

Efficacy and Mechanism Evaluation Programme

Public Minutes of the Sixth Meeting

Date	Tuesday 23 rd February & Wednesday 24 th February 2010
Place	Grange Holborn Hotel, 50-60 Southampton Row, London WC1B 4AR
Present Members	<p>Professor Rajesh Thakker (Chair) Professor Tom Walley (Programme Director) Professor Andrew Bradley Professor David Cameron Professor Rona Campbell Professor Andrew Carr Professor Graham Dunn Professor Richard Eastell Professor Diana Elbourne Professor Kim Fox Professor Jayne Franklyn Dr Simon Gates Professor Ian Goodyer Professor Pierre Guillou Professor Ian Harvey Professor Paul Little Professor Jane Norman Professor Munir Pirmohamed Professor Judith Stephenson Professor Jonathan Weber Professor John Williams (23rd only) Professor Bryan Williams Professor Moira Whyte (Deputy Chair)</p>
NCCEME Secretariat	<p>Professor Ian Cree (Director) Dr Lisa Douet (Research Fellow) (24th only) Dr Dani Preedy (Acting Assistant Director) James Preston (Programme Manager) (23rd only) Vicky Taylor (Senior Programme Manager) Fabia Ward (Programme Manager) (23rd only) Tracey Waterhouse (Administrator)</p>
Observers	<p>Sarah Buckland (Involve) (23rd only) Dr Ginny Munro (Senior Research Fellow, NETSCC) (24th only) Robin Ladkin (Ashridge) (24th only) Helen Millar (MRC Public Panel) Dr Morven Roberts (MRC) Professor Jeremy Pearson (British Heart Foundation) (item 09/100/05 only)</p>
Apologies	<p>Professor Lucinda Billingham Professor Martin Brown Professor Rona Campbell (afternoon of 23rd) Professor Andy Carr (afternoon of 24th) Professor Jayne Franklyn (afternoon of 24th) Professor Ian Goodyer (afternoon of 24th) Professor Paul Little (afternoon of 24th) Professor Judith Stephenson (afternoon of 24th) Professor John Williams (24th)</p>

DISCUSSION OF FULL PROPOSALS – Tuesday 23rd February 2010

Professor Thakker Chaired

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

Professors Guillou, Harvey and Cameron presented the proposal.

The Board invited the applicants to resubmit a full proposal in response to feedback provided. 09/100/31: Vaidya

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

Professors Cameron and Fox presented the proposal.

The proposal was not recommended for funding. 09/20/10: Hanemann

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 Trial]

Professors Norman, Campbell and Dunn presented the proposal.

The Board recommended the proposal for funding subject to changes. 09/100/10: Coomarasamy

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

Professor Whyte chaired the discussion. Professors Harvey, Pirmohamed and Eastell presented the proposal.

The proposal was not recommended for funding. 09/100/15 : Brunskill

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

Professors Carr, Dunn and J. Williams presented the proposal.

The proposal was not recommended for funding. 09/20/18: Jankowski

09/100/05 Effect of Remote Ischaemic preConditioning on clinical outcomes in high-risk patients undergoing Coronary Artery Bypass Graft surgery (RIC-CABG study): A multi-centre double-blind randomised controlled clinical trial

Dr Gates and Professors Franklyn and B. Williams presented the proposal.

The Board recommended the proposal for funding subject to changes. 09/100/05: Hausenloy

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 Whyte chaired the discussion. Professors Eastell, Dunn and Franklyn presented the proposal.

The proposal was not recommended for funding. 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 Whyte chaired the discussion. Professors Weber, Norman and Brown presented the proposal.

The proposal was not recommended for funding. 09/100/40: Sampson

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

Professors Little, Whyte and Harvey presented the proposal.

The Board recommended the proposal for funding subject to changes. 09/100/23: Deakin

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

Professors Cameron and Bradley presented the proposal.

