PSI 2025 CONFERENCE

8 - 11 JUNE 2025

WEMBLEY STADIUM
LONDON

CONFERENCE PROGRAMME

SUNDAY 8 JUNE | Novotel London Wembley

TIME	SESSION/LOCATION	
12:30	Registration opens	
	Pre-conference Course 1	Pre-conference Course 2
	Wembley 1	Wembley 2
13:00	**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.
14:45-15:15	Refreshment break	
17:00	Workshops end	
19:00 – 22:00	Sunday Welcome Reception at the White Horse Pub, Wembley	

MONDAY 9 JUNE | Wembley Stadium

TIME	SESSION/LOCATION			
08:00 – 09:00	Registration (Pre-Conference session: Introduction for students and new starters – Lizzi Pitt, Jemma Greenin and Oswald Dellimore)			
	Great Hall			
09:00 – 09:30	**Conference Opening Remarks** ***Sarah Williams, PSI Conference Chair***			
09:30 – 10:30	**Communicating the magic of maths (PL1)** *Chair:* ***Sarah Williams*** Alex Bellos is one of the UK's most celebrated maths communicators. He has sold more than a million books, writes a popular puzzle column in the Guardian and appears regularly on Radio 4. In this talk he will explain what he has learned about communicating maths to different audiences. You will hear stories, see beautiful images and solve some puzzles! - ***Alex Bellos***			
10:30 – 11:00	Refreshment Break in Bobby Moore Room			
	Great Hall	Wembley Suite	Pitch View East	The Arc
11:00 – 12:30	**The Fearless Statistician: Psychological Safety in Drug Development (O002)** *Chair:* ***Lucy Rowell*** Introduction to psychological safety and its relevance to statisticians working in the pharmaceutical Industry - ***Dirk Klingbiel*** Organizational Approaches to Psychological Safety: Building Inclusive and High-Performing Statistical Teams - ***Clélia Cahuzac*** Quantifying the costs of a lack of psychological safety - A case series - ***Anna Wiksten*** Panel discussion: ***Justine Rocheon, Dirk Klingbiel, Clélia Cahuzac and Anna Wiksten***	**AI/ML SIG: updates and applications (O003)** *Chair:* ***Sam Hadlington*** Predicting with uncertainty - ***Chris Harbron*** AI Generated Synthetic Control Arms to optimize Clinical Trials- ***Paola Berchialla and Danila Azzolina*** Explainable AI for Causal Inference and Heterogeneous Treatment Effect Estimation via AI/ML – a conceptual framework for late phase clinical trials - ***Karl Koechert and Eliana Garcia-Cossio*** Panel Discussion: ***Sam Hadlington, Chris Harbron, Paola Berchialla, Danila Azzolina, Karl Koechert and Eliana Garcia-Cossio***	**Borrowing Strength or Buying Trouble? Using External Data in Regulatory Context (O006)** *Chair:* ***Olivier Collignon*** Thinking beyond the norm: how to (fairly) evaluate Bayesian Dynamic Borrowing Designs - ***Gaëlle Saint-Hilary*** Another form of hybrid trial designs with external information: extrapolation in Paediatrics - ***Juan Jose Abellan*** Echo of the Past: The Pre-specification Challenge in Hybrid RCTs - ***Franz König*** Challenges when using external control data for regulatory decision making - ***Florian Klinglmueller***	**PFDD SIG: How to use PROs in early development (O011)** *Chair:* ***Konstantina Skaltsa*** Implementing Patient Reported Outcomes to Capture Tolerability in Early Phase Clinical Trials ***Peipert*** Project Optimus in Action: A Multistate Modeling Approach for Benefit-Risk Assessment in Oncology Dose Finding ***- Alexandra Lauer*** Missing PRO data: case-study example in sickle cell disease ***- Evgeniya Reshetnyak*** Hot topics: ***Rachael Lawrance***
12:30 – 13:30	SIGs at the Bar: *Come meet the SIGs and find out more about their work* Benefit Risk SIG, Regulatory SIG, AI & ML SIG, RWD SIG			
12:30 – 13:30	Lunch in Bobby Moore Room (Career Young Networking Session – *Lizzi Pitt, Jemma Greenin and Oswald Dellimore*) (Book Club Networking Session – *Emma May*)			

