Welcome to the first R&D trials newsletter of 2016, the plan is to generate a quarterly newsletter to provide information on our current trial portfolio, update on up and coming trials and highlight achievements.

**TOP RECRUITING TRIALS (over last 3 months)**

<table>
<thead>
<tr>
<th>Trial Name</th>
<th>Total Patients Recruited</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. White/White Hemi (PI – Eardley/ Baker)</td>
<td>74</td>
</tr>
<tr>
<td>Injuries and Emergencies</td>
<td></td>
</tr>
<tr>
<td>2. Thyrami (PI – Austin) Cardiovascular</td>
<td>25</td>
</tr>
<tr>
<td>3. e-Ultimaster (PI - Austin) Cardiovascular</td>
<td>24</td>
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</tbody>
</table>
OPENING SOON,

ADD- ASPIRIN — Phase 3 RCT evaluating the impact of aspirin on recurrence rate in early breast, upper GI, colorectal and prostate cancer (PI – Janine Graham) main contact – Lisa Wayman.

WiCS-LV - An implantable cardiac pacing system capable of delivering pacing energy to the heart without using a pacing lead (PI Simon James) main contact – Bev Atkinson.

NATTINA- clinical trial for adults with recurrent acute tonsillitis looking to establish the clinical and cost effectiveness of tonsillectomy compared with conservative management (PI Anirvan Banerjee) main contact – Karen Robinson

TRANSITION- Study to compare Pre-discharge and Post-discharge treatment initiation with LCZ696 therapy in heart failure patients with reduced ejection fraction after an acute decompensation event. (PI Jeetendra Thambyrajah) main contact – Cath Richardson

POST 4- Assessment of midodrine in the prevention of vasovagal syncope. (PI Nick Linker) Main contact – Maggie Finlayson

ECLIPSE- Emergency Treatment with Levetiracetam or Phenytoin in Status Epilepticus in Children (PI Ramesh Kumar) Main contact – Gill McIlhinney

UK WHIST- A Randomised Controlled Trial of standard wound management versus negative pressure wound therapy in the treatment of adult patients having surgical incisions for major trauma to the lower limb (PI Will Eardley) Main contact – Alanna Milne
NEW TRIALS OPENED IN LAST 3 MONTHS,

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>Area</th>
<th>PI</th>
<th>SUMMARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAT-ROC</td>
<td>Cancer</td>
<td>Sam Dresner</td>
<td>A Feasibility Study of Adjuvant Statin Therapy in the Prevention of Post-Operative Recurrence of Oesophageal Adenocarcinoma</td>
</tr>
<tr>
<td>HIlight Vitiligo Trial</td>
<td>Dermatology</td>
<td>Rob Ellis</td>
<td>Home Interventions and Light therapy for the treatment of vitiligo</td>
</tr>
<tr>
<td>Nerves</td>
<td>Surgery</td>
<td>Nitin Mukerji</td>
<td>Multi-centre randomised control trial comparing the clinical and cost effectiveness of trans-foraminal epidural steroid injection to surgical microdiscectomy for the treatment of chronic radicular pain secondary to prolapsed intervertebral disc herniation: NErve Root Block VErsus Surgery</td>
</tr>
<tr>
<td>GOT-IT</td>
<td>Reproductive Health</td>
<td>Deepika Meneni</td>
<td>A pragmatic group sequential placebo controlled randomised trial to determine the effectiveness of Glyceryl trinitrate for retained placenta.</td>
</tr>
</tbody>
</table>

ACHIEVEMENTS OF THE QUARTER,

1. POPPI – TOP STAGGER 2 RECRUITERS FOR THE 2ND TIME
2. VUE – 80TH PATIENT RANDOMISED–400% OF ORIGINAL TARGET
3. OPAL – 500TH PATIENT RECRUITED – 7 IN 1 DAY BY SARAH CROFT
A FEW RECRUITING TRIALS

SURGERY/CRITICAL CARE
POPPI – evaluating the clinical and cost-effectiveness of a nurse-led preventative psychological intervention in reducing patient-reported psychological morbidity at six months after intensive care.

Changing Health Behaviours prior to surgery - exploring attitudes, barriers and facilitators to implementing evidence-based behavioural changes to optimise patient’s health before major surgery.

