

Efficacy and Mechanism Evaluation Programme

Public minutes of the Fourth Meeting

Date	Tuesday 30 th June & Wednesday 1 st July 2009
Place	Hallam Cavendish Conference Centre, 44 Hallam Street London W1W 6JJ
Present Members	Professor Rajesh Thakker (Chair) Professor Tom Walley (Programme Director) Dr Lucinda Billingham Professor David Cameron Professor Rona Campbell Professor Diana Elbourne Professor Kim Fox Professor Jayne Franklyn Dr Simon Gates (1 st July) Professor Ian Goodyer Professor Ian Harvey Professor David Jones Professor Paul Little Professor Jane Norman Professor Moira Whyte Professor John Williams Professor Bryan Williams
NCCEME Secretariat	Melissa Caals (Administrator) (1 st July) Ian Cree (Director) Lisa Douet (Research Fellow) (1 st July) Dani Preedy (Senior Programme Manager) Jane Robertson (Assistant Director) (1 st July) Jane Sinclair (Programme Manager) (30 th June) Fabia Ward (Assistant Programme Manager) (1 st July) Tracey Waterhouse (Administrator) (30 th June)
Observers	Dr Morven Roberts (MRC)
Apologies	Professor Martin Brown Professor Graham Dunn Professor Richard Eastell Professor Munir Pirmohamed Professor Judith Stephenson

DISCUSSION OF FULL PROPOSALS – Tuesday 30th June 2009

Professor Thakker Chaired

08/52/01 ROLARR: Robotic versus Laparoscopic Resection for Rectal Cancer

Professor Guillou left the room. Professors Carr, J. Williams and Campbell presented the proposal.

The Board recommended the proposal for funding subject to changes. 08/52/01: Jayne

08/43/38 A multi-centre randomised controlled trial to study the efficacy of bicarbonate supplementation on renal graft function and polypeptide proximal tubular catabolism in patients with transplanted kidneys. BICARBGRAFT

Professor Walley left the room. Professor Franklyn, Dr Billingham and Professor B. Williams presented the proposal.

The proposal was not recommended for funding. 08/43/38: Rustom

08/43/55 Examination of the Role of Inflammation in Herpes Simplex Virus Encephalitis through a Randomised Double-Blind Placebo Controlled Trial of Adjunct Corticosteroids, a UK arm of a European Phase III study

Professor J Williams left the meeting. Professor Walley left the room. Professor B. Williams and Dr Billingham presented the proposal.

The proposal was not recommended for funding. 08/43/55: Solomon

08/99/03 Effect of Cyclosporine-A on Clinical Outcomes in Patients Presenting with an Acute Myocardial Infarction: The Cyclosporine-A in Acute Myocardial Infarction (CAMI) trial.

Professor Norman left the room. Professor Fox presented the proposal.

The proposal was not recommended for funding. 08/99/03: Hausenloy

08/99/04 Amino acid regimen and intravenous lipid composition in preterm parenteral nutrition: a randomised double blind controlled trial.

Professor Fox left the meeting. Professors Elbourne and J. Williams presented the proposal.

The Board recommended the proposal for funding subject to changes. 08/99/04: Uthaya

08/99/18 Study of Tolerance to Oral Peanut

Professor Goodyer left the room. Professors Whyte and Harvey presented the proposal.

The Board recommended the proposal for funding subject to changes. 08/99/18: Ewan

08/99/19 The role of gastric bypass surgery in the management of people with poorly controlled type 2 diabetes at high risk of cardiovascular disease

Professor Cameron joined the meeting. Professors Franklyn, Guillou and Elbourne presented the proposal.

The Board did not recommend the proposal for funding. 08/99/19: Johnston

08/99/22 Adjuvant systemic therapy to improve the survival of patients with Merkel Cell Carcinoma (MCC): A randomised phase II trial of chemotherapy and translational study investigating the role of Merkel cell polyomavirus in patients with MCC

Professor Franklyn and Dr Billingham left the room. Professors Harvey, Guillou and Cameron presented the proposal.

