Health Research Board
TMRN
Trials Methodology Research Network

15th May 2023
10:00-16:00

Online

Trials Methodology TMRP Research Partnership

Irish Critical Care Clinical Trials Network

Trial Steering Committee Workshop: A primer for TSC members

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. Julia Brown (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. Julia Brown** **Dr Fiona Manning** **Dr Birgit Whitman** **Prof. Peter Doran**
11:25 - 11:35	**Break (10 mins)**	
11:35 - 11:55	TSC Experiences	**Prof. Kerry Hood** **Prof. Alistair Nichol**

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Time	Title	Speaker(s)
11:55 - 12:10	Q&A – **Chair: Prof Matt Sydes**	Prof. Kerry Hood 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. Carol Gamble
14:45 - 15:05	Q&A – **Chair: Prof Athene Lane**	Dr Doreen Tembo Ms Edel Murphy Prof. Alan Montgomery Prof. Andrew Smyth Prof. Carol 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	Prof. Declan Devane
15:45 - 16:00	Closing remarks	Prof. Athene Lane

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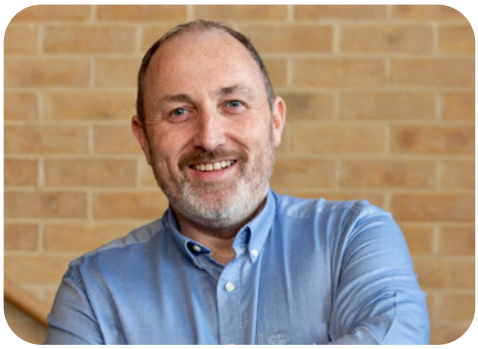
Professor Athene Lane
Trials Research in Population Health Sciences
University of Bristol

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. The has served on numerous Trial Steering Committees and Data Monitoring Committees.

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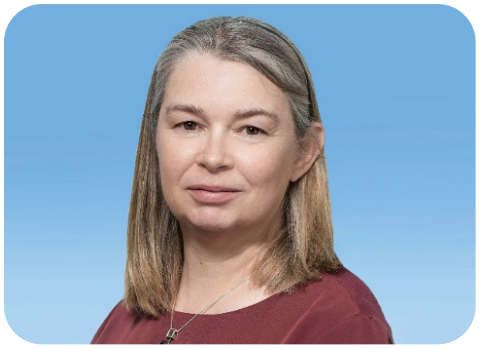
Professor Julia Brown
Director of Leeds Institute of Clinical Trials Research

Julia Brown is Professor of Clinical Trials Research, Director of the Leeds Institute of Clinical Trials Research, CRUK CTU at Leeds, UKCRC Registered CTU Network and is Deputy Dean in the Faculty of Health at the University of Leeds. She currently chairs the NIHR HTA General Funding Committee. She has over 30 years experience in clinical trials research and her main research interests are in the design and analysis of complex trials and the development and incorporation and analysis of patient reported outcomes in clinical trials. She is a NIHR Senior Investigator Emeritus.



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. Fiona has held a number of research Programme Manager positions in clinical and academic settings and previously held roles in Business Development and R&D in industry. She holds a PhD and recently completed an MSc in Healthcare Management from RCSI.

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

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

Prof. Peter Doran
Established Professor of Clinical Trials
Director of the Institute for Innovative Clinical Trials
University of Galway

Peter leads a significant biomarker research programme and has established a high throughput biomarker validation laboratory, which is contributing to major national and international end organ damage biomarker studies, reflecting his research interests in the molecular drivers of organ damage, biomarker discovery and translation to practice. Peter also has significant research interests in advancing trial conduct through primary methodology research, novel trial designs, research prioritisation and sustainable trials.

