

Monday 12th June

8:00 - 9:00	Registration (Pre-Conference session: Introduction for students and new starters Jemma Greenin)			
9:00 – 9:30	Chrissie Fletcher (Chair PSI Board of Directors) Conference Opening Remarks			
9:30 – 10:30	Timandra Harkness			
10:30 – 11:00	Break			
11:00 – 12:30	External Data	Small Steps Towards Patient Focused Benefit-Risk Assessment (Benefit-Risk SIG)	HTA	DMC Communication Workshop
	Andrew Hall (University of Leeds) <i>The UK Myeloma Research Alliance OPTIMUM Trial: A Synthetically-Controlled Phase II Trial in a Rare Sub-Population</i>	Shahrul Mt-Isa (MSD) <i>Manuscripts Working Group Preference-Based Benefit-Risk Assessment</i>	Claire Watkins (Clarostat Consulting Ltd) <i>Mistakes and Misinterpretations when Modelling Survival Adjusted for Treatment Switching for Health Technology Assessment</i>	Tim Friede (University Medical Center Göttingen) Mark Baillie (Novartis)
	Oliver Sailer (Boehringer Ingelheim) <i>Pharmacometrics-Enhanced Bayesian Borrowing for Paediatric Extrapolation – A Case Study of the DINAMOTM Trial</i>	Ursula Garczarek (Cytel) <i>Benefit-Risk Assessment in Clinical Trials with Composite Endpoints</i>	Byron Jones (Novartis) <i>Patient-Focused Drug Development</i>	David Lawrence (Novartis) Tobias Meutze (Novartis) Michael Cartwright (Parexel)

	James Matcham (Cytel) <i>Designing an Externally Controlled Single Arm Study in Paediatric Glioma: A Case Study</i>	Marco Boeri (Queens University) <i>Sample Size Calculations for Discrete Choice Experiments in Pharmaceutical and Health Care Applications</i>	Landan Zhang (AstraZeneca) <i>Four Alternative Methodologies for Simulated Treatment Comparison: How Could the use of Simulation be Re-invigorated?</i>		
	Damien Chimits (UCB) <i>Bayesian Model-Informed Analysis to Estimate Maintenance of Efficacy</i>		Daniel Gallacher (University of Warwick) <i>SurvInt: A Simple Tool to Obtain Precise Parametric Survival Extrapolations</i>		
12:30 – 13:15	Lunch (Career Young Networking Session - Jemma Greenin)				
13:30 – 15:00	ICH E9(R1) Impact Beyond Confirmatory Superiority Clinical Trials (EIWG)	Career Young Statistician	Importance of Patient Reported Outcomes in Clinical Studies	Positive Power and Influence workshop	Introduction to the Central Statistical Monitoring (CSM/QL SIG)
	Sue McKendrick (PPD, part of Thermo Fisher Scientific), Helle Lynggaard (Novo Nordisk A/S) <i>Does it make sense to apply the estimand framework to clinical pharmacology (CP) trials?</i>	Akshay Patil (MRC Biostatistics Unit) <i>Checklist and Reporting Guidelines for Estimands in Adaptive or Innovative Clinical Trial Designs</i>	Konstantina Skaltsa (IQVIA) <i>Towards More Patient Centricity – The Importance of PRO</i>	In collaboration with Chartwell Katie Thorn (GSK), Nicole Samson (GSK) and Vanessa Grey (Chartwell) <i>Positive Power and Influence</i>	Tim Rolfe (GSK) <i>Harnessing the Power of Centralized Statistical Monitoring in Post Pandemic Trial Conduct</i>
	Sunita Rehal (GSK) <i>The Estimands Framework in Non-Inferiority Trials: Past, Present and Future</i>	Stephen Schuurhuis (Charité University) <i>Handling Delayed Treatment Responses in a Two-Stage Group-Sequential Design with Continuous Endpoints</i>	Karl Karu (IQVIA) <i>Common Challenges in the Analysis of PRO Data</i>		Chris Wells (Roche) <i>Statistical Considerations for Quality Tolerance Limits</i>

