

EFSPI Regulatory Statistics Workshop

Principles for selection of members of the SC & LOC and Chair



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

Introduction – background

- Key to workshop continued success: hallmark “spirit” and specific focus:
 - Open and informal regulatory dialogue, fostering networking and sense of community, depth of discussions.
 - Non-technical strategic focus, inclusive of all drug developers, global openness.
 - Congenial mindset and low-key logistics, voluntary engagement rather than commercial support.
- Purpose of the overarching principles:
 - Promoting diversity, transparency and commitment in workshop scientific leadership.
 - Supporting sustained impact and success through organized renewal of committees.
 - Ensuring continuity of spirit, focus and level of engagement of the workshop.
- Not a rigid book of rules. Basis for discussion and a clarification of intent.
- Bodies: Local organizing committee (LOC), Scientific Committee (SOC).

Scientific Committee – guiding principles

- Regulators responsible for nominating their members (incl. HTA colleagues).
- Overarching principles:
 - Balanced representation of regulators / HTA and industry (beyond LOC).
 - Balanced representation of EFSPi regions.
 - Maximal one member per company (Exception: shadowing LOC members).
 - Diversity: drug development experience, gender, region, big / small pharma.
- Target: six industry members in addition to LOC (and shadowing) members.
 - The chair and the EFSPi Council liaison are mandatory members.
 - If not fully included (default), LOC to be represented **as a minimum** by the chair and the EFSPi Council liaison.
 - EFSPi Methods Leader Group represented with at least one member.
- Members elected for two years. Potential to apply for extension of one year.
- Final decision-maker no membership: EFSPi regulatory workshop lead (currently Helle Lynggaard).

Recruitment for members of SOC

- Make call through EFSPI Council and via linkedin.
- Clearly specify role and expectations (documented on workshop website).
 - Active presence at regulatory preparatory meetings (topics and speakers/panelists).
 - Co-chair session at workshop.
 - Collect topics for short topic session.
- If company already represented, it needs to be discussed internally in the company, who will be the SOC member (Exception: shadowing LOC members).

Local Organising Committee – guiding principles

- Overarching focus:
 - Strategic direction of the workshop organization and evolution, ensuring quality and sustainability of the workshop.
 - Maintaining the workshop hallmark “spirit” and strategic focus.
- Main tasks: organization and coordination of
 - on-site support (cameras, mics, chat observers, ...),
 - venue,
 - catering,
 - technicians,
 - set up of registration,
 - budget, payment administration, certificates.
- Approximately 5 members plus shadowing members.
- All members including shadowing members can be members of the SOC.
- Priority to truly local representatives.
Exceptions: if necessary, a non-local member can be considered for:
 - Specific key role: Chair, EFSPI Council liaison, treasurer.
 - Anticipated different location (shadowing the year before).

Recruitment for members of Local Organising Committee

- Primarily through local personal recruitment.
 - Reach out to local people through e.g., BBS or within local companies
- Maintaining continuity of workshop spirit, network & operating model.
 - Renewal of LOC members considered over the long term (no fixed frequency).
 - Use of a shadowing process to ensure onboarding and continuity of spirit over a sufficient period of time.
 - Monitoring and ad hoc adjustments of SOC contributions in case of shadowing.

Chair – guiding principles

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