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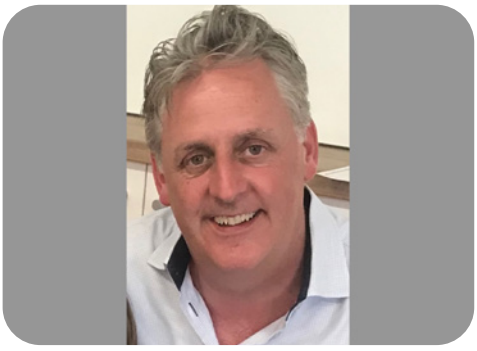

Professor Alistair Nichol
Critical Care Medicine
University College Dublin

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
University of Liverpool

Carrol Gamble is a medical statistician by background. Her initial interests in systematic reviews and meta-analysis later led to interests in clinical trial design, conduct and trials methodology research. Carrol is Director of the Liverpool Clinical Trials Centre with clinical trials experience covering areas such as paediatrics, infection, surgical trials, emergency care, investigational medicinal products and devices. Carrol's interests in Trials Methodology Research include deferred consent, recruitment, retention and patient and public involvement. Carrol has served on numerous Trials Steering Committees and Data Monitoring Committees as Chair or independent statistician.

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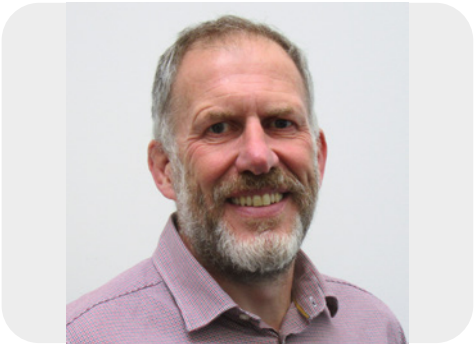

Professor Alan Montgomery
University of Nottingham

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.

Prof. Andrew Smyth
Director, HRB Clinical Research Facility Galway

Andrew is a medical graduate of University of Galway, trained in Internal Medicine and Nephrology in Ireland, Mayo Clinic and McMaster University (Canada). He holds a MSc and Structured PhD in Medicine / Clinical Epidemiology from University of Galway. Prof Smyth's research interests are in the epidemiology of chronic kidney disease, particularly modifiable risk factors for chronic kidney disease and the relationship between diet and health outcomes. He has published over 70 peer-review papers including first author publications in Lancet, Circulation and Kidney International.

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Doreen Tembo,
Senior Research Manager in Global Health and the Community Engagement and Involvement Lead at the UK National Institute for Health and Care Research (NIHR)

Doreen Tembo is a Senior Research Manager in Global Health and the Community Engagement and Involvement Lead at the UK National Institute for Health and Care Research (NIHR). Her areas of expertise are stakeholder engagement and involvement, co-production, research management, health policy and health systems research.

Doreen's early career was spent working with NGO's and international development agencies in Zambia. She worked with UNICEF using participatory action research to design culturally acceptable adolescent and youth sexual health and HIV/AIDS prevention programs. Doreen also worked with UNDP in the field of socioeconomic development. In the UK Doreen has worked with the Universities of Oxford, Essex and Southampton as well as the NIHR focusing on evidence based policy, public health and applied health research and research management.

Edel Murphy
National Programme Manager, PPI Ignite Network

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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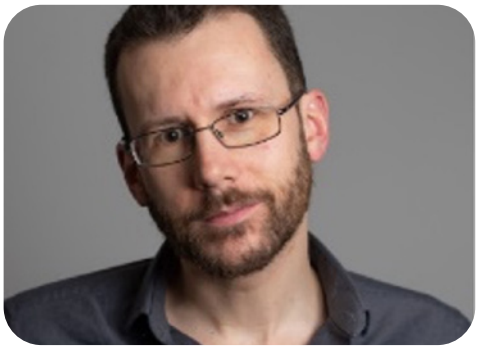

Professor Matt Sydes
MRC Clinical Trials Unit at UCL
UK

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-led 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 more than 200 IDMC and TSC meetings as an independent member, and many more as a reporting statistician.

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