Session 2 Breakout Group Tasks

- Collate a list of concrete actions YOU can take to help advance / commercialize these four topics, within your company and in our ecosystem at large

- Discuss where our two groups can intensify collaboration / support each other

Introduction

- „risk adverse" – what would regulators say
- Facilitate non-competitive discussions
  - Between companies and with regulators
  - Method leaders do not hold budgets and do not sit on relevant meetings
- Stats leaders and method leaders have different access to projects
  - Timeframes, resources, portfolio…
  - Methods, designs, …
- How are messages conveyed within the organization
- Why are we still talking about the same topics
  - Why are billions spent on AI, but we were not able to spend 300k on Bayesian statistics…

Group 1

How can Methods leaders better support Stats leaders?

- Be more specific around the "business cases"
    - Tangible benefits: reduce costs, faster results, …
- Support Stats leaders to have meaningful conversations with senior / top management
- Translate trends into practice; pilot and adapt new methods
- Create a framework to reassess "cold cases" for each of the four topics
    - Collect cold cases
    - Assess
    - Publish

How can Stats leaders better support Methods leaders?

- Bring the right topics to the method leaders; ensure that these are connected to real business cases.

- Help with "branding"
  - Articulate the problem
  - "Hurdles of translation"

- Align priorities

- Advocate for innovation, new methods

- Build a set of "cold cases"

Summary of concrete actions

Action	Target audience	Responsible	Deadline
Share results of EMA Bayesian meetings	Statisticians non-statistical R&D leaders	EFSPI attendees	October 2025
For each topic, have a few links as a reference Plus create "incentives", plus communication	R&D leaders, statisticians	Methods group	
"cold cases"	--	Stats leaders + methods	Framework before next meeting

Group 2

How can Methods leaders better support Stats leaders?

- Share more detailed planned deliverables for each of the 4 topics
- Make sure learnings are available

How can Stats leaders better support Methods leaders?

- Share redacted methodological HA feedback (+ve and –ve)

- Push for use of 4 topics in projects

- Share 4 topics with RA colleagues within companies to aid commercialization (Stat Methods leaders communicate to RA)

Summary of concrete actions

Action	Target audience	Responsible	Deadline
Build ambassadors within companies	Company Stats	Stat Leaders	
Strategic guidance to organisations (all 4 topics)	Company Stats	Stat Leaders	
Share use cases (new examples) with regulatory feedback from companies and vice versa (and at conferences across companies)	Stats Leaders and Method Leaders	Stat Leaders / Stat methods	
Mindset of considering both frequentist and Bayesian approaches (experiment with Bayesian FDA supplementary demonstration initiative)	Company Stats	Stat Leaders	
Method leaders to feedback from Bayesian EMA workshop in June 17	Stats Leaders	Stats Methods	
Understand pre-competitive versus competitive topics actually are (company specific differences)	Company Stats	Stat Leaders	
Examples on how to communicate (critical for companies not represented in Stat Methods)	Stat Leaders / Company stats	Stats Methods	
Understand link between M15 and using this framework more broadly		Stat Methods	

Group 3

How can Methods leaders better support Stats leaders?

- Enable us to input, let us know of the opportunities (e.g. EMA workshops).

- Internally, make our own companies more aware of the existence of this group (Stats Leaders) and how we can all benefit from this.

- Methods Leaders could provide a framework (slide deck?) so that each company can present internally to their leadership with a consistent message as to how they work and how they could help (and also how the stats leader can bring back into EFSPI). Second step: they could also come and present to our internal SLT's.

- Put on the agenda for EFSPI consortium work (IMI) and EFSPI can also create cross-pharma consortium on specific topics. Changing the perception!

- Put out there position papers, provide references for the Stats Leaders to build on! We would have something tangible to share and promote in our companies. **Note:** position papers that speak more to a cross-functional teams and to leadership and not to statisticians. Position papers should also have concretely the Operational details, these are just as relevant as the statistical details in accepting the whole concept.

- Help us establish THE NEW NORMAL

How can Stats leaders better support Methods leaders?

- Share the whole journey on Case Studies to build a Library of Case Studies.

- Make stakeholders aware internally what we can share, the topics and the benefits of the Stats Leaders Group.

- Improve the prioritization of the methods leaders: where can we REALLY have the biggest IMPACT?

- Ask our Internal company Regulatory colleagues to the Stats Leaders' meetings? To the EFSPI Regulatory Workshop? Could we "show" them that there opportunities in sharing?

- Introduce the idea of a "Blog" where we can share challenges and conversations on "difficult" topics; this can start us on the sharing (maybe the tool ould also attract the NextGen).

Group 4

How can Methods leaders better support Stats leaders?

- Sharing tips, best practice for statisticians, providing a 6 monthly newsletter

- Share experience with case studies

- Share also the others topics not selected in the 4 priorities – how we can help you to progress on that topics

How can Stats leaders better support Methods leaders?

- Promote the website, the activities of the methods groups, disseminate within our organization

- Share outside our stat community (clinicians, internal regulatory) – why these innovative methods could be useful ?

- How many companies have made progress on commercializing innovation ? Due to a survey

- Involve our local organization

- Estimands: challenge is to involve the clinicians, it is not just a statistical topic. Stat leaders should be the ambassador