

Session 2: How leaders are promoting innovation in drug development

Breakout Summary

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Group 1

Question 1: Why is uptake of useful inventions (think estimands, MCP-mod, futility analyses, adaptive designs, covariate adjustment, statistical engineering, ...) so heterogeneous between companies?

- Differing pipelines drive different priorities
- Heterogeneity within company (Across areas)
- Some companies better than others at collating information internally
- Ease of uptake driven by company (& stat function) size

BUT...

- Uptake driven by very small number of people
- Variable focus/time on methods training for statisticians
- Role of regulator?
- Can be too precious about inventions – could be more collaborative
- Reluctance to share information across companies – improving e.g. with more open-source software
- Partnership between R&D head and Stats head = easier to get ideas adopted

Question 1: Actions for EFSPI Leaders

- Enable publication (broad sense), internal information sharing, case studies – not necessarily the people who “did the work”
- Communications lead, intentional strategy, time availability /prioritisation
- Expectation setting/role-model/encourage cross-company working
- Increase focus on generalists/communicators within the function

Group 1: Actions for EFSPI Council

- Stat leaders & Methods leaders assessing SIGs (incl future needs)
- Some sort of placeholder about “breaking out of stats” across companies
 - Other professional bodies
 - Non-stats on Council?
 - DIA opportunities

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Group 2

Group 2: How can we better manage, sometimes avoid, large-scale implementation of inappropriate or insufficiently evaluated methods (think responder analysis, overuse of single-arm trials). How can we generate the trust with senior leaders that they reach out to us to evaluate “new” methods?

Short term

- Influence and partner with stakeholders within / outside the company, starting from KOL through Regulatory
- Offer help in quantifying the ROI / value of the proposed solutions, while understanding the time needed to answer.

Mid Term

- Develop advisory model with key sponsors, cross-functional team, to help non-statistician understand the challenges and the key findings in order for them to become ambassadors. Goal: build trust / proactively pick-up new methodology trends
- Drive open / collaborative mindset in assessing alternative methods / options / ideas

Long-Term

- Show value of internal know-how through dedicated methodological teams collaborating with external experts and across companies with the additional “goal” of popularising key methods
- Develop branding strategy showcasing innovation generating within the company. Focus on clarifying the value stat teams create (e.g. by metrics / ROI....)

Group 2: Actions for EFSPI Leaders

- Promote cross-company collaboration in pre-competitive space
- Develop stronger collaboration across companies to drive agenda in regulatory / stakeholders
- Pooling case studies to support methodological implementations
- Promote the understanding of the role / value of statistics in medical communities

- Develop / communicate / track priorities on statistical methodological topics that generate value for the company

- Develop advisory model with key sponsors, cross-functional team, to help non-statistician understand the challenges and the key findings in order for them to become ambassadors to proactively pick-up new methodology trends
- Encourage staff to embrace / demonstrate open / collaborative mindset in assessing alternative methods / options / ideas by role modelling / trainings ...

Group 2: Actions for EFSPI Council

- Facilitate within and outside EFSPI stronger collaboration across companies to drive agenda in regulatory / stakeholders.
- Develop communication strategy for the community on methodological aspects and the relevant implementations by targeting non statistical (e.g medical) journals
- Develop feedback mechanism from the SIGs to the Stats leaders on key messages to help us be more cohesive in our actions.
- Leverage what was done in one company to disseminate implementation in the different companies
- Promote the understanding of the value of statistics in medical communities

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Group 3



Group 3: What can statistical leaders do to promote meaningful statistical innovation in drug development? How can we better commercialize our "own" statistical inventions?

