

Efficacy and Mechanism Evaluation Programme

Public Minutes of the Seventh Meeting

Date	Thursday 24 th June & Friday 25 th June 2010
Place	Grange Holborn Hotel, 50-60 Southampton Row, London WC1B 4AR
Present Members	Professor Rajesh Thakker (Chair) Professor Tom Walley (Programme Director) Professor Cindy Billingham Professor Andrew Bradley Professor Martin Brown Professor David Cameron Professor Andrew Carr Professor Graham Dunn Professor Richard Eastell (24 th Only) Professor Jayne Franklyn Dr Simon Gates Professor Ian Goodyer Professor Ian Harvey Professor Paul Little Professor Jane Norman Professor Munir Pirmohamed Professor Jonathan Weber Professor John Williams Professor Bryan Williams Professor Moira Whyte (Deputy Chair)
NCCEME Secretariat	Professor Ian Cree (Director) Dr Lisa Douet (Research Fellow) (25 th only) Dr Dani Preedy (Acting Assistant Director) Jane Sinclair (Programme Manager) Fabia Ward (Programme Manager) (24 th only) Tracey Waterhouse (Administrator)
Observers	Alison Ford (PPI Manager, NETSCC) (25 th only) Dr Eleanor Guegan (Senior Research Fellow) (24 th only) Dr Declan Mulkeen (MRC) (25 th Only) Dr Morven Roberts (MRC)
Apologies	Professor Rona Campbell Professor Kim Fox Professor Richard Eastell (25 th Only)

DISCUSSION OF FULL PROPOSALS – Thursday 24th June 2010

Professor Thakker Chaired

09/150/32 A Randomised Double-Blind Placebo-Controlled Trial of Eplerenone to Halt or Induce Regression of Fibrosis in Hypertrophic Cardiomyopathy

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

The proposal was not recommended for funding. 09/150/32: Prasad

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

Professors Dunn, Norman and Goodyer presented the proposal.

The Board invited the applicants to resubmit a full proposal in response to feedback provided. 09/150/12: Lynch

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

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

The proposal was not recommended for funding. 09/150/20: Birrell

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

Professors Cameron, Harvey and Little presented the proposal.

The Board recommended the proposal for funding subject to changes. 09/150/16: Evans

10/27/01 Complete Versus Lesion-only Primary PCI pilot -Cardiac MRI substudy (CVLPRI-t-CMR)

Professors Franklyn, Pirmohamed and Dr Gates presented the proposal.

The Board recommended the proposal for funding subject to changes. 10/27/01: McCann

09/150/21 Tranexamic Acid in Paediatric Heart Surgery (TrAPS). A randomized 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 Brown, Carr and Harvey presented the proposal.

The proposal was not recommended for funding. 09/150/21: Arnold

09/150/08 Combined Local Immunotherapy and Radiotherapy of accessible lesions in non-resectable stage III - IV metastatic Melanoma (CLIRM-1)

Professors Bradley, Cameron and Pirmohamed presented the proposal.

The proposal was not recommended for funding. 09/150/08: Dalglish

09/100/31 TARGIT-B: An international randomised controlled trial 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 Little, Harvey and Cameron presented the proposal.

The proposal was not recommended for funding. 09/100/31: Vaidya

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)

Professors Weber, and Billingham presented the proposal.

The proposal was not recommended for funding. 09/150/18: Griffiths & Hall

09/150/28 Randomized Pilot Study Comparing Intracoronary Administration of Adenosine versus Sodium Nitroprusside Delivered via Micro-catheter for Prevention of Microvascular Obstruction During Primary Percutaneous Coronary Intervention

Professors Carr and Weber presented the proposal.

The Board recommended the proposal for funding subject to changes. 09/150/28: Gershlick

09/800/04 Randomised Controlled Trial of 6-Mercaptopurine versus Placebo to Prevent Recurrence of Crohn's Disease following Surgical Resection (TOPPIC)

Professors Franklyn, Dunn and Whyte presented the proposal.

The Board recommended that the application for extension should be supported.