	Great Hall	Wembley Suite	Pitch View East	The Arc
13:30 – 15:00	**Navigating the Move to Open Source - Effective Strategies for Adoption and Working with Different Software (O010)** *Chair:* ***Martin Brown*** R Adoption & Change Management – a Large CRO Perspective - ***Martin Brown*** Mastering the Art of Adopting R and Python: Innovative Strategies for Effective Change Management - ***Mark Bynens*** R you (all) right, SAS? – Replicating statistical results between software - ***Lyn Taylor and Christina Fillmore***	**Grow your own way (W2)** Session organisers: ***Isabelle Smith and Lucy Rowell*** Statisticians are a heterogenous group in terms of their career pathways. Roles can include delivery, consultancy, methodology, or even CEO, as well as many others. Throughout a career there may be many points where we reach a crossroads, and “how do I know what I want to do next?” or “how can I get to where I want to be?”. In this interactive workshop, we will work through the GROW coaching model and how it can be used to help shape decisions about career direction. This workshop will be facilitated by speakers with very different careers who will share how they have used these techniques to support their own goals. Participants will have the opportunity to practice each element of the GROW model through the session, and to get the most from the session, participants will be expected to bring a career goal (short or long term) of their own that they would be happy to discuss in a small group.	**SEE-ing the Future: Empowering Health Decisions through Structured Expert Elicitation (O008)** *Chair:* ***Min-Hua Jen*** Structured Expert Elicitation (SEE) is increasingly recognized as a vital methodology for informing healthcare decision-making, especially in contexts where empirical data are scarce or unavailable—a frequent challenge in oncology. However, conducting SEE exercises that uphold the highest standards of credibility, accuracy, consistency, and transparency in expert judgments remains a persistent challenge. This panel discussion, jointly organized by the Historical Data Special Interest Group (SIG) and the Health Technology Assessment (HTA) SIG, brings together distinguished experts in methodology, alongside representatives from industry, academia and HTA bodies. The panel will deliberate on the current state and future direction of SEE in regulatory and HTA frameworks. ***Roel Straetemans, Kate Ren, Christopher Jackson and Hugo Pedder***	**Career Young Statistician** *Chair:* ***Lizzi Pitt*** Powering RCTs for marginal effects with GLMs using prognostic score adjustment (CYS01) - ***Emilie Hojbjerre-Frandsen*** Is there really any benefit to stratified randomisation in practice? (CYS05) - ***Pavankumar Bhagat*** Frailty prediction using digital sensor data, an interpretable machine learning approach (CYS06) - ***Gaizka Pérez*** Reconstructing Individual Patient Level Survival Data from Aggregate Survival Data using a Simulation Approach (CYS07) - ***Sarwar Mozumder*** Development and Evaluation of a Predictive Ensemble Learning Framework for Breast Cancer Radiotoxicities at 2 Years (CYS08) ***Samana Bano and Rebecca Boucher***
15:00 – 15:30	Refreshment Break in Bobby Moore Room			
	Great Hall	Wembley Suite	Pitch View East	The Arc
15:30 – 16:45	**Causal Inference in clinical trails** Chairs: ***Nicola Scott and Tom Burnett*** DoubleMLDeep: Estimation of Causal Effects with Multimodal Data (O023) - ***Martin Spindler***	**Bayesian/Master Protocols** Chair: ***Julia Saperia*** Bayesian life-course modelling of Alzheimer’s Disease progression (O033) - ***David Lunn***	**Dose Optimisation** *Chair:* ***Ayon Mukherjee*** Designing a seamless P1/P2a open enrolment CRM dose escalation study (O025) - ***Elias Laurin Meyer***	**Career Young Statistician 2** Chair: ***Julia Niewczas*** Applying prognostic scoring adjustments to enhance clinical trial efficiency in neurodegenerative diseases (CYS02) - ***Harry Parr***

