

Efficacy and Mechanism Evaluation Programme

Public minutes of the Fifth Meeting

Date	Tuesday 17 th November & Wednesday 18 th November 2009
Place	Hallam Cavendish Conference Centre, 44 Hallam Street London W1W 6JJ
Present Members	Professor Rajesh Thakker (Chair) Professor Tom Walley (Programme Director) Professor Lucinda Billingham Professor Martin Brown Professor David Cameron (17 th Nov) Professor Rona Campbell Professor Andrew Carr Professor Graham Dunn Professor Richard Eastell Professor Kim Fox Professor Jayne Franklyn Dr Simon Gates Professor Paul Little Professor Jane Norman Professor Munir Pirmohamed Professor Judith Stephenson Professor John Williams Professor Bryan Williams Professor Moira Whyte
NCCEME Secretariat	Ian Cree (Director, NETSCC, EME) Dani Preedy (Senior Programme Manager) Tracey Waterhouse (Administrator) Fabia Ward (Programme Manager) Lisa Douet (Research Fellow) (18 th November)
Observers	Dr Joanna Winks (MRC) (17 th November) Sara Arnott (NETSCC, SDO) (17 th November)
Apologies	Professor David Cameron (18 th November) Professor Diana Elbourne Professor Ian Goodyer Professor Ian Harvey Professor Pierre Guillou

DISCUSSION OF FULL PROPOSALS – Tuesday 17th November 2009

Professor Thakker Chaired

09/20/01 Alexander Technique and Supervised Physiotherapy Exercises in back pain (ASPEN)

Professors Little, Campbell and Cree left the room. Professors Eastell, Carr and Dr. Gates presented the proposal.

The proposal was not recommended for funding. 09/20/01: Little

08/246/03 Investigation Of Reduction In Dialysate Temperature On Systemic Haemodynamics And Regional Left Ventricular Dysfunction In Paediatric Haemodialysis

Professors B. Williams, Campbell and J Williams presented the proposal.

The proposal was not recommended for funding. 08/246/03: Rees

09/20/16 Efficacy and mode of action of mesalazine in the treatment of diarrhoea predominant irritable bowel syndrome(IBS-D)

Professors J. Williams and Billingham presented the proposal.

The Board recommended the proposal for funding subject to changes. 09/20/16: Spiller

09/800/02 Improving the management of blood pressure in acute stroke: the Efficacy of Nitric Oxide in Stroke (ENOS) trial

Professors Brown, B. Williams and Dr. Gates presented the proposal.

The Board recommended that the application for extension should be supported subject to the feedback provided being satisfactorily addressed. 09/800/02: Bath

08/99/08 Hydroxymethylglutaryl-CoA reductase inhibition with simvastatin in Acute lung injury to Reduce Pulmonary dysfunction (HARP)

Professors Whyte, Pirmohamed and Dunn presented the proposal.

The Board recommended the proposal for funding subject to changes. 08/99/08: McAuley

DISCUSSION OF PRELIMINARY APPLICATIONS – Tuesday 17th November 2009

09/100/01 Improving patient outcomes in systemic vasculitis using a novel biomarker

Professors Dunn, Fox and Cameron presented the proposal.

The Board rejected 09/100/01: Smith

08/99/24 A novel anti-Wilms-Tumour-1 (WT1) vaccination strategy in haematological malignancy using DNA fusion vaccines delivered with electroporation

Professors Little and Cree left the room. Professors Billingham and Cameron presented the proposal.

The Board shortlisted 08/99/24: Ottensmeier

09/100/04 A randomised controlled trial to study the treatment of Rapid Eye Movement (REM) Sleep Behaviour Disorder

Professors Brown, Pirmohamed and Campbell presented the proposal.

The Board rejected 09/100/04: Anderson

09/100/24 A Randomised, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy of Oral Azithromycin as a Supplement to Standard Care for Patients with Acute Exacerbations of Asthma

Professor Cree left the room. Professors Whyte, Little and Eastell presented the proposal.

The Board rejected 09/100/24: Johnston

09/100/23 The Benefit of Minocycline on Negative Symptoms in Schizophrenia: Extent and Mechanisms

Professor Dunn left the room. Professors Little and Eastell presented the proposal.

The Board shortlisted 09/100/23: Deakin

09/100/25 A randomised controlled trial of eicosapentaenoic acid (EPA) and/or aspirin for colorectal adenoma (or polyp) prevention during colonoscopic surveillance in the NHS Bowel Cancer Screening Programme

Professor Cameron left the room. Professors Billingham, Carr and J. Williams presented the proposal.