09/800/04: Satsangi

DISCUSSION OF PRELIMINARY APPLICATIONS – Thursday 24th June 2010

09/160/23 Alexander Technique and Supervised Physiotherapy Exercises in back pain (ASPEN) Feasibility study

Professors Eastell, Norman and Dr Gates presented the proposal.

The Board shortlisted 09/160/23: Little

09/160/25 Remission With Individualised Very Intensive Therapy In Early Rheumatoid Arthritis (RIVIT) Trial

Dr Gates, Professors Carr and Eastell presented the proposal.

The Board rejected 09/160/25: Scott

09/160/03 A short duration double blind randomised controlled trial of low versus high dose vitamin D to delay the onset of multiple sclerosis in patients presenting with clinically isolated syndrome

Professor Dunn, B. Williams and Eastell presented the proposal.

The Board shortlisted 09/160/03: Zajicek

09/160/41 Proteomics in the investigation of the mechanism of Vitamin D mediated improvement in endothelial function -Randomised, double blind placebo controlled trial in predialysis chronic kidney disease patients

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

The Board rejected 09/160/41: Banerjee

09/160/20 Does cholinesterase inhibition (donepezil) leads to a reduction in fall's frequency in non-demented people with Parkinson's disease (PD)? (CHAFFINCH-PD)

Professors Brown, Pirmohamed and Eastell presented the proposal.

The Board rejected 09/160/20: Burn

09/160/10 A tailored motor control re-training exercise programme for shoulder impingement problems: effects of intervention and mechanisms of recovery

Professor Whyte chaired the discussion. Professors Billingham, Eastell and Bradley presented the proposal.

The Board rejected 09/160/10: Stokes

DISCUSSION OF PRELIMINARY APPLICATIONS – Friday 25th June 2010

Professor Thakker Chaired

09/160/01 Mass Spectrometry as a Novel Urinary Biomarker for Complications of Diabetes in Childhood

Professors Dunn, Franklyn and Whyte presented the proposal.

The Board rejected 09/160/01: Hindmarsh

09/160/02 Does combination antiretroviral therapy for the management of primary HIV infection alter cerebral function testing parameters 48 weeks after HIV acquisition?

Professors Harvey, Brown and Whyte presented the proposal.

The Board rejected 09/160/02: Winston

09/160/13 The REFER (REFER for Echocardiogram) study: a prospective validation of a clinical decision rule, NT-proBNP, or their combination, in the diagnosis of heart failure in primary care

Professors B. Williams, Dr Gates and Professor Little presented the proposal.

The Board shortlisted 09/160/13: Hobbs

09/160/22 Insight, Cognition, Adherence and Relapse in Schizophrenia (ICaRiS): A randomised controlled trial of Cognitive Behavioural Therapy for Relapse Prevention CBTrp in Schizophrenia

Professors Goodyer, Harvey and Carr presented the proposal.

The Board shortlisted 09/160/22: Gumley

09/160/27 An open-label phase II Trial of Everolimus in patients with Kaposi Sarcoma that is not amenable to local therapy (TEKS)

Professors Pirmohamed, Cameron and Weber presented the proposal.

The Board shortlisted 09/160/27: Nicholson

09/160/24 A phase II randomised clinical trial of conditioning cyclophosphamide and chemoembolisation with or without vaccination with dendritic cells pulsed with HepG2 lysate in vivo in patients with Hepatocellular Carcinoma : IMMUNOTACE Trial

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

The Board shortlisted 09/160/24: Adams

09/160/26 A double blind, randomised controlled trial comparing the effect of a low fibre and control diet on symptoms, neuroimmune interactions and the gut microbiota in Irritable Bowel Syndrome.

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

The Board rejected 09/160/26: Middleton

09/160/39 Evaluation of the efficacy, safety, pharmacokinetics and mechanisms of action of slow release metformin in reducing BMI in obese adolescents when combined with continued standard clinic or web-based enhanced support for lifestyle change and drug adherence. Acronym LIVE-SMART

Professors Norman and Dunn presented the proposal.

The Board shortlisted 09/160/39: Dunger

09/160/04 The effect of CCR5 inhibition on liver fibrosis in HIV/Hepatitis C co-infection- a novel strategy independent of conventional viral suppression

Professor Whyte chaired the discussion. Professors Weber, J. Williams and Billingham presented the proposal.

