


TRIAL STEERING COMMITTEE WORKSHOP: A PRIMER FOR TSC MEMBERS

 **6th June 2024 | 10:00 – 16:00 (UTC) | ONLINE**

Fee: €125 General, €75 Student


SCHEDULE

Time	Title	Speaker(s)
10:00 - 10:10	Welcome Address	Prof. Athene Lane Prof. Declan Devane
10:10 - 10:25	Trial Steering Committee research, including the role of the chair	Prof. Athene Lane
10:25 - 10:35	A funder perspective of a “successful Trial Steering Committee” – UK	Prof. Olivia Wu (NIHR)
10:35 - 10:45	A funder perspective of a “successful Trial Steering Committee” – Ireland	Dr Fiona Manning (HRB)
10:45 - 10:55	A UK sponsor perspective of a successful TSC	Dr Birgit Whitman
10:55 - 11:05	An Irish sponsor perspective of a successful TSC	Prof. Peter Doran
11:05 - 11:25	Q&A – Chair: Prof. Declan Devane	Prof. Athene Lane Prof. Olivia Wu Dr Fiona Manning Dr Birgit Whitman Prof. Peter Doran
11:25 - 11:35	Break (10 mins)	
11:35 - 11:55	TSC Experiences	Prof. Peter Bowyer Prof. Alistair Nichol

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Time	Title	Speaker(s)
11:55 - 12:10	Q&A – Chair: Prof Matt Sydes	Prof. Peter Bowyer Prof. Alistair Nichol
12:10 - 12:45	Breakout session 1 - What is the role of the TSC?	
12:45 - 13:30	Lunch	
13:30 - 13:40	TSC-Clinical Trials Units (UK) interactions	Prof. Alan Montgomery
13:40 - 13:50	TSC-Clinical Research Facilities (Ireland) interactions	Prof. Andrew Smyth
13:50 - 14:10	Patient and Public Involvement	UK – Dr Doreen Tembo Ireland – Ms Edel Murphy
14:10 - 14:20	Break (10 mins)	
14:30 - 14:45	Revising the TSC Guidance	Prof. Carrol Gamble
14:45 - 15:05	Q&A – Chair: Prof Athene Lane	Dr Doreen Tembo Ms Edel Murphy Prof. Alan Montgomery Prof. Andrew Smyth Prof. Carrol Gamble
15:05 - 15:25	Breakout session 2 – Mock TSC discussion	
15:25 - 15:40	Mock TSC discussion feedback	Prof. Matt Sydes
15:40 - 15:45	HRB-TMRN Placement Scheme overview	Dr Sandra Galvin
15:45 - 16:00	Closing remarks	Prof. Athene Lane

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Speakers:



Professor Athene Lane
*Trials Research in Population
Health Sciences
University of Bristol*

Athene Lane is a Professor in Trials Research in Population Health Sciences, University of Bristol. She is also a Senior Trial Methodologist in the Bristol Trial Centre. Her main research interests are in designing and conducting feasibility and definitive trials of healthcare and lifestyle interventions across a range of clinical areas. She has coordinated the NIHR HTA randomised trial of treatments for localised prostate cancer – ProtecT and the ten year median outcomes had international impact. Her research also includes the role of diet in cancer, PROMS design and utilisation. Fellow of the Society of Clinical Trials and Deputy Editor of Clinical Trials.




Professor Declan Devane
*Health Research Methodology
University of Galway*

Declan trained as a nurse and a midwife, meandered (with the help of opportunity, interest and luck) his way into trial methodology and evidence synthesis and his work now focusses on a blend across randomised trials and synthesising evidence across a number of clinical areas. Declan is the Chair in Health Research Methodology and Deputy Dean of the College of Medicine, Nursing and Health Sciences at the University of Galway. He is also the Scientific Director of the HRB-Trials Methodology Research Network, Director of Evidence Synthesis Ireland and Director of Cochrane Ireland. He has served on numerous Trial Steering Committees and Data Monitoring Committees.

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Dr Fiona Manning
*Programme Manager
Clinical Trials and Infrastructures
Health Research Board*

Fiona is Programme Manager for the HRB Clinical Trials and Infrastructures portfolio. She is responsible for managing the portfolio of HRB's clinical research investments, which includes infrastructures (Clinical Research Facilities, Cancer Trials Groups and Network, Clinical Trials Networks, TMRN, NCTO) and trial activities funding programmes (DIFA). Prior to her role at HRB, Fiona was Senior Research Officer at the Office for Research and Innovation at RCSI, where she managed support for researchers for national research funding programmes, including HRB and SFI, and played a leading role in developing the university's activities in PPI in research.