The Board shortlisted 09/100/25: Hull

09/100/08 Ubiquinone - Cardiac Arrest Trial: A multicentre study of efficacy and mechanisms of ubiquinone for neuroprotection administered in addition to therapeutic hypothermia after cardiac arrest
<i>Professors Thakker, B. Williams, Carr and Dr Gates left the room. Professor Whyte chaired the proposal. Professors Brown, Fox and Billingham presented the proposal.</i>
The Board rejected 09/100/08: Damian
09/100/48 Do statins improve immune response to influenza vaccine in the elderly? A randomised double-blind placebo controlled trial
<i>Professors Billingham and Franklyn left the room. Professors Pirmohamed, Stephenson and Dr Gates presented the proposal.</i>
The Board rejected 09/100/48: Nguyen-Van-Tam
09/100/35 A double blind randomized controlled trial investigating the effect of an Angiotensin Receptor Blocker on the prevention of the onset of microalbuminuria and renal failure in patients with Sickle Cell Disease who have evidence of early renal damage
<i>Professors Cameron, Franklyn and Stephenson presented the proposal.</i>
The Board rejected 09/100/35: Howard
09/100/30 Randomised Controlled Trial to assess the efficacy of prothrombin complex concentrate (PCC) as a treatment of bleeding after cardiac surgery compared with fresh frozen plasma (FFP)
<i>Professors B. Williams, Cameron and J. Williams presented the proposal.</i>
The Board rejected 09/100/30: Klein
09/100/26 Targeting Muscle Post-Exercise Metabolic Recovery as a Novel Treatment Approach for Fatigue in Primary Biliary Cirrhosis
<i>Professors J. Williams, Eastell and Norman presented the proposal.</i>
The Board rejected 09/100/26: Jones
09/100/27 An investigation of a novel endoscopic technique (Endobarrier) for the treatment of obesity
<i>Professors Billingham and Franklyn left the room. Professors Norman and Little presented the proposal.</i>
The Board rejected 09/100/27: Iqbal

DISCUSSION OF PRELIMINARY APPLICATIONS – Wednesday 18th November 2009
Professor Thakker Chaired
09/100/42 Increasing physical exercise to preserve beta cell function in patients with latent autoimmune diabetes of adults (LADA): a pilot study
<i>Professors Billingham and Franklyn left the room. Professors Eastell and Stephenson presented the proposal.</i>
The Board rejected 09/100/42: Narendran
09/100/16 Quadrupling the dose of inhaled corticosteroids to prevent asthma exacerbations: a multi centre, randomized, double blind, parallel group, placebo controlled clinical trial
<i>Professors Whyte, Little and Billingham presented the proposal.</i>
The Board rejected 09/100/16: Harrison
09/100/28 Evaluation of mechanisms of action and efficacy of deep brain stimulation in UK patients with severe treatment resistant depression
<i>Professors Carr, Campbell, Cree and Thakker left the room. Professor Whyte chaired the discussion. Professor Billingham presented the proposal.</i>
The Board rejected 09/100/28: Malizia
09/100/41 Improving Social Recovery in Psychosis (ISRIP): A Randomised Controlled Trial of Cognitive Behaviour Therapy to improve social recovery in psychosis
<i>Professor Dunn left the room. Professors Campbell, Carr and Billingham presented the proposal.</i>
The Board rejected 09/100/41: Fowler

09/100/50 Levodopa as an add-on treatment for enhancing cognitive performance in schizophrenia: A randomised controlled clinical trial
<i>Professor Billingham left the meeting. Professors Brown and Stephenson left the room. Professors Carr and Eastell presented the proposal.</i>
The Board shortlisted 09/100/50: Kapur
09/100/51 The modulation of cardiovascular and diabetes risk factors by long chain n-3 polyunsaturated fatty acid supplementation in obese subjects
<i>Professor Thakker left the room. Professor Whyte chaired the discussion. Professors Franklyn, J. Williams and Dunn presented the proposal.</i>
The Board rejected 09/100/51: McGinty
09/100/52 Evaluation of alpha blockers for the treatment of persistent allergic rhinitis.
<i>Professors Campbell, Whyte and B. Williams presented the proposal.</i>
The Board rejected 09/100/52: Lipworth
09/100/54 Graded Rehabilitation for Adolescents with Chronic Fatigue Syndrome: An Evaluation (GRACE).
<i>Professors Dunn and Carr presented the proposal.</i>
The Board rejected 09/100/54: Chalder
09/100/02 Contrast ultrasound to image intraplaque neovascularisation: risk stratifying patients with carotid atherosclerosis.
<i>Professor Fox left the room. Professors Stephenson, Brown and B. Williams presented the proposal.</i>
The Board rejected 09/100/02: Leen
09/100/05 Effect of Remote Ischaemic PreConditioning on clinical outcomes in patients Under going high-risk Coronary Artery Bypass Graft surgery (RIPC-CABG study): A multi centre randomised controlled clinical study
<i>Professors Fox, Brown and Stephenson left the room. Professors B. Williams, Franklyn and Dr Gates presented the proposal.</i>
The Board shortlisted 09/100/05: Hausenloy
09/100/31 TARGIT-B: An international RCT to compare targeted intra-operative radiotherapy boost with conventional external beam radiotherapy boost after conservative breast surgery for women with early stage breast cancer and a high risk of local recurrence
<i>Professor Stephenson left the room. Professor Norman presented the proposal.</i>
The Board shortlisted 09/100/31: Vaidya
09/100/39 Does glutamine supplementation reduce exacerbations of Chronic Obstructive Pulmonary Disease? A randomised controlled trial
<i>Dr Gates, Professors Franklyn and Whyte presented the proposal.</i>
The Board rejected 09/100/39: Fogarty
09/100/03 Developing Biomarker Use in Non-ST elevation myocardial infarction (NSTEMI) for risk stratification and therapy with Spironolactone
<i>Professor B. Williams left the room. Professor Fox and Dr Gates presented the proposal.</i>
The Board rejected 09/100/03: Loke Ng
09/100/17 Enhancing Vaccine Immunogenicity in Distressed Older Patients: An Investigation into Effectiveness and Bio-psychosocial Mechanisms
<i>Professor Campbell left the room. Professors Stephenson, Whyte and Little presented the Proposal.</i>
The Board rejected 09/100/17: Vedhara
09/100/36 A randomised controlled trial of rituximab to minimise immunosuppression in renal transplant patients
<i>Professors Norman, Campbell and Pirmohamed presented the proposal.</i>
The Board rejected 09/100/36: Mamode
09/100/06 Exercise therapy following surgery for varicose veins: impact on microvascular function and risk of venous ulceration
<i>Professors Campbell, Fox and Little presented the proposal.</i>
The Board rejected 09/100/06: Saxton