The Board did not recommend the proposal for funding. 08/99/22: Steven

08/99/27 A randomised controlled trial to compare the efficacy of laparoscopic gastric banding, roux-en-Y gastric bypass or intensive medical treatment for recent-onset type 2 diabetes and to determine the mechanisms responsible for diabetes

Professor Fox rejoined the meeting. Professor Walley left the room. Professors Guillou, Franklyn and Elbourne presented the proposal.

The Board did not recommend the proposal for funding. 08/99/27: Pinkney

08/99/28 Clinical efficacy of functional strength training for upper limb motor recovery early after stroke: neural correlates and prognostic indicators

Professors Thakker, Harvey and Goodyer left the room. Professor Whyte chaired. Professors Norman and Carr presented the proposal

The Board did not recommend the proposal for funding. 08/99/28: Pomeroy

08/99/29 Vitamin D (ergocalciferol) supplementation in children with early chronic kidney disease – a multicentre, randomised, double-blinded, placebo-controlled study.

Professor Norman and Dr Billingham presented the proposal

The Board did not recommend the proposal for funding. 08/99/29: Rees

08/246/01 Cognitive Behaviour Therapy for aggressive men with antisocial personality

disorder: MASCOT 2. *MASCOT: Men with Antisocial personality disorder treated with Cognitive Therapy
<i>Professors Goodyer and Harvey presented the proposal.</i>
The Board did not recommend the proposal for funding. 08/246/01: Davidson
08/246/02 Peroxisome Proliferator-Activated Receptor-gamma: a novel therapeutic target for asthma?
<i>Professors Harvey, Carr and Franklyn left the room. Professors Little and Whyte presented the proposal</i>
The Board recommended the proposal for funding subject to changes. 08/246/02: Knox
08/246/16 Investigation of the efficacy of pregnenolone in the treatment of rheumatoid arthritis (RA) patients and characterisation of the underlying biological mechanisms
<i>Professor Guillou left the room. Professors Elbourne, Whyte and Carr presented the proposal.</i>
The Board did not recommend the proposal for funding. 08/246/16: Emery

DISCUSSION OF FULL PROPOSALS – Wednesday 1st July 2009

Professor Thakker Chaired
08/99/24 A novel anti-Wilms-Tumour-1 (WT1) vaccination strategy in haematological malignancies using DNA fusion vaccines delivered with electroporation
<i>Professor Little left the room. Professor Cameron and Dr Billingham presented the proposal.</i>
The Board did not recommend the proposal for funding. 08/99/24: Ottensmeier
08/246/05 A randomised controlled trial of a pedometer-based intervention combined with primary care physical activity consultations, with or without accelerometer feedback, in patients aged 60-74 years.
<i>Professor Goodyer left the room. Professors Campbell and Little presented the proposal.</i>
The Board did not recommend the proposal for funding. 08/246/05: Harris
08/246/09 Does metformin reduce excess birth weight in offspring of obese pregnant women? A randomised controlled trial of efficacy, exploration of mechanisms and evaluation of other pregnancy complications.
<i>Professors Norman, Cameron and Goodyer left the room. Professors Campbell and Elbourne presented the proposal.</i>
The Board recommended the proposal for funding subject to changes. 08/246/09: Norman
08/246/24 Multi-centre Randomised Controlled Trial of the Optimisation of Cardiovascular Health with Growth Hormone Therapy in the Transition Phase
<i>Professors Norman and Goodyer left the room. Professors Fox, Franklyn and B. Williams presented the proposal.</i>
The Board did not recommend the proposal for funding. 08/246/24: Kelnar
DISCUSSION OF PRELIMINARY APPLICATIONS – Wednesday 1st July 2009
09/20/01 Alexander Technique and Supervised Physiotherapy Exercises in back pain (ASPEN)
<i>Professors Campbell, Little, and Cree left the room. Professors Carr, Gates and Norman presented the proposal.</i>
The Board shortlisted. 09/20/01: Little
09/20/02 New versus routine cancer biomarkers: the lead interval in high risk epithelial cancers after surgery
<i>Professors Guillou and Cameron presented the proposal.</i>
The Board rejected 09/20/02: Stebbing
09/20/03 DIRECT: Detection of improved recovery after childhood traumatic brain injury
<i>Professor Billingham left the room. Professors Little and Gates presented the proposal.</i>
The Board rejected 09/20/03: Forsyth
09/20/04 Does Group Bimanual Training (GBT) improve arm function in children with cerebral palsy who have hemiparesis?
<i>Professors Cameron and Guillou left the room. Professors Goodyer and Elbourne presented the proposal.</i>
The Board rejected 09/20/04: Bhakta

