

EFSPI Regulatory Statistics Workshop

Scientific Committee (SC) – principles of engagement

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EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY
Representing Statistical Associations in Europe

Principles of the EFSPI RSW

- The focus is on discussions less on presentations
 - Presentations should motivate and guide the discussions
 - But the discussion is where the interaction takes place
- Focus is on principles and not on statistical methodology
 - For statistical methodology there are many other events
 - But we also need one focused on strategic and regulatory development principles
- When discussing development principles and strategies focus is on the why
 - The why is essential to foster common understanding between regulators and in industry
- Content should be focused on 'hot' topics
 - Hot topics either for industry or regulators provides maximum value
 - Identification of hot topics essential task of the scientific committee

Why is this workshop different?

Workshop

Conference

Small

Scale

Large

Plenary (Single-Track)

Format

Parallel Sessions

Narrow, Strategic

Structure

Diverse, Technical

Quality

Focus

Quantity

Longer Coffee Breaks & Lunches

Networking

Shorter Breaks & Lunches

Ours

Outcome (Impression)

Mine

Low Cost, High Value

Cost/Value

High Cost, ??

Key themes of the workshop

- Focus on OURS, not Mine
 - Emphasizes "OUR" challenges over “My method”
 - Single plenary track facilitates common focus vs. fragmented discussions
 - Scientific Committee (SC) identifies and curates a program of the most important topics of mutual interest
- Discussion is the primary focus
- Create a safe space to discuss hard things
- Create a lasting impact

Why is discussion the primary focus?

- Intentionally different:
There are many other conferences where people can present their latest methods inventions
- Adoption of innovation is hard
 - Clear statement of the problem
 - Understand barriers
 - Create safe space for dialog
- Relationships take time to build

Local Organising Committee (LOC)

LOC – guiding principles

- Main tasks: organization and coordination of
 - on-site support (welcome desk, badges, banner, ...),
 - venue (access, equipment, relationships, ...)
 - catering,
 - technicians (IT, cameras, mics, chat observers, ...),
 - set up of registration + website maintenance,
 - budget, payment administration, certificates.
- Approximately 5 members.
- Priority to truly local representatives. Exceptions non-local member:
 - Chair, EFSPI Council liaison, treasurer, EFSPI Statistical Method Group member
 - Anticipated different location (shadowing the year before).

Recruitment for members of LOC

- Primarily through local personal recruitment.
 - Reach out to local people through, e.g., local EFSPI member group (BBS if event takes place in Basel) or within local companies

Scientific Committee

Scientific Committee – general spirit

- Scientific Committee discussions, while at times appearing inefficient, are important to ensure that the program represents a cohesive whole.
- The entire SOC needs to review and debate proposed sessions and associated messaging to ensure that the workshop program covers high priority strategic topics and fits together*.
- Members represent the broader drug development community - not themselves, their company / institution.

*This does not rule out the possibility to advance the planning in smaller dedicated teams or in writing in-between meetings of the entire SC.

Scientific Committee – general expectations

- Ambition to put together an interesting, balanced, and relevant program for the audience.
 - Presence at preparatory meetings and active contribution to the planning (topics, questions, and speakers/panelists)
 - Willingness to (co-)chair a session at the workshop, implying the intention to attend in-person
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- We aim for equal representation of regulators / HTA and industry
 - We aim for diversity: age (certain seniority needed), gender, region, areas of expertise (phases of drug development + HTA)

SC – Regulators & HTA decision makers

- Regulators and HTA colleagues are responsible for nominating their members

SC – industry members

- Target: ≤ 10 industry SC members
 - No more than **one member per company** (to be discussed internally in the company; exception: shadowing for LOC role)
 - Regular representation of all interested companies (incl. big & small pharma)
 - Mandatory SC members: the chair (LOC & SC), the EFSPI Council liaison,
at least one member of the EFSPI Methods Leader Group
 - LOC representation in SC: **as a minimum** by the chair and the EFSPI Council liaison
- **Recruitment and tenure**
 - Call through EFSPI newsletter / e-mail list, workshop in closure and/or “poster” (via link to workshop webpage), EFSPI Council, LinkedIn, ESIGs (in case that particular expertise is required)
 - Tenure of two years, with the possibility to apply for a one-year extension.

Chair

Chair – guiding principles

- Max three years.
- Experienced drug developer.
- Ideally, former member of the scientific committee ("shadowing").
- Well connected in Europe and beyond (industry & regulators, ideally also academia).