

Proposal for new EFSPI team: «Statistical methodology leaders in drug development»

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Proposal

- Form a new EFSPI team to create a community of ***statistical methodologist leaders***
- Suggested name of the team is

«Statistical methodology leaders in drug development»

- We believe this proposal aligns well with the **EFPSI objectives and priorities!**

- By ***statistical methodologists*** we mean individuals that devote relevant efforts to the development, dissemination and advocacy of innovative quantitative concepts and approaches in drug development (irrespective of size of company)
- By ***statistical methodologist leaders*** we mean individuals that drive corresponding strategies for their respective organizations

Statistical methodologists in industry - current status



Many companies (and numbers are growing) have / set up methods groups.



Efforts / knowledge exchange largely opportunistic and uncoordinated.



Occasional meetings of methods groups, largely based on personal contacts of members.



«Same» innovation / trainings happening at many companies in an uncoordinated way.

Objective of the new EFSPI team

Provide a platform to connect statistical methodology leaders and groups in Europe (with potential to expand globally)



Exchange and develop best practices on the following topics (list not exhaustive):

- Provide a support network and safe space for discussion for methodology leaders.
- How to establish, position, and sustain
 - An impactful statistical methodology strategy in an organization
 - A team of methodology statisticians in an organization
- Stakeholder management: company-internal partner functions, upper management, academia, regulators, NextGen methodologists, ...
- How to innovate? How to drive uptake and create impact («commercialize») of innovative concepts and approaches within organizations and beyond?
- Anticipate future trends (which concepts/methods will be relevant in x years?) + prioritization
- «Inspiration» for talent who look for career opportunities outside classical trial statistician/management/academic tracks
- Facilitate meetings of statistical methodologists. Currently one-offs between companies

Goals and planned activities

- Regular **TCs / F2F** meetings to pursue objectives
- Organize joint **conferences / sessions** (e.g. EFSPI / BBS seminars)
- Write **position paper** discussing the «role of a sound statistical methodology strategy to advance drug development»
- Set up **webpage** for:
 - Sharing which organizations have statistical methodologists working on drug development challenges + provide contacts
 - Sharing material (e.g. publications, best practices etc.)

Membership expectations: start in a focused way



Commitment is essential!

- No «I / our organization wants to be in to stay abreast, but we do not want to commit resources / work» attitude
- Committed to dial in to regular TCs and contribute to the team's scope



One member per organization. Need not be an *administrative* head of a group but rather a committed individual which is (co-) driving the strategy in terms of development/ dissemination and advocacy for innovative quantitative concepts and approaches

