TUESDAY 10 JUNE | Wembley Stadium

TIME	SESSION/LOCATION
08:00 – 08:45	Registration
	Great Hall
08:45 – 10:00	**Bridging the Divide: How Academia/Industry collaborations have the power to transform clinical development (PL2)** *Chair: Sue Todd* In this talk, Jen will talk about her journey from academia to industry, and what she has learnt along the way. She will discuss the differences between academic-run and industry-led clinical trials and what they can learn from each other. As we see a shift towards more innovative and complex clinical trials, it will become increasingly important to foster collaboration between the two groups. And as we see academics wanting to make the move into industry, how can we present ourselves as a viable alternative that is rich in research. The talk will be followed by a panel discussion with other industry speakers. ***Jennifer Visser Rogers*** *Panel Discussion: **Jackie Carter, Dominic Magirr and Vicky Marriot***
10:00 – 10:30	Refreshment Break in Bobby Moore Room

	Great Hall	Wembley Suite	Pitch View East	The Arc
10:30 – 12:00	**Causal inference eSIG: Introduction and applications of causal inference methodology in clinical trials (O012)** Chair: *Sanne Roels* Introducing the Causal Inference SIG - *Sanne Roels* Mediation analysis in longitudinal randomised clinical trials with visit related outcomes - *Martin Linder* Implementation of the ICH E9 (R1) Addendum in Vaccine Efficacy Studies: The Hypothetical and Principal Stratum Strategies *- Silvia Noirjean* Sense and sensitivity – *Tim Morris*	**Inclusive Work Cultures: Where Everyone Thrives (W3)** Session organisers: ***Addison Barnett, Emma Crawford, Ursula Becker, Nicola Hewson and Karen Smith*** *Session kindly sponsored by Alun Bedding Coaching* ALUN BEDDING Coaching & Consulting In this engaging session, we'll dive into key concepts of inclusion and belonging. You'll participate in group discussions that use a real-life scenario where you'll be asked to consider inclusivity in different aspects. We'll have Addison Barnett from Inclusive Employers introduce the concepts of inclusive work environments and how we can all be part of making our workplaces more inclusive.	**Statistical Software Engineering (O004)** Chairs: *Jyoti Kumari and Wilmar Igl* The Mythical Man Month (1975-2025) – Planning, Implementing, and Managing Statistical Software Projects - *Wilmar Igl* Continuous Integration (CI) practices for statistical software development - *Pravin Madhavan* Scaling Statistical Innovation and Open Source Collaborations - *Isaac Gravestock* Analysis Specification to Execution in R/Shiny - *Brian Lang*	**Evidence Synthesis for HTA. Squaring the Circle: Bridging Innovation with Application** Chair: *Lytske Bakker* ***Lytske Bakker*** ***Nicky Welton*** ***Min-Hua Jen*** ***Gregory Chen & Anders Gorst-Rasmussen*** ***Keith Abrams***

		Let's work together to build a workplace where everyone thrives! 💼✨	

	Great Hall			
12:00 – 13:00	**Annual General Meeting** *(PSI members only)* *Do you want to influence PSI's future direction?* If so, we invite you to join us for updates from PSI and the board of directors about 2024, 2025 and beyond. The directors will share their achievements in the past year and their plans for the future. However, the most crucial part of this meeting is your voice – our PSI members and community. Your feedback is invaluable in guiding our future direction. What are we doing well, and what can we improve? How can we best continue to support our members throughout their careers? In the spirit of transparency, we will present the financial update for the year, including a detailed breakdown of where membership fees and conference surplus are allocated. Yes, we have to cover the formal stuff, but we truly value your input in improving our organization and understanding what matters most to you. We look forward to your presence!)			
13:00 – 14:00	**SIGs at the Bar:** *Come meet the SIGs and find out more about their work* HTA SIG, Biomarkers SIG, Patient Focussed Drug Development SIG, Causal Inference SIG			
13:00 – 14:00	Lunch in Bobby Moore Room			
	BOX 3007			
13:15 – 14:00	Executive roundtable chaired by Inclusive Employers Beyond compliance: How can DEI drive clinical trial diversity and commercial success?			
	Great Hall	**Wembley Suite**	**Pitch View East**	**The Arc**
14:00 – 15:30	**Missing Data and Estimands** *Chair: Jyoti Soni* Continuous Composite Endpoints: How Bad is Too Bad? (O050) - *James Bell* Estimation for treatment policy strategies with missing data: Introducing retrieved dropout reference-base centred multiple imputation (O040) - *Suzi Cro* How many (multiple) imputations do I need for an important analysis? (O028) - *Tim Morris*	**Navigating Difficult Conversations in the Workplace (W1)** Session organisers: ***Emma May, Sam Ruddell and Katie Thorn*** Difficult conversations are inevitable in any professional setting. Whether it is providing constructive feedback, discussing career advancement, or negotiating project deliverables, these interactions can be challenging. Increasing our self-awareness is key to participating in a successful negotiation. In this interactive session you will tackle real-life, difficult conversations and learn how to negotiate and apply emotional intelligence to achieve a win-win outcome. Come ready to	**Quantitative Decision Making - How Frameworks Could Help You** Chair: ***Alex Carlton*** Session kindly sponsored by Pierre Fabre LABORATOIRES **Pierre Fabre** New ways to care Going beyond Probability of Success for Early Development studies (O017) - ***Trevor Smart*** Clinical Stage Gates: Reflections on improving decision making in drug development (O005) - *Gustaf Rydevik*	**Treatment Effect Heterogeneity SIG (O001)** *Chair: David Svensson* Bayesian shrinkage estimation for subgroup analysis in clinical trials: Examining the critical aspects - ***Björn Bornkamp*** A simulation study to compare Group Sequential Designs for subpopulation testing and enrichment procedure - ***Marie-Karelle Riviere*** Improving Outlier Detection in Subgroup Analysis using Bayesian Predictive Cross-validation Models - ***Wilmar Igl***

		share your experience and learn from each other. This workshop will give you insights and practical skills to handle difficult conversations with confidence. You will leave with actionable steps that you can take when next facing a challenging interaction, creating a more collaborative and productive workplace	Decision-Making Criteria and Methods for Initiating Late-Stage Clinical Trials from a Multi-Stakeholder Perspective: A Scoping Review (O019) - *Julien Tanniou* Financially Calibrated Risk-Scale: A Proposed Futility Design Framework to Enhance Portfolio-Level Profitability and Performance (O005) - *Nima Shariati*	
15:30 – 16:00	Refreshment Break in Bobby Moore Room			
	Great Hall			
16:00 – 17:30	**Regulatory Hot topics session (PL3)** The Regulatory Hot topic session will focus on two highly relevant topics: 1) Bayesian statistics in regulatory decision making; 2) ICH E20 draft guidance on adaptive design. *Peter van de Ven* (Dutch Medicines Evaluation Board, EMA) and *Nicky Best* (GSK) will present on Bayesian statistics in regulatory decision making. *Armin Koch* (Hannover Medical School), *Frank Bretz* (Novartis), and *Khadija Rantell* (MHRA) will provide their perspectives on the implications and key considerations within the new ICH E20 draft guidance. Conference attendees will have the chance to actively participate, with dedicated Q&A segments allowing for direct engagement with the presenters. The session will be moderated by *Jürgen Hummel* (NovoNordisk) and *Tobias Mütze* (Novartis).			
	Great Hall			
19:30 – 20:00	Drinks Reception			
20:00 – midnight	**Gala Dinner** *Kindly sponsored by Coronado Research*			