What actions do you expect from the EFSPI Statistical Methodology Leaders group which the group is not already doing?
Open-Ended Response

Collaborative methodology development (this was one of their objectives anyway per the linkedin post that introduces their objectives). It was nice that they reached out to the SIGs to ask for key areas of concern/interest for them, and I understood that was to help set the agenda for potential regulator consultations on methods topics.

I'm already impressed with what the group achieved. However, more pro-active interaction with regulators on getting acceptence of new methodologies (e.g. into guidelines) would be beneficial our industry

More visability to cross industry efforts and cross-industry tools to support the new methodologies

use of external control (hybrid and fully external) for pivotal study in

Evidence synthesis, integration of real-world data into clinical trials, connection of statistical methodology and AI/ML technologies

Become better advocates in their companies to drive the creation and adoption of innovation in drug development and to champion any key principles agreed by the EFSPI Stats Leaders (including clarifying their company endorses and supports them)

communicate what you need from EFSPI / Stats Leaders (ie., what we can do as an external organization, what we could do within our own organizations)

Identify accessible, relevant training resources for current hot methodological topics, provide a joint methodological "intelligence" (updates on trends and novel approaches) across pharma (both of which could support small companies or CROs to keep pace with methods development). Of course the key question is on competitive vs. pre-competitive domains, but this would match the open statsware movement.

add the topic on external data use for clinical development (augmented controls, bayesian borrowing, synthetic control arm, extrapolation...)

...

Discuss relevant innovative topics to form a position / common understanding that can be released as recommendations for implementation

start creating trainings (together with other EFSPI groups) on the 4 priority topics for the statistical community.

N/A

Keep the fundamentals as foundations for innovations.

What role should the EFSPI Statistics Leaders play in driving the adoption of innovative fit-for-purpose methodologies?
Open-Ended Response

Championing, facilitating their team members to have the tools and time

Whilst maintaining full statistical coherency and integrity, demystify methodology and ensure a narrative for non technicians

be responsible for the organizational change management needed within the group of statisticians but also in the general organization as new methodologies often are met with skepsis

Help seek out opportunities for implementation

reality check and influence HA position Share examples/experience

creating an environment that enables the implementation of such ffp methodologies, removing road blocks

Support innovation activities in the pre-competitive space

Ensure they are making available all the support mechanisms in their companies to enable their stats methods leader to get air time at key leadership forums for a call to action and get endorsement on next steps.   Where a leader does not have a representative in the stat methods leaders group, to take this role on themselves.

Endorsement, socialization with other nonstatistical leaders, funding to ensure adoption at scale

Share anonymized success and failure stories, understand innovative approaches and work with methods leaders to identify corresponding expected portfolio benefits to support adoption/innovation commercialization, better identify and share methodological needs from programs

Fascilitating the awareness of the methodologies in own company, discussing the application of these in own setting.

ESPI Stats Leaders should be informed and ensure that the outcome is acceptabel from their companies perspective

Champion, sell benefits to companies

Engage in Methodology Leaders Group network activities and leverage position within organization to promote new methodologies

promote innovative fit-for-purpose methodologies in their companies and apply in concrete situations to gain experience. Also forward new innovative methodologies ready for adaptation to the Stats Methods Leaders group.

Should push for these methods internally and promote externally

As many methods are misused, make visible the context for using or not using.

What role should the EFSPI Statistical Methodology Leaders play in driving adoption of innovative fit-for-purpose methodologies?
Open-Ended Response

Helping the community adopt via open-source tools, training

implementation and training sessions

Making methods accesible through development of fit-for purpose tools/code to implement the methods
speed, awareness, showing pragmatic approach
support implementation part (additional to invention part), cover/foster regulatory acceptance
Identify innovation topics of joint interest and work together on stakeholder (e.g., regulatory) acceptance and provision of corresponding tools (including training)

Be proactive and take this call to action to the Biostats Head with the support of the EFSPI Stat leader (if this is different) and align with what else the organisation should prioritise to drive adoption of more innovative methodologies.

