WEDNESDAY 11 JUNE | Wembley Stadium

TIME	SESSION/LOCATION			
08:00 – 09:45	Registration			
	Box 3004			
09:00 – 09:45	Urgent Meeting - Medical Statistician Apprenticeship Scheme Updates			
	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*** 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***	**Successful Use of Bayesian Dynamic Borrowing Methods in Regulatory Settings (O051)** Chair: ***Nicola Scott*** *Session kindly sponsored by Pfizer* Pfizer The GSK Biostatistics team has successfully used Bayesian Dynamic Borrowing (BDB) in a commercial setting, which allows for the re-use of 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.	**AI / Machine Learning** Chair: ***Julia Saperia*** Predicting the probability of clinical trials success from AI-based approaches using multimodal data (O032) - ***Nils Ternes*** 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***	**Rare diseases and special populations** *Chair:* ***Sue Todd*** Data sharing for rare diseases in INVENTS: Going Beyond Conventional RCTs for Rare and Paediatric Diseases – the Roche perspective (O022) - ***Markus Elze*** Statistical Challenges in Health Technology Assessment (HTA) for Rare Diseases (O042) - ***Samadhan Ghubade*** Randomization-based Inference for MCP-Mod (O037) - ***Lukas Pin***

		Nicky Best, Andrea Callegaro, Dawn Edwards and Jodie Crawford		
10:45 – 11:00	Changeover			
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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-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***	**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*** 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***	**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*** CH E11A and Beyond – ongoing regulatory initiatives - ***Andrew Thomson***	**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*** 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 ***- Pavel Mozgunov*** ***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			
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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*** Building High-Performing Teams: Leadership Strategies for Navigating Change and Driving Growth(T010) - ***Aga Rasinska*** Trust: The Backbone of Leadership (T005) - ***Alun Bedding***	**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***
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)** **Communicating Statistics and Uncertainty – The Case of Health Technology Assessment** The famous physicist Richard Feynman once said that it's more interesting to live with uncertainty than to live with answers that might be wrong. While this piece of wisdom is relevant for all statisticians, it is particularly acute in the new reality of EU HTA Joint Clinical Assessment. Here, statisticians must communicate statistical evidence and its inherent uncertainties while addressing HTA questions across 27 member states through a comprehensive evidence dossier. The resulting dossier and assessment report – and all of it's multitude of statistical analyses - will be highly public documents that will be used by multiple stakeholders to seek clear answers to their needs from their perspectives – but clouded by inherent uncertainty. How do we communicate in a way that reflects the needs of these different stakeholder groups, and the different lenses they will use to view the results. In this session, we will look at the perspectives of these stakeholders we can call the 6P's – Preparers (Drug Developers); aPprovers (regulators); Payor/HTA agencies; Provider (medical professionals); and Patients and the Public audience. This frames an HTA variant of our profession's universal communication challenge: how do we inclusively and effectively communicate statistics to many stakeholders at once? In this session, following a brief introduction to current information submissions requirements in HTA systems, a science journalist and an HTA statistician will present their perspectives on this question, followed by a plenary discussion of how to communicate about statistics in a way that can help build the trustworthiness of HTA systems.			

	Join us for this introduction to a dialogue on how to convey the complexity of the work that pharmaceutical statisticians in industry do to the multitudes of stakeholders who need to understand our work! ***Lara Wolfson, Maricarmen Climént, Nicholas Latimer and Anders Gorst-Rasmussen***
16:00 – 16:15	**Closing Remarks** *David Wright, PSI Board of Directors Chair*