

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	<p>TED</p> <p><i>A multi-arm multi-stage design for trials with no control arm and all pairwise testing (T001) - Peter Greenstreet</i></p> <p><i>The Role of Response Adaptive Randomization in Non-inferiority Oncology Trials (T011) - Maria Vittoria Chiaruttini</i></p> <p><i>(Sample) size matters! – demonstrating sample size calculations across software (T004) - Agnieszka Tomczyk and Lyn Taylor</i></p> <p><i>Frequentists United: A Safe Space for Embracing Bayes (T003) - Patrik Atkinson</i></p> <p><i>Biostatistical Challenges in Medical Device Clinical Trials - newly founded Special Interest Group Medical Devices (T012) - Michael Mader</i></p>	<p>Successful Use of Bayesian Dynamic Borrowing Methods in Regulatory Settings (O051)</p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>Nicky Best, Andrea Callegaro, Dawn Edwards and Jodie Crawford</i></p>	<p>AI / Machine Learning</p> <p><i>Predicting the probability of clinical trials success from AI-based approaches using multimodal data (O032) - Nils Ternes</i></p> <p><i>Enhancing Treatment Effect Estimation in Clinical Trials using Machine Learning: A Within-Study Prognostic Score Approach (O038) - Antigoni Elefsinioti</i></p> <p><i>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</i></p>	<p>Rare diseases and special populations</p> <p><i>Chair: Sue Todd</i></p> <p><i>INVENTS: Going Beyond Conventional RCTs for Rare and Paediatric Diseases – Insights from Year 1 of the European Collaboration (O022) - Marcus Elze</i></p> <p><i>Statistical Challenges in Health Technology Assessment (HTA) for Rare Diseases (O042) - Samadhan Ghubade</i></p> <p><i>Randomization-based Inference for MCP-Mod (O037) - Lukas Pin</i></p>
10:45 – 11:00	Changeover			

	Great Hall	Wembley Suite	Pitch View East	The Arc
11:00 – 12:30	<p>Marginal Estimands and Estimation with Covariate Adjustment for TTE Endpoints (O014)</p> <p>Sarwar Mozumder David Wright Rhian Daniel Dominic Magirr Sanne Roels Tim Morris</p>	<p>Patient preference studies</p> <p>Chair: Conny Berlin</p> <p><i>Published patient preference studies can influence the choice of endpoints in clinical trials: An example from Atopic Dermatitis (O018) – Byron Jones</i></p> <p><i>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</i></p> <p><i>Enhancing Generalizability in Patient Preference Studies: Addressing Sample Skewness in the associated Covariate Distribution (O020) - Divya Mohan</i></p> <p><i>Patient Preferences in Clinical Trials, Challenges and Opportunities (O013) - Cecilia Jimenez Moreno</i></p>	<p>Advances in pediatric extrapolation (O015)</p> <p>Chair: Foteini Strimenopoulou</p> <p><i>Introduction of the session objectives and presenters - Foteini Strimenopoulou</i></p> <p><i>Expert elicitation for pre-specification of priors in pediatric extrapolation studies: from one-parameter to multi-parameter scenarios - Christian Stock</i></p> <p><i>The role of modelling and simulation in accelerating pediatric clinical development: A case study on pJIA pediatric extrapolation - Rocío Lledó-García</i></p> <p><i>Developing Treatments for Rare Pediatric Diseases Using Bayesian Extrapolation - Björn Bornkamp</i></p> <p><i>Title TBC - Andrew Thomson</i></p>	<p>Future-proofing healthcare beyond today for tomorrow's medicines with advancement in benefit-risk assessments (BRA) (O009)</p> <p>Chair: Marco Boeri</p> <p>Shahrul Mt-Isa Ursula Garczarek Naomi Givens Pavel Mozgunov</p>
12:30 – 13:30	Lunch in Bobby Moore Room			
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13:30 – 14:30	<p>Leadership TED</p> <p><i>How to be wrong (T006) - Simon Cleall</i></p> <p><i>Stepping into leadership: How will I manage? (T002) - Catherine Dixon</i></p> <p><i>Enhancing Cross-functional Partnership in Early Oncology Clinical Development: A Practical Guide for Biostatisticians (T008) - Laura Barker</i></p>	<p>Use of external data to improve clinical trials</p> <p>Chair: Jyoti Soni</p> <p><i>Steps in using healthcare systems data as outcome data in clinical trials (O024) - Sharon Love</i></p> <p><i>Why Accurate Time to response prediction matters? (O026) - Donia Skanji</i></p> <p><i>Survival of the Fittest: Digitising Survival Data for Enhanced Decision-Making in Clinical Trials</i></p>	<p>Estimands: Methods, theory and case studies</p> <p><i>Sample size calculation for estimands and the impact of intercurrent events on power (O039) - Thomas Drury</i></p> <p><i>How Do Meta-Analyses Handle Treatment Switching? A Systematic Review (O041) - Rebecca Metcalfe</i></p> <p><i>Determining the non-inferiority margin in light of the ICH E9(R1) estimand framework (O034) - Sunita Rehal</i></p>	<p>Bayesian Dynamic Borrowing</p> <p><i>Unexpected results and challenges when using mixture priors for Bayesian borrowing (O031) - Darren Scott</i></p> <p><i>Non-monotonic power in Bayesian dynamic borrowing: insights and practical remedies (O035) - Gianmarco Caruso</i></p> <p><i>Biased borrowing or borrowing bias? Leveraging Bayesian borrowing and quantitative bias analysis for robust</i></p>

	<p><i>Trust actually: Building teams that love to work together (T007) - Zainab Walsh</i></p> <p><i>Building High-Performing Teams: Leadership Strategies for Navigating Change and Driving Growth(T010) - Aga Rasinska</i></p> <p><i>Trust: The Backbone of Leadership (T005) - Alun Bedding</i></p>	<p><i>(O044)- James Sykes and Nelson Kinnersley</i></p>	<p><i>comparative effectiveness insights (O049) - Grace Hsu</i></p>
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	<p>Closing Remarks</p> <p><i>David Wright, PSI Board of Directors Chair</i></p>		