

**Efficacy and Mechanism Evaluation Programme**

**Public Minutes of the Inaugural Meeting**

<b>Date</b>	Tuesday 24 <sup>th</sup> June & Wednesday 25 <sup>th</sup> June 2008
<b>Place</b>	Congress Centre, 28 Great Russell Street, London, WC1B 3LS
<b>Present Members</b>	<p>Professor Rajesh Thakker (Chair)          Professor Tom Walley (Programme Director)          Professor Martin Brown          Professor David Cameron (25<sup>th</sup> June)          Professor Rona Campbell          Professor Andrew J Carr          Professor Diana Elbourne          Professor Kim Fox          Professor Jayne Franklyn          Professor Ian Goodyer          Professor Pierre Guillou          Professor Ian Harvey          Professor David Jones          Professor Paul Little          Professor Jane Norman          Professor Munir Pirmohamed          Professor Graham Russell          Professor Stephen Senn (24<sup>th</sup> June)          Professor Judith Stephenson          Professor David J Webb          Professor Moira Whyte (25<sup>th</sup> June)          Professor John G Williams</p>
<b>NETSCC EME Secretariat</b>	<p>Dr Ruairidh Milne (Acting Director)          Miss Liz Dunn (Senior Programme Manager)          Dr Dani Preedy (Senior Programme Manager)</p>
<b>Observers</b>	<p>Dr Morven Roberts (MRC)          Ms Lynn Kerridge (Chief Executive Officer NETSCC) (24<sup>th</sup> June)          Miss Louise Dent (Medical Statistician NETSCC) (25<sup>th</sup> June)</p>
<b>Apologies</b>	<p>Professor David Cameron (24<sup>th</sup> June)          Professor Graham Dunn          Professor Stephen Senn (25<sup>th</sup> June)          Professor Moira Whyte (24<sup>th</sup> June)          Dr Angela Cooper (MRC Observer)</p>

<b>DISCUSSION OF OUTLINE PROPOSALS – Tuesday 24<sup>TH</sup> June 2008</b>
<b>08/43/08 Randomised placebo control trial of a multi species probiotic to prevent bowel dysfunction after Campylobacter gastroenteritis</b>
<b><i>Professor Thakker Chaired</i></b>
<i>Professors Williams, Jones and Pirmohamed presented the proposal</i>
<b>The Board shortlisted 08/43/08: Spiller</b>
<b>08/43/50 Increased intake of prebiotic carbohydrate will reduce appetite resulting in increased weight loss</b>
<i>Professors Williams, Campbell and Stephenson presented the proposal</i>
<b>The Board shortlisted 08/43/50: Frost</b>
<b><i>Ms Kerridge left the meeting</i></b>
<b>08/43/59 VNUS Closure Fast Ablation versus Laser for Varicose Veins (VALVV): A randomised clinical trial</b>
<i>Professors Brown, Williams and Russell presented the proposal</i>
<b>The Board rejected 08/43/59: Davies</b>
<b>08/43/58 Improved diagnosis of infections of prosthetic joints, intra-cardiac devices and sternal wounds – an evaluative and prospective study</b>
<i>Professors Carr, Guillou and Williams presented the proposal</i>
<b>The Board rejected 08/43/58: Wilson</b>
<b>08/43/10 Phase II trial to determine whether prevention of dark-adaptation slows or reverses the progress of diabetic retinopathy</b>
<i>Professors Norman and Franklyn presented the proposal.</i>
<b>The Board rejected 08/43/10: Arden</b>
<b>08/43/06 Nicotine titration therapy: a novel strategy for smoking cessation</b>
<i>Professors Campbell, Little and Elbourne presented the proposal</i>
<b>The Board rejected 08/43/06: Mortimer</b>
<b><i>Professor Thakker left the room for this session. Professor Walley chaired.</i></b>
<b>08/43/19 A phase II multicentre randomised controlled trial of intravenous recombinant human interleukin-1 receptor antagonist (rhIL-1RA) therapy in acute ischaemic stroke: effect on cerebral infarct expansion in patients with at-risk brain tissue.</b>
<i>Professors Senn, Goodyer and Fox left the room. Professors Brown, Pirmohamed and Webb presented the proposal</i>
<b>The Board shortlisted 08/43/19: Tyrrell</b>
<b>08/43/01 Minocycline and disease course progression in mild-to-moderate Alzheimer's disease: The MINIMAL trial</b>
<i>Professors Franklyn and Jones left the room. Professors Goodyer, Pirmohamed and Senn presented the proposal</i>
<b>The Board rejected 08/43/01: Howard</b>