	Decoding optimal methods in treatment switching: Recommendations from oncology-inspired simulation studies (O027) - ***Orlando Doehring*** Targeted Maximum Likelihood Estimation for Restricted Mean Survival Time in time-to-event data with low event rates: a case study using a previous non-randomised PAS study (O045) - ***Michael Seath*** Vaccine Efficacy waning estimation and extrapolation using causal inference (O047) - ***Jyoti Soni and Andrea Callegaro***	A basket trial design based on constrained hierarchical Bayesian model for latent subgroups (O036) - ***Atsuki Hashimoto*** Optimizing Paediatric Outcomes: Advanced Bayesian Modelling of Days Without Mechanical Ventilation in Respiratory Trials (O043) - ***Danila Azzolina***	Evaluating Early-Stage Oncology Clinical Trials in the Era of Project Optimus: A scoping review (O029) - ***Anais Andrillon*** A review of innovative seamless phase I/II design in early drug development in Oncology The Optimus Journey: FDA-Approved Examples of Dose Optimization in FIH Oncology Trials (O046) - ***Benoit Sansas***	Three new methodologies for calculating the effective sample size when performing population adjustment (CYS03) - ***Landan Zhang*** Context-dependent response-adaptive randomization for continuous endpoints and applications (CYS04) - ***Luca Rondano*** When to schedule the interim analysis in the presence of missing data? (CYS09) - ***Neža Dvoršak***
16:45 – 17:00	Changeover			
	Great Hall			
17:00 – 17:45	**Gone in 45 seconds** *Chairs:* ***Kate Taylor and Tom Burnett*** Come join us for a quick preview of all of our posters that will be presented during the poster session. Each poster presenter will have 45 seconds to tell you about their poster. Always a fun session (will they finish in the allocated time or get sent off?!) and you can use this time to decide which posters you'd like to visit.			
	Bobby Moore Room			
17:45 – 18:45	**The Posterwalk Session** *Sponsored by GSK*			
19:30 – 22:00	Monday Night Social at BOXPARK, Wembley *Sponsored by Alira Health*			

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 Sponsored by Alun Bedding Coaching** 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			
	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 share your experience and learn from each other.	**Quantitative Decision Making - How Frameworks Could Help You** Chair: ***Alex Carlton*** Going beyond Probability of Success for Early Development studies (O017) - ***Trevor Smart*** Quantitative Decision Making: How Frameworks Could Help You (O005) - ***Gustaf Rydevik and Nima Shariati*** Decision-Making Criteria and Methods for Initiating Late-Stage Clinical Trials from a Multi-Stakeholder Perspective: A Scoping Review (O019) - ***Julien Tanniou***	**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***

		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		
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 *Sponsored by Coronado Research*			

WEDNESDAY 11 JUNE | Wembley Stadium

TIME	SESSION/LOCATION			
08:00 – 09:45	Registration			
	Great Hall	Wembley Suite	Pitch View East	The Arc
09:45 – 10:45	**TED** Chair: ***Maria Efstathiou*** A multi-arm multi-stage design for trials with no control arm and all pairwise testing (T001) - ***Peter Greenstreet***	**Successful Use of Bayesian Dynamic Borrowing Methods in Regulatory Settings (O051)** Chair: ***Nicola Scott*** The GSK Biostatistics team has successfully used Bayesian Dynamic Borrowing (BDB) in a commercial setting, which allows for the re-use of	**AI / Machine Learning** Chair: ***Julia Saperia*** Predicting the probability of clinical trials success from AI-based approaches using multimodal data (O032) - ***Nils Ternes***	**Rare diseases and special populations** *Chair:* ***Sue Todd*** INVENTS: Going Beyond Conventional RCTs for Rare and Paediatric Diseases – Insights from Year 1 of the European Collaboration (O022) - ***Marcus Elze***

