Scientific Programme Summary

Sunday 6th October 2019		
08.00 – 18.00	Registration Open	
08.00 – 19.00	Exhibition & Poster Set Up	
09.00 – 13.00	**Pre-Conference Workshop 1.1** Using Studies Within A Trial (SWATs) to increase the evidence-base for trial process decisions: how to select, design and run them	**Preston**
	Pre-Conference Workshop 1.2 Design and analysis of clinical trials in the era of precision medicine	**Hall 4**
	Pre-Conference Workshop 1.3 Beyond the CONSORT extension for pilot trials: guideline, planning, abstracts and protocols	**Stamner**
13.00 – 14.00	**Lunch Break** (lunch not included)	
14.00 – 18.00	**Pre-Conference Workshop 2.1** Missing data in randomised trials: concepts and design	**Preston**
	Pre-Conference Workshop 2.2 Strategies for optimising recruitment to challenging randomised controlled trials: The QuinteT approach	**Hall 4**
	Pre-Conference Workshop 2.3 Finding and critically appraising a core outcome set (COS) for your trial	**Stamner**

Monday 7th October 2019		
07.30	**Registration & Speaker Preview Opens**	
09.30 – 09.45	**Welcome & Opening**	**Oxford Suite**
09.45 – 10.35	**Keynote -** *Dr Janet Dancey*	**Oxford Suite**
10.35 – 11.30	Coffee Break, Exhibition & Poster Viewing	
11.30 – 12.35	**Parallel Session 1A – Improving Follow-Up and Retention**	**Oxford Suite**
	Parallel Session 1B – Challenges in Statistical Analysis 1: Bias and Precision	**Preston**
	Parallel Session 1C – Health Economic Evaluation	**Hall 4**
	Parallel Session 1D – Rapid Abstracts	**Stanmer**
12.35 – 13.40	Break - Lunch, Exhibition & Poster Viewing	
13.00 – 13.40	**Lunchtime Symposium – Sponsored by NIHR**	**Preston**
13.40 – 14.45	**Parallel Session 2A – Improving Data Quality in Trials**	**Preston**
	Parallel Session 2B – Early Phase Study Designs 1: Platforms & Basket	**Oxford Suite**
	Parallel Session 2C – Complex Interventions and Recruitment + Retention	**Hall 4**
	Parallel Session 2D – Public and Patient Involvement and Engagement	**Stamner**
14.45 – 14.55	**Room Change**	
14.55 – 16.00	**Parallel Session 3A – Challenges with Trial Recruitment 1: Recent Experiences**	**Oxford Suite**
	Parallel Session 3B – Improving Trial Design	**Preston**
	Parallel Session 3C – Early Phase Study Designs 2: Advanced Issues	**Hall 4**
	Parallel Session 3D – Meta-Analysis and Evidence Synthesis	**Stamner**
16.00 – 16.55	Coffee Break, Exhibition & Poster Viewing	
16.55 – 18.00	**Parallel Session 4A – Pilot and Feasibility Studies**	**Oxford Suite**
	Parallel Session 4B – Challenges in Late Phase Trials	**Preston**
	Parallel Session 4C – Lessons from Trials in Practice	**Hall 4**
	Parallel Session 4D – HDR UK - New opportunities for digitally-enabled randomized clinical trials	**Stamner**

Tuesday 8th October 2019

07.30	Registration & Speaker Preview Opens	
08.45 – 09.50	Parallel Session 5A – Challenges with Trial Recruitment 2: Pilots and Alternatives	Oxford Suite
	Parallel Session 5B – Cluster and Stepped Wedge Trials & Simulation	Preston
	Parallel Session 5C – Using Real-World Data	Hall 4
	Parallel Session 5D – Patient-Reported and Core Outcome Measures	Stamner
09.50 – 10.30	Break - Lunch, Exhibition & Poster Viewing	
10.30 – 11.35	Parallel Session 6A – Retention to Trials	Preston
	Parallel Session 6B – Challenges in Statistical Analysis 2: Planning for Understanding	Hall 4
	Parallel Session 6C – Using Electronic Health Records	Oxford Suite
	Parallel Session 6D – HRA	Stamner
11.35 – 11.45	Room Change	
11.45 – 12.45	Doug Altman Memorial Keynote Lecture - *Prof. Marion Campbell*	
12.45 – 14.00	Break - Lunch, Exhibition & Poster Viewing	
13.00 – 14.00	Lunchtime Symposium – Sponsored by Elsevier	Stamner
14.00 – 15.05	Parallel Session 7A – Improving Trial Performance	Preston
	Parallel Session 7B – Late Phase Study Designs	Hall 4
	Parallel Session 7C – Reducing Research Waste	Oxford Suite
	Parallel Session 7D – Debate	Stamner
15.05 – 16.00	Break - Lunch, Exhibition & Poster Viewing	
16.00 – 17.05	Parallel Session 8A – Increasing Knowledge for Researchers and Participants	Preston
	Parallel Session 8B – Challenges in Statistical Analysis 3: Improving Generalisability and Interpretability	Oxford Suite
	Parallel Session 8C Wellcome Trust Session	Hall 4
	Parallel Session 8D – Debate	Stamner
19.30– 00.00	Conference Dinner	

Wednesday 9th October 2019

07.30	Registration & Speaker Preview Opens	
08.45 – 09.50	Parallel Session 9A – Making Trials More Efficient	Preston
	Parallel Session 9B - Challenges with Trial Recruitment 4: Towards Better Practice	Oxford Suite
	Parallel Session 9C - Early Phase Study Designs 3: Safety and Crm	Hall 4
	Parallel Session 9D - Learning from Qualitative Research	Stamner
09.50 – 10.35	Break - Coffee & Exhibition (Exhibition Closes)	
10.35 – 11.40	Parallel Session 10A – Challenges with Trial Recruitment 3	Preston
	Parallel Session 10B – Collecting and Using Electronic Data	Oxford Suite
	Parallel Session 10C - Challenges in Statistical Analysis 4: Missing Data	Hall 4
	Parallel Session 10D – UKCRC CTU Network Showcase	Stamner
11.40 – 11.50	Room Change	
11.50 – 12.40	Keynote Speaker - *Prof. David Beard*	Oxford Suite
12.40 – 13.00	Prizes & Closing Remarks	
14.00 – 17.30	Post-Conference Workshop 3.1 – Close Out and Archiving - a CTU guided workshop and discussion session on processes and procedures to conclude a trial	Preston
	Post-Conference Workshop 3.2 – Practical Implementation of Bayesian Adaptive Designs for Single-arm, Randomised, Basket and Platform Phase II Trials, with real-world case studies	Hall 4
	Post-Conference Workshop 3.3 – A hands-on introduction to health economics analysis plans (HEAPs)	Stamner