The Board rejected 09/160/04: Fox

09/160/12 Multinational European Trial for Children with the Opsoclonus Myoclonus Syndrome/Dancing Eye Syndrome (OMS/DES)

Professor Whyte chaired the discussion. Professors Little, Goodyer and Brown presented the proposal.

The Board rejected 09/160/12: Pike

09/160/31 Ubiquinone - Cardiac Arrest Trial: A multicentre study of efficacy and mechanisms of ubiquinone for neuroprotection administered in addition to therapeutic hypothermia after cardiac arrest

Professor Whyte chaired the discussion. Professors Billingham, and Brown presented the proposal.

The Board rejected 09/160/31: Damian

09/160/28 Optimising dose of nicotine replacement for smoking cessation: personalised and high dose v standard dose - comparison of efficacy and side effects

Professors Whyte, Harvey and Little presented the proposal.

The Board rejected 09/160/28: Walton

09/160/29 Preoperative intravenous iron to PREVENT blood Transfusion in major surgery (PREVENTT)

Professors Bradley, Dunn and Norman presented the proposal.

The Board rejected 09/160/29: Richards

09/160/34 Predicting response to anti-depressant treatment in a community-dwelling sample using genetic and cognitive data

Professors Pirmohamed, Dunn and Goodyer presented the proposal.

The Board rejected 09/160/34: Roiser

09/160/35 Pulmonary protection with low frequency ventilation during cardiopulmonary bypass in patients undergoing cardiac surgery: a multi-centre randomised controlled trial (PROTECTION)

Professor Whyte and Carr presented the proposal.

The Board rejected 09/160/35: Ascione

09/160/37 The efficacy of Neuro-Eye Therapy (NeET) in rehabilitation of visual field loss after brain injury due to stroke: A multi-centre, double blind, placebo-controlled randomised trial. Acronym: The NeET study

Professors Brown, Billingham and Goodyer presented the proposal.

The Board rejected 09/160/37: Sahraie

09/160/36 A randomised pilot study comparing high volume imaging guided injections (HVIGI) with and without steroid and anaesthetic in the treatment of recalcitrant Achilles tendinopathy: the treatment effect of fluid volume

Professors Carr, Franklyn and Dr Gates presented the proposal.

The Board rejected 09/160/36: Maffulli

09/160/05 Treatment of adolescents with acquired obesity plus one or more cardiovascular risk factors by isolated dietary fructose reduction: a randomized controlled trial

Professor Norman and Weber presented the proposal.

The Board rejected 09/160/05: Taylor

09/160/06 The effects of reducing worry in patients with persecutory delusions: an explanatory randomised controlled trial

Professor Norman and Weber presented the proposal.

The Board shortlisted 09/160/06: Freeman

09/160/07 The OBAMMA study (Optimising Bile Acid Malabsorption Management & Assessment): a phase 3, multi-centre, randomised, double blind, placebo controlled study of the efficacy of colesevelam vs. placebo in the treatment of bile acid malabsorption/diarrhoea and the optimisation of assessment of patients with bile acid malabsorption

Professor Pirmohamed and J. Williams presented the proposal.

The Board rejected 09/160/07: Andreyev

09/160/08 Gabapentin for Pelvic Pain (GAPP study)

Professor Franklyn, Bradley and Little presented the proposal.

The Board rejected 09/160/08: Horne

09/160/42 Multi-centre Randomised Controlled Trial of Intermittent Ultrafiltration using Peritoneal Dialysis with Icodextrin-based Solutions for Severe Congestive Heart Failure and Stage 3-4 Chronic Kidney Disease

Professor J. Williams, Billingham and Pirmohamed presented the proposal.

The Board shortlisted 09/160/42: McIntyre

09/160/09 Investigation of Obesity surgery and Pioglitazone Effect on Non-alcoholic Steato-hepatitis (IOPENS)

Professor Bradley, B. Williams and Dr Gates presented the proposal.

The Board rejected 09/160/09: Aithal

SUMMARY

- *9 preliminary applications were shortlisted to submit a full proposal for consideration at the October 2010 EME Board.*
- *4 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.*
- *6 full proposals were not recommended for funding.*