	The Role of Response Adaptive Randomization in Non-inferiority Oncology Trials (T011) - ***Maria Vittoria Chiaruttini*** (Sample) size matters! – demonstrating sample size calculations across software (T004) - ***Agnieszka Tomczyk and Lyn Taylor*** Frequentists United: A Safe Space for Embracing Bayes (T003) - ***Patrik Atkinson*** Biostatistical Challenges in Medical Device Clinical Trials - newly founded Special Interest Group Medical Devices (T012) - ***Michael Mader***	external data, synthesising new and existing data to increase efficiency whilst maintaining rigorous standards for regulatory decision making. The judging panel was impressed by the culmination of years of work invested in this project – starting with the development and publication of innovative methodology, followed by diligent efforts to communicate this methodology to regulators and stakeholders. The acceptance of Bayesian approaches by regulators is a big step forward, widely acknowledged within the industry and beyond. The award presentation took place at the PSI annual conference in Amsterdam, where Nicky Best and Andrea Callegaro collected the award on behalf of the Biostatistics team. ***Nicky Best, Andrea Callegaro, Dawn Edwards and Jodie Crawford***	Enhancing Treatment Effect Estimation in Clinical Trials using Machine Learning: A Within-Study Prognostic Score Approach (O038) - ***Antigoni Elefsinioti*** 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) (O048) - ***Teresa Greco***	Statistical Challenges in Health Technology Assessment (HTA) for Rare Diseases (O042) - ***Samadhan Ghubade*** Randomization-based Inference for MCP-Mod (O037) - ***Lukas Pin***
10:45 – 11:00	Changeover			
	Great Hall	Wembley Suite	Pitch View East	The Arc
11:00 – 12:30	Marginal Estimands and Estimation with Covariate Adjustment for TTE Endpoints (O014) Chair: *Sarwar Mozumder* Session Introduction - ***David Wright and Sarwar Mozumder*** Marginal hazard ratios and covariate adjustment – A causal inference perspective ***- Rhian Daniel*** Efficiency of nonparametric superiority tests based on restricted mean survival time versus the log-	**Patient preference studies** *Chair:* ***Conny Berlin*** Published patient preference studies can influence the choice of endpoints in clinical trials: An example from Atopic Dermatitis (O018) – ***Byron Jones*** Assessing the Readiness of the Patient Preference Study Landscape for Meta-Analyses and Benefit Transfers: Do We Always Need a New Preference Study (O021) - ***Michael Bui***	**Advances in pediatric extrapolation (O015)** *Chair:* ***Ian Wadsworth*** Introduction of the session objectives and presenters - ***Ian Wadsworth*** Expert elicitation for pre-specification of priors in pediatric extrapolation studies: from one-parameter to multi-parameter scenarios - ***Christian Stock*** Developing Treatments for Rare Pediatric Diseases Using Bayesian Extrapolation - ***Björn Bornkamp***	**Future-proofing healthcare beyond today for tomorrow's medicines with advancement in benefit-risk assessments (BRA) (O009)** *Chair:* ***Marco Boeri*** This session is a joint effort of the EFSPI/PSI Benefit-Risk ESIG. The speakers will emphasize recent developments in BRA methodologies for medicinal products. What does the CIOMS WG XII Benefit-Risk Assessment Report say? - ***Shahrul Mt-Isa***