Detailed Scientific Programme

Sunday 6th October 2019

08.00 – 18.00	Registration Open	
08.00 – 19.00	Exhibition & Poster Set Up	
09.00 – 13.00	**Pre-Conference Workshop 1.1** Using Studies Within A Trial (SWATs) to increase the evidence-base for trial process decisions: how to select, design and run them *Prof. Shaun Treweek, University of Aberdeen, UK* *Dr Catherine Arundel, University of York* *Prof. Peter Bower, University of Manchester, UK* *Prof. Declan Devane, NUI Galway, Ireland* *Dr Katie Gillies, University of Aberdeen, UK* *Dr Adwoa Parker, University of York, UK* *Prof. David Torgerson, University of York, UK*	**Preston**
	Pre-Conference Workshop 1.2 Design and analysis of clinical trials in the era of precision medicine *Prof. James Wason, Newcastle University, UK & University of Cambridge, UK* *Dr Haiyan Zheng, Newcastle University, UK*	**Hall 4**
	Pre-Conference Workshop 1.3 Beyond the CONSORT extension for pilot trials: guideline, planning, abstracts and protocols *Dr Sally Hopewell, Centre For Statistics in Medicine / Oxford Clinical Trials Research Unit, University of Oxford, UK* *Prof. Sandra Eldridge, Pragmatic Clinical Trials Unit, Queen Mary University of London, UK* *Prof. Christine Bond, Institute of Applied Health Sciences, University of Aberdeen, UK* *Prof. Mike Campbell, Medical Statistics Group, University of Sheffield, UK* *Prof. Lehana Thabane, Biostatistics Unit, McMaster University, Hamilton, Canada* *Prof. Gillian Lancaster, Institute of Primary Care and Health Sciences, Keele University, UK* *Mrs Claire Chan, Pragmatic Clinical Trials Unit, Queen Mary University of London, UK* *Mrs Karen Hughes, University of Liverpool*	**Stamner**
13.00 – 14.00	**Lunch Break** (lunch not included)	

Sunday 6th October 2019 continued

14.00 – 18.00	**Pre-Conference Workshop 2.1** Missing data in randomised trials: concepts and design *Dr. Ian White, MRC Clinical Trials Unit At UCL* *Dr. Finbarr Leacy, Health Products Regulatory Authority*	**Preston**
	Pre-Conference Workshop 2.2 Strategies for optimising recruitment to challenging randomised controlled trials: The QuinteT approach *Dr. Nicola Mills, University of Bristol* *Dr. Leila Rooshenas, University of Bristol* *Dr Caroline Wilson, University of Bristol* *Dr Julia Wade, University of Bristol* *Dr Carmel Conefrey, University of Bristol*	**Hall 4**
	Pre-Conference Workshop 2.3 Finding and critically appraising a core outcome set (COS) for your trial *Dr. Elizabeth Gargon, University of Liverpool* *Prof. Paula Williamson, University of Liverpool* *Dr Sara Brookes, University of Birmingham*	**Stamner**
14.00 – 18.00	Speaker Preview Open	

Monday 7th October 2019

07.30	**Registration & Speaker Preview Opens**	
09.30 – 09.45	**Welcome & Opening** *Matthew Sydes, ICTMC 2019 Scientific Committee Chair* **Introducing the new MRC/NIHR Trials Methodology Research Partnership** *Paula Williamson, University of Liverpool*	**Oxford Suite**
09.45 – 10.35	**Keynote** The Evolution of Academic Sponsored Clinical Trials in the 21st Century: Lessons Learned at the Canadian Cancer Trials Group *Dr Janet Dancey, Director of the Canadian Cancer Trials Group (CCTG) and Scientific Director of the Canadian Cancer Clinical Trials Network (3CTN)*	**Oxford Suite**
10.35 – 11.30	Coffee Break, Exhibition & Poster Viewing	
11.30 – 12.35	**Parallel Session 1A - Improving Follow-Up and Retention** **Chair:** *Amanda Farrin, University of Leeds*	**Oxford Suite**
	PS1A - O1 Conducting Studies Within A Trial (SWAT) – Identifying the Challenges and Offering Solutions *Catherine Arundel, York Trials Unit - University of York, UK*	
	PS1A - O2 Same intervention, different opinions: some challenges of doing Study Within A Trial (SWAT) replication studies *Dr Anne Duncan, Health Services Research Unit, University of Aberdeen, UK and Dr Kirsteen Goodman, NMAHP Research Unit, Glasgow Caledonian University, UK*	
	PS1A - O3 Two-by-two factorial randomised trial to evaluate strategies to improve follow-up in a randomised prevention trial *Ms Lucy Bradshaw & Prof. Alan Montgomery, Nottingham Clinical Trials Unit, University of Nottingham, UK*	
	PS1A - O4 Timing of text message reminders to increase trial participant response to postal questionnaires: an embedded randomized trial *Dr Stephen Brealey, University of York, United Kingdom*	
	PS1A - O5 Identifying trial retention uncertainties using a James Lind Alliance Priority Setting Partnership – The PRioRiTy II (Prioritising Retention in Randomised Trials) Study *Dr Katie Gillies, Health Services Research Unit, University of Aberdeen, UK*	
11.30 – 12.35	**Parallel Session 1B - Challenges in Statistical Analysis 1: Bias and Precision** **Chair:** *Richard Emsley, Kings College London*	**Preston**
	PS1B - O1 Nature and impact of time-to-treatment measurement error in clinical trials where early administration is essential *Mr Raoul Mansukhani, Clinical Trials Unit, London School of Hygiene & Tropical Medicine, UK*	
	PS1B - O2 Impact of the hazard rate on pre-specified methods of analysis in the presence of time-dependent treatment effects *Dr Rory Wolfe, Monash University, Melbourne, Australia*	

Monday 7th October 2019 continued

	PS1B - O3 An evaluation and application of statistical methods designed to analyse adverse event data in RCTs *Miss Rachel Phillips, Imperial College London, London, UK*	
	PS1B - O4 Analysis of responder-based endpoints: improving power through utilising continuous components *Prof. James Wason, Newcastle University, Newcastle upon Tyne, UK and MRC Biostatistics Unit, University of Cambridge, UK*	
	PS1B - O5 Exploring the Hawthorne Effect Using a Balanced Incomplete Block Design in The Aspire Cluster Randomised Controlled Trials *Mrs Michelle Collinson, Clinical Trials Research Unit, University of Leeds, UK*	
11.30 – 12.35	**Parallel Session 1C – Health Economic Evaluation** **Chair:** *Will Hollingworth, University of Bristol*	**Hall 4**
	PS1C - O1 MRC-NIHR Methodology Guideline Development on Utilising Benefit-Risk Assessments within Clinical Trials *Ms Nikki Totton & Prof. Steven Julious, University of Sheffield, UK*	
	PS1C - O2 Essential items for a Health Economics Analysis Plan (HEAP): expert Delphi consensus survey *Dr Joanna Thorn, University of Bristol, UK*	
	PS1C - O3 Developing items into questions for a new modular resource-use questionnaire *Miss Kirsty Garfield, MRC ConDuCT-II Hub for Trials Methodology Research, Population Health Sciences, Bristol Medical School, University of Bristol, UK*	
	PS1C - O4 A Bayesian Parametric Approach to Handle Missing Longitudinal Outcome Data in Trial-Based Health Economic Evaluations *Dr Andrea Gabrio, Department of Statistical Science, University College Londnon, UK*	
	PS1C - O5 Calculating health utilities from PedsQL quality of life scores for patients with hyperammonaemic disorders *Dr Elsa Marques, NIHR Bristol Biomedical Research Centre (Nutrition Theme), Bristol, UK*	
11.30 – 12.35	**Parallel Session 1D – Rapid Abstracts** **Chair:** *Matthew Sydes, University College London*	**Stamner**
	P-34 Assessing the quality of data collection in clinic; lessons from the Wound Healing in Surgical Trauma (WHiST) RCT *Marta Campolier, University of Oxford*	
	P-39 Managing the paper mountain – systems and processes for tracing, managing and transferring high volume trial data from paper sources *Karolina Rusiak, Bangor University*	
	P-40 Data completeness and quality using an electronic versus paper Case Report Form for collecting surgical data *Hana Tabusa, University of Bristol*	

Monday 7th October 2019 continued

P-77
Measuring speech development in infants: methodological considerations based on experiences within the TOPS trial
Rachel Cooper, University of Liverpool

P-99
Raising the Standards of Public Involvement in Clinical Trials
Steven Blackburn, Keele University

P-114
How qualitative methodologies can be used to address the top 10 research priorities for trial recruitment identified within the PRioRiTy study
Marita Hennessy, Nui Galway

