EFSPI **Σ** **European Federation of Statisticians in the Statistical Industry**
Promoting professional standards in Europe

BBS
Basel Biometric Society

FIRST ANNOUNCEMENT

Joint EFSPI & BBS virtual event

Addressing intercurrent events:
Treatment policy and hypothetical strategies

December 8, 2022, 14:00-17:00 (CET) &
December 15, 2022, from 14:00-17:30 (CET)
Registration free of charge: link.

Organizers: Marcel Wolbers (Roche), Tobias Mütze (Novartis), James Bell (Elderbrook Sol.)

The ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials is well-established in many pharmaceutical companies but there remain open questions. These workshops will focus on two prominent ICE strategies and discuss both conceptual issues and novel statistical estimation approaches.

Questions that will be discussed include:
- How to implement a treatment policy strategy if data after intercurrent events (ICEs) are frequently missing?
- When is a hypothetical strategy warranted and acceptable to regulators?
- Is it mandatory to remove data after the ICE for implementing a hypothetical strategy?
- How to estimate treatment effects for estimands with multiple intercurrent events and mixed estimand strategies?

The program features eminent statisticians from academia, pharma, and regulatory agencies.

We hope that many of you can attend and contribute to the discussion!

Program for December 8 focusing on the treatment policy strategy

14:00-14:05	**Welcome** – James Bell
14:05-14:30	**Reflections on the estimands addendum with a focus on the treatment policy strategy** - David Wright (AstraZeneca)
14:30-15:00	**Implementation of the treatment policy strategy for continuous longitudinal endpoints: A Comparison of Estimation Methods** – Thomas Drury (GSK)
15:00-15:15	Break
15:15-15:50	**Treatment policy estimation based on standard and reference-based conditional mean imputation** (including discussion of the rbmi R package) – Marcel Wolbers & Alessandro Noci (Roche)
15:50-16:15	**Other statistical software for continuous longitudinal endpoints**: - mmrm R package – Daniel Sabanés Bové (Roche) - SAS macros for multiple imputation – James Roger (LSHTM)
16:15-17:00	**Discussion** by Suzie Cro (Imperial College London), Lorenzo Guizzaro (EMA), and James Hung (FDA) followed by panel discussion and Q&A with all speakers – moderated by James Bell

Program for December 15 focusing on the hypothetical strategy

14:00-14:05	**Welcome** – Marcel Wolbers
14:05-14:30	**The hypothetical strategy: why, how, when?** – Mouna Akacha & Frank Bretz (Novartis)
14:30-15:00	**A case study of hypothetical strategies in acute pain** - Jinglin Zhong (Otsuka)
15:00-15:30	**Hypothetical estimands – a unification of causal inference and missing data methods** – Jonathan Bartlett (LSHTM)
15:30-15:45	Break
15:45-16:15	**g-estimation for the hypothetical strategy with an application to Alzheimer's Disease and COVID-19-related intercurrent events** – Florian Lasch (EMA)
16:15-16:45	**Estimation with multiple intercurrent events and mixed estimand strategies** – Ian White (UCL)
16:45-17:30	**Discussion** by Kelly van Lancker (Johns Hopkins) and Lei Nie (FDA) followed by panel discussion and Q&A with all speakers – moderated by Tobias Mütze