<b>08/43/05 A prospective, randomised, placebo-controlled double blind, multi-centre study of the effects of the angiotensin-II antagonist Losartan on aortic dilatation in Marfan syndrome</b>
<i>Professor Fox left the room. Professors Webb and Little presented the proposal</i>
<b>The Board rejected 08/43/05: Mullen</b>
<b>08/43/28 A Randomised Clinical Trial of High-intensity Focused Ultrasound Ablation Combined with Gemcitabine Chemotherapy for the Treatment of Patients with Metastatic Pancreatic Cancer</b>
<i>Professors Carr and Russell left the room. Professors Senn and Guillou presented the proposal</i>
<b>The Board rejected 08/43/28: Wu</b>
<b>08/43/49 Randomised controlled trial of immunosuppression reduction in tolerant renal transplant recipients who develop skin cancer</b>
<i>Professor Carr left the room. Professors Franklyn and Pirmohamed presented the proposal</i>
<b>The Board rejected 08/43/49: Harden</b>
<b>08/43/56 Randomised controlled trial on the efficacy, safety and mechanisms of pregabalin preventing post-thoracotomy neuropathic pain (PPP trial)</b>
<i>Professors Franklyn and Carr left the room. Professors Guillou, Fox and Senn presented the proposal</i>
<b>The Board shortlisted 08/43/56: Gao-Smith</b>
<b>08/43/17 A Randomised Controlled Trial of Lifestyle Change and Metformin in the Prevention of Type 1 Diabetes in Children</b>
<i>Professor Carr left the room. Professors Franklyn, Elbourne and Harvey presented the proposal</i>
<b>The Board rejected 08/43/17: Wilkin</b>
<b><i>Professor Thakker chaired</i></b>
<b>08/43/07 Insulin initiation in type 2 diabetes. Achieving sustained benefits at and beyond 3 months without excess weight gain.</b>
<i>Professors Franklyn, Senn and Harvey presented the proposal</i>
<b>The Board rejected 08/43/07: Kerr</b>
<b>08/43/53 Arterial Spin Labelling as Prognostic Marker of Major Depressive Disorder</b>
<i>Professors Pirmohamed and Campbell presented the proposal</i>
<b>The Board rejected 08/43/53: Mitterschiffthaler</b>
<b>08/43/25 Neural and biomechanical correlates of response to the use of an ankle-foot cast provided to improve walking recovery early after stroke. A Phase I/II trial.</b>
<i>Professor Harvey left the room. Professors Jones, Brown and Carr presented the proposal</i>
<b>The Board shortlisted 08/43/25: Pomeroy</b>
<b><i>Professors Jones and Pirmohamed left the meeting</i></b>

