



LIFE SCIENCE[®]
ACADEMY

European Statistical Forum

Advancing Clinical Trials: Master Protocols for Faster Drug Development

Date
27 and 28 October 2025

Language

English

Location
Bergamo

ABOUT

Advancing Clinical Trials: Master Protocols for Faster Drug Development | ESForum 15th Edition

Quick Overview

Master Protocols represent a paradigm shift in clinical trial design, offering a cohesive framework to test multiple hypotheses within a single overarching trial. By efficiently consolidating various sub-studies, multiple subpopulations and treatments, possible adaptive designs, and shared control arms, these protocols significantly enhance statistical power and operational efficiency.

They are particularly beneficial in the context of complex and multifaceted therapeutic areas, allowing



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for more robust and comprehensive data analysis, and facilitating faster, more flexible responses to emerging clinical evidence. This approach not only accelerates the pace of drug development but also enhances the flexibility and adaptability of clinical research.

However, it also adds some challenges like statistical complexity in determination of type I error rates or multiplicity control. Understanding and leveraging Master Protocols is critical for optimizing trial outcomes and accelerating the path to successful therapeutic innovations.

Key Conference Topics

The 15th edition of European Statistical Forum (ESForum) aims to explore methodologies, applications, and regulatory considerations associated with Master Protocols. This will include presentations focusing on:

- The concept of master protocol designs, including umbrella trials, basket trials, and platform trials
- The statistical challenges and innovations in implementing master protocols
- The ethical and regulatory implications of these complex trial designs
- Case studies and real-world examples of successful master protocol implementations

In addition to the scientific sessions, this conference offers ample opportunities for networking and collaboration.

Scientific Board

Jens-Otto Andreas - *BSO Business Operations Excellence Senior Lead, UCB Biosciences*

Lisa Comarella - *Senior Director Biostatistics, Alira Health Biometrics*

Fabiola La Gamba - *Associate Director Biostatistics, Novartis*

Who should attend?

This statistical conference is addressed to statisticians, pharmacometricians, data scientists, regulatory affairs specialists and other experts interested in the field belonging to: Pharmaceutical and Biotechnology companies, CROs, Universities/Hospitals and Research Institutes.

Networking Opportunities

- Industry expert roundtables
- Dedicated networking sessions
- Interactive workshops
- Collaborative discussion forums
- Case study presentations



Register now to join leading pharmaceutical companies, biostatisticians, and clinical researchers in advancing the future of clinical trials.

PROGRAMME

27 October 2025	
14:00 14:30	Registration
14:30 14:50	Welcome by the Scientific Board and Interactive Warm-Up Session
14:50 15:30	Pioneering the Future: Clinical Trial Methodologies on the Horizon Christine Fletcher VP Biostatistics at GSK
15:30 16:10	Designing Efficient Platform Trials Addressing Stakeholder Needs Tobias Mielke Senior Distinguished Scientist, QS Consulting / Statistics and Decision Sciences at J&J
16:10 16:40	Coffee break
16:40 17:20	Learning on 4 Dimensions in Fighting Malaria: the PLATINUM Trial Karin Meiser Director Biostatistics at Novartis Pharma AG
17:20 17:30	Wrap-up Day 1
28 October 2025	
09:00 09:15	Start Day 2
09:15 09:55	Methodological Aspects in Confirmatory Platform Trials and Regulatory Considerations Benjamin Hofner Head of Data Science and Methods at Paul-Ehrlich-Institut (PEI)
09:55 10:35	Master Protocol Trial Design: Options and Examples Tom Parke Director of Software Solutions at Berry Consultants
10:35 11:05	Coffee break



11:05 12:05	Efficient Design and Analysis of Basket Trials in Oncology and Beyond Haiyan Zheng Reader in Statistics at University of Bath
12:05 12:45	A two-stage Bayesian Adaptive Umbrella Design borrowing Information over Control Data Luke Ouma Senior Statistician at AstraZeneca
12:45 13:45	Networking Lunch
13:45 14:25	Interactive Quiz Session
14:25 15:05	In Sea of Design Options: Using OCTOPUS for Simulation Guided Design of Platform Studies Kyle Whaten Vice President, Scientific Strategy & Innovation at Cytel
15:05 15:35	Coffee break
15:35 16:15	Learning from the Piranga Platform Trial: Drug Combination Development to Treat HBV Ruchi Upmanyu Senior Principal Statistical Scientist at F. Hoffmann-La Roche
16:15 16:25	Conclusions by the Scientific Board