	rank test under proportional hazards - ***Dominic Magirr*** Covariate adjustment in time-to-event data: single and doubly-robust methods - ***Sanne Roels*** Ensuring covariate adjustment methods for TTE outcomes are fit for use - ***Tim Morris*** Discussion Panel: Thoughts from A Regulator's Perspective – What are the Expectations? ***Armin Koch, David Wright, Rhian Daniel, Dominic Magirr, Sanne Roels and Tim Morris***	Enhancing Generalizability in Patient Preference Studies: Addressing Sample Skewness in the associated Covariate Distribution (O020) - ***Divya Mohan*** Patient Preferences in Clinical Trials, Challenges and Opportunities (O013) - ***Cecilia Jimenez Moreno***	CH E11A and Beyond – ongoing regulatory initiatives - ***Andrew Thomson***	Innovative trial designs and effect size estimation - bias, de-biasing, and when is it considered to be important - ***Ursula Garczarek*** Implementing innovative safety evaluation methods: Overcoming challenges and sharing successes - ***Naomi Givens*** Methodological aspects and practical application of a drug quantitative benefit-risk assessment: a case study ***Zhaoyang Teng, Hua Liu, Zhaowei [Zoe] Hua, Rui [Sammi] Tang, Gaëlle Saint-Hilary*** ***Shahrul Mt-Isa, Ursula Garczarek Naomi Givens and Pavel Mozgunov***
12:30 – 13:30	SIGS at the Bar: *Come meet the SIGs and find out more about their work* AIMS SIG, openstatsware SIG, L&L SIG			
12:30 – 13:30	Lunch in Bobby Moore Room			
	Great Hall	Wembley Suite	Pitch View East	The Arc
13:30 – 14:30	**Leadership TED** Chair: **Kate Taylor** How to be wrong (T006) - ***Simon Cleall*** Stepping into leadership: How will I manage? (T002) - ***Catherine Dixon*** Enhancing Cross-functional Partnership in Early Oncology Clinical Development: A Practical Guide for Biostatisticians (T008) - ***Laura Barker*** Trust actually: Building teams that love to work together (T007) - ***Zainab Walsh***	**Use of external data to improve clinical trials** *Chair:* ***Jyoti Soni*** Steps in using healthcare systems data as outcome data in clinical trials (O024) - ***Sharon Love*** Why Accurate Time to response prediction matters? (O026) - ***Donia Skanji*** Survival of the Fittest: Digitising Survival Data for Enhanced Decision-Making in Clinical Trials (O044) - ***James Sykes and Nelson Kinnersley***	**Estimands: Methods, theory and case studies** Chair: ***Tobias Muetze*** Sample size calculation for estimands and the impact of intercurrent events on power (O039) - ***Thomas Drury*** How Do Meta-Analyses Handle Treatment Switching? A Systematic Review (O041) - ***Rebecca Metcalfe*** Determining the non-inferiority margin in light of the ICH E9(R1) estimand framework (O034) - ***Sunita Rehal***	**Bayesian Dynamic Borrowing** Chair: ***Julia Saperia*** Unexpected results and challenges when using mixture priors for Bayesian borrowing (O031) - ***Darren Scott*** Non-monotonic power in Bayesian dynamic borrowing: insights and practical remedies (O035) - ***Gianmarco Caruso*** Biased borrowing or borrowing bias? Leveraging Bayesian borrowing and quantitative bias analysis for robust comparative effectiveness insights (O049) - ***Grace Hsu***

	Building High-Performing Teams: Leadership Strategies for Navigating Change and Driving Growth(T010) - ***Aga Rasinska*** Trust: The Backbone of Leadership (T005) - ***Alun Bedding***			
14:30 – 15:00	Refreshment Break in Bobby Moore Room			
	Great Hall			
15:00 – 16:00	**EU HTA: readying ourselves for the road to 2025 and beyond (PL4)**			
16:00 – 16:15	**Closing Remarks** *David Wright, PSI Board of Directors Chair*			