P-116
Identification and comparison of key criteria for allocating funding from external peer reviews, applicant feedback and applicant guidance.
Kathryn Fackrell, NIHR Evaluation Trials And Studies Coordinating Centre

P-165
What proportion of ethically approved randomised clinical trials can be found in a trial registry?
Benjamin Speich, University of Oxford

P-169
Decision-making practices used by UK and international health related funding organisations
Katie Meadmore, NIHR Evaluation Trials and Studies Coordinating Centre

P-195
Controlled multiple imputation: an accessible flexible tool for estimating hypothetical estimands in clinical trials
Suzie Cro, Imperial College London

P-200
Options and challenges of analysing data from recruitment intervention studies
A lesson from MRC START Hi-Light data analysis
Wei Tan, University of Nottingham

P-202
A simulation study to compare longitudinal methods for the analysis of randomised trials and the implications for sample size calculation
Bethan Copsey, University of Oxford

P-209
Review of reporting of time to event analyses and the proportional hazards assumption in meta-analysis
Ashma Krishan, University of Liverpool

Monday 7th October 2019 continued

P-218
A comparison of statistical methods to compensate for missing data in longitudinal cluster-randomised controlled trials
Coutney McDerrmott, University College Dublin

P-222
A new instrument to assess the credibility of effect modification analyses (ICEMAN) in randomized controlled trials and meta-analyses
Matthias Briel, Department of Clinical Research

P-223
On the need to adjust for multiplicity in confirmatory clinical trials with master protocols
Peter Kimani, University of Warwick

P-234
Systematic review of prospective studies comparing different monitoring strategies in clinical intervention studies
Katharaina Klatte, Department of Clinical Research University Hospital Basel

P-238
A proposed review of selected clinical trial protocols and publications to better understand the inadequate reporting of safety data
Genevieve Helen Wills, MRC Clinical Trials Unit at UCL

P-242
Trial data access: the trials and tribulations of implementing a new approach within a CTU
Victoria Yorke-Edwards MRC Clinical Trials Unit at UCL

P-251
Automation of clinical trial statistical monitoring
Laura Collett, University of Bristol

P-253
Do consent procedures differ when recruiting outside of the UK versus within the UK: data from the international Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage (TICH-2) study
Lisa Woodhouse, University of Nottingham

P-276
Continuity of researchers collecting outcome data within randomised controlled trials - any evidence of an impact on QoL measures?
Rachel Evans, Bangor University

P-289
Design, Analysis and Reporting of Multi-Arm Trials and Strategies to Address Multiple Testing
Dmitry Gryaznov, University Hospital Basel

Monday 7th October 2019 continued

12.35 – 13.40	Break - Lunch, Exhibition & Poster Viewing	
13.00 – 13.40	**Lunchtime Symposium – Sponsored by NIHR** **NIHR & Expertise in novel trial delivery** **Speaker:** *Denise Wilson, NIHR Business Development Manager*	**Preston**
13.40 – 14.45	**Parallel Session 2A - Improving Data Quality in Trials** **Chair:** *Tony Marson, University of Liverpool*	**Preston**
	PS2A - O1 Data Dashboards – a novel approach of accurately tracking and monitoring electronic Case Report Form (eCRF) data return rates and missing data items for ongoing clinical trials, using a combination of data reporting and analysis tools capable of drilling down to data point level *Mr Joshua James Northey, Southampton Clinical Trials Unit, University of Southampton, UK* **PS2A - O2** Development of a standardised set of metrics for monitoring site performance in multicentre randomised trials: a Delphi study *Alan A Montgomery, University of Nottingham, UK* **PS2A - O3** Improving data entry and study compliance efficiently using immediate audit and feedback tools. *Dr Katie Banister, Health Services Research Unit, University of Aberdeen, UK* **PS2A - O4** The importance of communication and teamwork in achieving high quality data in clinical trials *Miss Laura A Pankhurst, Clinical Trials Unit NHS Blood and Transplant, Cambridge and Bristol, UK* **PS2A - O5** Current recommendations/practices for anonymising data from clinical trials in order to make it available for sharing: A scoping review *Ms. Aryelly Rodriguez, Edinburgh Clinical Trials Unit (ECTU), Usher Institute of Population Health Sciences and Informatics, the University of Edinburgh (UoE), UK*	

13.40 – 14.45	**Parallel Session 2B - Early Phase Study Designs 1: Platforms & Basket** **Chair:** *James Wason, Newcastle University*	**Oxford Suite**
	PS2B - O1 Radiant-BC Platform Trial: Development of an efficient multi-arm multi-stage early phase trial of radiosurgery with immunotherapy and systemic therapies in breast cancer patients with brain metastases using a flexible Bayesian framework *Prof. Christina Yap, The Institute of Cancer Research, UK & The University of Birmingham, UK* **PS2B - O2** Operational challenges of running platform trials – ICR-CTSU experience based on the plasmaMATCH trial *Claire Snowdon, Clinical Trials and Statistics Unit at The Institute of Cancer Research (ICR-CTSU), London, United Kingdom* **PS2B - O3** Designing and implementing a phase II targeted treatment platform study: a modular approach in metastatic Castration Resistant Prostate Cancer (mCRPC) *Miss Stephanie Burnett, The Institute of Cancer Research, Clinical Trials & Statistics Unit, London, UK* **PS2B - O4** Borrowing of information across similar subpopulations in Bayesian basket trials *Dr Haiyan Zheng, Newcastle University, UK* **PS2B - O5** Bayesian trial monitoring and power estimation in a complex Hepatitis C treatment trial (VIETNARMS) *Ms Leanne McCabe, MRC Clinical Trials Unit at UCL, UK*	
13.40 – 14.45	**Parallel Session 2C – Complex Interventions and Recruitment + Retention** **Chair:** *Jon Nicholl, University of Sheffield*	**Hall 4**
	PS2C - O1 A hypothesis test of feasibility for external pilot trials assessing recruitment, follow-up and adherence rates *Dr Duncan T. Wilson, Leeds Institute of Clinical Trials Research, University of Leeds, UK* **PS2C - O2** Strategies to improve recruitment to a trial of less treatment: a mixed methods study of the OPTIMA prelim trial in early breast cancer *Dr Carmel Conefrey, University of Bristol, UK* **PS2C - O3** Development of a complex intervention to support informed decision-making by family members of adults who lack capacity to consent to trials *Mrs Victoria Shepherd, Centre for Trials Research, Cardiff University, UK & Division of Population Medicine, Cardiff University, UK* **PS2C - O4** Why is the early intervention development phase for complex health care interventions important? An overview of new guidance. *Prof. Pat Hoddinott, University of Stirling, UK* **PS2C - O5** ORRCA and ORRCA2: A large-scale, international, collaboration to map recruitment and retention literature. *Mrs Anna Kearney, North West Hub for Trials Methodology Research and Clinical Trials Research Centre, University of Liverpool, UK*	