SPEAKERS



Scientific Board
Jens-Otto Andreas
BSO Business Operations Excellence
Senior Lead at UCB Biosciences GmbH



Scientific Board
Lisa Comarella
Senior Director Biostatistics
at Alira Health Biometrics





Scientific Board
Fabiola La Gamba
Associate Director Biostatistics at Novartis



Speaker
Christine Fletcher
VP Biostatistics at GSK



Speaker
Benjamin Hofner
Head of Data Science and Methods at Paul-Ehrlich-Institut (PEI)



Speaker
Karin Meiser
Director Biostatistics at Novartis Pharma AG



Speaker
Tobias Mielke
Senior Distinguished Scientist, QS Consulting / Statistics and Decision Sciences at J&J



Speaker
Luke Ouma
Senior Statistician at AstraZeneca



Speaker
Tom Parke
Director of Software Solutions at Berry Consultants



Speaker
Ruchi Upmanyu
Senior Principal Statistical Scientist at F. Hoffmann-La Roche



Speaker
Kyle Whaten
Vice President, Scientific Strategy & Innovation at Cytel



Speaker
Haiyan Zheng
Reader in Statistics at University of Bath

NETWORKING DINNER

Do you want to have a unique opportunity to foster meaningful connections with peers and thought leaders in the pharmaceutical statistics field? Reserve your seat at the **Networking Dinner**.

The dinner will take place at **Il Sole Ristorante Bergamo**, Via Colleoni 1, 24129 Bergamo.
Monday, October 27th, 2025, at 8:00 PM (meeting point at the restaurant at 7:45 PM).

[View the Menu](#)



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Registration for the dinner is conditional on attendance at the conference.

Cultural Discovery

Is this your first visit to Bergamo?

Take the opportunity to visit Bergamo on a guided tour at the end of the first day of the conference.

The tour will take you on a complimentary guided walking tour of the Upper Town, the historic heart of Bergamo, a UNESCO World Heritage Site and a symbol of Italian cultural heritage.

It will introduce participants to the rich history and architectural beauty of this medieval town, with highlights including Corsarola, its iconic main street, and the timeless charm of Piazza Vecchia, the heart of the Upper Town. This enriching experience provides an ideal prelude to the evening's networking event.

- **Duration:** 40 minutes
- **Language:** English
- **Meeting point and time:** 7:00 PM

Don't miss this opportunity to combine professional development with a touch of cultural enrichment in one of Italy's most fascinating cities.



REGISTRATION FEE

€ 590,00 Early Bird fee **extended until 13 October 2025**

€ 710,00 Ordinary fee

€ 410,00 Freelance, Individual, Academy, Public Administration

Fee includes: seat at the conference, pdf copy of presentations of Speakers who allow the distribution, networking lunch, coffee breaks, organisational office assistance, certificate of attendance.



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USEFUL INFORMATION

The conference will take place at:

Bergamo Congress Center Giovanni XXIII

Viale Papa Giovanni XXIII, 106
24121 Bergamo - Italy

How to reach the conference venue:

BY CAR

From the Bergamo motorway exit, follow the signs 'centro città'-'stazione'.

Once in the centre, at the traffic lights in Via Bonomelli, turn left into via Papa Giovanni XXIII. You will see the Centro on the left before the next crossroads with Via Paleocapa. The nearest paid parking is in Via Paleocapa 3 (turn left).

Parking Special Price

Central Parking - via Paleocapa 3, Bergamo - walking distance to Bergamo Congress Center

BY TRAIN

Railway Station is 1 minute far from the Congress Center (150 meters).

BY PLANE

Bergamo Congress Center is 10 minutes far from Orio al Serio Airport, 40 minutes from Linate Airport and 120 minutes from Malpensa.

Looking for a hotel for an overnight stay?

[NH Bergamo](#) - 2 min walking distance to Bergamo Congress Center

[Mercure Bergamo Centro Palazzo Dolci](#) - 2 min walking distance to Bergamo Congress Center

[Hotel Cappello d'Oro](#) - 5 min walking distance to Bergamo Congress Center

CONFERENCE VENUE



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