IBIG
Italian Biostatistics Group

SIMeF
Società Italiana di Medicina Farmaceutica
Italian Society of Pharmaceutical Medicine

SAPIENZA
UNIVERSITÀ DI ROMA

IBIG Forum
Rome, 21-23 October

Pre-Forum Courses

- **Platform, Basket and Umbrella Trials. Master protocols**
  Danila Azzolina, University of Naples Federico II

- **Unlocking Global Regulatory Expectations: Winning Strategies for FDA, NMPA, and PMDA**

  Valentina Brazzo, Rebecca Moretti, Chiesi Farmaceutici

Forum Topics

- **Early Phase Studies**
- **Real-World Evidence**
- **Issues in RCTs and Observational Studies**
- **Poster session**

Registration Fees

VAT not included in the costs below	Until 31/7	From 01/09
Pre Forum Course		
SIMeF members	220,00€	320,00€
Non members	360,00€	480.00€
IRCCS/No Profit/Public Institutions	250,00€	360,00€
Students*	110,00€	200,00€
Forum		
SIMeF members	450,00€	600,00€
Non members	600,00€	750,00€
IRCCS/No Profit/Public Institutions	500,00€	650,00€
Students*	230,00€	350,00€
20% off for registration to both course and Forum		
*Students are those who have no paid professional activities. Employees or freelancers who are also studying are not eligible for students discounted fee		
20% discount for poster presenters for Forum only		

CLICK HERE TO REGISTER

Forum Agenda | 22 October 2026

TIME	TOPIC	CHAIR
8.45 – 9.30	Registration	
9.30 – 9.40	Welcome & Introduction	Marco Costantini, Fulvio De Santis, Stefania Gubbiotti
EARLY PHASE STUDIES		**Giulia Zigon, Stefano Vezzoli**
9.40 – 10.10	A ballad of a Basket trial and historical information borrowing: application in neurodegenerative diseases	Pavel Mozgunov, MRC
10.10 – 10.40	Bayesian Optimal Phase II design	Maria Vittoria Chiaruttini, Italfarmaco
10.40 – 11.10	**COFFEE BREAK**	
11.10 – 11.40	Optimus project	Andrea Nizzardo & Luca Genetti, Evotec
11.40 – 12.10	Anchoring the Winner: A Refined Conditional Test for Enhancing Efficiency in Multi-Arm Selection Trials	Marco Ratta, Saryga
12.10 – 12.40	From Design to Execution: Implementing a Bayesian Adaptive Phase 1 Study	Fabian Tibaldi, GSK
12.40 – 13.00	Speed poster presentation	
13.00 – 14.00	**LUNCH**	
REAL-WORLD EVIDENCE		**Luca Grassano, Lucia Simoni**
14.00 – 14.30	Effectiveness of Cannabidiol in Patients with Rare Epilepsies Compared with External Placebo Control: A Post Hoc Analysis from the Expanded Access Program	Teresa Greco, Jazz Pharmaceuticals
14.30 – 15.00	Informing Men B Vaccine for Adolescent Booster Immunization: Strategies through External Comparisons and Persistence Modeling	Meike Adani, GSK
15.00 – 15.30	Generative AI–Derived Synthetic Cohorts for Robustness Assessment and Sensitivity Analysis in Target Trial Emulation: A Framework for Real-World Treatment Effect Estimation	Paolo Messina, InSilicoTrials
15.30 – 16.00	**COFFEE BREAK**	
16.00 – 16.30	Evaluation of Artificial Intelligence-Generated Synthetic Data for Clinical Research in Secondary Cardiovascular Prevention of Patients with Dyslipidemia	Alice Bonomi, Centro Cardiologico Monzino
16.30 – 17.00	Evaluating historical benchmark Targeted Single-Arm Trials with External Controls single-arm platform trial in glioblastoma	Ajsi Kanapari, University of Padua

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ISSUES IN RCTs AND OBSERVATIONAL STUDIES		Andrea Nizzardo, Andrea Vele
9.00 – 9.30	Robust (Exchangeability) Bayesian Methods for Vaccines Targeting Multiple Serotypes	Margherita Annaratone, GSK
9.30 – 10.00	Design of Single-Arm Time-to-Event Studies Using Simulation: Median, 95% CI and Optimal Sample Size using Shiny application	Bianca Bracco, IQVIA
10.00 – 10.30	RCTs vs Real-World Studies: Operational Insights from Academic Experience	Lorena Torroni, Unicamillus
10.30 – 11.00	COFFEE BREAK	
11.00 – 11.30	Behind the Scenes of Real-World External Comparator Studies: Operational Issues and Lessons from the Field	Alessandra Mignani, IQVIA
11.30 – 12.00	Event Prediction in clinical trials	Bastiaan Jansen & Tom Cattaert, SGS
12.00 – 12.30	The importance and pitfalls of surrogate endpoints	Tom Cattaert, SGS
12.30 – 12.40	FORUM CLOSURE	