Monday 7th October 2019 continued

13.40 – 14.45	**Parallel Session 2D - Public and Patient Involvement and Engagement** **Chair:** *Joy Adamson, University of York*	**Stamner**
	PS2D - O1 Agreeing outcomes that matter to patients – co-production of an animation to explain core outcome sets *Mrs Heather Bagley & Dr Sarah Gorst, University of Liverpool, UK*	
	PS2D - O2 Patient and public involvement (PPI) in trial oversight: an ethnographic study of eight clinical trials. *Dr Karen Coulman, MRC ConDuCT-II Hub for Trials Methodology Research, Population Health Sciences, Bristol Medical School, University of Bristol, UK*	
	PS2D - O3 Patient and Public Involvement in the Delivery of Platform Trials – ICR-CTSU experience *Sarah Kernaghan, Clinical Trials and Statistics Unit at The Institute of Cancer Research (ICR-CTSU), London, UK*	
	PS2D - O4 The 'Schools Teaching Awareness of Randomised Trials (START)' Initiative *Dr Linda Biesty, School of Nursing and Midwifery, NUI Galway, Ireland & Evidence Synthesis Ireland, NUI Galway, Ireland*	
	PS2D - O5 Complexities of informed consent in an emergency, perinatal, cluster-randomised pilot study: The experience of developing the ACROBAT study (Administering Cryoprecipitate in Obstetric Bleeding at an Earlier Time) *Ms Doris Lanz, Queen Mary University of London, UK*	
14.45 – 14.55	**Room Change**	
14.55 – 16.00	**Parallel Session 3A - Challenges with Trial Recruitment 1: Recent Experiences** **Chair:** *Richard Emsley, Kings College London*	**Oxford Suite**
	PS3A - O1 QuinteT Recruitment Intervention in the By-Band-Sleeve study: trials, tribulations and lessons learnt *Dr Sangeetha Paramasivan, University of Bristol, UK*	
	PS3A - O2 TRCPAD: Accelerating Participant Recruitment in AD Clinical Trials *Mr Oliver Langford, University of Southern California, San Diego, US*	
	PS3A - O3 Challenges to and facilitators of recruitment to an Alzheimer's Disease Clinical Trial: Findings and recommendations from a qualitative interview study *Ms Clare Clement, Bristol Trials Centre & Population Health Sciences, Bristol Medical School, University of Bristol, UK*	

Monday 7th October 2019 continued

	PS3A - O4 Can nurse peer support improve recruitment to complex clinical trials? – Experience from the ISCOMAT trial *Miss Suzanne Hartley, University of Leeds, UK*	
	PS3A - O5 Achieving high-volume, low-cost participant screening and enrolment through automation and centralisation: experiences from the T4DM diabetes prevention trial *Ms Karen Bracken, NHMRC Clinical Trials Centre, University of Sydney, Australia*	
14.55 – 16.00	**Parallel Session 3B - Improving Trial Design** **Chair:** *Matthew Sydes, University College London*	**Preston**
	PS3B - O1 DELTA2 guidance on choosing the target difference and undertaking and reporting the sample size calculation for a randomised controlled trial *Prof. Jonathan A. Cook, University of Oxford, UK*	
	PS3B - O2 Optimising the design and delivery of placebo surgical interventions in randomised controlled trials: The DITTO framework *Dr Sian Cousins, National Institute for Health Research (NIHR) Bristol Biomedical Research Centre Surgical Innovation Theme, University of Bristol, UK*	
	PS3B - O3 Clinical trial simulation and value of information to optimise design of clinical trials from a pharmaceutical industry perspective *Mr Daniel Hill-McManus, Bangor University, UK*	
	PS3B - O4 Two-stage adaptive enrichment designs with time to event data: Point and interval estimation *Dr Peter Kimani, University of Warwick, Coventry, UK*	
	PS3B - O5 Trial design and management challenges for clinical trials of novel cell therapies: results from a mixed methods study *Dr Ruchi Higham, Leeds Institute of Clinical Trials Research, University of Leeds, UK*	

Monday 7th October 2019 continued

14.55 – 16.00	**Parallel Session 3C - Early Phase Study Designs 2: Advanced Issues** **Chair:** *Jon Nicholl, ScHARR, University of Sheffield*	**Hall 4**
	PS3C - O1 Optimal curtailed designs for single arm phase II clinical trials *Mr Martin Law, Hubs for Trials Methodology Research, Medical Research Council Biostatistics Unit, University of Cambridge, UK* **PS3C - O2** Two-stage single-arm oncology trials: More adjusted analyses needed *Dr Michael Grayling, Newcastle University, Newcastle upon Tyne, UK* **PS3C - O3** BOP2: Bayesian Optimal Design for Phase II Clinical Trials with Binary, Co-primary and Other Complex Endpoints *Prof. Ying Yuan, University of Texas MD Anderson Cancer Center, Houston, US* **PS3C - O4** How to use a margin of practical equivalence to include considerations other than efficacy in randomised selection trials *Dr Hakim-Moulay Dehbi, Comprehensive Clinical Trials Unit at UCL, London, UK* **PS3C - O5** The critical and recommended characteristics for the reporting of treatment-as-usual in behaviour change trials *Miss Neza Javornik, University of Aberdeen, UK*	
14.55 – 16.00	**Parallel Session 3D - Meta-Analysis and Evidence Synthesis** **Chair:** *Peter Brocklehurst, University of Birmingham*	**Stamner**
	PS3D - O1 Framework for approaches to address statistical multiplicity in pragmatic RCTs through systematic review and surveys of statistical practice *Miss Katie Pike, Clinical Trials and Evaluation Unit, Bristol Trials Centre, University of Bristol, UK* **PS3D - O2** Assessing the impact of early stopping on systematic reviews: Recommendations for interpreting guidelines *Prof. Ian Marschner, NHMRC Clinical Trials Centre, Sydney, Australia, & University of Sydney, Australia* **PS3D - O3** Reporting of methodological aspects of randomised trials: 1996-2016; has it changed over time? *Dr Shona Fielding, University of Aberdeen, UK* **PS3D - O4** How well are binary outcomes analysed and the findings reported? – A systematic review of randomised trials *Dr Ines Rombach, Oxford Clinical Trials Unit, Oxford, UK, and Centre for Statistics In Medicine, Oxford, UK, and Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Science, Oxford, UK* **PS3D - O5** Overestimation of Event Rate and Target Difference among Randomized Clinical in sample size calculations Trials: a cross-sectional survey review *Dr Tao Chen, Liverpool School of Tropical Medicine, UK*	

Monday 7th October 2019 continue

16.00 – 16.55	Coffee Break, Exhibition & Poster Viewing	
16.55 – 18.00	**Parallel Session 4A - Pilot and Feasibility Studies** **Chair:** *Tony Marson, University of Liverpool*	**Oxford Suite**
	PS4A - O1 Internal pilots in clinical trials: Current practice in design and assessment *Anna Rosala-Hallas, Clinical Trials Research Centre, University of Liverpool, a member of the Liverpool Health Partners, Liverpool, UK* **PS4A - O2** External Pilot and Feasibility Studies: Past, Present and Future Challenges *Prof. Lehana Thabane, McMaster University, Hamilton, Canada* **PS4A - O3** Assessing differences in start-up between a pilot and main RCT in the ICU: The CYCLE international multicentre rehabilitation study. *Dr Michelle E. Kho, McMaster University, Hamilton, Canada and St. Joseph's Healthcare, Hamilton, Canada* **PS4A - O4** Distinctive ethical aspects of consent in pilot and feasibility studies *Prof. Julius Sim, School of Primary, Community and Social Care, Keele University, UK and Keele Clinical Trials Unit, Keele University, UK* **PS4A - O5** Determining sample size for progression criteria using hypothesis testing in pragmatic pilot RCTs *Dr Martyn Lewis, School of Primary, Community & Social Care, Keele University, UK*	
14.55 – 16.00	**Parallel Session 4B - Challenges in Late Phase Trials** **Chair:** *Marion Campbell, University of Aberdeen*	**Preston**
	PS4B - O1 Considerations concerning the use of health economics in the design and analysis of adaptive clinical trials – a qualitative study *Miss Laura Flight, University of Sheffield, UK* **PS4B - O2** Stopping a clinical trial early based on the probability that cost-effectiveness is unlikely: An extension of conditional power computations to economic evaluation. *Dr Iftekhar Khan, University of Oxford, Oxford, United Kingdom* **PS4B - O3** Cost-Effective Clinical Trial Design: Application of a Bayesian Sequential Stopping Rule to the Prof. HER Pragmatic Trial *Dr Martin Forster, University of York, UK* **PS4B - O4** Dealing with unavoidably high loss to follow-up in care home trials - The DCM-EPIC trial *Dr Rebecca Walwyn, University of Leeds, UK* **PS4B - O5** To fund or not to fund a paediatric severe asthma trial: that is the question *Dr Daphne Babalis and Dr Victoria Cornelius, Imperial Clinical Trials Unit, Imperial College London, UK*	