The Board recommended the proposal for funding subject to changes. 08/99/24: Ottensmeier

09/100/50 Levodopa as an add-on treatment for enhancing cognitive performance in schizophrenia: A randomised controlled clinical trial

Professors Goodyer, Carr and Elbourne presented the proposal.

The proposal was not recommended for funding. 09/100/50: Kapur

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: The seAFood polyp prevention trial
<i>Professors J. Williams and Carr presented the proposal.</i>
The Board recommended the proposal for funding subject to changes. 09/100/25: Hull
09/100/47 A randomised placebo-controlled trial of STAtin Therapy in COPD (STATIC Trial)
<i>Professors Little, Stephenson and Fox presented the proposal.</i>
The proposal was not recommended for funding. 09/100/47: MacNee
DISCUSSION OF PRELIMINARY APPLICATIONS – Tuesday 23rd February 2010
09/150/09 Sucrose in combination with local anaesthesia in infants undergoing Achilles tendon lengthening: Double-blind randomized controlled clinical trial
<i>Professor Carr, Dr Gates and Professor Bradley presented the proposal.</i>
The Board rejected 09/150/09: Roposch
09/150/03 Does vitamin D supplementation in pregnancy reduce risk of asthma, wheezing illness, atopy, and health care use in offspring at three years of age? The VIP (Vitamin In Pregnancy) Asthma and Allergy Prevention Trial
<i>Professors Norman, Whyte and Dr Gates presented the proposal.</i>
The Board rejected 09/150/03: Griffiths
09/150/26 Effect of Sodium Nitrite Injection on Infarct Size in Patients with Myocardial Infarction undergoing Primary Angioplasty
<i>Professors B. Williams, Elbourne and Whyte presented the proposal.</i>
The Board shortlisted 09/150/26: Webb
09/150/17 Assessing Attenuation of Accelerated Aortic Ageing with Angiotensin Antagonism - The STRAIGHT A's study
<i>Professors Norman and Fox presented the proposal.</i>
The Board rejected 09/150/17: Williams
09/150/08 Combined local immunotherapy and radiotherapy for melanoma metastases (CLIRM)
<i>Professors Bradley, Cameron and Pirmohamed presented the proposal.</i>
The Board shortlisted 09/150/08: Fernihough

DISCUSSION OF PRELIMINARY APPLICATIONS – Wednesday 24th February 2010
<i>Professor Thakker Chaired</i>
09/150/22 Randomized Controlled Trial of Posterior Hypothalamic Deep Brain Stimulation (DBS) in Cluster Headache Intractable to Medical Treatments and Occipital Nerve Stimulation
<i>Professors Campbell, Goodyer and Little presented the proposal.</i>
The Board rejected 09/150/22: Matharu
09/150/13 Phase II Study of Guided Self Help for Post Traumatic Stress Disorder
<i>Professors Goodyer and Campbell presented the proposal.</i>
The Board rejected 09/150/13: Bisson
09/150/28 Randomized Pilot Study Comparing Intracoronary Administration of Adenosine versus Sodium Nitroprusside Delivered either via Guide-catheter or Micro-catheter for Prevention of Microvascular Obstruction During Primary Percutaneous Coronary Intervention
<i>Professors Fox, Carr and Stephenson presented the proposal.</i>
The Board shortlisted 09/150/28: Gershlick
09/150/18 EDAHMS: A 3-arm phase III randomised controlled trial comparing adjuvant Electromotive Drug Administration of Mitomycin-C (EMDA-MMC) plus sequential bacillus Calmette-Guérin (BCG) and Hyperthermia plus Mitomycin-C (HT-MMC) to Standard maintenance BCG following transurethral resection in patients with BCG-naïve high risk non-muscle invasive bladder cancer (NMIBC)
<i>Professors Weber and Guillou presented the proposal.</i>
The Board shortlisted 09/150/18: Griffiths

09/150/01 Targeting the dynamic component of portal hypertension: a randomized, placebo-controlled, parallel-assignment pilot study of sulfasalazine or carvedilol in alcoholic liver disease induced portal hypertension (SCALP)

Professors Pirmohamed and Dunn presented the proposal.