1. Prioritize innovations to put forward: budget is limited
Make or buy off-the-shelf?
2. Build trust with your stakeholders
3. Understand the business value: you cannot plug and play academia
We are a development organization, not a pure research organization.
4. Use a combination of bottom-up, top-down and sideways approach

Group 3: Actions for EFSPI Leaders - internal

- The methodologist should be a catalyst.
Find the right level of help that methodologists can provide to study statisticians.
- The inventors and the sellers need to both be credited.
- Challenge the right collaborators: the *innovators* and the *settlers*
Why are we re-using that same method? How sure are we that it is the best approach?
- Identify innovations ahead of the curve

Group 3: Actions for EFSPI Leaders - trust

- Build trust with upper management:
have a seat at the table or create the table
show that they learn something from you
do not over-interpret what they say
- Talk to external leaders: external view has more value

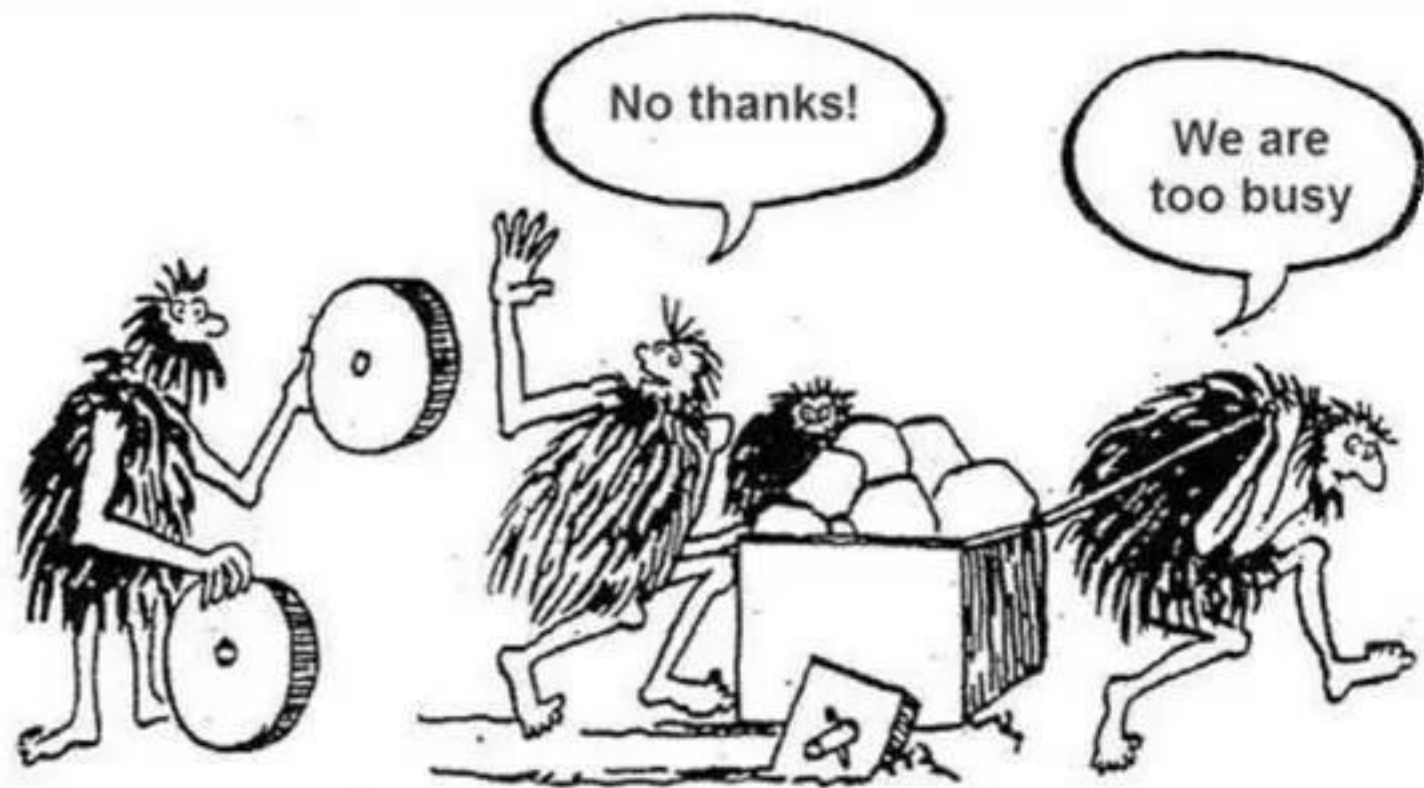
Group 3: Actions for EFSPI Leaders

The blue-sky idea

- Have a communication expert in each Biometrics Department?

