SUNDAY 8 JUNE | Novotel London Wembley

TIME	SESSION/LOCATION	
	Pre-conference Course 1	Pre-conference Course 2
	Wembley 1	Wembley 2
13:00 – 17:00	**Unlocking Insights: Advanced Pooled Analyses Techniques for Clinical Trial Statisticians**	**Adaptive and Complex Innovative Designs across trial phases for accelerated approval**
	Dr. Thomas Debray, Smart Data Analytics and Statistics B.V., The Netherlands *Prof. Tim Friede, University Medical Center Göttingen, Germany* This course provides a comprehensive introduction to pooled analyses of randomized controlled trial (RCT) data, with a focus on methodologies and applications essential for clinical trial statisticians. Pooled analyses provide significant benefits during various stages of drug development, and may help to examine subgroup effects, analyse rare (e.g., adverse) events, and estimate more individualized treatment effects. We will cover statistical techniques for analysing individual participant data (IPD) from multiple trials, with a particular focus on meta-analysis methods that address potential heterogeneity between study populations. To ground these concepts, the course will include applied case studies that demonstrate how IPD meta-analyses enhance the precision and applicability of findings, ultimately supporting more personalized and impactful analyses in clinical research. This course equips statisticians with the expertise to apply advanced meta-analysis techniques to real-world clinical trial data, strengthening their ability to conduct rigorous and meaningful analyses that inform evidence-based decision-making.	*Dr. Thomas Burnett, Lecturer, Department of Mathematical Sciences and Institute for Mathematical Innovation (IMI) University of Bath* *Dr. Ayon Mukherjee, C. Stat, Director Biostatistics, Eli Lilly* *Dr. David Robertson, Senior Research Associate at the MRC Biostatistics Unit, University of Cambridge* *Dr Sofia Villar, MRC Investigator (Programme Leader) at the MRC Biostatistics Unit, University of Cambridge* This course will provide an introduction to the use of adaptive designs across all phases of clinical research, highlighting its evolution, use and how it fits into the various regulatory initiatives such as Project Optimus and the CID programme, with a focus on statistical considerations. These designs are often more efficient, informative and ethical than traditional study designs, but pose specific challenges (both statistical and practical). The course will start with introducing the basics of different types of adaptive design methods and also the concept of Bayesian statistics which is frequently used for many of such designs. We would proceed to discuss the evolution of these designs and what makes them an attractive alternative to traditional clinical trial designs. We would then introduce the CID programme and Project Optimus and discuss how such designs fit into the benefits of such regulatory initiatives and the challenges one can face when practically implementing such designs. During the last part of the course, we will focus on the methods of response adaptive randomization (RAR) and covariate-adjusted response adaptive (CARA) randomization, which has been widely discussed in the literature and also among the regulatory and industry, who have been weighing their usefulness against the operational challenges for their practical use. Following Roberson et al. (2023), we would also discuss the myths and practical challenges of using RAR and CARA methods and explore how such methods can fit within the CID programme of FDA at various phases of clinical research.
19:00 – 22:00	Drinks reception at the White Horse Pub, Wembley	