EFSPI Statistics Leaders Meeting 2022

Session 1 Breakout Summary

Session 1 Summary

Q1 What networks and collaborations are key for statisticians?

- New EMA methodology working group via Regulatory SIG
- HTA forums via HTA SIG
- Other groups that the SIGs are partnering with – can these be shared/mapped?
- Professional statistical and data science societies – at country, EU and international levels
- Academic groups and links with Universities
- Industry / Pharma groups e.g. EFPIA, PhUSE, ISPOR, DIA
- Statistical career development forums
  - (new) Managers network (e.g. below EFSPI Statistics Leaders forum)
  - (new) Junior statisticians network (e.g. new graduates)

Session 1 Summary

Q2 How could EFSPI strengthen collaborations with other groups?

- Define topics that are of mutual interest with other groups, identify priority areas for focus
- Develop a partnership strategy, roadmap and engagement plan
- Develop a stakeholder map with contact names and highlight connections between groups
- Write more position papers / share views on emerging issues
- Develop an up to date of 'what is EFSPI' to promote and communicate key activities
- Identify EFSPI ambassadors to be point of contacts to partner closely with key priority groups
- Consider holding 'hackathons' and use agile approaches e.g. NextGen Statisticians
- Use a range of approaches to connect with stakeholder groups

Session 1 Summary

Q3: How could EFSPI strengthen collaborations with EFPIA / Industry associations?

- Formalise connections and establish where could both groups work more closely together
  - E.g. EFPIA formally requests EFSPI when seeking statistical expertise
  - E.g. EFPIA formally recognises EFSPI as a key stakeholder for clinical research
- Seek to partner more closely on key topics
  - E.g. when reviewing guidelines, emerging trends, stakeholder engagement
- Communicate in EFSPI the EFPIA objectives and activities that are of most relevance to EFSPI
- Acknowledge EFSPI and EFPIA have very different mandates (EFPSI is a professional society, EFPIA is an Industry association)

Session 1 Summary

Q4: What is the role of EFSPI Statistical Leaders in influencing / shaping who EFSPI networks with?

- Raise awareness of EFSPI and key activities within their companies, encourage individuals to get involved in committees/SIGs/activities

- Help to improve the branding of EFSPI with other groups

- Share their professional networks (create stakeholder map)

- As a group, develop a call for action and identify key topics that EFSPI should be involved with

- Offer to facilitate discussions and share their insights / experiences

- Form subgroups to progress ideas and suggestions

Session 1 Summary

Q5: How can EFSPI help statisticians build networks and get involved in professional collaborations?

- New forum for future statistics leaders (succession planning)

- NextGen meeting

- Give key talent the time and opportunity to be part of SIGs/committees

- Identify role models to be mentors or coaches

- Create ambassadors to encourage people to be part of networks (we could agree core principles)

- Share career paths and how networking and being involved in external activities has supported career development / led to new opportunities

- Award prizes for people who contribute hugely to work of EFPSI

Each breakout team feedback to each question

Q1: What networks and collaborations are key for statisticians?

- Differences in membership between different organisations, e.g. not all EFSPI members are EFPIA members
- Different purpose for EFPIA and EFSPI; EFPIA focuses more on regulatory issues
- What priorities do we have with different collaborating organisations?
- New Methodology Working Group has been established; important that EFSPI is seen by them as the key voice of the statistical community; EFSPI is not a lobbying group
- American organisation narrower membership; limited to top 20 pharma companies
- Question: do we have the right membership; noted that we do not have academic members; would be good to have a list of academic members
- Long term would be good to influence stats course content
- Collaboration with physicians and patient groups happening in SIGs; would be good to have that information documented for wider awareness; action for Emmanuel / Adam
- Do we need to check what other organisations do we need to reach out to; e.g. EMWA

Q1: What networks and collaborations are key for statisticians?

- Colleagues within the own company (within stats and across functions), especially in times of Covid

- Recruitment is a challenge => workload increase => decrease of collaboration in general
=> so we have active support interaction
=> due to turnover internal networks could not taken for granted

- Network for managers not represented in the EFSPI stats leader group?

- SIG groups are available and very helpful. Having also a special interest group on people management?

Q1: What networks and collaborations are key for statisticians?