Group 3: Actions for EFSPI Council

- Together, it is easier to promote successful case studies.
- Scoping exercise:
How is statistical innovation being perceived by different stakeholders?
Leverage EFSPI statistical associations.



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Group 4

Group 4: Where and how is potential for collaboration to address the above questions, e.g. between stats and methods leaders? Or with other stakeholders? 1

- Health Authority interactions, Consortia, Working Groups, where can we build synergies?
- These points are discussed in the Leadership Teams, but there are differences between bottom-up and top-down “currents”; type of organization matters (biotech or big pharma).
- Where can we have the best impact, for example do we talk investments and resources and, if so, would we speak to the “right” stakeholder (e.g. CFO). **Lead by example.**
- Emphasize the right points, under-selling some and over-selling others. Can we correct the aim?

Group 4: Where and how is potential for collaboration to address the above questions, e.g. between stats and methods leaders? Or with other stakeholders? 2

- To create case studies, could we get upper management buy-in and then pilot the innovation in a couple of projects. Again, lead by example.
- Emphasis on collaboration upstream, with proper metrics.
- Step up as stats leaders and be able to frame the problem statement, the resources, the costs and, **ultimately, the GAIN/ADDED VALUE.**
We need to verbalize well how does success look like?
Set up the METRICS well and at the beginning.
- Why is causal inference not having more traction? Can we position it and provide also the narration?

Group 4: Where and how is potential for collaboration to address the above questions, e.g. between stats and methods leaders? Or with other stakeholders? 3

- **Socialization** (before **commercialization!**): show me the added value and that it was useful in another, similar context.
- Could the Methods Leaders come to the EFSPI Stats Leaders and “teach” why there is worth in the innovative methods (each one in turn)? But do it with examples and impact!
- Subject matter experts are needed, amplifiers, advocates that can divulge the new methods. They will need to have time (resources!) to do this and this will need to be formally acknowledged.
- TOP 5 suggestions from Methods Leaders to EFSPI and then connect to HA/FDA to “put it on the map” and collaborate.

Group 4: Where and how is potential for collaboration to address the above questions, e.g. between stats and methods leaders? Or with other stakeholders? 4

- OPEN Question: how can we influence the Companies/TA/Functions' FPI's? Who owns and can influence them?
- We should celebrate the successes (e.g. 10 Years of Estimands) with the impact.
- Put futility (for example) in a narrative that emphasizes the patients saved, the time saved, the resources saved.
- Collaboration between Stats Leaders, Methods Leaders and the "consumers".

Group 4: Actions for EFSPI Leaders

- Share with the other Stats Leaders success stories and celebrate them with the appropriate metrics that would speak to the “consumers” of these methods.
- Try and emphasize a culture of **metrics** with which we **value** innovation. No innovation for the sake of innovation but innovation to gain tangible value that we can socialize.
- Sharing examples! Be mindful of the audience!
- Increasing the collaborations/partnerships with Commercial and other functions that may have a completely different slant.
- Understanding the needs of the organizations and how innovation can help achieve them.
- Should we discuss the role fo standardization in innovation?

Group 4: Actions for EFSPi Council

- Have more opportunity to discuss successful case studies and share it with everybody. Speak more about case internal studies that could have points in common with others and their impact.
- Both from Stats Methods Leaders but also from SIG's, which do great work. We should leverage the SIG's to come back to us on the council and give examples on how methods have been commercialized by them.