<p><b>08/43/38 A multi-centre randomised controlled trial to study the renoprotective effect of bicarbonate supplementation for two years on renal graft function and polypeptide proximal renal tubular catabolism in patients with transplanted kidneys. BICARBGRAFT</b></p> <p><i>Professor Walley left the room. Professors Russell and Franklyn presented the proposal</i></p> <p><b>The Board shortlisted 08/43/38: Rustom</b></p>
<p><b>08/43/42 A phase II trial of a nurse led complex intervention for childhood constipation and soiling</b></p> <p><i>Professors Senn and Walley left the room. Professors Stephenson, Elbourne and Campbell presented the proposal</i></p> <p><b>The Board shortlisted 08/43/42: Tappin</b></p>
<p><b><i>Professor Stephenson left the meeting</i></b></p>
<p><b>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</b></p> <p><i>Professor Walley left the room. Professors Russell and Williams presented the proposal</i></p> <p><b>The Board shortlisted 08/43/55: Solomon</b></p>
<p><b>08/43/23 Optimising anatomical and physiological adaptations in the radial artery with exercise training prior to and following trans-radial coronary procedures.</b></p> <p><i>Professor Walley left the room. Professors Elbourne, Webb and Fox presented the proposal</i></p> <p><b>The Board rejected 08/43/23: Wright</b></p>
<p><b>08/43/52 Imaging perfusion deficits and thrombolysis safety and efficacy in acute ischaemic stroke. The Third International Stroke Trial (IST-3)</b></p> <p><i>Professor Senn left the meeting. Professor Thakker chaired. Professor Norman left the room. Professors Fox and Brown presented the proposal</i></p> <p><b>The Board shortlisted 08/43/52: Wardlaw</b></p>
<p><b>08/43/37 Multi-centre randomised control trial of cognitive-behavioural therapy and systemic cognitive-behavioural therapy compared with waiting list control in young people with bulimia nervosa: Outcome, acceptability and mediators and moderators of change</b></p> <p><i>Professors Elbourne, Campbell, Goodyer presented the proposal</i></p> <p><b>The Board rejected 08/43/37: Eisler</b></p>
<p><b>08/43/09 The efficacy of strength training and nutritional supplements as measures to improve the recovery and quality of life of older orthopaedic patients.</b></p> <p><i>Professor Harvey left the room. Professors Campbell, Elbourne and Carr presented the proposal</i></p> <p><b>The Board rejected 08/43/09: Stewart</b></p>
<p><b>08/43/21 A randomized controlled trial for challenging behaviour in autism spectrum disorders: efficacy of treatment and mediating mechanisms</b></p> <p><i>Professors Goodyer and Little presented the proposal</i></p> <p><b>The Board rejected 08/43/21: Simonoff</b></p>

<b>DISCUSSION OF OUTLINE PROPOSALS - Wednesday 25<sup>th</sup> June 2008</b>
<b><i>Professor Thakker chaired</i></b>
<b>08/43/33 Health at every size: Evaluating the efficacy of a psychological intervention to increase physical activity in obese and overweight adults</b>
<i>Professors Harvey and Goodyer presented the proposal</i>
<b>The Board rejected 08/43/33: Coulton</b>
<b><i>Professors Walley and Webb joined the meeting</i></b>
<b>08/43/39 Antigluco-corticoid augmentation of anti-depressants in Depression (the ADD study)</b>
<i>Professors Harvey, Goodyer and Franklyn presented the proposal</i>
<b>The Board shortlisted 08/43/39: Ferrier</b>
<b>08/43/34 IMPORT-IGRT: Intensity Modulated and Partial Organ Radiotherapy - Image Guided Radiotherapy</b>
<b><i>Professor Jones joined the meeting</i></b>
<i>Professors Guillou and Brown presented the proposal</i>
<b>The Board rejected 08/43/34: Evans</b>
<b><i>Professor Cameron joined the meeting</i></b>
<b>08/43/48 A double-blind placebo-controlled trial of the effect of dietary levels of n-3 polyunsaturated fatty acids on depressed mood and conduct disorders in adolescents</b>
<i>Professors Williams, Harvey and Goodyer presented the proposal</i>
<b>The Board rejected 08/43/48: Smith</b>
<b>08/43/18 Chemotherapy-induced painful peripheral neuropathy: a study of predictive factors, diagnosis and treatment in patients with ovarian carcinoma</b>
<i>Professor Fox left the room. Professors Norman and Cameron presented the proposal</i>
<b>The Board rejected 08/43/18: Riley</b>
<b>08/43/27 Reduction of Abdominal Fat in Teenagers (RAFT): Randomised controlled trial of metformin in obese insulin resistant pubertal adolescents</b>
<i>Professors Goodyer and Stephenson left the room. Professors Little, Norman and Franklyn presented the proposal</i>
<b>The Board shortlisted 08/43/27: Viner</b>
<b>08/43/41 Statin Treatment for Onset-Prevention of Dementia. Double-blind, randomized controlled trial with older adults with Down syndrome (The STOP Dementia Study)</b>
<i>Professors Norman and Goodyer left the room. Professors Harvey and Russell presented the proposal</i>
<b>The Board shortlisted 08/43/41: Cooper</b>
<b><i>Professor Walley left the meeting</i></b>