Monday 7th October 2019 continued

16.55 – 18.00	**Parallel Session 4C – Lessons from Trials in Practice** **Chair:** *Amanda Farrin, University of Leeds*	**Hall 4**
	PS4C - O1 Application of a Sequential Multiple Assignment Randomized Trial (SMART) Design in Older Patients with Chronic Lymphocytic LeUKemia *Prof. Sumithra Mandrekar, Mayo Clinic, Rochester, United States* **PS4C - O2** The challenges of delivering a time-critical intervention in emergency care *Mrs Helen Thomas, NHS Blood and Transplant Clinical Trials Unit, Cambridge and Bristol, UK* **PS4C - O3** Optimising surgical trials through clinician engagement: Strategies for enhancing trainee engagement in trials *Dr Athene Lane, University of Bristol, UK* **PS4C - O4** Design of Vaccine Efficacy Trials for Priority Emerging and Epidemic Diseases *Dr Conall Watson, University of Oxford, UK & London School of Hygiene & Tropical Medicine, UK*	
16.55 – 18.00	**Parallel Session 4D – HDR UK - New opportunities for digitally-enabled randomized clinical trials** **Chair:** *Martin Landray, Research Director HDR UK, University of Oxford*	**Stamner**
	Low cost trials - a perspective from Scotland *Prof. Isla Mackenzie, University of Dundee, UK* Low cost trials - a perspective from England *Miss Jennifer Dumbleton, University of Nottingham, UK* Using secondary care data to run efficient, low cost trials *Dr Marion Mafham, University of Oxford, UK*	

Tuesday 8th October 2019

07.30	**Registration & Speaker Preview Opens**	
08.45 – 09.50	**Parallel Session 5A – Challenges with Trial Recruitment 2: Pilots and Alternatives** **Chair:** *Elizabeth Allen, University of Cape Town*	**Oxford Suite**
	PS5A - O1 When to do an external or internal pilot study: Findings from an interview study with research funders *Miss Katherine Fairhurst, Centre of Surgical Research & Medical Research Council (MRC) ConDuCT-II (Collaboration and innovation for Difficult and Complex randomised controlled Trials in Invasive procedures) Hub for Trials Methodology Research, Bristol Medical School, Department of Population Health Sciences, University of Bristol, UK* **PS5A - O2** Exploring patient treatment preferences enhances trial recruitment, so why do trial recruiters often avoid doing it? *Prof. Bridget Young, Institute of Population Health Sciences, University of Liverpool, UK* **PS5A - O3** Review of use of the Trials within Cohorts (TwiCs) design approach *Dr Clare Relton, Queen Mary University of London, UK* **PS5A - O4** Using a Discrete Choice Experiment to Examine the Factors Influencing Clinical Trial Participation *Dr Michelle Queally, J.E. Cairnes School of Business & Economics, NUI Galway, Ireland and CÚRAM Centre for Research in Medical Devices, NUI Galway, Galway, Ireland,* **PS5A - O5** Physical Rehabilitation Core Outcomes in Critical Illness (PRACTICE): a secondary modified thematic analysis characterising reasons for change in rating importance of outcomes for physical rehabilitation trials *Dr Bronwen Connolly, Guy's and St. Thomas' NHS Foundation Trust, UK and King's College London, UK and The University of Melbourne, Australia*	
08.45 – 09.50	**Parallel Session 5B - Cluster and Stepped Wedge Trials & Simulation** **Chair:** *Will Hollingworth, University of Bristol*	**Preston**
	PS5B - O1 Open-cohort designs in institutional settings: findings from a literature review of cluster-randomised trials and epidemiological studies *Ms Laura Marsden, University of Leeds, UK* **PS5B - O2** Power calculations for Cluster Randomised Trials (CRTs) with truncated Poisson-distributed outcomes: A motivating example from a malaria vector control trial *Dr Lazaro M. Mwandigha, MRC Centre for Global Infectious Disease Analysis, Imperial College London, UK* **PS5B - O3** Comparison of different randomisation methods in a cluster randomised vaccine effectiveness trial: a simulation study using real-world data *Dr Xinxue Liu, Oxford Vaccine Group, Department of Paediatrics, University of Oxford, UK*	

Tuesday 8th October 2019 continued

	PS5B - O4 Common concerns about the feasibility of stepped-wedge cluster randomised trials and issues encountered during trials of this design: findings of an online questionnaire. *Ms Caroline Kristunas, Health Sciences, University of Leicester, UK* **PS5B - O5** Optimal incomplete stepped wedge trials with continuous recruitment *Dr Richard Hooper, Queen Mary University of London, UK*	
08.45 – 09.50	**Parallel Session 5C - Using Real-World Data** **Chair:** *Matthew Sydes, University College London*	**Hall 4**
	PS5C - O1 Health System Trials *Dr Clare Relton, Pragmatic Clinical Trials Unit, Queen Mary University of London, UK* **PS5C - O2** Dealing with real world data in clinical trials *Mrs Catriona Keerie, Edinburgh Clinical Trials Unit, University of Edinburgh, UK* **PS5C - O3** Using routine practice-aggregated data in primary care implementation laboratory trials: benefits and challenges *Dr Sarah Alderson, University of Leeds, UK* **PS5C - O4** COS and the healthcare research ecosystem *Prof. Paula R Williamson, University of Liverpool, UK* **PS5C - O5** MOUSE – Mapping OUtcomes measured in pre-clinical Studies against randomised phase 3/4 Effectiveness trials. Do core outcome sets developed for phase3/4 effectiveness trials translate to pre-clinical research? *Dr Nicola L Harman, University of Liverpool, UK*	
08.45 – 09.50	**Parallel Session 5D – Patient-Reported and Core Outcome Measures** **Chair:** *Joy Adamson, University of York*	**Stamner**
	PS5D - O1 Using data from routine sources in the development of an objective measure of early outcome after surgery *Mrs Rachel Maishman, Clinical Trials and Evaluation Unit, Bristol Trials Centre, University of Bristol, UK* **PS5D - O3** Participating in core outcome set development via Delphi surveys: Qualitative interviews from the EPITOME study provide pointers to inform guidance *Miss Alice Mary Biggane, University of Liverpool, UK and Paris Descartes University, France* **PS5D - O2** Exploring the barriers and facilitators to core outcome set (COS) uptake: assessing the impact of a funder's recommendation to use COS followed by qualitative interviews with clinical trialists *Mrs Karen L Hughes University of Liverpool, UK* **PS5D - O4** The impact of patient-reported outcome (PRO) data from clinical trials: a systematic review and critical analysis *Samantha Cruz Rivera, Centre for Patient Reported Outcomes Research, Institute of Applied Health Research, College of Medical and Dental Sciences, University of Birmingham, UK*	

