



10th STATISTICS & BIOPHARMACY CONFERENCE

Advancing drug development
through innovative designs and
efficient data use

Paris

8 - 10 October



DAY 1: 8th October 2025

8:00 – 9:00 *Registration*

Pre-conference short course (optional)

9:00 – 12:30 **Sebastian Weber (Novartis, Switzerland), Lukas Widmer (Novartis, Switzerland)**
Applied Modelling in Drug Development - Flexible regression modelling in Stan via brms

Modern clinical trials: the challenges of small populations and novel endpoints

13:00 – 14:00 *Registration*

14:00 – 14:10 *Opening*

Session chair: Sarah Zohar (HeKA, France)

Invited speakers

14:10 – 14:55 **Nigel Stallard (Warwick Clinical Trials Unit, UK)**
(45 min) Advances in statistical methods for clinical trials in rare diseases: an overview

14:55 -15:40 **Mia Tackney (MRC-Biostatistics Unit, University of Cambridge, UK)**
(45 min) Eight Methodological Questions for Digital Outcome Measures

15:40 – 16:10 *Coffee break*

Session chair: Sebastian Weber (Novartis, Switzerland)

Contributed speakers

16:10 – 16:30 **Anais Andrillon (Saryga, France)**
(20 min) Evaluating Early-Stage Oncology Clinical Trial Designs in the Era of Project Optimus: A scoping review

16:30 – 16:50 **Arnaud Monseur (Pharmalex, Belgium)**
(20 min) A Seamless Bayesian Phase I-II Design for dose selection in relapsing-remitting multiple sclerosis

16:50 – 17:10 **Beatriz Farah (Mathématiques Appliquées Paris 5, France)**
(20 min) Univariate and multivariate tests of equality of quantiles with right-censored data

17:10 – 17:30 **Alex Ocampo (Novartis, Switzerland)**
(20 min) Simplifying Causal Mediation Analysis for Time-to-Event Outcomes using Pseudo-Values

Session chairs: Annette Kopp-Schneider (German Cancer Research Center, Germany) and Gaele Saint-Hilary (Saryga, France)

17:40 – 18:10 *Poster speed presentations*

18:10 – 20:00 *Poster & Wine*

DAY 2: 9th October 2025

Use of external information to improve decision making (part 1)

Session chair: Kit Roes (Chair of MWP EMA, Radboud UMC, Netherlands)

Invited speaker

9:00 – 9:45
(45 min)

Simon Wandel (Novartis, Switzerland)

The Good, the Bad and the Ugly: Experiences When Utilizing External Information in Clinical Trials

Contributed speakers

9:45 – 10:05
(20 min)

Silvia Calderazzo (German Cancer Research Center, Germany)

Contrasting Bayesian and frequentist hypothesis testing in hybrid-control clinical trial designs

10:05 -10:25
(20 min)

Arnab Sarkar (Sanofi, Germany)

Assurance-guided phase 3 transition targeting binary outcomes: a Bayesian paradigm integrating internal/ external evidence

10:25 – 11:00

Coffee break

Session chair: Annette Kopp-Schneider (German Cancer Research Center, Germany)

11:00 – 11:20
(20 min)

Frank Kleinjung (Sanofi, Germany)

A Novel Approach to build External Control Arms Under Presence of Missing Values

11:20 – 11:40
(20 min)

Max Menssen (Leibniz University Hannover, Germany)

Considering external information in multiple testing procedures

Invited speaker

11:40 – 12:25
(45 min)

Kit Roes (Chair of MWP EMA, Radboud UMC, Netherlands)

Regulatory view on use of external information: Considerations from design to assessment

12:25 – 14:00

Lunch break

Modern clinical trials: multiple subgroups and multiple endpoints

Session chair: Pascale Tubert-Bitter (Inserm, France)

Contributed speakers

14:00 – 14:20
(20 min)

Valeria Mazzanti (Cytel, Switzerland)

Subpopulation Analysis Using Graphical Approach to Recycle Alpha Between Groups Being Tested

- 14:20 – 14:40
(20 min)** **Drifa Belhadi (Saryga, France)**
Bayesian decision analysis for clinical trial design with binary outcome in the context of Ebola Virus Disease outbreak: a simulation study
- 14:40 – 15:00
(20 min)** **Virginie Rondeau (INSERM U1219, BPH, France)**
Win ratio and Joint models to design clinical trials and evaluate treatment effects on hierarchical composite endpoints
- 15:00 – 15:20
(20 min)** **Roland Matsouaka (Duke university, US)**
Power and sample size calculations for the win measures
- 15:20 – 15:50** *Coffee break*

Improving statisticians' communication and coding skills

Session chair: Sarah Zohar (HeKA, France)

Invited speakers

- 15:50 – 16:35
(45 min)** **Fanny Chevalier (University of Toronto, Canada)**
Data Insights: Bridging the Gap Between Numbers and Knowledge
- 16:35 -17:20
(45 min)** **Daniel Sabanés Bové (RCONIS, Germany)**
Why we Need to Improve Software Engineering in Biostatistics - A Call to Action
- 19:00 – 22:00** Dinner at the restaurant *Le train bleu* (adress [Gare de Lyon, Pl. Louis Armand hall 1, 75012 Paris](#))

DAY 3: 10th October 2025

Use of external information to improve decision making (part 2)

Session chair: Sebastian Weber (Novartis, Switzerland)

Invited speaker

**9:00 – 9:45
(45 min)** **Andrea Callegaro (GSK, Belgium)**
Covariate-adjusted Robust Mixture Prior approach in clinical trials with historical controls

Contributed speakers

**9:45 – 10:05
(20 min)** **Alfredo Farjat (Bayer BV, Netherlands)**
A Comprehensive Bayesian Dynamic Borrowing Approach for Integrating External Data in Clinical Trial Analysis

**10:05 -10:25
(20 min)** **Matthias Monnereau (Oncostat, Horiana, France)**
Performance of causal inference methods in the setting of small sample size for external control arms with time-to-event endpoints: a simulation study

10:25 – 11:00 **Coffee break**

Session chair: Gaelle Saint-Hilary (Saryga, France)

**11:00 – 11:20
(20 min)** **Remi Khellaf (Inria, France)**
Federated Causal Inference from Multi-Site Observational Data via Propensity Score Aggregation

**11:20 – 11:40
(20 min)** **Ahmed Boughdiri (Inria, France)**
A Unified Framework for the Transportability of Population-Level Causal Measures

Invited speaker

**11:40 – 12:25
(45 min)** **Beate Wieseler (IQWiG, Germany)**
Health Technology Assessment view on use of external information

12:25 – 12:35 **Closing**

Post-conference short course (optional)

14:00 – 17:30 **Daniel Sabanés Bové (RCONIS, Germany), Jack Talboys (Novartis, Switzerland)**
Good Software Engineering Practice for R Packages