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** ***From John Graunt to Next Slide Please: What a 17th Century haberdasher can teach us about data, risk and the public.*** *Kindly sponsored by Daiichi Sankyo*			
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) *The UK Myeloma Research Alliance OPTIMUM Trial: A Synthetically-Controlled Phase II Trial in a Rare Sub-Population*	Shahrul Mt-Isa (MSD) *Manuscripts Working Group Preference-Based Benefit-Risk Assessment*	Claire Watkins (Clarostat Consulting Ltd) *Mistakes and Misinterpretations when Modelling Survival Adjusted for Treatment Switching for Health Technology Assessment*	Tim Friede (University Medical Center Göttingen) Emma May (ICON) David Lawrence (Novartis) Tobias Meutze (Novartis) Michael Cartwright (Parexel)
	Oliver Sailer (Boehringer Ingelheim) *Pharmacometrics-Enhanced Bayesian Borrowing for Paediatric Extrapolation – A Case Study of the DINAMOTM Trial*	Ursula Garczarek (Cytel) *Benefit-Risk Assessment in Clinical Trials with Composite Endpoints*	Byron Jones (Novartis) *Patient-Focused Drug Development*	

	James Matcham (Cytel) *Designing an Externally Controlled Single Arm Study in Paediatric Glioma: A Case Study*	Marco Boeri (Queens University) *Sample Size Calculations for Discrete Choice Experiments in Pharmaceutical and Health Care Applications*	Landan Zhang (AstraZeneca) *Four Alternative Methodologies for Simulated Treatment Comparison: How Could the use of Simulation be Re-invigorated?*		
	Guillemette de la Borderie (UCB) *Bayesian Model-Informed Analysis to Estimate Maintenance of Efficacy*		Daniel Gallacher (University of Warwick) *SurvInt: A Simple Tool to Obtain Precise Parametric Survival Extrapolations*		
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/QTL SIG)**
	Sue McKendrick (PPD, part of Thermo Fisher Scientific), Helle Lynggaard (Novo Nordisk A/S) *Does it make sense to apply the estimand framework to clinical pharmacology (CP) trials?*	Stephen Schüürhuis (Charité University) *Handling Delayed Treatment Responses in a Two-Stage Group-Sequential Design with Continuous Endpoints*	Konstantina Skaltsa (IQVIA) *Towards More Patient Centricity – The Importance of PRO*	POSITIVE POWER AND INFLUENCE *In collaboration with Chartwell* Katie Thorn (GSK)	Tim Rolfe (GSK) *Harnessing the Power of Centralized Statistical Monitoring in Post Pandemic Trial Conduct*
	Sunita Rehal (GSK) *The Estimands Framework in Non-Inferiority Trials: Past, Present and Future*	Alexander Luo (Veramed) *Remove Your Bias: MCMC Algorithms to set you on the Right Path*	Karl Karu (IQVIA) *Common Challenges in the Analysis of PRO Data*	Nicole Samson (GSK) Vanessa Grey (Chartwell)	Chris Wells (Roche) *Statistical Considerations for Quality Tolerance Limits*
		Amal Mawass (Alira Health)	Khadija Rantell (MHRA)	Greg Spencer (Chartwell)	Maciej Fronc (GSK)

	Antonia Morga (Astellas Pharma Europe Ltd), Pepa Polavieja (Novo Nordisk) *The ICH E9(R1) Addendum in the context of Health Technology Assessments: methodological considerations and recommendations*	*A Composite Endpoint Capturing Quality of Life Endpoints* Sarah Robson (Veramed) *Animations in R: The Dark Horse of Data Visualisation*	*Experience with PRO in Regulatory Submission* Anja Schiel (Norwegian Medicines Agency) *Patient Reported Outcomes (PROs): A Health Technology Assessment (HTA) View*		*Statistical Methods for Central Statistical Monitoring* Monika Jelizarow (UCB) *Bayesian Predictive Distributions and Historical Data for Quality Tolerance Limits*
15:00 – 15:15	Changeover				
15:15 – 16:30	**Data Visualisation**	**Basket/Platform CYS**	**Use of External Data (Bayesian Borrowing)**	**HTA SIG: A cacophony of comparisons? Multiplicity in future EU HTA Joint Clinical Assessments**	**Seamless Designs**
	Martin Karpefors (AstraZeneca) *The Maraca Plot – A Novel Visualisation of Hierarchical Composite Endpoints – Concept and Implementation in R*	Peter Greenstreet (Lancaster University) *Why Keeping Data may be Detrimental in Platform Trials with One of the Active Arms Becoming Standard of Care*	Mark Whitlock (Pfizer) *Practical applications of the robust meta-analytic predictive prior approach to Phase 2 studies at Pfizer*	Martin Scott (Numerus) *One Size Fits All – The EU's Joint Clinical Assessment System and Its Implication for Statisticians*	Pavel Mozgunov (MRC Biostatistics Unit) *A Seamless Phase I/II Platform Design with a Time-To-Event Efficacy Endpoint for Novel Potential COVID-19 Therapies (AGILE Platform)*
	Nils Ternès (Sanofi) *IDEO: An R Shiny Application Integrating Clinical and Biomarker Results and Designed*	Lukas D. Sauer (University of Heidelberg)	Christian Stock (Boehringer Ingelheim)	James Ryan (AstraZeneca)	Loïc Darchy (Sanofi) *A General Statistical Framework for Designing and Assessing a*

	to Support Faster Study Team Decision Making Process	*Optimising Basket Trials Using Constrained Optimisation Techniques*	*Partial extrapolation in pediatric drug development using robust meta-analytic predictive priors, tipping point analysis and expert elicitation*	*PICOs in EU HTA: How Many, How Varied?*	*Combined Phase 2/3 Surrogate Endpoint Driven Adaptive Design*
	Nathan Johnson (eClinical Solutions) *Driving Efficiency for Safety Analysis with Data Visualisation*	Lou E Whitehead (Newcastle University) *Bayesian Borrowing for Basket Trials with Longitudinal Outcomes* Luke Ouma (Newcastle University) *A Two-Stage Bayesian Adaptive Umbrella Design Borrowing Information Over the Control Data*	Julia Niewczas (Janssen) *Augmenting historical information into control arm – overview and comparison of Bayesian methods*	Stephen Senn *Can more really be less?* William Wang (MSD) Balanced Multiplicity Approach in Safety Evaluation	Stella Jinran Zhan (University of Warwick) *Efficiently Incorporating Adaptive Seamless Designs in the Two-Trial Paradigm*
16:30 – 17:00	**Break**				
17:00 – 18:00	**Gone in 60 seconds: 1 Minute Poster Previews**				
18:00 – 19:00	**Poster Session** *Kindly sponsored by GSK*				
19:00 – 20:00	**Free Time**				
20:00 – 22:00	**Social Event** *Kindly sponsored by Exploristics*				