Tuesday 18th June				
08:00 – 18:00	**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 **Annika Scheffold**	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	15:45	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	**Come and shape the future of PSI – Annual Updates & AGM**			
12:15 – 13:15	**Tackling the challenges of poor data with Design of Experiments** · Efficient experimentation for non-clinical statistics in CMC pharma · Tackling model uncertainty in the presence of more than 100 potential effects · Multi-response optimization using probability of success			
13:15 – 14:15	**Lunch**			
13:15 – 14:15	**Informal schools outreach chat** Drop in to our lunchtime session at the conference and ask any questions about how to get involved in our PSI Schools Outreach Champion network. Discover how to actively engage with schools using our workshops, which will we demonstrate, or take the next step and join our team to help organise and support our outreach efforts. We are seeking enthusiastic individuals passionate about statistics to inspire the next generation and make a meaningful impact in schools and the wider community.			

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**	**Innovative Dose Escalation Designs**	**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 **Sanne Roels, Joris Menten (Johnson & Johnson)**	Methodologies to adjust for measured confounding in ITC: an overview of population adjustment approaches **David Philippo, University of Bristol**	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 **Kristine Broglio, Di Ran, Fanni Zhang, Alasdair Henderson, Sima Shahsavari**
	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**

		Case Study ***Nicolas Scheuer, Roche***	Comparing Dose Escalation Methods: i3+3, mTPI, BOIN, Bayesian Logistic Regression (CRM) **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** In the Regulatory Hot Topics Session, we will discuss three topics that are relevant for both regulatory agencies and pharmaceutical companies. For each topic, we will have presenters from a regulatory agency and a pharmaceutical company. They will present their views on the topic, followed by a Q&A session where you can ask questions and share your opinions. The three topics are: Topic 1: AI/ML in drug development Topic 2: Real-word evidence Topic 3: Summary of product characteristics (SmPC) – Section 5.1 **Juan Jose Abellan (EMA)** **Elina Asikanius (Finnish Medicines Agency)** **Khadija Rantell (MHRA)** **Kit Roes (EMA)** **Mouna Akacha (Novartis)** **Chris Harbron (Roche)** **Josie Wolfram (Astellas)**			
17:45 – 19:30	**Break & Free Time**			
19:30 – 23:45	**Gala Dinner: Beurs van Berlage** **Location: Grote Zaal**			