<b>08/43/54 OncoCyber - an evaluation of the Cyberknife in the treatment of early breast and prostate cancer and of vertebral metastases</b>
<i>Professor Webb left the room. Professors Jones, Carr and Stephenson presented the proposal</i>
<b>The Board rejected 08/43/54: Kunkler. The applicants are to be invited to resubmit a revised outline proposal which fully considers the feedback from the Board</b>
<b>08/43/40 Hypothermia for acute ischaemic stroke: An international randomised controlled clinical trial</b>
<i>Professors Norman and Webb left the room. Professors Carr, Elbourne and Brown presented the proposal</i>
<b>The Board rejected 08/43/40: Macleod</b>
<b>08/43/30 A randomised, double blind, placebo controlled, parallel groups, comparative trial of antibiotic treatment of culture-negative pyuria in the management of patients with overactive bladder symptoms</b>
<i>Professor Stephenson left the room. Professors Little, Norman and Jones presented the proposal</i>
<b>The Board rejected 08/43/30: Malone-Lee</b>
<b>08/43/29 The Diagnostic Efficacy of Circulating C-reactive protein-Very low density lipoprotein Complexes in Sepsis and an Evaluation of its Underlying Mechanism.</b>
<i>Professor Pirmohamed left the room. Professors Elbourne, Whyte and Jones presented the proposal</i>
<b>The Board shortlisted 08/43/29: Toh</b>
<b>08/43/12 Therapeutic potential of Vitamin D Immunomodulation of Subclinical Hypothyroidism (DISH)</b>
<i>Professors Norman, Russell and Franklyn presented the proposal</i>
<b>The Board shortlisted 08/43/12: Pearce</b>
<b>08/43/44 A feasibility study comparing cryotherapy versus conservative management in men with radiation relapsed localised prostate cancer.</b>
<i>Professor Goodyer left the room. Professors Stephenson, Cameron and Guillou presented the proposal</i>
<b>The Board shortlisted 08/43/44: Leung</b>
<b><i>Professor Walley rejoined the meeting</i></b>
<b>08/43/57 Effect of Sodium Nitrite Injection on Infarct Size in Patients with Myocardial Infarction undergoing Primary Angioplasty.</b>
<i>Professors Whyte, Fox and Webb presented the proposal</i>
<b>The Board shortlisted 08/43/57: Webb</b>
<b>08/43/32 A phase II randomised trial to investigate the safety and efficacy of recombinant human erythropoietin on infarct size in patients undergoing primary percutaneous coronary intervention for ST-segment elevation myocardial infarction</b>
<i>Professor Fox left the room. Professors Webb and Whyte presented the proposal</i>
<b>The Board rejected 08/43/32: Kooner</b>

