Wednesday 19th June

08:00 – 09:45	**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 & Pushkar Madhav Joshi (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 Quantitativee Decision Making in Early Clinical Development: A Case-Study **Nicola Scott (GSK)**	Empowering Newcomers: Fostering Connections and Knowledge **Kristina Weber**	Advanced Trial Simulation in the Design of a Pivotal Cardiovascular Study: A Case Study **James Matcham**

<table>
<tr><td></td><td></td><td></td><td>Learning Lessons: How to Run a Useful Lessons Learned Meeting and Track Actions
Sam Ruddell</td><td></td></tr>
<tr><td>10:45 – 11:00</td><td colspan="3">Changeover</td><td></td></tr>
<tr><td rowspan="3">11:00 – 12:30</td><td>Updates on the Difficulties in Estimating Treatment Effect Heterogeneity in Clinical Trials and Observational data; Practical Examples and Benchmarking</td><td>Estimands in Non-inferiority Trials: Challenges in Implementation</td><td>Use of External Data for Safety Review</td><td>Career Young Session</td></tr>
<tr><td rowspan="2">Considerations on when and how to perform subgroup selection in Phase 2/3 programs
Tobias Mielke (Janssen)</td><td rowspan="2">Non-inferiority and the estimands framework
Helle Lynggaard</td><td rowspan="2">Using longitudinal Bayesian Dynamic Borrowing methodology applied to external control arms within an open label extension study.
Adrian Mander, Ben Hartley</td><td>REMoDLing Phase II trial to incorporate historical information on a time-to-event endpoint
Alessandra Serra</td></tr>
<tr><td>RWD and its Practical Challenges
Andisheh Bakhshi</td></tr>
<tr><td></td><td></td><td>Blinded safety signal detection integrating internal and external evidence – A Bayesian meta-analytic approach using time-to-event modelling
Arnab Sarkar</td><td>Controlled Multiple imputation in Time-To-Event data using tipping point analysis
Clement Daniel</td></tr>
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	Comparison of modern approaches for subgroup identification from clinical and observational data **David Svensson (AstraZeneca)**	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)**		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**			
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**	**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**

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)**