- Royal Statistical Society
- DSBS + academic society in Denmark
- FenStat (much broader than pharma)
- PACE network (Pharma Data Science Network).
- Finland Society of Biostatistics (more academic and broader)
- Connect to academia more generally
- Regulators
- HTAs
- Asia??? China/Japan?
- Africa
- India – India Stats Leaders meetings

Q1: What networks and collaborations are key for statisticians?

- Industry & Academia
  - EFSPI, PSI (industry only), academics (IBS and local region), ISCB (good mix between academia and industry), ISCTM & DIA & AAPS (stats and clinicians / scientists)
- Regulators, Health Technology Assessment (HTAI)
- Direct relation with academia
  - Helping them developing cursus more in line with industry practice
  - How do we connect better with university ? (internship with local university)
- Data sciences
  - Scraping data, exploring vs. designing data vs. embracing variability
  - Conference on data sciences, on statistics (ASA, Rstudio, clinical & non clinical conf)

Q1: What networks and collaborations are key for statisticians?

- We interpreted this question as applying to statisticians working in pharma industry

- We noted this differs for junior staff versus senior staff/leaders

- For younger statisticians it's key to retain links from university studies to other students and to academics
  - Academic links remain important for all experience levels for innovative collaborations

- Company-internal cross-functional networks are critical: with colleagues in clinical, R&D, even marketing, portfolio management. As well as to other quantitative disciples such as data scientists (if in the same or in different departments) – there is increased overlap in work than in the past with these groups – pharmacometricians, RWE, or analysts working on whatever source of data.
  - Creates a path for influence, and also facilitates training of non-statisticians on stats/stat thinking

- External groups important for our teams such as PSI SIGs, as well as conference attendance

- Links to regulatory statisticians for informal interaction – might be perceived as a conflict of interest, but would be good to find routes to open up more channels for communication. To increase mutual understanding of industry stat vs reg stats views. Need more than just conference panel discussions. There are some collaborations in Europe, such as the PSI Reg SIG which meets with EMA and MHRA statisticians.

- For leaders: this stat leader forum is very important

- Link to medics, internal and also external, close collaboration of our disciplines generates ideas

- Statistical programmers, Phuse, submissions standards, use of R etc. also important

- Leverage platforms such as LinkedIn

Q2: How could EFSPI strengthen collaborations with other statistical groups, statistical leader groups and related professional societies?

- How can we strengthen links to other national level organisations within each country; e.g. PSI with ABPI

- How do we strengthen links to data scientists; there is a Data Science SIG; are we connected sufficiently?

- FENSTATS is a statistical organisation; but very limited links to them

- What other statistical organisations are there in member countries such as RSS in UK; should have at least a list of who these organisations are

Q2: How could EFSPI strengthen collaborations with other statistical groups, statistical leader groups and related professional societies?

- We need an ambassador to facilitate, somebody how is active (e.g. what Chrissie is doing)
- We have to be focused
  => topics where we have to focus on?
  => "direct" obvious like RSS, APF, IBS
  => "indirect" not obvious like DIA
  => What's about more involvement of academics
- HTA – special situation in UK (NICE)
- Identify for the appropriate forums (neutral ground) to interact with Agencies, HTA, etc; how to involve academia
- Collaborations in general a strong, maybe ad-hoc
  => at the moment no big gap identified (our blind spot?)
- Facilitate bringing new methodologies into play

Q2: How could EFSPI strengthen collaborations with other statistical groups, statistical leader groups and related professional societies?

- Stats Leaders group – listen to position in China, India – how do we get an invite?

- Create master slide deck to use in presentations to these groups.

- Define purpose of collaboration – include create list of hot topics, create a call to arms to work on these projects, write a position paper, abstract to a conference.

- Academia – find mutually beneficial research topics, key skills we expect from newly qualified statisticians/data scientists. RSS data science accreditation. We should define Core principles of what is required for future statisticians in pharma. Reach out to Professors who are more open (maybe with previous pharma experience).

Q2: How could EFSPI strengthen collaborations with other statistical groups, statistical leader groups and related professional societies?