DEX CSDH – A randomised, double blind, placebo-controlled trial of a two-week course of dexamethasone for adult patients with a symptomatic Chronic Subdural Haematoma

PAIN
Adjust - Analgesic efficacy of high density spinal cord stimulation at 1 KHz

CARDIO
Re-Dual – A prospective Randomised, open label, blinded endpoint study to Evaluate DUAL antithrombotic therapy with dabigatran etexilate plus clopidogrel or ticagrelor vs. triple therapy strategy with warfarin plus clopidogrel or ticagrelor and aspirin in patients with non valvular atrial fibrillation that have undergone a percutaneous coronary intervention with stenting

Thyrami – Thyroxine in Acute Myocardial Infarction

IMPULSE – Quality of Care Study to Improve Outcomes in Aortic Stenosis

NEONATAL
E-TIPS – Early Therapy in Perinatal Stroke: Pilot Feasibility Study
BABY-OSCAR – Outcome After Selective Early Treatment for Closure of Patent Ductus Arteriosus in Pre-term Babies

RENAL
Causes and Predictors of Outcome in IgAN Nephropathy - Identifying causes and predictors of outcome in IgA nephropathy

UKPDOPPS - UK Peritoneal Dialysis Outcomes and Practice Patterns Study

Speak – Social, educational and medical outcomes of established renal failure in adolescents and young adults
STOP-ACEi – Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease

CANCER RAPPER – Radiogenomics: assessment of polymorphisms for predicting the effects of radiotherapy

MARS 2 - A study to determine if it is feasible to recruit into a randomised trial comparing (extended) pleurectomy decortication versus no pleurectomy decortication in the multimodality management of patients with malignant pleural mesothelioma

TUXEDO - Phase I/II feasibility study of cetuximab with 5FU and Mitomycin C or cisplatin with concurrent radiotherapy in muscle invasive bladder cancer

NIMRAD – RCT looking at synchronous Nimorazole versus radiotherapy alone in patients with locally advanced head and neck cancer not suitable for synchronous chemo or cetuximab. PI – Aynsley, main contact Emma Thompson.

SOPHIA - A Phase 3, Randomized Study of Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of Patients with HER2+ Metastatic Breast Cancer Who Have Received Two Prior Anti-HER2 Therapies and Require Systemic Treatment

DIABETES EASE-3 - A Phase III, randomised, double blind, placebo-controlled, parallel group, efficacy, safety and tolerability trial of once daily, oral doses of Empagliflozin as Adjunctive to inSulin thErapy over 26 weeks in patients with Type 1 Diabetes Mellitus

FLIPS - Evaluation of the Accuracy of the FreeStyle Libre Flash Glucose Monitoring System – Use in Pregnancy Label Extension Study (CE)

FIGARO - A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone on the reduction of cardiovascular morbidity and mortality in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease in addition to standard of care.

FIDELIO - A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone, in addition to standard of care, on the progression of kidney disease in subjects with type
2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease

**DERMATOLOGY**

**ALPHA** – Comparison of Alitretinoin with PUVA as the first line treatment in patients with severe chronic hand eczema.

**MUSE** – Mirvaso® Utilization and Patient Satisfaction Study

**LEO** – Efficacy and Safety of LEO 43204 in Field Treatment of Actinic Keratosis on Face or Chest including 12-month follow-up

**REPRODUCTIVE HEALTH**

**GAPP 2**- Gabapentin for Pelvic Pain.

**ANODE** - a randomised controlled trial of prophylactic ANtibiotics to investigate the prevention of infection following Operative vaginal DELivery.

**Understanding Haematopoiesis in Down Syndrome**- Cord Blood Collection for Understanding Haematopoiesis in Down Syndrome

**PITCHES**- Phase III trial in Intrahepatic Cholestasis of Pregnancy (ICP) to Evaluate ursodeoxycholic acid (UDCA) in improving perinatal outcomes

**OPHTHALMOLOGY**

**LEAVO**- A Multicentre Phase III Double-masked Randomised Controlled Non-Inferiority Trial comparing the clinical and cost effectiveness of intravitreal therapy with ranibizumab (Lucentis) vs aflibercept (Eylea) vs bevacizumab (Avastin) for Macular Oedema due to Central Retinal Vein Occlusion (CRVO).

**CANDLE** - Noctura400 treatment for Diabetic Retinopathy: Pilot study to demonstrate and evaluate the care pathway for NHS adoption
GI
UKAIH – The United Kingdom Autoimmune Hepatitis Cohort (UK-AIH): a multi-centre platform for research and translational medicine

Bergamot and Juniper trial. - A phase III, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of etrolizumab as an induction and maintenance treatment for patients with moderately to severely active crohn’s disease

MSK
KFORT – Knee Fix or Replacement Trial. A feasibility study comparing fixation vs replacement in elderly patients sustaining a distal femoral fracture.

RESPIRATORY
EMBARC - The European Bronchiectasis Registry

STROKE
RIVER REGISTRY - Prospective, multicentre, international Registry of male and female patients newly diagnosed with Atrial Fibrillation and treated with Rivaroxaban