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 HP2-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](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](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](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](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](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](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](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](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](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](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](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](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](http://www.ndph.ox.ac.uk/team/christina-reith)