Wednesday 19th June

08:00 – 16:30	**Registration**			
9:45 – 10:45	**Bayesian Borrowing**	**Decision Making**	**Non-technical TED**	**Adaptive Designs**
	Digital Twins and Bayesian Dynamic Borrowing: two recent approaches for incorporating historical control data **Carl-Fredrik Burman**	Detriment Index based Ranking Technique for painkiller drugs in Noncommunicable Diseases (NCD's) **Samadhan Ghubade (ICON)**	The Ukrainian experience: working under stressful conditions and uncertainty. **Angelina Rozmarytsia**	Defining good guidelines for futility stopping based on conditional power or predictive power **Christopher Jennison**
	Navigating Challenges in RCT Conduct: A Bayesian Adaptive Semiparametric Approach Handling Primary and Secondary Endpoints in Paediatric Trial Design **Danila Azzolina**	Assurance (probability of success) methods for designing a survival trial with a delayed treatment effect **James Salsbury (University of Sheffield)**	Emotional Intelligence for the Statistically Brilliant **Emma May** Unveiling the Power of Public Speaking to Statistician: A Path to Leadership **Guillaume Desachy**	Confidence intervals for adaptive designs **David Robertson**
	Bayesian Dynamic Borrowing and Prognostic Covariates: An Empirical Comparison **Erik Hermansson**	Application of Quantitative Decision Making in Early Clinical Development: A Case-Study **Nicola Scott (GSK)**	Empowering Newcomers: Fostering Connections and Knowledge **Kristina Weber** Learning Lessons: How to Run a Useful Lessons Learned Meeting and Track Actions	Advanced Trial Simulation in the Design of a Pivotal Cardiovascular Study: A Case Study **James Matcham**

			Sam Ruddell	
			Stats, drugs and rock & roll: a Graduates Perspective of the Industry **Patrik Atkinson**	
10:45 – 11:00	**Changeover**			
11:00 – 12:30	**Updates on the Difficulties in Estimating Treatment Effect Heterogeneity in Clinical Trials and Observational data; Practical Examples and Benchmarking**	**Estimands in Non-inferiority Trials: Challenges in Implementation**	**Use of External Data for Safety Review**	**Career Young Session**
	Comparison of modern approaches for subgroup identification from clinical and observational data **David Svensson (AstraZeneca)**	Non-inferiority and the estimands framework **Helle Lynggaard**	Using longitudinal Bayesian Dynamic Borrowing methodology applied to external control arms within an open label extension study. **Adrian Mander, Ben Hartley**	REMoDLing Phase II trial to incorporate historical information on a time-to-event endpoint **Alessandra Serra**
				RWD and its Practical Challenges **Andisheh Bakhshi**
			Blinded safety signal detection integrating internal and external evidence – A Bayesian meta-analytic approach using time-to-event modelling **Arnab Sarkar**	Controlled Multiple imputation in Time-To-Event data using tipping point analysis **Clement Daniel**

	Considerations on when and how to perform subgroup selection in Phase 2/3 programs **Tobias Mielke (Janssen)**	How the estimands framework affects choice of noninferiority margin **David Wright**	Statistical Technology to Facilitate Safety Signal Assessment in Data Monitoring Committee (DMC) Data Review Meetings **Dwaine Banton**	Investigating the impact of Data Monitoring Committee's recommendations on the probability of trial success (PoS) **Luca Rondano**
	Structured approach for assessing treatment effect heterogeneity **Kostas Sechidis (Novartis)**	Panel discussion **Kit Roes, Khadija Rantell, Florian Lasch**	Monitoring safety signals in ongoing blinded trials with Julia **Kristian Brock, Daniel Sabanés Bové**	Seeking early conditional approval in Randomised Clinical Trials with time-to-event endpoints via historical information borrowing **Marco Ratta**
12:30 – 13:30	**Lunch**			
12:30 – 13:30	HTA SIG Social Session As the January 2025 implementation of the EU HTA Regulation edges ever closer, the external environment continues to evolve and emphasize the importance of statistical analysis and thinking....come join the HTA ESIG for a discussion on the latest developments, including updates from the June meetings of CIRS and the EU HTA Stakeholder network, and updates from the parallel HTAi conference.			
13:30 – 14:30	**Innovative Approaches**	**Master Protocols**	**R Sessions**	**Technical TED**
	Implementing Innovative Statistical Methods in Pharmaceutical Drug Development **Margaret Jones (Weatherden consultants)** **Andy Grieve (UCB)**	Practical guidance for conducting late-phase platform clinical trials: Insights from experienced UK academic clinical trials units **Sharon Love**	Development of an AI-Enhanced Profiling Tool for R Code Optimization Using Shiny **Camilo Rojas, Mark Bynens**	Evaluating Re-Identification Risk Scores in Publicly Available Clinical Trial Datasets: Insights and Implications **Aryelly Rodriguez**

	Implementation of statistical innovation in a pharmaceutical company **Kaspar Rufibach (Roche)**	Visualising master protocols **Deepak Parashar**	Sailing, not Sinking – Journey of the First Roche Phase III Study to Use R for Primary Analysis and Potential Filing **Guiyuan Lei**	A Bayesian approach to decision making in early development clinical trials: An R solution. **Audrey Yeo**
				Expert Judgement to support a clinical hybrid Bayesian network approach on pancreatic cancer **Erica Secchettin**
				A conservative approach to leveraging prior evidence about treatment effects for effective group sequential clinical trial design **Fabio Rigat**
	Implementing Bayesian Augmented Control Designs into Business Practice: Insights and Reflections on a Journey from a Tool to a Mindset **Monika Jelizarow (UCB)**	Designing an exploratory phase 2b platform trial in NASH with correlated co-primary binary endpoints **Elias Laurin Meyer**	Generating reproducible company documents from R **Janina Linnik**	CPIM: Conditional-Power-Induced Migraine: How Logical Inconsistencies lead to illogical decisions and consistent misinterpretations **Simon Cleall**
				To Master Protocol or Not To Master Protocol? **Elizabeth Pilling**

				Stat-GPT: Harnessing AI for Medical Statisticians **Sam Hadlington**
14:30 – 15:00	**Break**			
15:00 – 16:15	**EU HTA: Finish line or starting gate?** Thomas Ecker (Founder and co-CEO Ecker & Ecker) Overview of implementing acts and dossier templates Sandro Gsteiger & Per-Olof Thuresson (Roche) EU HTA, the future is here – what did we learn from the EUnetHTA Join Actions and will it be a bumpy ride? Jelena Stevanovic (BMS) The relevance of JCA for national decision-making: the Dutch perspective			
16:15 – 16:30	**Closing Remarks:** **David Wright (Chair PSI Board of Directors)**			