<b>08/43/36 The influence of circulation on osteoporosis</b>
<i>Professors Carr, Whyte and Williams presented the proposal</i>
<b>The Board rejected 08/43/36: Tucker</b>
<b>08/43/61 Does L-dopa drug treatment in combination with routine NHS occupational and physical therapy, delivered early after stroke within a stroke rehabilitation service, improve functional motor recovery including walking ability and arm function?</b>
<i>Professors Franklyn and Guillou left the room. Professors Little, Stephenson and Brown presented the proposal</i>
<b>The Board shortlisted 08/43/61: Bhakta</b>
<b>08/43/47 An evaluation of the effects of aciclovir therapy in combination with statins on cytomegalovirus-mediated inflammation in cardiovascular disease.</b>
<i>Professors Franklyn and Guillou left the room. Professors Webb, Fox and Harvey presented the proposal</i>
<b>The Board rejected 08/43/47: Moss</b>
<b>08/43/13 Clopidogrel vs Aspirin in Congestive HEart failure - The 'CACHE' Trial</b>
<i>Professor Franklyn left the room. Professors Fox, Guillou and Webb presented the proposal</i>
<b>The Board rejected 08/43/13: Cleland but the outline proposal will be passed to the HTA programme</b>
<b>08/43/16 A study of circulating markers of apoptosis and cell death as predictors of clinical outcomes in patients receiving anti-cancer treatment for solid tumours.</b>
<i>Professors Cameron, Russell and Whyte presented the proposal</i>
<b>The Board rejected 08/43/16: Banerji</b>
<b>08/43/26 Cluster Randomised Approach to Stroke Treatment - Blood Pressure (CRAST-BP)</b>
<i>Professor Harvey left the room. Professors Brown, Russell and Stephenson presented the proposal</i>
<b>The Board rejected 08/43/26: Lees but the outline proposal will be passed to the HTA programme</b>
<b>08/43/24 Blinded evaluation of the value of FDG PET/CT (F-18 Fluorodeoxyglucose positron emission tomography/computerised tomography) in assessing the response to chemotherapy of patients with oesophageal cancer considered for radical treatment.</b>
<i>Professor Franklyn left the room. Professors Guillou, Cameron and Jones presented the proposal</i>
<b>The Board rejected 08/43/24: O'Doherty</b>
<b>08/43/03 Parent-determined oral montelukast therapy for preschool wheeze with stratification for arachidonate-5-lipoxygenase promoter genotype</b>
<i>Professor Jones left the room. Professors Whyte and Pirmohamed presented the proposal</i>
<b>The Board shortlisted 08/43/03: Grigg</b>

<b>08/43/04 Identifying diagnostic and treatment-responsive neural markers of bipolar spectrum disorder in depressed patients in secondary care</b>
<i>Professors Jones, Goodyer and Norman presented the proposal</i>
<b>The Board rejected 08/43/04: Phillips</b>
<b>08/43/15 A randomised controlled trial of losartan as an anti-fibrotic agent in non-alcoholic steatohepatitis</b>
<i>Professors Pirmohamed, Stephenson and Norman presented the proposal</i>
<b>The Board shortlisted 08/43/15: Day</b>
<b>08/43/14 Open label randomised clinical trial comparing the effectiveness and cost effectiveness of conventional nicotine replacement therapy and oral smokeless tobacco (snus) in smoking cessation.</b>
<i>Professors Little and Campbell presented the proposal</i>
<b>The Board rejected 08/43/14: Britton</b>
<b>08/43/11 Non-exercise assessment of VO<sub>2</sub>max (maximal oxygen uptake) by measurement of myoglobin and haemoglobin as predictors of intraoperative O<sub>2</sub>-delivery and related risks</b>
<i>Professors Fox, Whyte and Carr presented the proposal</i>
<b>The Board rejected 08/43/11: Williams</b>
<b>SUMMARY</b>
<ul style="list-style-type: none"> <li>• 19 outline proposals were shortlisted and invited to submit a full proposal for consideration at the March 2009 EME Board.</li> <li>• 1 applicant was invited to resubmit an outline proposal to the EME programme after full consideration of the feedback from the Board.</li> <li>• 2 outline proposals were passed to the HTA programme for consideration as they did not fall within the EME programme remit and the Board considered that they might be within the HTA programme remit.</li> </ul>