
*Status as of July 30, 2025*: This is a draft program subject to changes, updates will be posted on a regular basis.

## DAY 1: 8th October 2025

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| **8:00 – 9:00** | ***Registration*** |

## Pre-conference short course (optional)

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

## Modern clinical trials: the challenges of small populations and novel endpoints (part 1)

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| **13:00 – 14:00** | ***Registration*** |
| **14:00 – 14:10** | ***Opening*** |
| | *Invited speaker* |
| **14:10 – 14:55**<br>**(45 min)** | **Nigel Stallard (Warwick Clinical Trials Unit, UK)**<br>Advances in statistical methods for clinical trials in rare diseases: an overview |
| **14:55 -15:40**<br>**(45 min)** | **Mia Tackney (MRC-Biostatistics Unit, University of Cambridge, UK)**<br>Eight Methodological Questions for Digital Outcome Measures |
| **15:40 – 16:10** | ***Coffee break*** |
| | *Contributed speaker* |
| **16:10 – 16:30**<br>**(20 min)** | **Anais Andrillon (Saryga, *France*)**<br>Evaluating Early-Stage Oncology Clinical Trial Designs in the Era of Project Optimus: A scoping review |
| **16:30 – 16:50**<br>**(20 min)** | **Marco Munda (Pharmalex, *Belgium*)**<br>A Seamless Bayesian Phase I-II Design for dose selection in relapsing-remitting multiple sclerosis |
| **16:50 – 17:10**<br>**(20 min)** | **Norés Farah (Mathématiques Appliquées Paris 5, *France*)**<br>Univariate and multivariate tests of equality of quantiles with right-censored data |
| **17:10 – 17:30**<br>**(20 min)** | **Alex Ocampo (Novartis, *Switzerland*)**<br>Simplifying Causal Mediation Analysis for Time-to-Event Outcomes using Pseudo-Values |
| **17:40 – 18:10** | ***Poster speed presentations*** |
| **18:10 – 20:30** | ***Poster & Wine*** |

## DAY 2: 9th October 2025

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

*Invited speaker*

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| **9:00 – 9:45 (45 min)** | **Simon Wandel (Novartis, *Switzerland*)**<br>The Good, the Bad and the Ugly: Experiences When Utilizing External Information in Clinical Trials |

*Contributed speakers*

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| **9:45 – 10:05 (20 min)** | **Silvia Calderazzo (German Cancer Research Center, *Germany*)**<br>Contrasting Bayesian and frequentist hypothesis testing in hybrid-control clinical trial designs |
| **10:05 -10:25 (20 min)** | **Arnab Sarkar (Sanofi, *Germany*)**<br>Assurance-guided phase 3 transition targeting binary outcomes: a Bayesian paradigm integrating internal/ external evidence |
| **10:25 – 11:00** | ***Coffee break*** |
| **11:00 – 11:20 (20 min)** | **Frank Kleinjung (Sanofi, *Germany*)**<br>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*)**<br>Considering external information in multiple testing procedures |

*Invited speaker*

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| **11:40 – 12:25 (45 min)** | **Kit Roes (Chair of MWP EMA, Radboud UMC, *Netherlands*)**<br>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 (part 2)

*Contributed speakers*

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| **14:00 – 14:20 (20 min)** | **Valeria Mazzanti (Cytel, *Switzerland*)**<br>Subpopulation Analysis Using Graphical Approach to Recycle Alpha Between Groups Being Tested |
| **14:20 – 14:40 (20 min)** | **Drifa Belhadi (Saryga, *France*)**<br>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*)**<br>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*)**<br>Power and sample size calculations for the win measures |
| **15:20 – 15:50** | ***Coffee break*** |

## Improving statisticians' communication and coding skills

*Invited speakers*

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| **15:50 – 16:35 (45 min)** | **Fanny Chevalier (University of Toronto, *Canada*)**<br>Data Insights: Bridging the Gap Between Numbers and Knowledge |
| **16:35 -17:20 (45 min)** | **Daniel Sabanés Bové (RCONIS, *Germany*)**<br>Why we Need to Improve Software Engineering in Biostatistics - A Call to Action |
| **19:00 – 22:00** | **Dinner** |

# DAY 3: 10th October 2025

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

*Invited speakers*

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

*Contributed speakers*

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|---|---|
| **9:45 – 10:05 (20 min)** | **Alfredo Farjat (Bayer BV, *Netherlands*)**<br>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*)**<br>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** |
| **11:00 – 11:20 (20 min)** | **David Jesse (Roche, *Switzerland*)**<br>Bayesian Causal Inference Methods for Borrowing Historical Control Data in Clinical Trials: A Neutral Comparison Study |
| **11:20 – 11:40 (20 min)** | **Ahmed Boughdiri (Inria, *France)***<br>A Unified Framework for the Transportability of Population-Level Causal Measures |

*Invited speakers*

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| **11:40 – 12:25 (45 min)** | **Beate Wieseler (IQWiG, Germany)**<br>Health Techology Assessment view on use of external information |
| **12:25 – 12:35** | **Closing** |

## Post-conference short course (optionnal)

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