09/20/05 A randomised controlled trial assessing the anti-inflammatory effects of rosuvastatin versus placebo in adults with cystic fibrosis

Professors Franklyn and Billingham left the room. Professors B. Williams and Whyte presented the proposal.

The Board rejected 09/20/05: Nash

09/20/06 Randomised, placebo controlled, efficacy and mechanism study of omega-3 polyunsaturated fatty acid supplementation to treat mild cognitive impairment or mild dementia

Professors Campbell and Goodyer presented the proposal.

The Board rejected 09/20/06: Stewart

09/20/08 Pilot Study to Evaluate Treatment of Premature Ovarian Failure with Hormone Replacement Therapy or the Combined Oral Contraceptive Pill, and Observation of Women Selecting No Treatment

Professor Norman left the room. Professors Franklyn and Campbell presented the proposal.

The Board rejected 09/20/08: Rymer

09/20/10 Phase II multi-centre double-blind randomised placebo-controlled trial of sorafenib for treatment of vestibular schwannomas in NF2 patients: a paradigm for merlin's tumours

Professor Walley left the meeting. Professor Thakker left the room. Professor Whyte chaired. Professors Billingham, Cameron and Fox presented the proposal.

The Board shortlisted 09/20/10: Hanemann

09/20/11 A randomised placebo controlled trial of aldosterone antagonism in hypertrophic cardiomyopathy

Professor Fox left the room. Professor B. Williams presented the proposal.

The Board rejected 09/20/11: Elliott

09/20/12 An RCT of the treatment of impaired mother-infant interactions in the context of infant cleft lip

Professors Thakker, Carr and Goodyer left the room. Professor Whyte chaired. Professor Harvey presented the proposal.

The Board rejected 09/20/12: Murray

09/20/13 An observational study to test the clinical efficacy of image guidance in partial breast radiotherapy

Professors Cameron, Guillou and Billingham presented the proposal.

The Board rejected 08/246/13: Harris

09/20/14 A Phase II randomized control trial comparing G-CSF followed by leukapheresis and infusion of expanded autologous bone marrow derived adult haematopoietic stem cell progenitors with best medical treatment in patients with liver insufficiency.

Professors J. Williams, Little and Harvey presented the proposal.

The Board rejected 09/20/14: Khan

09/20/15 Personalised therapy for smoking cessation: a randomised controlled clinical trial

Professors Campbell and Little presented the proposal.

The Board rejected 09/20/15: Walton

09/20/16 Efficacy of mesalazine the treatment of patients with the Irritable Bowel Syndrome

Professors, Guillou, Norman and J. Williams presented the proposal.

The Board shortlisted 09/20/16: Spiller

09/20/17 A randomised controlled trial to assess catheter Ablation versus Rate-Control in the management of persistent atrial fibrillation in patients with chronic Heart Failure (ARC-HF)

Professor Fox left the room. Professors B. Williams, Harvey and Whyte presented the proposal

The Board rejected 09/20/17: Wong

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

Professors B. Williams and Cree left the room. Professors J. Williams and Carr presented the proposal.

The Board rejected 09/20/18: Jankowski

SUMMARY

- *3 preliminary applications were shortlisted to submit a full proposal for consideration at the November 2009 EME Board*
- *5 full proposals were funded, subject to changes in response to Board feedback and further clarification on specific issues raised by the Board*
- *1 full proposal was invited to submit a revised preliminary application*
- *12 full proposals were not recommended for funding*