09/100/09 Pilot randomized trial of copper chelation with TETA (tri-ethylene-tetramine, or trientine) versus placebo to reduce tissue injury in type 2 diabetes (left ventricular mass, arterial stiffness and (micro)albuminuria), and to assess the drug's safety

Professor Dunn left the room. Professors Franklyn, Carr and Fox presented the proposal.

The Board rejected 09/100/09: Cruickshank

09/100/47 A randomised placebo-controlled trial of Statin Therapy in COPD (STATIC Trial)

Professors Pirmohamed, Norman and Walley left the room. Professors Little, Stephenson and Fox presented the proposal.

The Board shortlisted 09/100/47: MacNee

09/100/10 Efficacy and mechanism of thyroxine treatment on pregnancy and neonatal outcomes in women with thyroid antibodies: A randomised, placebo-controlled, double-blind, multi-centre trial [The TABLET (Thyroid AntiBodies and LEvoThyroxine) Trial]

Professors Pirmohamed, Franklyn, Walley and Dr Gates left the room. Professors Norman, Campbell and Dunn presented the proposal.

The Board shortlisted 09/100/10: Coomarasamy

09/100/49 Antiviral therapy to slow progression in Alzheimer's disease: a feasibility study

Professor Dunn left the room. Professors Brown and Pirmohamed presented the proposal.

The Board rejected 09/100/49: Purandare

09/20/18 Barrett's Esophagus Ablation Trial (BEAT)

Professor Cree left the room. Professors Carr, Dunn and J. Williams presented this proposal.

The Board shortlisted 09/20/18: Jankowski

**09/100/15 A clinical trial of C-peptide to treat nephropathy in type 1 diabetes mellitus
The C-Pep-D-Neph Trial**

Professors Carr and Thakker left the room. Professor Whyte chaired the discussion. Professors Eastell and Pirmohamed presented the proposal.

The Board shortlisted 09/100/15: Brunskill

09/100/18 Deep Electrical Modulation of Neuropathic PAIN Trial (D.E.M.O.N. PAIN Trial)

Professors Carr and Thakker left the room. Professor Whyte chaired the discussion. Professors B. Williams, Brown and Dr Gates presented the proposal.

The Board rejected 09/100/18: Green

09/100/44 Enhanced recovery after hip fracture with rapid repletion of vitamin D: double blind randomized clinical trial of efficacy and safety [RED- HIP: Rapid repletion of vitamin D after HIP fracture]

Professor Fox left the meeting. Professors Carr, Little, Thakker and Dr Gates left the room. Professor Whyte chaired the discussion. Professors Eastell, Dunn and Franklyn presented the proposal.

The Board shortlisted 09/100/44: Javaid

09/100/40 A randomised, double blind, placebo-controlled study of Everolimus in the treatment of neurocognitive problems in tuberous sclerosis

Professor Thakker left the room. Professor Whyte chaired the discussion. Professors Brown and Norman presented the proposal.

The Board shortlisted 09/100/40: Sampson

SUMMARY

- 12 preliminary applications were shortlisted to submit a full proposal for consideration at the February 2010 EME Board
- 2 full proposals were funded, subject to changes in response to Board feedback and further clarification on specific issues raised by the Board
- The board recommended that the application for extension for 1 full proposal should be supported subject to the feedback provided being satisfactorily addressed
- 2 full proposals were not recommended for funding