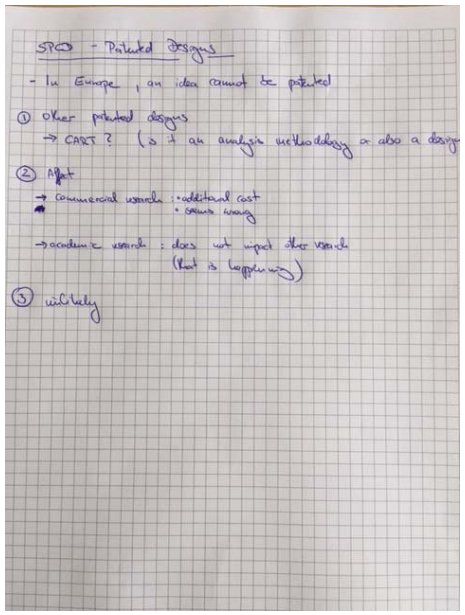
1. Are there any other patented clinical trial designs known?
2. How can patented clinical trial designs affect
    - commercial clinical research,
    - academic clinical research,
    - the freedom of science?
3. What is the potential for further patented clinical trial designs?
4. Is there a need/ does it make sense to take action and which?
5. Is there any other aspect to patented clinical trial designs?

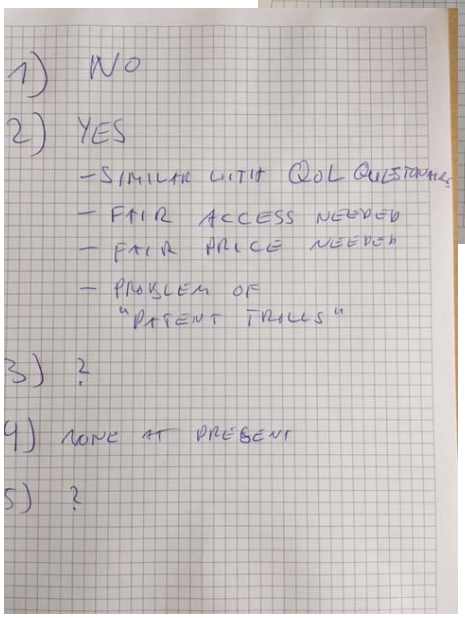
Patented trial designs

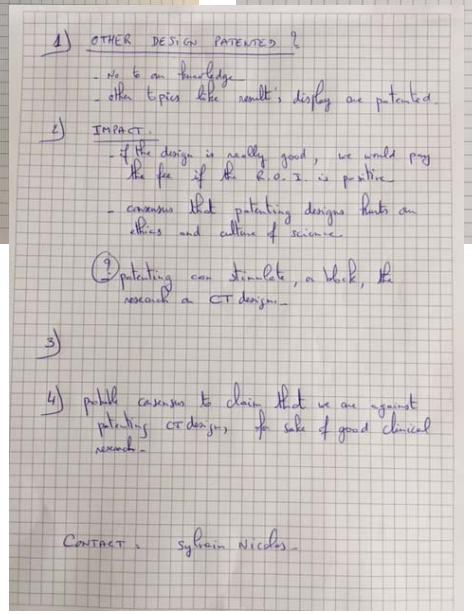
- Breakout groups – results











Data Science

- Breakout groups – questions

1. Brainstorm: what are the main opportunities and challenges
2. What are the top 3 areas we should address as statistical leaders
3. What immediate action should we take next?

Data Science Break out -Emerging Themes

- That Pharma Statisticians should be open minded towards, and embrace, DS
  - Statistics departments should be seen as open for DS business, within their companies
  - Statistics departments should collaborate within their companies by organizing cross-functional workshops and working groups
  - Statistics departments should communicate within their companies about DS
  - Statistics departments should explore opportunities for training within their companies
  - Statisticians should feel confident to apply DS techniques and to learn ”on-the-job” – dig into the data, find out how the data were collected (meta data) and expand their armory.
  - Re-enforce that you do not have to call yourself a DS to do DS

Data Science Break out -Emerging Themes

- That EFSPI should be open minded towards, and embrace, DS
  - Collaborate with other organizations, such as RSS and PhUSE, to organize joint meetings
  - Promote statistical rigor within DS, not rigidity
  - Investigate what training courses should be made available for statisticians in DS, perhaps in conjunction with other organizations
  - Encourage the sharing of DS experiences and case studies
  - Re-enforce that statisticians do not have to call themselves a Data Scientist to do DS

Data Science Break out - Opportunities

- Big Data
  - Establishing off-label use to control risk
  - Understanding disease better (disease trajectories and co-morbidity)
  - Building historical controls

- Internet of Things (IoT)
  - Predicting patient events
  - Tracking trends
  - Improving patient compliance (visits/medication) and data accuracy more generally
  - Understanding disease populations and disease clusters

Data Science Break out -Opportunities

- Decision Science
  - Statistics at the heart of the decision making process
  - Combine external with internal data for decision making
  - Bring Statistics and DS closer

- Automation (AI)
  - Potential to gain process efficiencies
  - Understanding what the question is key

Data Science

- Breakout groups – results