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	PS5D - O5 An exploratory study of the limitations of outcome measures used in a randomised controlled trial of a complex intervention in dementia. *Mr Benjamin Thompson, ScHARR, The University of Sheffield, UK*	
09.50 – 10.30	Coffee Break, Exhibition & Poster Viewing	
10.30 – 11.45	**Parallel Session 6A - Retention to Trials** **Chair:** *Peter Brocklehurst, University of Birmingham*	**Preston**
	PS6A - O1 Making trials less lossy: is there anything worth knowing from non-randomised evaluations of trial retention strategies? *Mr Adel El Feky, University of Aberdeen, UK* **PS6A - O2** Exploring retention in clinical trials: A meta-ethnographic synthesis of studies reporting participant reasons for drop out *Dr Katie Gillies, Health Services Research Unit, University of Aberdeen, UK* **PS6A - O3** Assessing non-adherence in non-inferiority trials: implications from a simulation study *Dr Yin Mo, Mahidol-Oxford Research Unit (MORU) Thailand, and Nuffield Department of Medicine, University of Oxford, UK, and National University Hospital, Singapore* **PS6A - O4** Statistical transparency in clinical trials: an evaluation of unexplained discrepancies between planned and conducted analyses *Mr Brennan Kahan, Pragmatic Clinical Trials Unit, Queen Mary University of London, UK* **PS6A - O5** 'Better healthcare through more inclusive research' – an NIHR workstream to improve trial delivery for underserved groups *Prof. Miles Witham, NIHR Clinical Research Network Cluster E Specialty Team, Newcastle University, UK*	
10.30 – 11.45	**Parallel Session 6B – Challenges in Statistical Analysis 2: Planning for Understanding** **Chair:** *James Wason, Newcastle University*	**Hall 4**
	PS6B - O1 Covariate adjustment in individually randomised trials *Dr Elizabeth Williamson, London School of Hygiene & Tropical Medicine, London, UK and Health Data Research UK London, UK* **PS6B - O2** Practical choice of a method to account for baseline covariates in randomised trials *Dr Tim Morris, MRC Clinical Trials Unit at UCL, London, UK* **PS6B - O3** Exploring mechanisms of action in clinical trials of complex interventions using mediation *Prof.Linda Sharples, London School of Hygiene and Tropical Medicine, London, UK* **PS6B - O4** Quantifying bias of naive per-protocol (PP) versus intention-to-treat (ITT) analysis in randomised controlled trials: A meta-epidemiological study *Mr Mohammod Mostazir, College of Life and Environmental Sciences (CLES), University of Exeter, Exeter, England, UK* **PS6B - O5** Misinterpretation of factorial design trials and inappropriate meta-analysis: misleading the reader *Prof. Tim Clayton, London School of Hygiene & Tropical Medicine, London, UK*	

Tuesday 8th October 2019 continued

10.30 – 11.35	**Parallel Session 6C - Using Electronic Health Records** **Chair:** *Elizabeth Allen, University of Cape Town*	**Oxford Suite**
	PS6C - O1 Paper versus electronic completion of patient reported outcomes: What do we know? *Dr Kirsteen Goodman, NMAHP Research Unit, Govan Mbeki building, Level 6, Glasgow Caledonian University, Cowcaddens Road, Glasgow, G4 0BA, UK* **PS6C - O2** Paper diary capture vs. electronic data capture for patient reported outcomes in Primary Care: an investigation into completion rates *Ms Jenna Grabey, University of Oxford, UK* **PS6C - O3** A machine learning algorithm and tools for automatic detection of spin (distorted presentation of results) in articles reporting randomized controlled trials *Anna Koroleva, LIMSI, CNRS, Université Paris-Saclay, Orsay, France, and Academic Medical Center, University of Amsterdam, Netherlands* **PS6C - O4** The use of regular text messaging over one year to collect primary outcome data in a randomised controlled trial *Mr Kieran James Bromley, School of Primary, Community & Social Care, Keele University, UK, and Keele Clinical Trials Unit, Keele University, UK* **PS6C - O5** Feasibility of collecting digital images of surgical wounds taken by patients themselves after leaving hospital: a method for remote and blinded outcome assessment (The Selfi wound study) *Ms Rhiannon Macefield, Population Health Sciences, Bristol Medical School, University of Bristol, UK*	
10.30 – 11.35	**Parallel Session 6D – HRA** **Chair:** *Juliet Tizzard, Director of Policy, Health Research Authority*	**Stamner**
	Make it Public: an HRA panel discussion about communicating results to participants and the public **Panellists:** *Neil Bennett, Head of Research, Action Duchenne* *Delia Muir, Patient and Public Involvement Officer, Leeds Institute of Clinical Trials Research* *Annabelle South, MRC Clinical Trials Unit at UCL* *Derek Stewart, public contributor and member of the HRA's Research Transparency Strategy Group*	
11.35 – 11.45	**Room Change**	
11.45 – 12.45	**Doug Altman Memorial Keynote Lecture** The future of the randomised controlled trial in the era of real world evidence *Prof. Marion Campbell, Professor of Health Services Research & Vice Principal (Research), University of Aberdeen*	**Oxford Suite**
12.45 – 14.00	Break - Lunch, Exhibition & Poster Viewing	
13.00 – 14.00	Lunchtime Symposium – **Sponsored by Elsevier** **Where real-world and clinical trial data meet: Strategies to securely manage and share data to improve patient outcome** **Speaker:** *Oli Cram, Senior Product Manager*	**Stamner**

Tuesday 8th October 2019 continued

14.00 – 15.05	**Parallel Session 7A - Improving Trial Performance** **Chair:** *Emily Webb, LSHTM*	**Preston**
	PS7A - O1 Monitoring performance of sites within multicentre randomised trials: a systematic review of performance metrics *Kate Walker, University of Nottingham, UK* **PS7A - O2** Using systematic data categorisation to quantify the types of data collected in clinical trials *Dr Gordon Fernie, Centre for Healthcare Randomised Trials, Health Services Research Unit, University of Aberdeen, UK* **PS7A - O3** Do RCTs reflect patient populations and does it matter? Considerations and a case study *Mr Mike Bradburn, Clinical Trials Research Unit, University of Sheffield, UK* **PS7A - O4** Development of a framework to improve the process of recruitment to randomised controlled trials (RCTs): the SEAR (Screened, Eligible, Approached, Randomised) framework *Dr Caroline Wilson, Bristol Medical School, University of Bristol, UK* **PS7A - O5** Rewards and challenges of undertaking health-related research within the UK Police setting *Mrs Alison Booth, University of York, UK*	
10.30 – 11.35	**Parallel Session 7B - Late Phase Study Designs** **Chair:** *Richard Emsley, Kings College London*	**Hall 4**
	PS7B - O1 Using Bayesian adaptive designs to improve phase III randomised controlled trials *Dr Elizabeth Gabrielle Ryan, Cancer Research UK Clinical Trials Unit, University of Birmingham, UK* **PS7B - O2** Designing trials for small populations *Dr Victoria Cornelius, Imperial Clinical Trials Unit, Imperial College, UK* **PS7B - O3** Multi-arm multi-stage designs with fixed stage-wise sample sizes *Dr Michael Grayling, Newcastle University, Newcastle upon Tyne, UK* **PS7B - O4** Investigating the application of a multi-arm, multi-stage (MAMS) design to compare optimal treatment duration of Herceptin in a non-inferior setting in treating early breast cancer patients. *Mr Pankaj Mistry, University of Warwick, Coventry, UK* **PS7B - O5** Experiences of setting up Trials within Cohort Studies: Overcoming challenges and maximising efficiency – a case study *Dr Ines Rombach, Oxford Clinical Trials Unit, Oxford, UK, and Centre for Statistics In Medicine, Oxford, UK, and Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Science, Oxford, UK*	