- EFSPI could help orienting companies to rely more on internship and junior career training
  - In line with university program (e.g.. timelines)
  - White paper
- Identifying common topics (interest for us, for EFSPI, for industry…)
  - May include several networks and collaborations
  - Creating sub committee with different purpose
    - Working group Training, white paper, conference
  - EFSPI can help having approval from companies to get their employees working on such topic to foster innovation
- Identify topics for hackathons that answer real industry questions
  - Target next generation (student and junior employees)

Q2: How could EFSPI strengthen collaborations with other statistical groups, statistical leader groups and related professional societies?

- Cross-attendance at occasional meetings between the different groups (EFSPI leaders, BSLC)
- Identify groups of interest and just reach out – the standing of EFSPI is such that it should be welcomed, and points of collaboration then agreed. That worked for today with BSLC!
- EFSPI is perhaps largely content-focused, need to keep in mind the importance of networking, pro-activity, "selling", and external focus; mindset for stat community. Younger generation may respond well to more use of social media.
- EFSPI council to monitor/update more frequently on collaborations
  - Including the country members & who they link to
  - Which EFPIA WGs are relevant?; where are & where should statisticians involved
- Landscape the groups to connect to, and map out the existing and desired network – document the relationships so more explicit & transparent
- Relevant professional societies: EFPIA, other geographies such as China, RSS, Phuse.. ISCB, IBS, ISPOR , ISPE, DIA and relevant WGs thereof..
  - Website cross-linking
- Increase EFSPI presence at conferences (not just individuals from companies presenting, connected to the country society as well as EFSPI's "respected umbrella", may encourage other groups to reach out as profile raises)
- How can members flag potential fruitful areas to EFSPI? (e.g., if they go to a non-typical conference and see an opportunity)
- How might EFSPI connect to development led by tech companies? DCTs, wearables, ML/AI, data vendors..

Q3: How could EFSPI strengthen collaborations with EFPIA and other Industry associations?

- We would like EFPIA to reach out to EFSPI members for expertise; rather than EFPIA reaching out to statisticians in member companies

- Could we try to lobby for EFPIA having an employed statistician?

- Ask EFPIA to recognize EFSPI as a stakeholder for clinical research

Q3: How could EFSPI strengthen collaborations with EFPIA and other Industry associations?

- We need an ambassador to facilitate, somebody how is active (e.g. what Chrissie is doing)

- What do both groups need from each other having the common goals in mind
  => Stats support by EFSPI to EFPIA?
  => Medics support by EFPIA to EFSPI?
  leading to more deep dive discussions like on guidance assessments

- Why are this are 2 different organisations (Brand)?
  Need to change or keep as it is as it somehow working due to the overlap

- It's based on a small number of people ….
  - this is an advantage (focused) and an disadvantage (few people only)

Q3: How could EFSPI strengthen collaborations with EFPIA and other Industry associations?

- Reflection we weren't aware of some of the things EFPIA were doing.

- How do we access this info?

- Need a condensed version/highlights. EFPSI newsletter could maybe doing this. Agree on contact (from Stats Leaders) for a particular workstream.

- More join EFPIA/EFSPI workstreams.

Q3: How could EFSPI strengthen collaborations with EFPIA and other Industry associations?

- Do we want to strengthen collaboration ?
  - Likely yes, but how would we do that ?
- EFPIA needs to understand the full scope of activities of statisticians (not only regulatory stats)
- Take profit for the fact that EFSPI (science) is composed from statisticians that are more neutral compared to EFPIA (company view - lobby)
  - Better understand when EFSPI/PSI and EFPIA can help companies
  - EFPIA can request the position or some inputs of EFSPI (instead of individual statisticians) on specific tricky stat questions, and then can make a feedback to authority (e.g. about an EMA guidance or question or proposal, etc.)
    - May be difficult (EFSPI should NOT be the stat group of EFPIA and opinions of stats would certainly never be in line with policy-driven texts)
    - But would bring more transparency

Q3: How could EFSPI strengthen collaborations with EFPIA and other Industry associations?

- We should maintain image of independent methodologists and not industry representatives, keep this in mind in connections with industry groups

- IMI, Horizon 2020 – landscape and identify where to contribute

- Move from adhoc to more formal approach
  - EFSPI has various roles (regulatory, communication, training, SIGs etc.), need a role for this topic? "external engagements lead"

- What groups are there that we should consider in Asia (Japan, China..)

Q4: What is the role of EFSPI Statistical Leaders in influencing and shaping who EFSPI networks and collaborates with?