Professor Olivia Wu
*Co-Director, Health Economics
and Health Technology
Assessment (HEHTA) Research
Group, University of Glasgow
Chair, NIHR Clinical Evaluations
and Trial Funding Committee*

Olivia holds the William R Lindsay Chair of Health Economics and is Co-Director of HEHTA at the University of Glasgow. Her research spans across a wide range of clinical areas but focuses on adapting and applying HTA methodologies in context. She has led numerous economic evaluations alongside clinical evaluations and trials, which influenced health intervention adoption decisions. She also has a body of work on novel and effective use of evidence synthesis approaches to maximise the value of existing data for informing clinical and economic evaluations. Her work has informed clinical guidelines and health policy decisions, both at national and international levels. Olivia collaborates widely and is chief and co-Investigators of active research projects with a cumulative value of over £50 million. In addition to her research, Olivia is a long-standing advisor to HTA agencies within and out with the UK. She has previously served as member of the NICE Technology Appraisal committee for 10 years.


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Professor Alistair Nichol
*Critical Care Medicine
University College Dublin*

Professor Alistair Nichol is the Chair of Critical Care Medicine in University College Dublin and the Director of the Irish Critical Care- Clinical Trials Network and Consultant in St Vincent's University Hospital, Dublin. He has been an investigator on peer reviewed grants worth over 65 million euros from Ireland, Europe, Australia, New Zealand and Canada. He has completed the hat trick of first author publications- in NEJM, Lancet and JAMA. Currently he is completing trials in the critically ill which will randomize over 20,000 patients in the next 5 years. He has academic interests in Pandemic Preparedness, Cardiac Arrest, Trauma and Mechanical Ventilation.




Professor Carrol Gamble
*Professor of Medical Statistics
University of Liverpool*

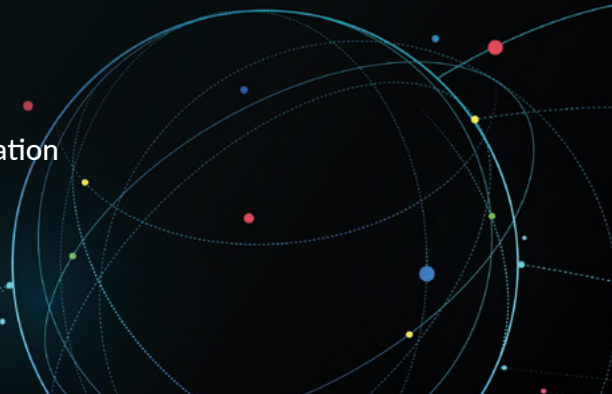
Carrol Gamble is a Professor of Medical Statistics at the University of Liverpool, an NIHR Senior Investigator and Director of the Liverpool Clinical Trials Centre, a fully UK Clinical Research Collaboration (UKCRC) registered Clinical Trials Unit (CTU). Carrol is a member of the Trials Methodology Research Partnership Statistical Analysis and Health Informatics Working Groups and co-chairs the Data Sharing sub group. Carrol chaired the UK network of statisticians in UKCRC registered Clinical Trials Units for 10 years, was a member of the UKCRC registered CTU group on data sharing and is now deputy Chair for the Policy Group.

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Alan is Professor of Medical Statistics and Clinical Trials at the University of Nottingham, and Director of the Nottingham Clinical Trials Unit. He works collaboratively on large, multicentre randomised trials across a wide range of clinical specialties and settings. Alan is an experienced member and chair of Steering and Data Monitoring committees.

Professor Alan Montgomery
University of Nottingham




Andrew is the Professor of Clinical Epidemiology at University of Galway and Consultant Nephrologist at Galway University Hospitals. He is the former Director of the HRB Clinical Research Facility Galway and MSc Clinical Research at University of Galway and is an experienced clinical trialist. In addition to leading core research infrastructure at University of Galway (providing supports to investigators for a broad clinical trial portfolio) he also has experience as Chief Investigator, Trial Steering Committee Member, Data Safety and Monitor Board Chair and Chair of Event Adjudication Committee and is a Member of the National Research Ethics Committee for Clinical Trials.

Professor Andrew Smyth
*Professor Clinical Epidemiology
University of Galway*

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Dr Doreen Tembo

Head of Public Involvement and Engagement at Health Data Research UK & Strategic Lead of Public Engagement with Data Research Initiative

Doreen Tembo is Head of Public Involvement and Engagement at Health Data Research UK and the Strategic Lead of the Public Engagement with Data Research Initiative. She spent her early career working in the social economic development sector in Zambia where she developed her unending passion for the active engagement and involvement of public partners in health and care research, policy, and delivery. Doreen has research, partnership and stakeholder development and management experience from the national and global health research sector having held leadership positions with regional, national, and global programmes in the UK National Institute for Health and Care Research (NIHR) since 2010.