Tuesday 8th October 2019 continued

14.00 – 15.05	**Parallel Session 7C - Reducing Research Waste** **Chair:** *Tony Marson, University of Liverpool*	**Oxford Suite**
	PS7C - O1 Outcome assessment by central adjudicators versus site investigators in randomised stroke trials: A systematic review and meta-analysis *Mr Peter J Godolphin, Nottingham Clinical Trials Unit, University of Nottingham, UK* **PS7C - O2** Introducing the extension of the CONSORT 2010 Statement for the reporting of multi-arm parallel-group randomised controlled trials *Ed Juszczak, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, UK* Dealing with unreported mean and standard deviation in meta-analysis: reducing waste in evidence synthesis *Professor Christopher Weir, University of Edinburgh* **PS7C - O3** Increasing the trial process evidence base without increasing research waste *Prof. Shaun Treweek, on behalf of the Trial Forge initiative, University of Aberdeen, UK* Preclinicaltrials.eu: international register of preclinical trial protocols *Mira van der Naald, UMC Utrecht*	
14.00 – 15.05	**Parallel Session 7D – Debate** **Chair:** *Peter Brocklehurst, University of Birmingham*	**Stamner**
	Trials that conclude "not clinically effective but cost effective" – paradox or contradiction? *Prof. Will Hollingworth, University of Bristol, UK & Prof. James Raftery, University of Southampton, UK*	
15.05 – 16.00	Coffee Break, Exhibition & Poster Viewing	
16.00 – 17.05	**Parallel Session 8A - Increasing Knowledge for Researchers and Participants** **Chair:** *Emily Webb, LSHTM*	**Preston**
	PS8A - O1 Staff training to improve participant recruitment into surgical randomised controlled trials: a feasibility study embedded within four randomised controlled trials *Dr Adwoa Parker, The University of York, UK* **PS8A - O2** Good Statistical Practice: GCP for Statisticians *Ms Helen Mossop, Institute of Health & Society, Newcastle University, UK* **PS8A - O3** Career development for Trial Managers: a survey of UK-based trial management Professionals *Ms Eleanor Mitchell, Nottingham Clinical Trials Unit, University of Nottingham, UK* **PS8A - O5** Transparency in Clinical Research: An Audit of Feedback Provision to Participants in Phase III Pragmatic Clinical Trials *Mr Mohammad Zulfiqar Raza & Dr Hanne Bruhn & Dr Katielth Services Research Unit, University of Aberdeen, UK* **PS8A - O4** What information should be fed back to trial participants? – Findings from a Q-methodology study with trial stakeholders. *Dr Hanne Bruhn, University of Aberdeen, Aberdeen, UK*	

Tuesday 8th October 2019 continued

16.00 – 17.05	**Parallel Session 8B - Challenges in Statistical Analysis 3: Improving Generalisability and Interpretability** **Chair:** *James Wason, Newcastle University*	**Oxford Suite**
	PS8B - O1 Using the learning curve and Bayesian analysis to decide when surgeons are ready to randomise *Dr Fei Shan, Nuffield Department of Surgical Sciences, University of Oxford, UK, and Gastrointestinal Cancer Center, Peking University Cancer Hospital & Institute, Beijing, China* **PS8B - O2** Statistical considerations in a non-inferiority trial: results from the *PERSEPHONE early breast cancer herceptin duration trial.* *Prof. Janet A Dunn, University of Warwick, Coventry, UK* **PS8B - O3** Methods to Evaluate the Benefit-Risk Trade-Off in Individual Patients *Ms Ruth Owen, Department of Medical Statistics, London School of Hygiene and Tropical Medicine, London, UK* **PS8B - O4** The ADAPTT Study: Using routinely-collected data to emulate a randomised trial *Dr Jessica Harris, Clinical Trials and Evaluation Unit, Bristol Trials Centre, University of Bristol, UK* **PS8B - O5** The use of visual analytics for clinical trial safety outcomes: a methodological review *Miss Rachel Phillips, School of Public Health, Imperial College London, UK*	
16.00 – 17.05	**Parallel Session 8C - Wellcome Trust Session** **Chair:** *Matthew Sydes, University College London*	**Hall 4**
	New Approaches to Good Clinical Practice (GCP) *Prof. Martin Landray, Senior Lead, Joint Initiative on Good Practice in Clinical Research University of Oxford*	
16.00 – 17.05	**Parallel Session 8D - Debate** **Chair:** *Amanda Farrin, University of Leeds*	**Stamner**
	Trials methodology meets social care research: issues and opportunities *Prof. Jörg Huber, RDS SE & University of Brighton, UK, Ms Ann-Marie Towers, Centre for Health Services Studies, Canterbury, UK, Dr Phillip Whitehead, Northumbria University, Newcastle, UK*	
19.30– 00.00	Conference Dinner	

Wednesday 9th October 2019

07.30	**Registration & Speaker Preview Opens**	
08.45 – 09.50	**Parallel Session 9A – Making Trials More Efficient** **Chair:** *Matthew Sydes, University College London*	**Preston**
	PS9A - O1 Undertaking trials methodology research using data from clinical trial registries: an exemplar related to core outcome set uptake *Dr Jamie J Kirkham, University of Liverpool, UK & University of Manchester, UK* **PS9A - O2** Estimating site performance (ESP): can trial managers predict which trial sites will fail to recruit? Results from an exploratory study *Dr Hanne Bruhn, University of Aberdeen, UK* **PS9A - O3** To add or not to add a new treatment arm to an on-going trial *Dr Kim May Lee, University of Cambridge, UK* **PS9A - O4** Introducing the CONsolidated Standards of Reporting Trials (CONSORT) statement for randomised controlled trials (RCTs) using cohorts and routinely collected health data *Dr Chris Gale, Imperial College London, UK* **PS9A - O5** Developing an approach to evaluate bias, conflicts of interest, and spin in clinical trials of breastmilk substitutes *Dr Bartosz Helfer, Imperial College London, UK*	
08.45 – 09.50	**Parallel Session 9B - Challenges with Trial Recruitment 4: Towards Better Practice** **Chair:** *Kerry Hood, Cardiff University*	**Oxford Suite**
	PS9B - O1 Trial recruitment decision-making: crucial but not evidence-based *Prof. Shaun Treweek, University of Aberdeen, UK* **PS9B - O2** Enrolling patients without capacity to trauma trials; successes and challenges *Ms Stephanie Wallis, University of Oxford, UK* **PS9B - O3** Prediction and monitoring of patient recruitment in clinical trials: gaps between current practice and available methodology *Miss Efstathia Gkioni, Department of Biostatistics, University of Liverpool, UK & Paris Descartes University, Sorbonne Paris Cité, France* **PS9B - O4** Traumatic Decisions; Research Recruitment and Randomisation in an Acute Emergency Setting *Ms Claire Cochran, University of Aberdeen, UK* **PS9B - O5** Enhancing practitioner explanations and parental understandings of recruitment and consent- an adapted model for paediatric emergency medicine trials *Dr Louise Roper, Institute of Population Health, University of Liverpool, UK*	