MONDAY 9 JUNE | POSTER SESSION | 17:45 – 18:45

Poster ID	Title	Presenting Author
P001	Using a Poisson Mixed-Effects Model to Improve Detection of Underreporting and Overreporting of Adverse Events in Multicentre Clinical Trials	Lawson Wang
P002	Adaptive design of clinical trials with delayed treatment effects using elicited prior distributions	James Salsbury
P003	Optimising graph-based multiple testing procedures by incorporating clinical considerations into flexible power objectives for FWER control	Alex Spiers
P004	Enhancing Clustering Quality Through the Integration of Missing Data Patterns: A Hierarchical Approach	Berit Hunsdieck
P005	Empirical aspects of MCPMod for Time to Event with Bayesian Borrowing	Erik Hermansson
P006	Project Optimus: A generalised Bayesian analytical framework for multi-endpoint dose optimisation	Miguel Pereira
P007	A basket trial design for dose optimization using Bayesian model averaging	Belay Birlie Yimer
P008	SISAQOL-IMI Recommendations: Statistical Considerations for Advancing PRO Analysis for Cancer Clinical Trials	Michael Schlichting
P009	An Alternative Estimand for Overall Survival in the Presence of Treatment Discontinuation: Simulation Results and Case Study	Kara-Louise Royle
P010	Assessing the Effects of Additional Investment in Earlier Phase Trials to Enhance Overall Program Probability of Success Through Informed Priors	Valeria Mazzanti
P011	PolyMAIC: Retain more of your hard-earnt clinical trial information	Jason Wilson
P012	A modelling strategy for the dose-escalation Phase I trials with a large number of combination-schedules	Weishi Chen
P013	On the use of the intraclass correlation coefficient for validation of count data endpoints in clinical trials	Antonio Rodríguez
P014	Targeted Maximum Likelihood Estimation for covariate adjustment in a Phase 3 randomized controlled study	Michael Seath
P015	Optimizing Clinical trials	Tom Parke
P016	Integrating Synthetic Data and AI in Paediatric Intensive Care Clinical Trials: A Bayesian Framework for Ethical and Scientific Advancement	Danila Azzolina
P017	Collaborative initiative for joint modelling of clinical, biomarker, and pharmacometrics data for dose and schedule optimization in an oncology phase-1 clinical trial	Federico Rotolo
P019	From Classroom to Clinical Trials: How PSI is inspiring the next generation of statisticians	Katie Law
P020	Navigating Non-Randomized Data in Health Technology Assessments in light of the EU HTA - complexities and solutions	Mona Bierl
P021	Multivariate signature modelling of itch outcomes in primary biliary cholangitis	Jasna Cotic
P022	Diversifying Clinical Trials with Adaptive Targeted Maximum Likelihood Estimation (A-TMLE): A Data Fusion Approach for Real-World Evidence	Emilie Højbjerre-Frandsenaga
P023	Sample Size Re-estimation: Exploding the Myths	Christopher Jennison
P024	Streamlining clinical trial data visualisation and reporting: a Python and R hybrid solution	Miguel Pereira
P025	Ordering Treatments Under Uncertainty	Justin Chumbley
P026	Population Adjustment for Indirect Comparisons: Making Apples and Oranges Play Nice	Sarah Robson
P027	Improving Model Accuracy for Skewed Data: A Depression Trial Example	Mohd Rashid Khan
P028	Hurricanes, Elections and Clinical Trials: Some novel approaches to visualising uncertainty.	Steve Mallett
P029	Adaptive group sequential designs with constraints on the information fraction	Fredrik Öhrn
P030	The Underlap Coefficient: A Novel Alternative to ROC-Based Summary Measures for Evaluating Biomarkers' Discriminatory Ability in Multi-Class Settings	Zhaoxi Zhang

P031	Introducing {verifyr2}: An R package for accelerating clinical study output review process	Anna Wiksten
P032	Potential applications of the principal stratum strategy in PRO endpoints	Konstantina Skaltsa
P033	Mind the EGAP: Using the Evidence Generation Analysis Plan to coordinate analyses that are outside the scope of existing analysis plans	Katy White
P034	ePRO for primary endpoints?	Barbara Arch
P035	Exploring PSI's Introduction to Industry Training (ITIT) Course: Benefits for Participants and Hosts	Sam Ruddell
P036	Conducting Efficient Clinical Trials in Immuno-oncology: Insights from Seven Years of the Morpheus Platform Trial	Clelia Cahuzac
P037	Enhancing Precision in Subgroup Analyses Using Bayesian Shrinkage Estimation: A Case Study	Dawn Edwards
P038	Evaluating External Control Feasibility for an Investigational Therapy in a Neuromuscular Disorder: A Simulation Study	Robbie Peck
P039	Investigating Causal Effects in Survival Analysis: How Adjustment Methods Shape Treatment Estimates	Frederikke Agerbo Modin
P040	Proof of target engagement in phase 1 trials with MCP-Mod	Valeria Bonapersona
P041	Machine Learning in Precision Medicine: A Collaborative Approach	Laura Schlieker
P042	Championing Diversity and Inclusion: PSI's New DE&I Working Group	Justyna Mlynarczyk
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