- System awareness: awareness of potential issues and know who to reach out to for each of them; expert network

- Can we ask the EFSPI leaders on who their professional network contacts are for certain areas?

- What do we want to do and why? This should then determine who we should collaborate with

- Who do we need to educate about EFSPI outside the statistical community? Need for branding EFSPI

- EFSPI website: clarify when a statistician is needed and what for

- Which areas are we not involved in? e.g.: HTA involvement; lead by HTA SIG

Q4: What is the role of EFSPI Statistical Leaders in influencing and shaping who EFSPI networks and collaborates with?

- We have to identify what is the focus which triggers then the needed collaborations

- The EFSPI stats leader meeting is an important networking element => Flow of information between US and EU by making use of the diversity of the leaders attending the meeting, e.g. Midwest US headquarter vs central Germany headquarter based company
- might be even more important as travel budgets go down

Q4: What is the role of EFSPI Statistical Leaders in influencing and shaping who EFSPI networks and collaborates with?

- Raise awareness, educate, be visible,

- As a group formulate a call to action – drive things – create workgroups/workstreams, like SIGs.

- Improve Branding i.e. to emphasize the benefits of being part of an EFSPI network and an active collaborator.

Q4: What is the role of EFSPI Statistical Leaders in influencing and shaping who EFSPI networks and collaborates with?

- Facilitating discussion like the one of today
- Stimulating ideas that can be proposed to others
- Sharing experience to see what outcome may be reached with what collaborators

- start collaborative events (e.g. regulatory statistics conference, or so, under EFSPI umbrella)

- Identify topics to implement collaborations
  - more difficult, but conferences may help !
  - Ex : in PH4 post approval safety studies (PASS), how can we better leverage the studies requested by authorities and deliver more accurate results using the observational data
    - Collaboration with epidemiologist, data scientists, etc.
    - "what are we allowed to do with observational data regarding privacy, authority, publish results ? Etc."

Q4: What is the role of EFSPI Statistical Leaders in influencing and shaping who EFSPI networks and collaborates with?

- We propose to put higher on agenda, the mapping out as detailed on prior slides – then leaders can feedback on the map & engagement process, priorities

- Stat leaders might help form a subgroup to progress that

- Cluster by theme: CT methods, geography, operational, RWE, data science..

Q5: How can EFSPI help statisticians to build networks and get involved in professional collaborations?

- When is the right time to attract statisticians to join EFSPI; next generation probably keen to join early

- Do we need a forum for future stats leaders; succession planning

- Next generation stats leaders meeting? When to engage and identify them?

- Does it make sense long term for organisations to set up regionally? Better to have a global organisation? Not replace EFSPI, but supplement it

Q5: How can EFSPI help statisticians to build networks and get involved in professional collaborations?

- Advertisement for Working groups / SIG which triggers us to advertise within our teams to network
  - e.g. the SIG session at Leuven was helpful to remind us on this
  => reminding us on available networks and pave the way

- Dark spot: SIGs outside EFSPI/PSI
  => have an inventory of available activities/groups (how to set-up without setting up a bureaucratic monster)
  => Marketplace to bring people / ideas together?

Q5: How can EFSPI help statisticians to build networks and get involved in professional collaborations?

- Support SIGs.
- Give key talent the time and opportunity to be part of groups.
- Role models to be mentors or coaches
- Create mentors to encourage people to be part of networks (we could agree core principles)
- Sharing career paths.
- What is hindering people being on groups.
- Prizes for people who contribute hugely to work of EFPSI.
- What are criteria for selection of SIG members?

Q5: How can EFSPI help statisticians to build networks and get involved in professional collaborations?

- EFSPI can help providing good-fit statisticians for specific questions (whereas in EFPIA, 'random' statisticians are often selected, or not even statisticians if non is available)
  - Encourage EFPIA to request the type of profile they need for their topics

-

Q5: How can EFSPI help statisticians to build networks and get involved in professional collaborations?

- Encourage team members to join SIGs and other WGs

- An available "map" (document) will orient and facilitate statisticians to identify and navigate interest areas and build networks – host on an EFSPI website with links to learn more, resource for all members

- Platforms for younger statisticians to speak (like the PSI new starters session, e.g. table at regulatory workshop for <5 years exp, forums targeted for juniors)