



# STATISTICAL METHODOLOGY LEADERS IN DRUG DEVELOPMENT



## Origins

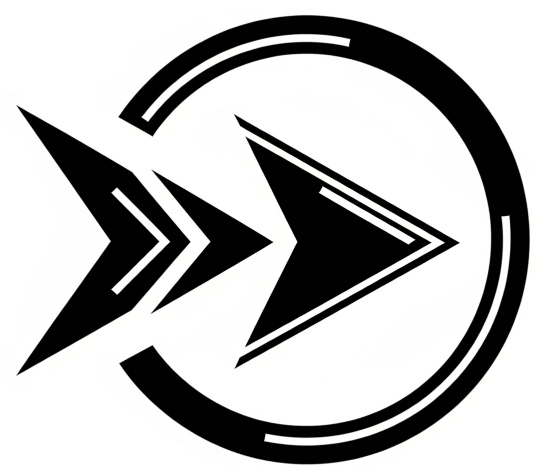
Statistical innovation is a key driver of progress in drug development.

Formed in September 2023, this group aims to capitalize on opportunities for synergy across experts at different companies.



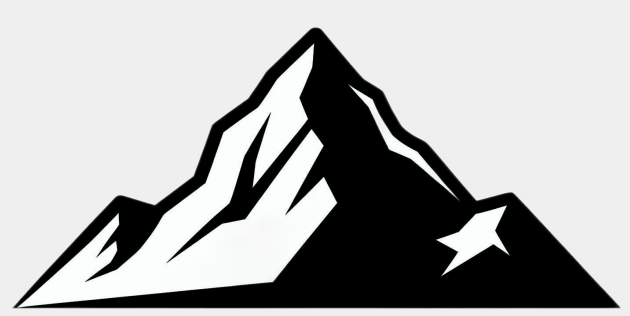
## Opportunities

- Position & sustain strategic, pre-competitive collaborations on joint research, training, and policy positioning
- Co-develop & scale innovation
- Anticipate & shape future trends
- Facilitate an impactful career path for methodologists



## Priority Topics

- Improve understanding of applications of Bayesian methods in confirmatory settings
- Influence consideration of covariate adjustment
  - Including Targeted Learning approaches, nonlinear models, and non-parametric analysis in time to event analysis
- Special topics in Estimand implementation
- Framework to assess assumptions and models (eg., ICH M15)



## Accomplishments

- Active participation in EMA Workshops:
  - ACT-EU Methodology - Nov 2023
  - EMA MWP - June 2024
  - Use of Bayesian Statistics in Clinical Development - June 2025

- Organized BBS / EFSPi webinar "From Statistical Innovations to Common Practice, How to innovate with impact?"
- Represented Methodology Leaders WG at EFSPi Regulatory Workshop & ASA - Regulatory Industry Statistics Workshop (RISW), EFSPi Statistics Leaders



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