	<p>Antonia Morgia (Astellas Pharma Europe Ltd), Pepa Polavieja (Novo Nordisk) <i>The ICH E9(R1) Addendum in the context of Health Technology Assessments: methodological considerations and recommendations</i></p>	<p>Alexander Luo (Veramed) <i>Remove Your Bias: MCMC Algorithms to set you on the Right Path</i></p> <p>Amal Mawass (Alira Health) <i>A Composite Endpoint Capturing Quality of Life Endpoints</i></p> <p>Sarah Robson (Veramed) <i>Animations in R: The Dark Horse of Data Visualisation</i></p>	<p>Khadija Rantell (MHRA) <i>Experience with PRO in Regulatory Submission</i></p> <p>Anja Schiel (Norwegian Medicines Agency) <i>Patient Reported Outcomes (PROs): A Health Technology Assessment (HTA) View</i></p>	<p>Maciej Fronc (GSK) <i>Statistical Methods for Central Statistical Monitoring</i></p> <p>Monika Jelizarow (UCB) <i>Bayesian Predictive Distributions and Historical Data for Quality Tolerance Limits</i></p>	
15:00 – 15:15	Changeover				
15:15 – 16:30	<p>Data Visualisation</p> <p>Martin Karpefors (AstraZeneca) <i>The Maraca Plot – A Novel Visualisation of Hierarchical Composite Endpoints – Concept and Implementation in R</i></p>	<p>Basket/Platform CYS</p> <p>Luke Ouma (Newcastle University) <i>A Two-Stage Bayesian Adaptive Umbrella Design Borrowing Information Over the Control Data</i></p>	<p>Use of External Data (Bayesian Borrowing)</p> <p>Mark Whitlock (Pfizer) <i>Practical applications of the robust meta-analytic predictive prior approach to Phase 2 studies at Pfizer</i></p>	<p>HTA SIG: A cacophony of comparisons? Multiplicity in future EU HTA Joint Clinical Assessments</p> <p>Martin Scott (Numerus) <i>One Size Fits All – The EU's Joint Clinical Assessment System and Its Implication for Statisticians</i></p>	<p>Seamless Designs</p> <p>Pavel Mozgunov (MRC Biostatistics Unit) <i>A Seamless Phase I/II Platform Design with a Time-To-Event Efficacy Endpoint for Novel Potential COVID-19 Therapies (AGILE Platform)</i></p>

	<p>Nils Ternès (Sanofi) <i>IDEO: An R Shiny Application Integrating Clinical and Biomarker Results and Designed to Support Faster Study Team Decision Making Process</i></p>	<p>Peter Greenstreet (Lancaster University) <i>Why Keeping Data may be Detrimental in Platform Trials with One of the Active Arms Becoming Standard of Care</i></p>	<p>Christian Stock (Boehringer Ingelheim) <i>Partial extrapolation in pediatric drug development using robust meta-analytic predictive priors, tipping point analysis and expert elicitation</i></p>	<p>James Ryan (AstraZeneca) <i>PICOs in EU HTA: How Many, How Varied?</i></p>	<p>Loïc Darchy (Sanofi) <i>A General Statistical Framework for Designing and Assessing a Combined Phase 2/3 Surrogate Endpoint Driven Adaptive Design</i></p>
	<p>Nathan Johnson (eClinical Solutions) <i>Driving Efficiency for Safety Analysis with Data Visualisation</i></p>	<p>Lukas D. Sauer (University of Heidelberg) <i>Optimising Basket Trials Using Constrained Optimisation Techniques</i></p>	<p>Julia Niewczas (Janssen) <i>Augmenting historical information into control arm – overview and comparison of Bayesian methods</i></p>	<p>Stephen Senn <i>Can more really be less?</i></p>	<p>Stella Jinran Zhan (University of Warwick) <i>Efficiently Incorporating Adaptive Seamless Designs in the Two-Trial Paradigm</i></p>
		<p>Lou E Whitehead (Newcastle University) <i>Bayesian Borrowing for Basket Trials with Longitudinal Outcomes</i></p>		<p>William Wang (MSD) <i>Balanced Multiplicity Approach in Safety Evaluation</i></p>	
16:30 – 17:00	Break				
17:00 – 18:00	Gone in 60 seconds: 1 Minute Poster Previews				
18:00 – 19:00	Poster Session				
19:00 – 20:00	Free Time				
20:00 – 22:00	Social Event				