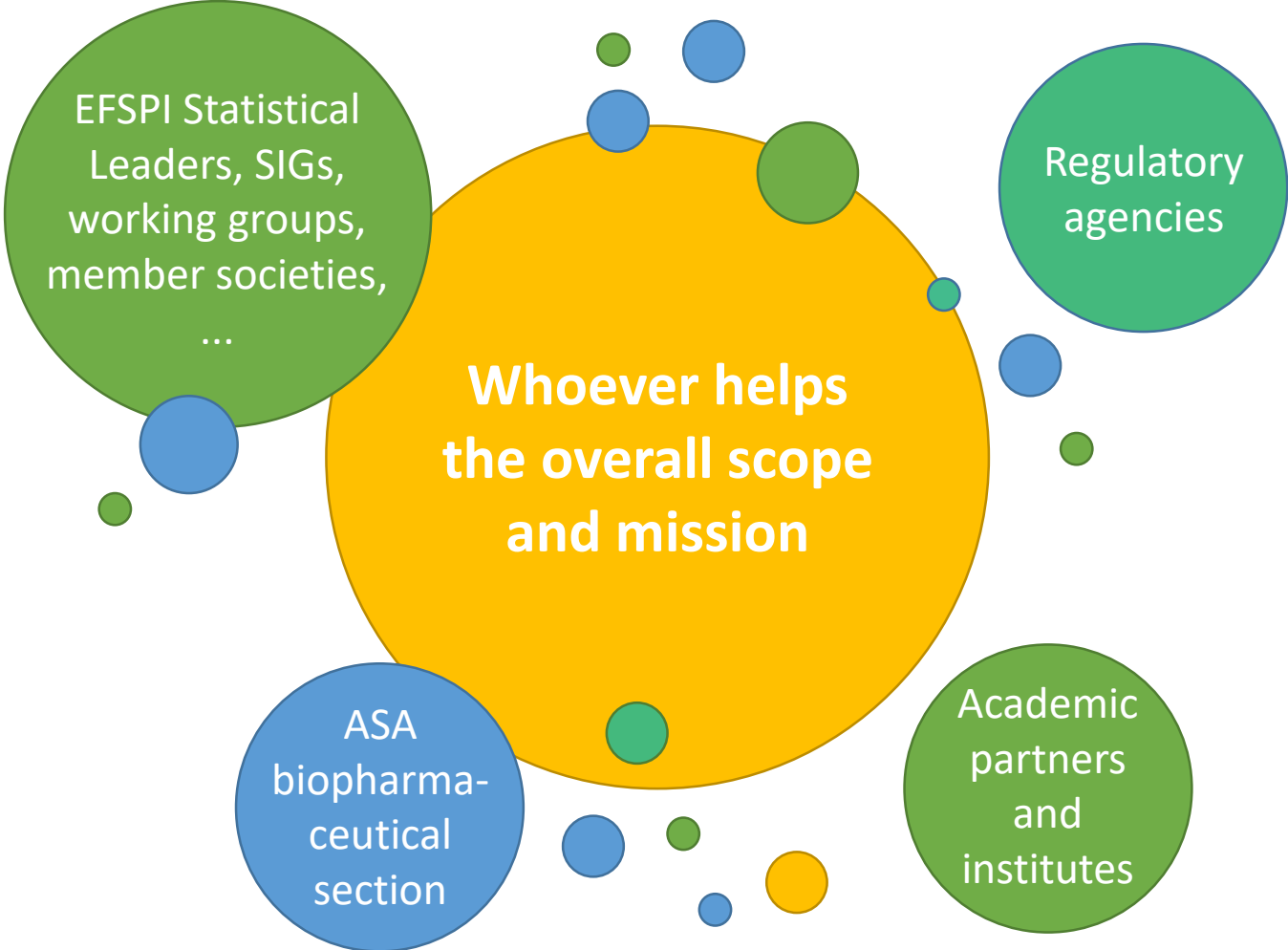


Option of setting up (self-subscribing) **mailing list** for information sharing.

