Trial Steering Committee Workshop: A primer for TSC members

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<tr>
<th>Time</th>
<th>Title</th>
<th>Speaker(s)</th>
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<tr>
<td>10:00 - 10:10</td>
<td>Welcome Address</td>
<td>Prof. Athene Lane</td>
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<td>Prof. Declan Devane</td>
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<td>10:10 - 10:25</td>
<td>Trial Steering Committee research, including the role of the chair</td>
<td>Prof. Athene Lane</td>
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<td>10:25 - 10:35</td>
<td>A funder perspective of a “successful Trial Steering Committee”</td>
<td>Prof. Julia Brown (NIHR)</td>
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<td>– UK</td>
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<td>10:35 - 10:45</td>
<td>A funder perspective of a “successful Trial Steering Committee”</td>
<td>Dr Fiona Manning (HRB)</td>
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<td>– Ireland</td>
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<td>10:45 - 10:55</td>
<td>A UK sponsor perspective of a successful TSC</td>
<td>Dr Birgit Whitman</td>
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<td>10:55 - 11:05</td>
<td>An Irish sponsor perspective of a successful TSC</td>
<td>Prof. Peter Doran</td>
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<td>11:05 - 11:25</td>
<td>Q&amp;A – Chair: Prof. Declan Devane</td>
<td>Prof. Athene Lane</td>
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<td>Prof. Julia Brown</td>
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<td>Prof. Peter Doran</td>
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<td>11:25 - 11:35</td>
<td>Break (10 mins)</td>
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<td>11:35 - 11:55</td>
<td>TSC Experiences</td>
<td>Prof. Kerry Hood</td>
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<td>Prof. Alistair Nichol</td>
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**FEE:** €125 General, €75 Student

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This workshop was previously developed with funding from NIHR CTU
**15th May 2023**
**10:00-16:00**

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| 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?                  | Prof. Alistair Nichol  
Prof. Alan Montgomery  
Prof. Andrew Smyth  
Dr Doreen Tembo  
Ms Edel Murphy  
Prof. Carol Gamble                                                                 |
| 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                            | Prof. Athene Lane                                                                 |
| 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                                                     |                                                                            |

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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.

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.
Julia Brown is Professor of Clinical Trials Research, Director of the Leeds Institute of Clinical Trials Research, CRUK CTU at Leeds, UHCRC 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.

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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Professor Alistair Nichol
Chair of 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.

Carrol Gamble
Medical Statistician
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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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.

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 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 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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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.

Professor Matt Sydes
MRC Clinical Trials Unit at UCL
UK

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