Tuesday 18th June

08:00 – 08:30	**Registration**			
08:45 – 10:15	**Theo Smith Neurodiversity at Work: Unleashing Potential in Every Mind**			
10:15 – 10:45	**Break**			
10:45 – 12:15	**Recent Development of Advanced Randomization Designs**	**Quantitative Decision Making in Drug Development**	**Bridging The Gap Between Bayesian & Frequentist Adaptive Designs**	**Advancements in Digital Health Technology: Opportunities, Challenges and Solutions**
	Thinking outside the blocks – Moving towards fit-for-purpose randomization in our clinical trials **Johannes Krisam**	Simple approaches for portfolio quantitative decision-making **Gaëlle Saint-Hilary (Saryga)**	Forecasting with Confidence: Harnessing Predictive Probabilities in Practice **Cora Allen-Savietta**	Challenges in Decentralized Clinical Trials and Digital Health Technology Implications within Industry **Susanne Schaefer (ICON)**
	InnoRand – an innovative R-based tool for randomization in clinical trials **Loek Bour**	Incorporating durability endpoints in decision making in early oncology clinical trials **Rosalind Hobson (AstraZeneca)**	Adaptations, Interim Analyses and Multiplicity in Clinical Trials - Ignoring, Bayesian, Frequentist or a little bit of everything? **Franz König**	Digital Endpoints: Key Themes from a Multi-stakeholder Knowledge Exchange Event **Mia Tackney (MRC Biostatistics Unit, University of Cambridge)**
	Selecting a randomization method for a multi-centre clinical trial with	Use of Conditional Assurance for Decision Making in Phase 1 Dose Escalation		Data Handling in Digital Health Technology: Challenges With Missing Data and Intercurrent events

	stochastic recruitment considerations **Volodymyr Anisimov** A fair and efficient randomization scheme for multi-arm seamless two-phase clinical trials **Peter Jacko**	**Wei Quan (AstraZeneca)**	Regulatory considerations on complex clinical trials and adaptive designs with Bayesian design elements **Benjamin Hofner**	**Rosemary Abbott (ICON)**
12:15 – 13:15	**PSI Annual General Meeting**			
13:15 – 14:15	**Lunch**			
14:15 – 15:45	**Advanced Statistical Methods In Vaccine Clinical Trials**	**Bias In Indirect Treatment Comparisons And Evolving Methodology: Implications For Health Technology Assessment And Beyond**	**Dose Finding Studies**	**Comparison of Bayesian Methods for External Controls**
	Joint modelling of sparse immune response data and time-to-disease for prediction of vaccine efficacy **Greg Papageorgiou (GSK)**	Overview on the PICO concept and introduction to ITC needs from an EU HTA perspective ***Lauren Abderhalden, MSD***	Incorporating patient-reported outcomes in dose-finding clinical trials with continuous patient enrolment **Anaïs Andrillon**	Integration of Historical Data into the Design and Analysis of Clinical Trials for Rare Diseases. **Emilie Jounot, Lucie Truffaut-Chalet, Xiangmin Zhang**
	Application of causal inference methodology in evaluation correlates of risk	Methodologies to adjust for measured confounding in ITC: an overview of population adjustment approaches	A Comparison of Model-Free Phase I Dose Escalation Designs for Dual-Agent Combination Therapies **Helen Barnett**	Evaluating External Control Incorporation Methods in Clinical Trials: A DAPA-HF Case Study

	Sanne Roels, Joris Menten (Johnson & Johnson)	**David Philippo, University of Bristol**		**Kristine Broglio, Sima Shahsavari, Di Ran, and Fanni Zhang**
	Harmonizing the collection of solicited adverse events in prophylactic vaccine clinical trials **Bart Spiessens (Johnson & Johnson)**	*Methodologies to adjust for unmeasured confounding in ITC* ***Kate Ren, University of Sheffield***	Guiding Oncology phase I dose escalation for modern therapies with short to long-term safety monitoring and variable dosing regimens **Lukas A. Widmer**	Bayesian sample size using historical data with interpretable discrepancy weights **Lou E. Whitehead, James M.S. Wason, Oliver Sailer, Haiyan Zheng**
		Nicolas Scheuer, Roche	**Tom Parke**	Comparison of operating characteristics of applying robust MAP versus Normalized Power Prior for clinical trials with augmented control with only one historical external data source available. **Roel Straetemans, Bart Michiels and Tobias Mielke**
15:45 – 16:15	**Break**			
16:15 – 17:45	**Regulatory Hot Topics Session** Kit Roes (EMA) Ina Rondak (EMA) Khadija Rantell (MHRA) Elina Asikanius (finish HA)			

17:45 – 19:30	**Break & Free Time**
19:30 – 00:45	**Gala Dinner: Beurs van Berlage** **Location: Grote Zaal**