22nd October 2025 - Pre-forum Courses (9.00 – 17.00)

Hotel RAMADA by Wyndham Naples, Via Galileo Ferraris, 40 Napoli

A Practical Introduction to Simulating Complex Trial Designs

Pavel Mozgunov, Dominique-Laurent Couturier (MRC Biostatistics Unit, University of Cambridge)

This course provides a comprehensive and hands-on introduction to the use of Monte Carlo simulation studies for the evaluation of innovative clinical trial designs.

In contrast to fixed trial designs, which consider pre-defined and unchanging protocols throughout the study, innovative trial designs allow for the dynamic adaptation of trial procedures based on interim analyses. This course will focus on Multi-Arm Multi-Stage (MAMS) designs that allow for the dropping of experimental arms before the end of a trial – either for efficacy or futility – based on pre-specified efficacy and futility bounds, thereby allowing for a more optimal allocation of resources and reducing the risk of exposing patients to ineffective treatments.

Operating characteristics of complex designs often cannot be derived analytically and are therefore obtained by running extensive Monte Carlo simulations. This course offers a hands-on introduction to Monte Carlo simulation in which participants, following a lecture that introduces them to MAMS and the basics of simulation, will learn to simulate MAMS trials inspired by a real study, the TREADON trial (ISRCTN12418153). By exploring cases of increasing complexity, participants will learn to derive summary statistics (mean, quantile) related to complex operating characteristics such as trial duration, number of participants, and number of recruited participants as a function, for example, of accrual rate.

Regulatory Pathways: Mastering FDA Submission Strategies from Statistical programming point of view

Gabriele Di Domenico, Giulia Caldarazzo (GSK Vaccines, Siena)

In the increasingly complex landscape of pharmaceutical submissions, mastering the strategies for successful FDA interactions is crucial for statistical programmers. This comprehensive one-day course offers participants a unique opportunity to delve into these regulatory pathways through the lens of recent experiences shared by statistical programmers from GSK.

Our journey will focus on the intricacies of crafting effective FDA submissions from a statistical programming standpoint. Participants will gain insights into the key components that define a successful submission, including the creation and verification of CDISC-compliant datasets, along with the development of robust statistical evidence to support product approvals and partnering submission team roles, not only Biostatisticians but also Regulatory Affairs team, Clinical figures, etc...

The course will provide real-world examples, showcasing specific challenges encountered during recent GSK submissions to the FDA (in particular to CBER division). Through these case studies, participants will learn valuable lessons about navigating complex regulatory requirements and discover practical strategies for overcoming obstacles in data preparation, validation, and communication. The objective is not only to share knowledge but to engage participants in dynamic discussions that address common pitfalls and explore solutions.

IBIG Forum 23-24 October

Università degli Studi di Napoli Federico II

Dipartimento di Giurisprudenza Aula Conforti, Via Porta di Massa, 32 Napoli – Ground Floor

Day 1

Time	*Topic*	*Chair*
9.00 – 9.30	**Registration**	
9.30 – 9.45	**Welcome & Introduction**	IBIG Steering Committee
2026 – 2030 Horizon: Are You Getting Ready?		**Andrea Nizzardo**
9.45 – 10.15	**The new ICH E20 on adaptive clinical trials**	Frank Bretz, Novartis AG
10.15 – 10.45	**ICH E6(R3) update and its impact**	Gabriele Pesavento, Evotec
10.45 – 11.15	**Adoption of R and open-source technologies in Biostatistical Department: the GSK experience**	Federico Baratin, GSK Vaccines
11.15 – 11.40	**Coffee Break**	
AI&ML in the Pharmaceutical Research		**Luca Grassano**
11.40 – 12.10	**The role of Machine Learning in Clinical Trials: current applications and novel randomization approaches**	Ajsi Kanapari, University of Padua
12.10 – 12.40	**Improving precision of vaccine efficacy estimate using machine learning methods**	Giulia Zigon, GSK Vaccines
12.40 – 13.10	**Federated Learning Approach for Estimating Average Treatment Effects in Pediatric Clinical Trials**	Mohd Rashid Khan, University of Padua
13.10 – 14.00	**Lunch**	
Success Prediction via Innovative Quantitative Methods		**Stefano Vezzoli**
14.00 – 14.30	**Methodological aspects and practical application of a drug quantitative benefit-risk assessment: a case study**	Pavel Mozgunov, MRC Cambridge
14.30 – 15.00	**Phase III Probability of Success when Early Development is Based on a Putative Surrogate Endpoint: a Vaccine Efficacy Case Study**	Alessia Eletti, GSK Vaccines
15.00 – 15.30	**Probability of Success and power-related random variables**	Francesco Mariani, University of Bologna
15.30 – 16.00	**Simulation-based Bayesian predictive probability of success for interim monitoring of clinical trials with competing event data: two case studies**	Chiara Micoli, Karolinska Institutet
16.00 – 16.15	**Speed Poster Presentation**	
16.15 – 17.30	**Coffee Break & Poster Discussion**	

Day 2

AI&ML in the Pharmaceutical Research		Daniele Bottigliengo
9.00 – 9.30	**Beyond Prediction: Machine Learning in causal inference for epidemiology**	Chiara Moccia, University of Turin
9.30 – 10.00	**Application of causal inference to identify determinants of seizure reduction and quality of life in patients with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), and tuberous sclerosis complex (TSC) treated with cannabidiol (CBD)**	Teresa Greco, Jazz Pharmaceuticals
10.00 – 10.30	**From Noise to Signal: Detecting Unusual Profiles Using Isolation Forests in R ("isotree" Package)**	Ignazio Craparo, Alira Health
10.30 – 11.00	**Coffee Break**	
Bayesian Statistics Applications to RCTs		**Danila Azzolina**
11.00 – 11.30	**Bayesian dynamic borrowing in group-sequential design for medical device studies**	Maria Vittoria Chiaruttini, Padua University
11.30 – 12.00	**The Bayesian Brain: Advancing Clinical Research in Psychiatry and Neuroscience**	Martino Belvederi Murri, University of Ferrara
12.00 – 12.30	**Joint control of error probabilities in Bayesian sample size determination**	Susanna Gentile, University of Rome "La Sapienza"
12.30 – 13.00	**Prior Predictive Probability for Sequential Decision-Making in Basket Trials: Leveraging External-Trial Data for Rare Disease Applications**	Giulia Risca, University of Milan "Bicocca"
13.00 – 13.10	**Closure**	IBIG Steering Committee