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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*
	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*
	Pre-Conference Workshop 1.3 Beyond the CONSORT extension for pilot trials: guideline, planning, abstracts and protocols *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*
13.00 – 14.00	**Lunch Break** *(lunch not included)*

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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*
	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*
	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*
14.00 – 18.00	**Speaker Preview Open**

Monday 7th October 2019

07.30	Registration & Speaker Preview Opens
09.30 – 09.45	**Welcome & Opening**
09.45 – 10.35	**Keynote Speaker** The Evolution of Academic Sponsored Clinical Trials in the 21st Century: Lessons Learned at the Canadian Cancer Trials Group *Dr Janet Dancey, Clinician Scientist I and Scientific Director, Canadian Cancer Clinical Trials Network*
10.35 – 11.30	Coffee Break, Exhibition & Poster Viewing

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11.30 – 12.35	**Parallel Session 1A - Improving Follow-Up and Retention** **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** **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* **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*

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11.30 – 12.35	**Parallel Session 1C – Health Economic Evaluation** **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** *Speakers to be confirmed*
12.35 – 13.40	Break - Lunch, Exhibition & Poster Viewing
13.40 – 14.45	**Parallel Session 2A - Improving Data Quality in Trials** **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*

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	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** **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** **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*

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	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*
13.40 – 14.45	**Parallel Session 2D - Public and Patient Involvement and Engagement** **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** **p**atient 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**

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14.55 – 16.00	**Parallel Session 3A - Challenges with Trial Recruitment 1: Recent Experiences** **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* **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** **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*

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14.55 – 16.00	**Parallel Session 3C - Early Phase Study Designs 2: Advanced Issues** **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** **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*

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16.00 – 16.55	Coffee Break, Exhibition & Poster Viewing
16.55 – 18.00	**Parallel Session 4A - Pilot and Feasibility Studies** **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*
16.55 – 18.00	**Parallel Session 4B - Challenges in Late Phase Trials** **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*

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16.55 – 18.00	**Parallel Session 4C – Lessons from Trials in Practice** **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** *Speakers to be confirmed*

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** **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*

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	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** **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* **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** **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*

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	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** **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, Department of Biostatistics, University of Liverpool, Liverpool, UK and INSERM, U1153 Epidemiology and Biostatistics Sorbonne Paris Cité Research Center (CRESS), Methods of therapeutic evaluation of chronic diseases Team (METHODS), Paris Descartes University, Sorbonne Paris Cité, Paris, 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* **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 – 11.35	**Parallel Session 6A - Retention to Trials** **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*

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	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 – 11.35	**Parallel Session 6B – Challenges in Statistical Analysis 2: Planning for Understanding** **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*
10.30 – 11.35	**Parallel Session 6C - Using Electronic Health Records** **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**

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	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** Make it Public: an HRA panel discussion about communicating results to participants and the public *Speakers to be confirmed*
11.35 – 11.45	**Room Change**
11.45 – 12.45	**Doug Altman Memorial 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*
12.45 – 14.00	Break - Lunch, Exhibition & Poster Viewing
14.00 – 15.05	**Parallel Session 7A - Improving Trial Performance** **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*

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	PS7A - O5 Rewards and challenges of undertaking health-related research within the UK Police setting *Mrs Alison Booth, University of York, UK*
14.00 – 15.05	**Parallel Session 7B - Late Phase Study Designs** **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*
14.00 – 15.05	**Parallel Session 7C - Reducing Research Waste** **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* **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*
14.00 – 15.05	**Parallel Session 7D – Debate** 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*

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15.05 – 16.00	Coffee Break, Exhibition & Poster Viewing
16.00 – 17.05	**Parallel Session 8A - Increasing Knowledge for Researchers and Participants** **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 Katie Gillies, Health 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*
16.00 – 17.05	**Parallel Session 8B - Challenges in Statistical Analysis 3: Improving Generalisability and Interpretability** **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*

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	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** **New Approaches to Good Clinical Practice (GCP)** *Speakers to be confirmed*
16.00 – 17.05	**Parallel Session 8D – Debate** 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**

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07.30	Registration & Speaker Preview Opens
08.45 – 09.50	**Parallel Session 9A – Making Trials More Efficient** **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*

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	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** **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*
08.45 – 09.50	**Parallel Session 9C - Early Phase Study Designs 3: Safety and Crm** **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

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	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** **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, Centre for 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*
09.50 – 10.35	Break - Coffee & Exhibition (Exhibition Closes)
10.35 – 11.40	**Parallel Session 10A – Challenges with Trial Recruitment 3** **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*

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	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** **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* **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** **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*

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	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:** Prof Julia Brown Director UK CRC CTU Network **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*
10.35 – 11.40	**Room Change**
11.40 – 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*
12.40 – 13.00	**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 *Dr. Gordon Fernie, University of Aberdeen* *Ms. Karen Innes, University of Aberdeen* *Mrs. Tracey Davidson, University of Aberdeen*
	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

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	Prof. Christina Yap, The Institute of Cancer Research *Prof. Ying Yuan, University of Texas MD Anderson Cancer Center*
	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*