Ms Edel Murphy

National Programme Manager, PPI Ignite Network

Edel Murphy is the national Programme Manager for the PPI Ignite Network in Ireland. Edel has worked in the area of public and patient involvement (PPI) in research for a number of years, working with researchers across all disciplines and with the public to build PPI capacity among both constituencies, delivering education and training and providing support to help researchers understand how to plan for and embed the public and patient voice across their research. In her current role, Edel is driving the development and growth of an energetic, collaborative and innovative Network, which brings together a diverse range of stakeholders nationally and internationally to build a shared voice for PPI in research in Ireland.

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Professor Peter Doran

*Director of the UCD Clinical Research Centre,
Director of Research at St Vincent's Healthcare Group
Professor of Clinical Trials at the UCD School of Medicine*

Prof Doran leads UCD's multisite-clinical research and directs its major investigator initiated trials programme. Prof Doran has a significant track record in the leadership of clinical research and has established a significant programme at UCD. The clinical research, directed by Prof Doran, helps discover ways to improve medical care and to establish new treatments which in turn will improve the quality of life for patients who are living daily with chronic illness. Prof Doran leads a major research programme in trial methodology including novel trial designs, predictive modelling and better trial outcomes. In addition to his research and leadership roles, Prof Doran established and previously led the graduate taught programme in clinical and translational research at UCD and Chaired the Biomedical research Degrees Committee at the UCD School of Medicine. He was previously Associate Dean for Research at the UCD School of Medicine, Vice Principal for Research, Innovation & Impact at the UCD College of Health and Agricultural Science and Director of the Institute for Clinical Trials at the University of Galway.




Professor Peter Bower

National Specialty Lead for Health Services Research

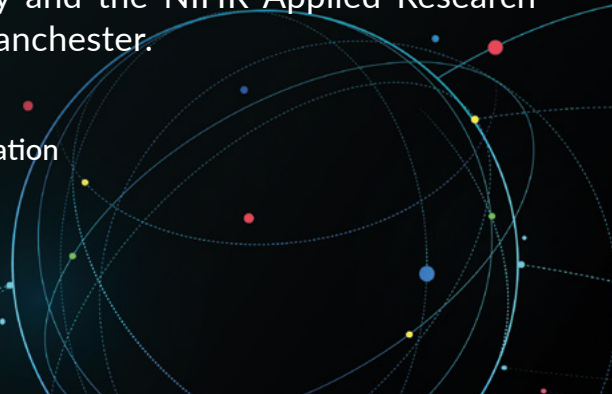
Peter leads the Health Services Research Specialty Group and is a Professor of Health Services Research at the Centre for Primary Care, University of Manchester. He is also Specialty Lead for health services research for Greater Manchester. He has been conducting health services research in Manchester for over 20 years, with a focus on the management of depression, long-term conditions, and integrated care. He is part of the NIHR School for Primary Care Research, the NIHR Policy Research Unit for Older People and Frailty and the NIHR Applied Research Collaborative Greater Manchester.

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Professor Matt Sydes
MRC Clinical Trials Unit at UCL
UK


Matt Sydes was part of the DAMOCLES project in data good practice for Data Monitoring Committees where he undertook two reviews on DMC use and practice, and co-edited the development of the IDMC charter which is now commonly used in academic trials. Matt has extensive experience of designing, running, analysing and disseminating clinical trials and associated methodology. He leads the Trial Conduct Methodology research area at MRC CTU at UCL. He has attended nearly 300 IDMC and TSC meetings as an independent member, and many more as a reporting statistician.

Dr Birgit Whitman
Head of Research
Governance & Integrity
University of Birmingham

Birgit joined the University of Birmingham as Head of Research Governance & Integrity after 11 years in this role at the University of Bristol. Prior to this, she worked 20 years in the NHS as a Research Assistant in Surgery, pre-implantation QA lead for the national abdominal aortic aneurysm screening programme, NHS R&D Manager and Trust Innovation Lead. She completed her PhD in the Wellcome Unit for the History of Medicine at Glasgow University looking at Breast Cancer treatment and patient narratives. Birgit has worked for the Leonard Cheshire Foundation (an international Foundation that has the aim of changing attitudes towards disability) and has completed a degree in History and Women's studies.

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