Grow roots and first line experience into actual drug development and regulatory challenges to ensure new methods address a real need, better identify and communicate on new methods advantages and assumptions and risks from a development perspective.

Creating the awareness and make it tangible through practical examples that are relatable

PArtner with their respective EFSPI Statistics leader to promote methodologies in their company
create solutions, sell benefits to statistical community
Webinars, publishing case studies, white papers

support statisticians who want to apply innovative fit-for-purpose methodology in concrete business cases if needed. Clarify the acceptance with regulatory authorities if applicable, Provide (reference to) software to facilitate implementation.

Encouragement, push depending on each member's capacity / role

Publish and provide guidance.

Challenge 1: Please name two concrete actions you plan in your organization to foster the adoption of the four priority topics.

Open-Ended Response

Bayesian: have a working group, adopting BOIN designs in many studies, also Bayesian QDM
Estimands: we are refining our internal training materials

Study group on casual inference Understanding and implementation of g-estimation

Bayesian subgroup formed Working group on covariate adjustment Using these to communicate to broader groups of associates, training etc

(1) integrate those into priorities for the organzation, including measurable indicators (2) support foundational aspects e.g. computational environment

Internally developed training courses combined with external expert trainings Assignment of resources to specifically support statistical innovation topics

1. Included a specific Biostatistics objective in 2025 to use covariate adjustment methods e.g. PROCOVA and super-covariates as primary analyses in appropriate non-confirmatory and confirmatory trials. 2. Developing a formal framework for key quantitative groups to better collaborate both at the disease level and compound level in terms of modelling activities including MIDD, QSP, predictive models etc.

- Strategic rollouts (training and learning seminars emphasizing not only the technical how to but the strategic advantages for drug development...eg., cov adjustment) - updating templates to enable adoption at scale

Inform myself to be able to propose those to existing programs, connect people and projects

Currently we are implementing the bayesian approach in two trials and discussing the acceptability of these with authorities

- Inform statistics senior leadership team about outcome - Organize information sessions for statistics units as appropriate

1. Timely dissemination of information/materials from Methodology Leaders Group 2. Promote training offers on each topic

- covariate adjustment: presentation within department and with clinical leadership before summer - estimands: repeat presentation on estimands, and have estimands implemented in all new trials in 2025.

Provide training programs of my team members for Bayesian methods Invite experts on Bayesian methodology to present

* Engage in considering covariate adjustment as a priority on any other analysis supposed to identify or to use predictors. * Reflect on estimand framework according specific designs / indications / studies

Challenge 2: Please name two concrete actions you plan beyond your organization to foster the adoption of the four priority topics.

Open-Ended Response

Some publications on designs, conference presentations, short courses (esp. Bayesian area).

Training in Estimand framework Decision framework using Bayesian methods

Discussing topics such as covariate adjustment and MIDD at stakeholder level with RA, Clinical etc

(1) within company, beyond stats: partner with other stats and non-stats departments (2) beyond company: join x-industry working groups (EFSPI, PSI, ASA...)
Close interaction and training sessions for other non-statistical departments

1. Company wide release of a new paradigm for drug development. 2. Identified a set of priority assets and teams and actioned them to incorporate the innovative methodologies.

Facilitate / champion inclusion or discussion at other scientific forums

Communicate on those, foster visibility and dialogue

- Continuous training on estimands - working group: AI/machine learning in clinical dev

In the Danish Society for Biopharmaceutical Statistics (DSBS) we strive to have these topics on the agenda at meetings and conferences. Recently we organised a course on 'Probability of Success' with Corine Bayeen which in turn has resulted in the forming of a local interest/network group across the danish pharma on this topic.
- discuss on national stats leaders level ways to promote and adopt outcome

- forward the 4 priorities within the PSDM community, explain and ask for feedback. - ... not sure yet

Present in conferences/webinars on Bayes Publish on Bayes

* Reflect on estimands framework for observational study, and safety.