The Board rejected 09/150/01: Fallowfield

09/150/02 Optimal Selection of Chemotherapy And Response: A phase III randomised comparison of standard chemotherapy vs. chemotherapy selection directed by molecular phenotype in women with operable breast cancer suitable for neoadjuvant chemotherapy; 'OSCAR'

Professors Cameron, Campbell and Harvey presented the proposal.

The Board rejected 09/150/02: Rea

09/150/12 Dialectical Behaviour Therapy for Treatment-Resistant Depression – A Randomised Controlled Trial

Professor Whyte chaired the discussion. Professors Dunn, Stephenson and Goodyer presented the proposal.

The Board shortlisted 09/150/12: Lynch

09/150/15 A prospective, multi-centre, randomised trial comparing primary catheter ablation, standard medical therapy and anti-arrhythmia drug therapy in patients with ventricular tachycardia

Professor Whyte chaired the discussion. Professors Pirmohamed, Elbourne and B. Williams presented the proposal.

The Board rejected 09/150/15: Sporton

09/150/07 Evaluation of new technologies for testing for anal intraepithelial neoplasia in high-risk populations in the UK

Professor Whyte chaired the discussion. Professors Harvey, Guillou and Weber presented the proposal.

The Board rejected 09/150/07: Patnick

09/150/29 Effect of maternal vitamin D supplementation during pregnancy on infant and child bone health ('Babybones')

Professor Whyte chaired the discussion. Professors Eastell, Franklyn and Dr Gates presented the proposal.

The Board rejected 09/150/29: Poston

09/150/21 Tranexamic Acid in Paediatric Heart Surgery (TRAPS). A randomised controlled trial of the efficacy of tranexamic acid to reduce bleeding during paediatric heart surgery, to examine the optimal dosing and genetic determinants of response

Professors Guillou, Elbourne and Brown presented the proposal.

The Board shortlisted 09/150/21: Arnold

09/150/31 Assessment of diaphragm function in infants and children

Professors Whyte and Elbourne presented the proposal.

The Board rejected 09/150/31: Rafferty

09/150/24 Exploring the glucose lowering potential of the sunshine vitamin – a 12 month randomised controlled trial of Vitamin D replacement in insulin resistant British south Asians

Professors Franklyn, Fox and Weber presented the proposal.

The Board rejected 09/150/24: Davies

09/150/20 Progression of Structure in Osteoarthritis with Sulfasalazine Study (PSOAS): an Evaluation of Efficacy and Mechanism

Professors Stephenson, Eastell and Dr Gates presented the proposal.

The Board shortlisted 09/150/20: Birrell

09/150/32 A randomised double-blinded placebo-controlled trial using Cardiovascular Magnetic Resonance scanning to assess remodelling and regression of fibrosis in Hypertrophic Cardiomyopathy with Eplerenone

Professor B. Williams presented the proposal.

The Board shortlisted 09/150/32: Prasad

09/150/19 Antioxidant intervention in primary small vessel vasculitis (PSV) targeting cardiovascular and immune pathology

Professors Pirmohamed, B. Williams and Bradley presented the proposal.

The Board rejected 09/150/19: Harper

09/150/14 Multicentre double blind sham operated randomised controlled trial of endobiliary radiofrequency for maintenance of metal stent patency in unresectable pancreatobiliary malignancy

Professors Guillou, Bradley and B. Williams presented the proposal.

The Board rejected 09/150/14: Habib

09/150/16 Evaluation of Image Guided Radiotherapy (IGRT) for more accurate Partial Breast Intensity-Modulated Radiotherapy: comparison with standard imaging technique

Professor Cameron presented the proposal.

The Board shortlisted 09/150/16: Harris

SUMMARY

- *9 preliminary applications were shortlisted to submit a full proposal for consideration at the June 2010 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 resubmit, in response to Board feedback.*
- *7 full proposals were not recommended for funding.*