

DESIGNING AND RUNNING STREAMLINED RANDOMIZED TRIALS
HOW TO CONDUCT TRIALS WHICH PRODUCE RELIABLE ANSWERS

*Clinical Trial Service Unit and Epidemiological Studies Unit,
Nuffield Department of Population Health, University of Oxford*

Draft program

Monday 11th April 2016

- 12.00-12.45 *Lunch*
12.45-13.00 Welcome
13.00-15.00 Lecture: Choosing the research question
Workshop: Identify an appropriate primary outcome and plausible treatment effect
15.00-16.45 Lecture: Sample size
Workshop: Identify an appropriate sample size
Tea
17.00-17.45 Lecture: Trial design
17.45-18.00 Lecture: Patient and public involvement

Tuesday 12th April 2016

- 9.00-10.30 Lecture: Streamlined recruitment methods
Workshop: Specify inclusion criteria and an outline recruitment plan
10.30-11.15 Lecture: Randomization methods
Workshop: Specify an appropriate randomization method
Coffee
11.30-12.30 Lecture: Data-collection methods including electronic data capture and laboratory systems
12.30-13.00 Lecture: Effective monitoring
Lunch
13.45-14.45 Lecture: Completeness of follow-up and adherence to study treatment
Workshop: Anticipate the loss of adherence and develop mitigation strategies
14.45-15.15 Lecture: Event processing and adjudication (including use of routine data sources)
15.15-15.45 Lecture: Pharmacovigilance and regulatory requirements
Tea
16.15-17.30 Workshop: Build remaining trial protocol
17.30-18.30 Individual sessions with a senior faculty member to discuss specific projects
(15 minutes per delegate)

Wednesday 13th April 2016

- 9.00-10.30 Protocol presentations: Delegates present and critique the protocols
10.30-11.00 Lecture: The data monitoring committee
Coffee
11.15-12.45 Lecture: Analysis and dissemination of results
Workshop: Draft an outline data analysis plan
12.45-13.00 Closing remarks
Lunch

In each workshop, delegates will work together in small groups on a pre-specified trial scenario aiming to build a study protocol by completion of the course.

Faculty

Jane Armitage (Professor of Clinical Trials and Epidemiology, CTSU and Honorary Consultant in Public Health Medicine)

- Principal investigator for several large trials of lipid modification in people at risk of vascular events including the 20,000 participant Heart Protection Study, the 12,000 patient SEARCH and 25,000 HPS2-THRIVE studies
- Co-principal investigator for the ASCEND trial of aspirin and fish oils involving 15,000 people with diabetes

<http://www.ndph.ox.ac.uk/team/jane-armitage>

Colin Baigent (Professor of Epidemiology and Deputy Director of CTSU)

- Principal investigator for the 9000 participant Study of Heart and Renal Protection (SHARP)
- Principal investigator for the Cholesterol Treatment Trialists' (CTT) Collaboration and the Anti-Thrombotic Trialists' Collaboration (ATT)

<http://www.ndph.ox.ac.uk/team/colin-baigent>

Derrick Bennett (Senior Statistician, CTSU)

- Senior statistician within the Heart Studies Group at CTSU
- Extensive experience in collaborative analysis of individual participant data and genetic epidemiology

<http://www.ndph.ox.ac.uk/team/derrick-bennett>

Louise Bowman (Associate Professor, CTSU and Honorary Consultant Oxford University Hospitals NHS Foundation Trust)

- Co-principal investigator for the ASCEND trial and the 30,000 participant international REVEAL study
- MRC HTMR Executive Committee Member for the MRC CTSU Hub

<http://www.ndph.ox.ac.uk/team/louise-bowman>

Richard Bulbulia (Senior Research Fellow, CTSU and Vascular Surgeon Gloucester Hospitals NHS Foundation Trust)

- Co-principal investigator of ACST-2 (a large trial of endarterectomy vs stenting in asymptomatic carotid disease)
- Co-ordinates the long-term follow-up of HPS and SEARCH, using data linkage to electronic health records

<http://www.ndph.ox.ac.uk/team/richard-bulbulia>

Jo Crocker (Research Fellow, Nuffield Department of Primary Care Health Sciences, University of Oxford)

- Research area involves evaluating and assessing the impact of patient and public involvement (PPI) in research
- Member of the MRC Network of Hubs for Trials Methodology Research - Recruitment Working Group

<http://www.phc.ox.ac.uk/team/joanna-crocker>

Jonathan Emberson (Associate Professor, CTSU)

- Statistical lead for CTSU's vascular overviews and renal studies groups
- Oxford based principal investigator for the Mexico City Prospective Study of 150,000 middle-aged Mexican adults

<http://www.ndph.ox.ac.uk/team/jonathan-emberson>

Richard Haynes (Associate Professor, CTSU and Consultant Nephrologist Oxford University Hospitals NHS Foundation Trust)

- Clinical co-ordinator for the 3C trial assessing immunosuppression treatment in kidney transplant recipients
- Member of the Renal Association clinical trials committee

<http://www.ndph.ox.ac.uk/team/richard-haynes>

William Herrington (Senior Clinical Research Fellow, CTSU)

- Research area includes the impact of outcome adjudication and the use of routine data sources in clinical trials
- Experience in the development of streamlined laboratory methods

<http://www.ndph.ox.ac.uk/team/will-herrington>

Carol Knott (Head of Monitoring and Nurse Training, CTSU)

- Co-ordinated the training and monitoring team for several large international trials
- Extensive experience of trial audit and regulatory inspection

<http://www.ndph.ox.ac.uk/team/carol-knott>

Sarah Lewington (Associate Professor and Director of Graduate Studies, CTSU)

- Principal investigator for the Prospective Studies Collaboration
- Oxford-based principal investigator for several large observational studies conducted in Russia, Cuba and India

<http://www.ndph.ox.ac.uk/team/sarah-lewington>

Marion Mafham (Clinical Research Fellow, CTSU)

- SHARP steering committee member
- Co-ordinating team for the SEARCH, SHARP, ASCEND and REVEAL studies

<http://www.ndph.ox.ac.uk/team/marion-mafham>

Christina Reith (Senior Clinical Research Fellow, CTSU)

- Co-ordinating team for the SHARP study, and the CTT and ATT collaborations
- Member of the international Clinical Trials Transformation Initiative (CTTI) and Sensible Guidelines groups

<http://www.ndph.ox.ac.uk/team/christina-reith>