Wednesday 9th October 2019

08.45 – 09.50	**Parallel Session 9C - Early Phase Study Designs 3: Safety and Crm** **Chair:** *Marion Campbell, University of Aberdeen*	**Hall 4**
	PS9C - O1 A comparison of Phase I dose-escalation designs in clinical trials with monotonicity assumption violation *Prof. Thomas Jaki, Lancaster University, UK* **PS9C - O2** A meta-analysis of toxicity and efficacy outcomes by dose in recent phase I trials in oncology *Dr Kristian Brock, University of Birmingham, UK* **PS9C - O3** Dose-Transition Pathways for Time-to-event Continual Reassessment Method: To wait or not to wait? *Prof. Christina Yap, University of Birmingham, UK & The Institute of Cancer Research, UK* **PS9C - O4** Practicalities in running early-phase trials using the Time-to-Event Continual Reassessment Method for interventions with long toxicity periods *Miss Elena Frangou, MRC Clinical Trials Unit at UCL, London, UK* **PS9C - O5** Setting up a stopping boundary for safety in a phase II trial: the Poppi trial *Ms Jennifer L Bell, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, UK*	
08.45 – 09.50	**Parallel Session 9D - Learning from Qualitative Research** **Chair:** *Joy Adamson, University of York*	**Stamner**
	PS9D - O1 Optimising the efficiency of identifying and addressing trial recruitment issues through pre-trial and 'real-time' qualitative investigation *Dr Leila Rooshenas, University of Bristol, UK* **PS9D - O2** Are participant-researcher relationships during complex intervention trials an intervention component, engagement tool or trial retention strategy? *Prof. Pat Hoddinott, University of Stirling, UK* **PS9D - O3** What worked for us in which circumstances, and what didn't; reflections upon incorporating a realist evaluation within a clinical trial of a complex intervention. *Dr Paul Leighton, University of Nottingham, UK* **PS9D - O4** Experiences of providing and receiving sham treatment – the LiTEFORM trial (A Randomised Controlled Trial of the Clinical and Cost Effectiveness of Low Level Laser in the Management of Oral Mucositis in Head and Neck Cancer Irradiation). *Dr Nikki Rousseau, Newcastle University, UK* **PS9D - O5** Unique challenges and proposed solutions for designing and conducting pilot and feasibility work to optimise surgical trials *Miss Katherine Fairhurst, Hub for Trials Methodology Research, University of Bristol, UK*	

Wednesday 9th October 2019 continued

09.50 – 10.35	Break - Coffee & Exhibition (Exhibition Closes)	
10.35 – 11.40	**Parallel Session 10A – Challenges with Trial Recruitment 3** **Chair:** *Emily Webb, LSHTM*	**Preston**
	PS10A - O1 "I was meaning to read that, but..." – An international qualitative study of how time-poor trialists choose their recruitment strategies *Dr Heidi Gardner, University of Aberdeen, UK* **PS10A - O2** Do investigator meetings improve recruitment into clinical trials? – A retrospective review of data from nine trials. *Ms Eleanor Mitchell, Nottingham Clinical Trials Unit, University of Nottingham, UK* **PS10A - O3** SWATs at scale: meta-analysis of the results of the first co-ordinated programme of SWATs exploring improvements to patient information in trials *Mrs Vichithranie Madurasinghe, Queen Mary University London, UK* **PS10A - O4** Evaluation of the validity and reliability of the DevPIC tool for measuring quality of informed consent discussions during trial recruitment. *Dr Julia Wade, University of Bristol, UK* **PS10A - O5** PS10A - O1 Why do patients take part in research? An overview of systematic reviews, and mapping to theory and trial recruitment research. *Dr Peter Knapp, University of York & The Hull York Medical School, UK*	
10.35 – 11.40	**Parallel Session 10B – Collecting and Using Electronic Data** **Chair:** *Will Hollingworth, University of Bristol*	**Oxford Suite**
	PS10B - O1 Health informatics (HI) innovations in randomised trials and clinical cohorts - Identification, screening, stratified care and data collection during primary care consultations *Mr Simon Wathall, Keele Clinical Trials Unit, Keele University, UK & Primary Care Centre Versus Arthritis, Research Institute for Primary Care & Health Sciences, UK* **PS10B - O2** Utility of routine electronic health records used as outcome measures in UK randomised trials: a systematic review *Ms Sharon Love, MRC CTU at UCL, London, UK* **PS10B - O3** Routinely-collected hospital datasets can be used to identify endpoints predictive of overall survival outcomes in randomised controlled trials (RCT): a prostate cancer study within the STAMPEDE protocol (NCT00268476) *Miss Harriet P Mintz, Warwick Medical School, University of Warwick, Coventry, UK & University Hospitals Birmingham NHS Foundation Trust, UK*	

Wednesday 9th October 2019 continued

	PS10B - O4 Getting animated about routine data: Using animations to inform and engage future trial participants about linkage to routinely collected data to aid recruitment. *Dr Fiona Lugg-widger, Cardiff University, UK* **PS10B - O5** Does regulation of routine data sharing pose a risk for Individual Patient Data (IPD) meta-analysis? A review of some key challenges in a UK context. *Prof. Michael Robling, Cardiff University, UK*	
10.35 – 11.40	**Parallel Session 10C - Challenges in Statistical Analysis 4: Missing Data** **Chair:** *James Wason, Newcastle University*	**Hall 4**
	PS10C - O1 Estimating treatment effects in the presence of informative missingness *Dr Ruwanthi Kolamunnage-Dona, University of Liverpool, UK* **PS10C - O2** Reference-based multiple imputation for data missing not-at-random in cost-effectiveness analysis *Baptiste Leurent, London School of Hygiene and Tropical Medicine, UK* **PS10C - O3** A framework for extending trial design to facilitate missing data sensitivity analyses *Dr Alexina Jane Mason, London School of Hygiene & Tropical Medicine, UK* **PS10C - O4** Methods to deal with missing data in area under the curve outcomes in randomised controlled trials: the OPEN trial case study *Ms Beatriz Goulao, Health Services Research Unit, University of Aberdeen, UK* **PS10C - O5** The value of including recurrent events in the analysis of cardiovascular outcomes trials *Dr John Gregson, Department of Medical Statistics, London School of Hygiene and Tropical Medicine, UK*	
10.35 – 11.40	**Parallel Session 10D – UKCRC CTU Network Showcase** **Chair:** *Julia Brown, Director, UK CRC Registered CTU Network*	**Stamner**
	PS10D – O2 Challenges and constraints in evaluating novel therapies for neurodegeneration. *Prof Kerry Hood, Dr Cheney Drew, Centre for Trials Research, Cardiff University* **PS10D – O1** Design and analysis challenges in the LIBERATES trial of continuous glucose monitoring in Type 2 diabetic patients with recent-onset heart attack. *Colin C Everett MSc, Leeds Clinical Trials Research Unit, University of Leeds* **PS10 – O3** The challenges associated with delivering digital outcomes in a trial (PD STAT) *Dr Alison Jeffery, Rebecca Chapman, Peninsula Clinical Trials Unit, University of Plymouth*	

Wednesday 9th October 2019 continued		
11.40 – 11.50	**Room Change**	
11.50 – 12.40	**Keynote Speaker** The Surgical Evaluation High Wire – balancing conceptual, methodological, and pragmatic aspects of surgical trial design. *Prof. David Beard, Prof. of Musculoskeletal and Surgical Science and Rosetrees RCSEng Director, Surgery and Interventional Trials Unit [SITU NDORMS], University of Oxford*	**Oxford Suite**
12.40 – 13.00	**Prizes and Closing Remarks** *Paula Williamson, ICTMC 2019 Local Organising Committee Chair* *Matthew Sydes, ICTMC 2019 Scientific Committee Chair*	
14:00 – 17:30	**Post-Conference Workshop 3.1** Close Out and Archiving - a CTU guided workshop and discussion session on processes and procedures to conclude a trial *Dr. Gordon Fernie, University of Aberdeen* *Ms. Karen Innes, University of Aberdeen* *Mrs. Tracey Davidson, University of Aberdeen*	**Preston**
	Post-Conference Workshop 3.2 Practical Implementation of Bayesian Adaptive Designs for Single-arm, Randomised, Basket and Platform Phase II Trials, with real-world case studies *Prof. Christina Yap, The Institute of Cancer Research* *Prof. Ying Yuan, University of Texas MD Anderson Cancer Center*	**Hall 4**
	Post-Conference Workshop 3.3 A hands-on introduction to health economics analysis plans (HEAPs) *Dr. Joanna Thorn, University of Bristol* *Prof. William Hollingworth, University of Bristol* *Dr. Melina Dritsaki, University of Oxford*	**Stamner**