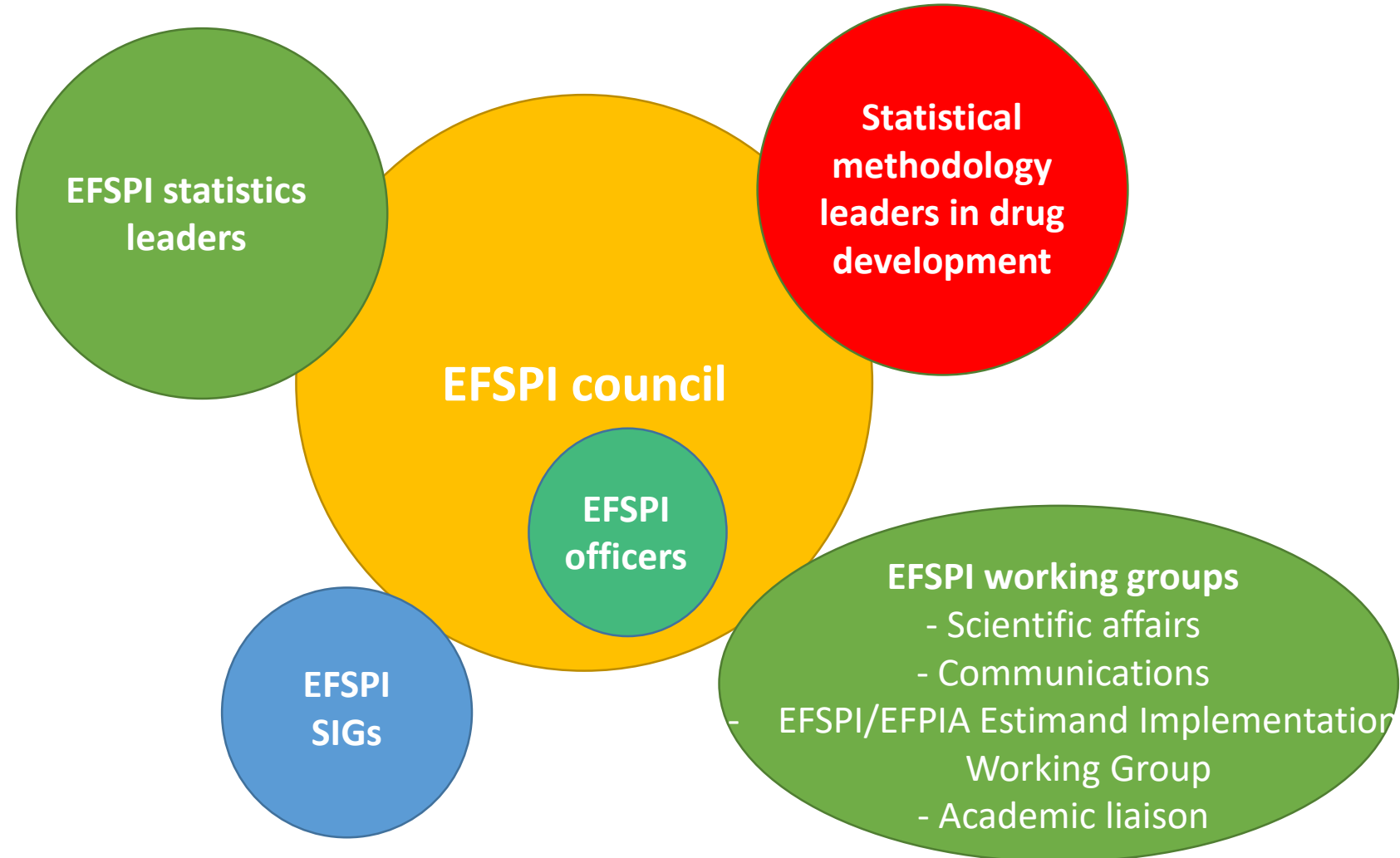


Representation of organizations > regional representation: If an organization wants to be represented by a methodologist outside Europe that is acceptable

Envisaged collaborations



How the new group fits into the EFSPi landscape



How does the new team fit in EFSPI's landscape?

- Complements and collaborates with «Statistics leaders meeting».
- Support EFSPI strategically in
 - coordination of methods development,
 - dissemination,
 - training
 - and advocacy with regulators and academia.
- Team plans to organize, coordinate, and contribute to scientific meetings. Offer to work with **EFSPI scientific affairs committee** on this.
- Team will naturally work with academics and universities, building on already existing ties. Offer to coordinate these efforts with **EFSPI academic liaison**.
- Team aware of EFSPI's mission to involve smaller regions / countries.

Why is this group needed? Are its objectives not covered by existing SIGs and the Statistical Leaders team?

- EFSPI has already many SIGs and working groups:
 - [SIGS \(psiweb.org\)](http://psiweb.org)
 - [Working Groups \(efspi.org\)](http://efspi.org)
- SIGs cover a broad range of quantitative topics and application areas – it is no intention of the new team to interfere here, beyond what is requested by SIGs.
- However, to our knowledge the strategic aspects on the «objective» slide are currently not explicitly covered by any of the SIGs or the Statistical Leaders team

Statistical leadership has at least two aspects:

- **Building and maintaining a statistics / data science organization within a company:** covered by Statistics Leaders Meeting
- **Content leadership:** covered by SIGs, but they usually do not cover strategic aspects discussed on objective slide

Questions & Answers

- Is this only for large pharma companies?
 - No, we are happy to involve folks from small companies, CROs etc.
- Is this only for already established methodology leaders/groups...
 - No, also for aspiring statistical methodologists with clear focus on developing a methodology strategy
- Can only statisticians from pharma companies join or is this open to academia?
 - Focus is on methodologists from pharma and collaboration with academics is envisaged to be mainly on content. However, the general spirit is inclusive – if academics are interested in contributing to the group's objectives we would welcome them to contribute.